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, 2021

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. ☒

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 nonaffiliates, 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, 2021)**:** $727,984,802

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 25, 2022: 72,304,792 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 2022 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, 2021. Except with respect to information specifically incorporated by reference in the Annual Report on From 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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Use of Names

References in this Annual Report to "OraSure" mean OraSure Technologies, Inc. References in this Annual Report to "we," "us," "our," or the "Company" mean OraSure and its consolidated subsidiaries, unless otherwise indicated.

Disclosure Regarding Forward Looking Statements

This Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Annual Report") contains certain “forward-looking statements,” within the meaning of the Federal securities laws. These may include statements about our 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 our 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:

- *risk that our exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions.*
- *the diversion of management's attention from our ongoing business and regular business responsibilities and due to our exploration of strategic alternatives;*
- *our ability to resolve our InteliSwab® COVID-19 Rapid Tests manufacturing challenges and satisfy customer demand;*
- *our ability to market and sell products, whether through our internal, direct sales force or third parties;*
- *Our ability to fulfill our commitments under our contracts with the U.S. government for InteliSwab® COVID-19 Rapid Tests;*
- *impact of significant customer concentration in the genomics business;*
- *our ability to successfully scale-up our manufacturing for InteliSwab® COVID-19 Rapid Tests;*
- *failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products;*
- *our ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements;*
- *our 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;*
- *our ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (or "FDA"), or other regulators;*
- *the impact of the COVID-19 pandemic on our business;*
- *the impact of COVID-19 on our supply chain;*
- *our ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations, transport work-in-process goods and finished products and commercialize such products for COVID-19 testing;*
- *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;*
- *our ability to meet increased demand for our products;*
- *the impact of replacing distributors on our business;*
- *inventory levels at distributors and other customers;*
- *our ability to achieve our financial and strategic objectives and continue to increase our revenues, including the ability to expand international sales;*
- *the impact of competitors, competing products and technology changes on our business;*
- *reduction or deferral of public funding available to customers;*
- *competition from new or better technology or lower cost products;*
- *our ability to develop, commercialize and market new products;*
- *market acceptance of oral fluid or urine testing, collection or other products;*
- *market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services;*
- *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, or "CDC" or other agencies; ability to fund research and development and other products and operations;*
- *our 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 our products;*
- *the impact of contracting with the U.S. government on our business;*

- *the impact of negative economic conditions on our business;*
- *our ability to maintain sustained profitability;*
- *our ability to increase our gross margins;*
- *the ability to utilize net operating loss carry forwards or other deferred tax assets;*
- *volatility of our 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;*
- *our ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms;*
- *adverse movements in foreign currency exchange rates;*
- *loss or impairment of sources of capital;*
- *our ability to attract and retain qualified personnel;*
- *our 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.*

These and other factors that could affect our 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 we undertake no duty to update these statements, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have 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. We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own a number of trademarks, including the OraSure®, Intercept®, Intercept i2® *he*, OraQuick®, OraQuick ADVANCE®, OraSure Quick Flu®, Q.E.D.®, InteliSwab®, Oragene®, DNA Genotek®, OMNImet™, ORAcollect®, OMNIgene®, goDNA™, Diversigen®, CoreBiome®, Boostershot®, MetaGene™, Benchmark™, Novosanis®, Colli-Pee®, UCM®, UAS™, AUTO-LYTE®, prepIT® and Hemagene® trademarks. We also own many of these marks and others in several foreign countries and we are pursuing registration of several other trademarks.

PART I

ITEM 1. Business.

The overall goal of OraSure Technologies, Inc. (“OraSure” or “the Company”) is to empower the global community to improve health and wellness by providing access to accurate essential information through effortless tests, collection kits and services. Our business consists of two segments: our “Diagnostics” segment, and our “Molecular Solutions” segment.

Diagnostics

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of simple, easy to use diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our 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. Through our Diagnostics business we are also developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient’s urine or blood, as well as point-of-care products currently in development.

Molecular Solutions

Our Molecular Solutions business is operated by our wholly-owned subsidiaries, DNA Genotek, Inc. ("DNAG"), Diversigen, Inc. ('Diversigen"), and Novosanis NV ("Novosanis"). Our Molecular Solutions business sells its products and services directly to its customers, primarily through its internal sales force in the U.S. domestic market, and in many international markets, also through distributors. Our products primarily consist of collection kits and services used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. Most of our Molecular Solutions revenues are derived from product sales to commercial customers and sales into the academic and research markets. A significant portion of our total sales is from repeat customers in both markets. Molecular Solutions customers span the disease risk management, diagnostics, pharmaceutical, biotech, companion animal and environmental markets.

We have expanded the market focus of our Molecular Solutions business by selling existing collection products for use with COVID-19 tests. We have also developed new collection devices for the emerging microbiome market, which focuses on studying microbes and their effect on human health. Our primary product offering in the microbiome market, OMNIgene® • GUT, is focused on the human gut microbiome (microbes living in human stool). In 2021, the OMNIgene® • GUT collection device (OMD-200) was granted “FDA De Novo classification for the preservation and stabilization of the relative abundance of microbial nucleic acids in clinical samples.” We leverage our existing sales force and global research connections to engage microbiome customers worldwide to establish ourselves among the leaders in ease-of-collection, stabilization, and transport of this challenging sample type.

Our Molecular Solutions segment includes the Colli-Pee® device, developed and sold by our Novosanis subsidiary, for the volumetric collection of first void urine. This product is in its early stages, and initial sales are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. Our Molecular Solutions business also offers laboratory and analytical services for both genomics and microbiome customers to more fully meet their needs. These services are primarily provided to pharmaceutical, biotech companies, and research institutions.

Business Update Related to InteliSwab® Covid-19 Rapid Tests

In June 2021, we received three Emergency Use Authorizations ("EUA") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab® COVID-19 Rapid Tests (“InteliSwab®”) for non-prescription OTC, professional point-of-care use and prescription home use. We began recording revenues on the sales of our InteliSwab® tests during the third quarter of 2021. In September 2021, the Defense Logistics Agency awarded the Company a procurement contract for the InteliSwab® for OTC use, which the Defense Logistics Agency estimated to have a value of $205 million and which will provide InteliSwab® tests to up to 20,000 sites throughout the United States from October 2021 through September 2022. Also in September 2021, we entered into an agreement with the Biomedical Advanced Research Development Authority (“BARDA”), which is part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (“HHS”), pursuant to which BARDA would provide the Company with up to $13.6

million in funding to obtain 510(k) clearance and Clinical Laboratory Improvement Amendments ("CLIA") waiver of the InteliSwab® tests.

In the latter part of 2021, we have focused our efforts on scaling up our operations to meet the increasing demand for the InteliSwab® tests. In September 2021, we receive $109 million in funding from the U.S. Department of Defense (the "DOD"), in coordination with the HHS, to build additional manufacturing capacity in the United States for our InteliSwab® test as part of the nation's pandemic preparedness plan. This funding will be used to expand the Company's production capacity by 100 million tests annually and will be paid based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment.

We have obtained WHO pre-qualification for our OraQuick® HIV-1/Antibody Test, OraQuick® HIV Self-Test and OraQuick® HCV Test.

Exploration of Strategic Alternatives

The COVID-19 pandemic has provided us an opportunity to fundamentally transform into a higher growth, more innovative and efficient organization with broader customer reach, both within and outside the United States. We believe we are well positioned to address current public health challenges and capitalize on diagnostic trends in the market and enhance its operational and competitive profile. Against this backdrop, our Board of Directors is exploring and evaluating a broad range of strategic alternatives with the goal of maximizing value for stockholders There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

Diagnostics Segment Products

The following is a summary of our principal products for the infectious disease and risk management markets, which comprise the Diagnostics segment of our business:

InteliSwab®COVID-19 Rapid Test

InteliSwab® is our rapid immunoassay platform 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 and allowed to develop. The specimen and developer solution flow through the test device and test results are observable in 30 minutes. The InteliSwab® test has received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for non-prescription, over-the-counter home use in individuals aged 2 years or older, with and without symptoms of COVID-19.

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 over-the-counter version, except that the test is run and interpreted by a healthcare provider. This test has received EUA from the U.S. FDA for use by laboratories located in the United States certified under CLIA. We have also received a CLIA waiver for use of the test enabling the test to be used by numerous additional sites in the United States not certified under CLIA to perform high and moderately complex tests, such as outreach clinics, community-based organizations and physicians' offices. This test is also indicated for individuals aged two 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 U.S. FDA for prescription home use with individuals aged 2 years or older who are suspected of COVID-19 infection by their healthcare provider within the first seven days of symptom onset.

OraQuick® Rapid HIV Test

OraQuick® is our rapid point-of-care test platform designed to test oral fluid, whole blood (i.e., both finger-stick and venous), plasma and serum samples for the presence of various antibodies or analytes. 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, plasma or serum is 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 allowed to develop. In all cases, the specimen and developer solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a

screening test and requires a confirmation test where an initial positive result is obtained. 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 test has received pre-market approval ("PMA") from the U.S. Food and Drug Administration ("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. This test is available for use by laboratories located in the United States certified under the Clinical Laboratory Improvements Amendment of 1988 ("CLIA"), to perform moderately complex tests. We have 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.

On the international front, we have obtained a CE mark for our OraQuick *ADVANCE*® test so that we can sell this product in Europe and other countries accepting the CE mark for commercialization and this product is registered for sale in other countries. We have distributors in place for several countries and are seeking to increase awareness and expand our distribution network for this product throughout the world. We have also received World Health Organization ("WHO") pre-qualification for our 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 our OraQuick *ADVANCE*®HIV 1/2 Antibody Test. We 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, we have established toll-free, 24/7, 365-day per year customer telephone support to provide additional information and referral services for consumers that use this product.

OraQuick® HIV Self-Test

The OraQuick® HIV Self-Test is sold for use by individuals in certain foreign countries to meet the needs of those markets. This product has received WHO pre-qualification and is eligible for procurement by purchasing entities entitled to access funding and other resources from the Global Fund, UNITAID and other agencies. The OraQuick® HIV Self-Test received CE Mark in 2021 and is being sold in certain European Countries.

OraQuick® HCV Rapid Antibody Test

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

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

OraQuick® Ebola Rapid Antigen Test

We have received 510(k) clearance from the FDA for our 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.

OraSure® Collection Device

Our OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies. The generic version of this product can be used for other analytes. This device consists of a small, treated cotton-fiber pad on a handle that is placed in a person's mouth for two to five minutes. The device collects oral mucosal transudate ("OMT"), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

The OraSure® collection device is FDA approved for use in the detection of HIV-1 antibodies. The generic version is a Class I medical device for the detection of cocaine and cotinine in oral fluid specimens for risk assessment testing. HIV-1 antibody detection using the OraSure® collection device involves three steps:

- Collection of an oral fluid specimen using the OraSure® device;
- Screening of the specimen for HIV-1 antibodies at a laboratory with an enzyme immunoassay ("EIA") screening test approved by the FDA for use with the OraSure® device; and
- Laboratory confirmation of any positive screening test results with a blood-based nucleic acid test.

A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested.

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 "OMT" for oral fluid drug testing. We have 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. Our Intercept® device and oral fluid assays are sold in the U.S. primarily through laboratory distributors.
We believe that the Intercept® device has several advantages over competing urine and other drugs-of-abuse testing products, including its lower total testing cost, its non-invasive nature, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection facilities and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow our customers to test for drug impairment and eliminate scheduling costs and inconvenience, thereby streamlining the testing process.

We have also developed a next-generation collection device, which we are marketing under the tradename "Intercept i2® *he*". This device offers several important advantages over our original Intercept® device, including a sample adequacy indicator that provides a visual prompt when the appropriate volume of oral fluid has been collected, the ability to collect a larger sample required by current laboratory testing protocols and a more optimized chemistry that results in improved recovery of the targeted drug analytes. The Intercept i2®*he* device is currently being sold as a forensic use only device within the criminal justice and drug treatment markets along with a NIDA-5 panel of fully-automated high-throughput oral fluid drug assays that we distribute under an agreement with Thermo Fisher Scientific.

Immunoassay Tests and Reagents

We develop and sell immunoassay tests in formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of our customers. We also sell fully-automated high-throughput oral fluid drug assays developed under our agreement with Thermo Fisher. Our MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in 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 we are selling a NIDA-5 panel of microplate assays supplied by Thermo Fisher 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.

Q.E.D.® Saliva Alcohol Test

Our 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.

Each Q.E.D.® test kit contains a collection stick that is used to collect a sample of saliva and a disposable detection device that displays results in a format similar to a thermometer. The Q.E.D.® device is easy to operate and instrumentation is not required to read the result. The product has a testing range of 0 to 0.145% blood alcohol and produces results in approximately two minutes.

Molecular Solutions Segment

Genomic Products

We sell many genomic products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA, RNA, as well as both DNA and RNA together from human and animal biological samples. Our 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.

Our 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 immediately protect 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 that are required for most genetic testing and analysis methods.

We believe 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:

- The reliable collection of high-quality and stable genetic samples.
- The use of 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.

We also sell 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.

COVID Collection Products

Since 2020, we have actively engaged with several laboratories and researchers to demonstrate the effectiveness of our existing collection products for use with COVID-19 molecular testing. The stabilization solution in our molecular collection products can accommodate a vast spectrum of microbiome activity, spanning bacteria to viruses. We have collected data on the usability of our kits for this purpose. We believe that oral samples collected using devices from our product lines for liquid saliva or oral swab samples are a suitable alternative to more commonly used samples collected with a nasopharyngeal or oropharyngeal swab. Our products are optimized for self-collection, unlike nasopharyngeal and oropharyngeal swabs, which cannot be self-administered easily. That means healthcare providers, retailers, and online vendors can ship our kits directly to an individual's home, eliminating unnecessary trips to hospitals, doctors' offices, and testing facilities. Self-collection also supports the social distancing guidelines in many communities, reduces the burden on testing sites and healthcare facilities, and provides wider access to testing. Moreover, the chemistry in our products stabilizes nucleic acids, including RNA, which is the nucleic acid used by most labs for COVID-19 testing. The chemistry is bacteriostatic and inactivates viral activity in the sample. These products' usability and form factors are conducive to use at home or in clinic settings. As a result, since 2020, we have sold our ORAcollect® • RNA and OMNIgene® • ORAL collection devices for use in connection with COVID-19 molecular testing. These products have become an increasingly important part of our business and accounted for 47% of 2020 revenue generated by our Molecular Solutions segment and 40% in 2021.

Microbiome Products

We also market several microbiome collection products designed to collect, stabilize, and transport the microbial profile from multiple sample types. Unlike genomic DNA, the microbiome of a sample can change over time, especially when exposed to temperature and environmental fluctuations. A reliable method captures and preserves ("snapshots") the microbiome after collection until an analysis is required to optimize and standardize sample results. We believe our products provide such a reliable method.

Our 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. 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. We believe our product ensures that the microbial DNA in the fecal sample is fully stabilized immediately upon collection and maintains an accurate and reliable bacterial profile for weeks at room temperature. Recently, we have applied these principles of sample stabilization to other sample types, including oral, skin, and vaginal samples. In 2021, the Microbiome portfolio grew to support collecting and stabilizing metabolites found in fecal samples.

Laboratory and Data Analytical Services

Our Molecular Solutions business also offers our customers microbiome laboratory testing and analytical services. These services reflect the collective benefits of our Diversigen subsidiaries, which were combined under the Diversigen name during 2020. Our services focus on accelerating microbiome discovery for customers in the pharmaceutical, agriculture, and research communities. Our goal is to help customers unleash the translational potential of the microbiome and providing fast and information-rich characterizations of microbial diversity and function paired with expert analytics. We also offer comprehensive microbiome and metagenomics services to improve human, animal, and environmental health. Diversigen has extensive experience with highly diverse microbiome sample types and provides complete project life cycle consulting services, including pre-project consulting, study design, extraction, and sequencing to complete bioinformatics analysis. Diversigen is at the forefront of setting quality standards for this industry and has obtained the College of American Pathologists ("CAP") accreditation at its laboratory facilities. We are also in the process of integrating the services offered through GenoFIND™, under the Diversigen brand.

Products Under Development

Diagnostic Products

Our research and development efforts include programs targeted at expanding and enhancing our diagnostics business. These programs typically focus on products related to drug adherence and rapid tests for various diseases. In 2021, significant time and resources were dedicated to the development of our COVID-19 Rapid Antigen Self-Test (InteliSwab®). We introduced our antigen test to the market in 2021 for three different uses:

- **Professional Test** (CLIA Waived) for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers. In this instance, a physician would prescribe the test and the patient would conduct a self-swab in the presence of a healthcare provider who would then interpret the result.
- **Prescription Self-Test** for use by individual consumers (with prescription) at home or in any location, by employers/universities on- or off-site, or by physicians or public health via remote testing. In this instance, a physician would prescribe the test and the patient would conduct a self-swab at home, or in any location, where they would then interpret their own result.
- **OTC Self-Test** for use by consumers who would purchase online or at retail without prescription, and conduct the test and receive the result themselves anytime, anywhere.

We completed the InteliSwab® product development and clinical studies in 2021 and received three EUA authorizations for this test in June 2021.

In the first and second quarter of 2021, the clinical studies were completed and the EUAs were submitted to the FDA. Throughout 2021, limit of detection studies were completed with live coronavirus in certified third party analytical laboratories, confirming that InteliSwab® is able to detect all the variants of concern thus far including Omicron. The company has transferred the technology for the making of the devices to manufacturing which is ramping up and optimizing operations.

In 2021, we also received a $13.6 million grant from BARDA, which provides the funding necessary to obtain a 510(k) for InteliSwab® for both professional use (CLIA waived) and OTC use.

Molecular Solutions

In order to intersect evolving customer needs within the academic and commercial markets, our molecular 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, we continue to focus research and development work on collecting and stabilizing microbial DNA, RNA and metabolites from multiple sample types including gut, skin, vagina and saliva.

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

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic arrangements and independent distributors. Our 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.

We market our products in the United States and internationally. Consolidated net revenues attributable to customers in the United States were $188.4 million, $130.8 million, and $107.3 million in 2021, 2020, and 2019, respectively. Consolidated net revenues attributable to international customers amounted to $45.3 million, $40.9 million, and $47.3 million or 19%, 24%, and 31% of our total revenues in 2021, 2020, and 2019 respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Notes 2 and 14 to our consolidated financial statements included elsewhere in this Annual Report.

Diagnostics - Professional

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

We market 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. We sell our OraQuick *ADVANCE*® test to hospitals and physician offices in the U.S. primarily through distributors. In addition, we distribute our OraQuick® HIV test in certain foreign countries through distributors.
Our OraQuick® HCV test is sold primarily to the same markets where our OraQuick® ADVANCE HIV test is sold, including public health organizations, hospitals, physicians and retail clinics. We also sell this test in other countries through distributors.

Diagnostics - OTC and Self-Test

We sell our InteliSwab® COVID-19 Rapid Test product in the U.S. retail and consumer markets. 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 US military.

We sell our OraQuick® In-Home test in the U.S. retail or consumer market. The product is also available for purchase on-line through certain retailers and from our website, www.oraquick.com. The primary target population for our HIV-OTC test comprises young, sexually active adults, with greater purchase intent found in high-risk sub-groups, such as men who have sex with men, African Americans and Latino Americans. We also sell our OraQuick® HIV Self-Test in certain international markets. Under a Charitable Support Agreement with the Bill & Melinda Gates Foundation ("Gates Foundation") we are able to offer our OraQuick® HIV Self-Test at an affordable price in 50 developing countries in Africa and Asia with funding from the Gates Foundation. The funding consists of support payments tied to the volume of product we sell and reimbursement of certain related costs. The agreement was entered into in 2017 and has a four-year term and enables non-governmental organizations in the eligible countries that receive funding from government or public sector agencies and donors to access our HIV Self-Test at reduced pricing. The agreement with the Gates Foundation provides for an aggregate funding amount not to exceed $20.0 million over the four-year term or $6.0 million each year of the agreement. The term of this agreement expired in June 2021.

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

Substance Abuse Testing

Our 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.

We have entered into agreements for the distribution of our Intercept® collection device and associated MICRO-PLATE assays for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors and internationally for workplace, criminal justice and forensic toxicology testing through other distributors. We also market the Intercept® collection device on its own and as a kit in combination with laboratory testing services. To better serve our workplace customers, we

have contracted with commercial laboratories to provide prepackaged Intercept® test kits, with prepaid laboratory testing and specimen shipping costs included.

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

As discussed above, we also sell our next generation Intercept i2® *he* collection device with a NIDA-5 panel of fully-automated high-throughput oral fluid assays developed with Thermo Fisher for the detection of PCP, THC, opiates, cocaine, methamphetamines and amphetamines. These products are currently sold into the criminal justice and drug treatment markets.

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

Molecular Solutions

Our Molecular Solutions business sells its products directly to its customers, primarily through its own internal sales force in U.S. domestic markets. However, in many international markets, distributors are used.

Most of our Molecular Solutions revenues are derived from product sales to commercial customers and sales into the academic and research markets. Sales to commercial customers providing consumer genetics and clinical diagnostic services have been increasing and account for a majority these revenues. A significant portion of total sales are derived from repeat customers in both markets. Molecular Solutions also has customers in the livestock and companion animal markets.

We have expanded the market focus of our Molecular Solutions business by selling certain existing collection products for use in COVID-19 tests and by developing new collection devices for the emerging microbiome market, which is focused on the study of microbes and their effect on human health. Our primary product offering in the microbiome market, OMNIgene® • GUT, is focused on the human gut microbiome (microbes living in human stool). We are leveraging our existing sales force and global research connections to engage microbiome customers around the world and establish ourselves as among the leaders in ease-of-collection, stabilization and transport of this challenging sample type.

Our Molecular Solutions segment includes the Colli-Pee® device, a product developed and sold by our Novosanis subsidiary, for the volumetric collection of first void urine. This product is in its early stages and initial sales are occurring primarily through distributors and collaborations for use in the liquid biopsy and sexually transmitted disease markets.

This segment is offering laboratory and analytical services for both genomics and microbiome customers in order to more fully meet the needs of its customers. These services are primarily provided to pharmaceutical and biotech companies and research institutions. During 2019, we substantially expanded our ability to offer microbiome laboratory and bioinformatics services with the acquisition of CoreBiome and Diversigen. The laboratory operations of CoreBiome and Diversigen were combined during 2020 under the Diversigen brand.

Significant Products and Customers

Several different product lines have contributed significantly to our financial performance, accounting for 10% or more of our 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,		
	2021	2020	2019
Genomics	$ 63,350	$ 36,878	$ 56,200
OraQuick® HIV	42,373	44,224	43,092
COVID-19 collection kits	54,167	50,927	—
Inteliswab®	22,405	—	—

One of our customers accounted for approximately 15% of our net consolidated revenues in 2019. We had no customers that accounted for more than 10% of our net consolidated revenues for the years ended December 31, 2021 and 2020.

Supply and Manufacturing

We manufacture all of our OraQuick *ADVANCE*® Rapid HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraQuick® Ebola test, OraSure®, Intercept® and Intercept i2® *he* collection devices, AUTOLYTE and MICRO-PLATE assays and Q.E.D.® saliva alcohol test in our Bethlehem, Pennsylvania facilities. We expect to continue to manufacture these products at this location for the foreseeable future.

We have contracted with a third party in Thailand for the assembly of the OraQuick® Rapid HIV test and the OraQuick® HIV In-Home Test in order to supply certain international markets. We believe 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. We have long-term agreements in place for the contract manufacturing in Thailand and one of our suppliers has been manufacturing for us for the past 20 years.

We can purchase the HIV antigens, the nitrocellulose and certain other critical components, and the HCV and Ebola antigens used in our OraQuick® product lines only from a limited number of sources. If for any reason these suppliers are unwilling or no longer able to supply our antigen or nitrocellulose needs, we believe 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 our products would require FDA approval and some additional development work. This in turn could require significant time to complete, increase our costs and disrupt our ability to manufacture and sell the affected products.

We manufacture all of the proprietary chemistry and assay cards for our InteliSwab® COVID-19 Rapid Tests in our Bethlehem, Pennsylvania facilities. We made significant capital investments during 2021 in order to scale this manufacturing. On September 30, 2021, we entered into an agreement for $109 million in capital funding from the US Department of Defense, in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for our InteliSwab® COVID-19 Rapid Tests as part of the nation’s pandemic preparedness plan. Under the Agreement, the funding will be used to expand our production capacity by 100 million tests annually. Funding will be paid to us based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment. An existing Company location in Bethlehem, PA is being retrofitted to accommodate increased manufacturing and an additional new facility will be added in another U.S. location to be determined.

Our MICROPLATE and AUTO-LYTE assays require the production of highly specific and sensitive antibodies corresponding to the antigen of interest. Substantially all our antibody requirements are provided by contract suppliers. We believe that we have adequate reserves of antibody supplies and that we have access to sufficient raw materials for these products.

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

Our wholly-owned subsidiary, DNA Genotek, Inc. ("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. We are actively seeking to qualify other suppliers that can manufacture and supply the raw materials and components for the DNAG products. All DNAG products in our Molecular Solutions segment are produced in Canada. We have increased the capacity for our molecular collection kits to meet demand for COVID molecular testing to 60 million kits per year (including non-COVID kits) with another 20 million kits per year to be qualified by end of 2022.

Our Colli-Pee® device is currently manufactured at our Belgian assembly facility with components supplied by third party vendors.

Our GenoFIND™ genomics laboratory services are provided to our customers by a third party laboratory. We believe there are other laboratories that can also provide these services. Our microbiome laboratory testing and analytical services are provided by our subsidiary, Diversigen.

Human Capital Resources

In order to achieve the goals and expectations of our Company, it is crucial that we continue to attract and retain top talent. To facilitate talent attraction and retention, we strive to make OraSure a safe and rewarding workplace with opportunities for our employees to grow and develop in their careers.

As of December 31, 2021, we had 785 full-time employees, which compares to 570 employees as of December 31, 2020. The increase in employees during 2021 was primarily the result of the need to add manufacturing capacity for our InteliSwab® COVID-19 Rapid Test and molecular collection devices used in COVID-19 molecular testing. Our employees are not currently represented by a U.S. collective bargaining agreement.

We believe our employees are among our most important resources and are critical to our continued success. We focus significant attention to attracting and retaining talented and experienced individuals to manage and support our operations, and our 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 our workforce is fundamental to the success of our business. We safeguard our people, projects and reputation by striving for zero employee injuries and illnesses, while operating and delivering our work responsibly and sustainably. We provide our 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.

During 2021, in response to the changing impact of the COVID-19 pandemic, we continued to implement safety protocols and new procedures to protect our employees, our subcontractors and our customers. These protocols include complying with social distancing and other health and safety standards as required by federal, state and local government agencies, taking into consideration guidelines of the Centers for Disease Control and Prevention and other public health authorities. In addition, we continued to modify the way we conduct many aspects of our business to reduce the number of in-person interactions.

As part of our compensation philosophy, we believe that we must offer and maintain market competitive compensation and benefits programs for our 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 a diverse, equitable, and inclusive workplace that reflects and contributes to the global communities in which we do business and the customers and partners we serve. This includes all communities impacted by our corporate presence. Our management teams and all of our employees are expected to exhibit and promote honest, ethical and respectful conduct in the workplace. All of our employees must adhere to a Code of Conduct that sets standards for appropriate behavior and includes required annual training on preventing, identifying, reporting and stopping any type of unlawful discrimination. We strive to recruit the best people for the job regardless of gender, ethnicity or other protected trait and it is our policy to fully comply with all laws (domestic and foreign) applicable to discrimination in the workplace. We have an active Diversity, Equity and Inclusion Council that strives to drive diversity, equity and inclusion within the workplace. At OraSure, we believe a variety of perspectives are critical to achieving success, and that diversity, equity and inclusion are key drivers to growth-based innovation and profitability. We aim to create a culture where all people feel valued, supported, and inspired to be themselves fearlessly, without judgement. We believe that when all voices are heard, we honor and exemplify our core values and best serve our communities.

Competition

Diagnostics Segment

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

The primary competitive factors for our 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 us 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.

We expect 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 our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them, before we can do so. These developments could have a material adverse effect on our 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. Our 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. Our OraQuick ADVANCE HIV rapid test is the only oral fluid test for HIV in the United States, and as such, enables outreach testing outside of clinics. Our 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.

Our OraQuick® In-Home HIV oral fluid test is the only rapid HIV test approved by the FDA for sale in the US OTC market.

Outside the U.S., our 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 our HIV and HCV rapid oral fluid tests. There are no other oral fluid tests for HCV outside the US with WHO Prequalification status and the CE mark. The majority of our sales outside the US are in Africa due to the greater incidence of HIV in that region. In 2021, we obtained the CE mark for our OraQuick® HIV Self-Test which will enable us to enter the European over-the-counter market for HIV. In addition, in 2021, we received registration of our OraQuick® HIV Self-Test, and the Thai Free Sales Certificate which enables us to obtain registrations in Asia and Latin America.

The United States COVID-19 rapid testing market consists of tests used by medical professionals at the point-of-care as well as over-the-counter tests purchased and used by consumers. Currently, there are 45 professional point-of-care EUA authorizations by the US FDA. There are also 13 OTC Antigen rapid tests and 3 OTC rapid molecular tests authorized under EUA by the FDA. Our InteliSwab® test competes in both the professional point-of-care and OTC segments with these products.

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

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

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

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

Molecular Solutions Segment

Our 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 we believe 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. Our Oragene® and ORAcollect® products are also facing increasing competition from similarly designed collection systems which are beginning to enter the market. With the receipt of authorizations for use in connection with COVID-19 molecular tests, our Oragene® and ORAcollect® products now compete against COVID-19 testing systems and the collection methods used in those systems.

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, we are one of the few vendors to offer a solution that fully meets these requirements.

Our genomic and microbiome 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

We seek patents and other intellectual property rights to protect and preserve our proprietary technology and our right to capitalize on the results of our research and development activities. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to provide competitive advantages for our products in our markets and to accelerate new product introductions. We regularly search for third-party patents in fields related to our business to shape our 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.

We have two United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. The U.S. patents expire from June 2022 to December 2026. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

We have one United States patent for our OraQuick® platform expiring in 2028, as well as corresponding related international patents. We also have patent applications pending internationally. We have five pending patent applications in the United States for our InteliSwab® COVID-19 Rapid Test, and we have filed and expect to file additional patent applications for this product in certain international markets.

We hold, through our subsidiary, DNAG, twenty-four 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. These patents expire from February 2022 through April 2035.

We hold through our subsidiary, Novosanis, one granted United States patent and numerous foreign patents covering a medical device for capturing a predetermined volume of first void urine. This patent expires in September 2033.

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

We require our employees, consultants, outside collaborators and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual’s relationship with us 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 us or the performance by the consultant of services for us will be our exclusive property.

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own a number of trademarks, including the OraSure®, Intercept®, Intercept i2®*he*, OraQuick®, OraQuick *ADVANCE*®, OraSure QuickFlu®, Q.E.D.®, Inteliswab®, Oragene®, DNA Genotek®, OMNImet™, ORAcollect®, OMNIgene®, goDNA™, Diversigen®, CoreBiome®, Boostershot®, MetaGene™, Benchmark™, Novosanis®, Colli-Pee®, UCM®, UAS™, AUTO-LYTE®, prepIT® and Hemagene® trademarks. We also own many of these marks and others in several foreign countries and we are 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 our business. Competitors may be able to produce products competing with our patented products without infringing our 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 our 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. We believe that our products and procedures are in material compliance with all applicable regulations, but the regulations regarding the manufacture and sale of our products may be unclear and are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

Many of our 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, we must continue to comply with other FDA requirements applicable to marketed products and are 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 our ability to manufacture and sell these products. In addition, the FDA could refuse permission to obtain certificates needed to export our products if the agency determines that we are not in compliance.

Domestic Regulation

Most of our 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 emergency use authorization.

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. 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 request for de novo classification or a premarket approval application ("PMA") 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 our business, financial condition and results of operations.

Another option for marketing a product in the U.S. is through an Emergency Use Authorization ("EUA"). 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 following a determination by the Secretary of Health and Human Services that there is 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 our 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 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 our products are used for research only or other nonclinical or non-diagnostic purposes. Our molecular collection products are sold to many academic and research institutions for research purposes and our 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 lifecycle of a medical device, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing as well as complaint handling, corrective and preventative actions, and internal auditing. In complying with the QSRs, manufacturers must continue to expend time, money and effort in the area of production, quality, and post-market surveillance to ensure full compliance.

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

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

The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") prohibit 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. We consider the applicability of CLIA requirements in the design and development of our products. We have obtained a waiver of the CLIA requirements for our OraQuick ADVANCE® rapid HIV-1/2 antibody test, our OraQuick® HCV rapid antibody test and our Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. In addition, the supplier of the OraSure Quick-Flu® test has obtained a CLIA waiver for that product. The InteliSwab® COVID-19 Rapid Test Pro is authorized for use in patient care settings operating under CLIA Certificate, Certificate of Compliance and Certificate of Accreditation.

The laboratory services provided by our subsidiary, Diversigen, are subject to CLIA and consist of microbiome and metagenomics sequencing, bioinformatics and analysis. Diversigen has recently received a CLIA certificate of registration in Minnesota, and is pursuing accreditation from the College of American Pathologists (CAP). A CLIA certificate of compliance is issued once a state regulator or the Center for Medicare and Medicaid Services determines that the laboratory is compliant with the applicable CLIA requirements. Under CLIA, certain organizations—including CAP—can accredit laboratories performing testing on specimens from human beings or animals, using methodologies and clinical applications within the expertise of the laboratory accreditation program.

Certain of our products may also be affected by state regulations in the United States, which can restrict the use and sale of certain diagnostic products. We are presently working with legislators or regulators in certain of these states in an effort to modify or remove any restrictions affecting our ability to sell 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 ("FTC") and by other federal and state regulatory and enforcement authorities, including the Department of Justice ("DOJ"), 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, we may not promote our products for such "off-label" uses and can only market our 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 our promotional materials or training constitute promotion of an uncleared or unapproved use, it could request that we modify our training or promotional materials or subject us 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. FTC enforcement actions often result in consent decrees that constrain future actions. DOJ 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 FTC, our reputation could be damaged and sales of our 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 our facilities or procedures do not comply with the QSR regulations, it may refuse to provide such certificates until we resolve the issues to the FDA's satisfaction. Failure to obtain a CFG could inhibit our ability to export our products to countries that require such certificates.

International

We are 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. We generally pursue approval only in those countries that we believe have a significant market opportunity.

The International Organization for Standardization ("ISO") is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of the ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services. ISO 13485 certification indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution.

In the European Union ("EU"), products that fall under the scope of the Medical Devices Directive ("MDD") and the In Vitro Diagnostic Medical Devices Directive ("IVDD") are not subject to the prior approval of a regulatory authority, but, depending on the class of product, may require prior review by a notified body. Notified bodies are accredited and supervised by national regulatory authorities to conduct conformity assessment procedures of medical devices or other products. Such products must comply with certain essential requirements listed in those directives. ISO certification creates a rebuttable presumption that the product satisfies the applicable requirements. Compliance with these requirements allows us to complete the applicable conformity assessment procedure, involving a notified body where necessary, and to affix the CE mark to our products, without which they may not be placed on the market in the EU.

In addition, the EU has adopted the EU Medical Devices Regulation (the "EU MDR") and the In Vitro Diagnostic Medical Devices Regulation (the "EU IVDR"), which will repeal and replace the MDD and IVDD. The EU MDR and EU IVDR impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The EU MDR requirements are in effect as of May 2021 and manufacturers of currently approved medical devices have until May 2022 to meet the EU IVDR requirements. Compliance with these regulations may be expensive and

time-consuming. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements. We also note 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 our international strategy.

We must also comply with certain registration and licensing requirements as dictated by Health Canada, prior to commencing sales in Canada. We have completed this process for several of our 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"). We received this certification for our Diagnostics segment (previously named "OSUR") in January 2019 as well as for our Molecular Business Unit in February 2020.

We have obtained WHO pre-qualification for our OraQuick® HIV-1/Antibody Test, OraQuick® HIV Self-Test and OraQuick® HCV.

Anti-Kickback and Other Fraud and Abuse Laws

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

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

Our 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 our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our 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 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 our ability to operate in these jurisdictions and significant damage to our reputation.

We are 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 us 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 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 health care providers. 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, we have implemented necessary systems to accurately track gifts and other payments.

We have implemented a written Policy on Interactions with Health Care Professionals, which is based on the Code of Conduct for Interactions with Health Care Professionals promulgated by the Advanced Medical Technology Association, or 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 we believe that our 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 we are 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. Our present and future business has and will continue to be subject to the FCPA and various other laws, rules and/or regulations applicable to us as a result of our international sales. We also are subject to the FCPA's accounting provisions, which require us 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 we are subject as a result of our international sales also include the U.K. Bribery Act (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 our current and proposed research, development, and manufacturing processes, we are 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 we sell in Europe are subject to regulation in European Union, or 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 us to alter our manufacturing processes, thereby increasing our manufacturing costs, or may impose other additional obligations on us or our products. We believe that our products and manufacturing processes at our 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 our business should be read in conjunction with the consolidated financial statements and accompanying notes included in Item 15 of this Annual Report.

ITEM 1A. Risk Factors

Summary of Risk Factors

Investing in our Common Stock involves risk. Below is a summary of the principal factors that could adversely affect our business, operations and financial results. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report, including our consolidated financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, before investing in our Company. This summary does not address all of the risks that we face. 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 our business.
- Our future success depends upon market acceptance of our existing and future products and service offerings.
- We may not realize anticipated revenue from our COVID-19 diagnostic assays.
- The COVID-19 pandemic continues to cast uncertainty over our consolidated results of operations, financial position and cash flows, while the consequences of COVID-19 and the governmental response to the pandemic and pandemic-related macroeconomic impacts could negatively affect our operations and share price;
- Marketing of our COVID-19 tests and collection kits under EUAs from FDA is subject to certain limitations and we are 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, our future results may suffer.
- We expect to face increasing competition from other providers of diagnostic tests, sample collection products and molecular laboratory services.
- Our product sales cycles can be lengthy and may depend on public funding, which can cause variability and unpredictability in our operating results.
- Our inability to expand international sales could adversely affect our business and results of operations.
- Our international presence may increase our risks and expose our business to regulatory, cultural or other restraints.
- Our U.S. government contracts require compliance with numerous laws and increases our risk and liability.
- Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.
- Our business will suffer if we do not effectively manage challenges to our manufacturing processes and we may be unable to successfully scale-up manufacturing of our products in sufficient quality and quantity to meet demand, which would negatively impact revenue expectations.
- Our business results depend on our ability to manage disruptions in our domestic and global supply Chains and distribution channels.
- Our U.S. government contracts may affect our intellectual property rights.
- Certain of or products depend on components form a sole-source supplier, the loss of which would cause us to be unable to deliver such products.
- Our U.S. government contracts and related administrative processes are subject to audits and cost adjustments by the federal government.
- We may not be able to fulfill our obligations under government contracts, which could result in reduced sales and profits, contract penalties or terminations and damages to customer relationships.

Risks Relating to Our Industry, Business and Strategy

- Consolidation in the healthcare industry could adversely affect our future revenues and operating results.
- Our research, development and commercialization efforts may not succeed and our competitors may develop and commercialize more effective or successful offerings.

- Acquisitions or investments may not generate the expected benefits and could disrupt our ongoing business, distract our management, increase our expenses and adversely affect our business.
- There are risks relating to our acquisitions of Diversigen, Novosanis and UrSure.
- The future results of acquired companies may be adversely impacted if we do not effectively manage our expanded operations.
- Our revenues could be affected by third-party reimbursement policies and potential cost constraints.
- Changes in healthcare regulation could affect our revenues, costs and financial condition.
- New or changed testing guidelines could affect sales of our diagnostic products.
- Reductions in government funding and research budgets could adversely affect our business and financial results.

Risks Relating to Our Dependence on Third Parties

- The use of third party supply sources for critical components of our products could adversely affect our business.
- Our failure to maintain existing distribution channels, or develop new distribution channels, may result in lower revenues.
- We may need strategic partners to assist in developing and commercializing some of our products.

Risks Relating to Intellectual Property

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

Regulatory Risks

- The need to obtain regulatory approvals could increase our costs and adversely affect our financial performance.
- Failure to comply with FDA, EMA or other regulatory requirements may require us to suspend production or sale of our products or institute a recall which could result in higher costs and loss of revenues.
- Our inability to respond to changes in regulatory requirements could adversely affect our business.
- Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.
- We are subject to numerous government regulations in addition to FDA requirements, which could increase our costs and affect our 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.
- FDA regulation of laboratory-develop tests and genetic testing could affect demand for our products.
- Our international sales create potential exposure under anti-corruption laws.

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

- Economic volatility and disruption, including those related to the COVID-19 pandemic could adversely affect our business, financial performance, results of operations, cash flow and financial condition or those of our customers and suppliers.
- An impairment of goodwill and intangible assets could reduce our earnings.
- We have experienced losses in the past and may not be able to maintain profitable operations.
- Changes in foreign currency exchange rates could negatively affect our operating results.

Risks Relating to Our Common Stock

- Our stock price could continue to be volatile.

- Future sales of our Common Stock by existing stockholders, executive officers or directors could depress the market price of our Common Stock and make it more difficult for us to sell stock in the future.
- Because we do not intend to pay cash dividends on our Common Stock, an investor in our Common Stock will benefit only if our Common Stock appreciates in value.
- Certain provisions in our Certificate of Incorporation and Bylaws and under Delaware law could make a third-party acquisition of us difficult.

General Risk Factors

- We may face product liability claims for injuries resulting from the use of our products.
- Performance of our products may affect our revenues, stock price and reputation.
- Our ability to sell products could be adversely affected by competition from new and existing products and services.
- Failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.
- If we lose our key personnel or are unable to attract and retain qualified personnel as necessary, our business could be harmed.
- If our essential employees who are unable to telework become ill or otherwise incapacitated our operations may be adversely impacted.
- Increases in demand for our products and services could require use to expend considerable resources or harm our customer relationships if we are unable to meet that demand.
- We rely on information technology in our operations and any material failure, inadequacy, interruption or security breach of that technology could harm our ability to efficiently operate our business.
- Security breaches and other disruptions could compromise our information, expose us to liability and harm our reputation and business.
- Federal and state laws pertaining to healthcare fraud and abuse could adversely affect our business, financial condition and results of operations.
- We may experience fluctuations in our financial results or fail to meet our financial projections.
- We may require future additional capital.
- Terrorist attacks, natural disasters, public health crises or other catastrophic events outside of our control may adversely affect our business.
- Future sales of shares of our common stock could adversely affect the trading price of our common stock and our ability to raise funds in new equity offerings.

Risk Factors

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

Risks Relating to Products, Marketing and Sales

Changes in the Genomics Market May Adversely Affect our Business.

The genomics market has been the largest component of our overall molecular business segment for some time and the major driver of this market has been consumer genomics, which offers products and services to consumers to provide them with personalized health and genealogical information. The ancestry portion of this market may be maturing and our sales to customers with offerings in this market have been volatile. Our genomics revenues have been volatile due to changes in promotional strategies and purchasing patterns by one of our largest customers which serves the consumer ancestry and genetic testing market. This trend in the ancestry testing market may continue and revenues in this segment may continue to be volatile.

In an effort to increase our molecular revenues, we have devoted increasing time and attention to expanding sales of our genomics products both domestically and internationally, including in the Asia-Pacific and other markets. While we believe these new markets represent large growth opportunities, there is no assurance that we will be successful in capitalizing on these opportunities or that we will be able to increase our international product sales consistent with our expectations. Factors that include, but are not limited to, the market acceptance of our products, available funding, cost containment strategies implemented by customers, increasing competition and regulatory constraints could limit sales of our genomics products into these international markets. To the extent that we are unsuccessful or limited in expanding our business in the Asia-Pacific or other new markets, our revenues and results of operations could be negatively affected.

Despite the challenges that we face in the ancestry segment of the consumer genomics market, we believe there is significant growth opportunity for our genomics products in the area of disease risk management ("DRM"), which includes genetic risk testing, prenatal testing, carrier screening, pharmacogenomics testing and population heath studies.

Our Future Success Depends Upon Market Acceptance of Our Existing and Future Products and Service Offerings.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new 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, our future revenues will depend on market acceptance of new uses for our saliva collection products, including for COVID-19 testing, and our new service offerings, such as the microbiome laboratory testing and analytical services we provide through Diversigen. To commercially market new uses of our products and to achieve market acceptance, we will likely be required to undertake clinical studies to validate the new uses for our 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 our 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 our customers is uncertain. Also, we have started the process of developing and seeking 510(k) regulatory clearance for the InteliSwab® tests, and it is uncertain whether we will be successful in our 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 our expenses to develop and market any such products, including, without limitation our InteliSwab® tests, will exceed any benefit in revenues, which may be short-lived. In addition, other products that compete with ours may achieve 510(k) clearance earlier than we do, providing market advantages.

We May Not Realize Anticipated Revenue From Our InteliSwab® COVID-19 Rapid Test.

While we expect to continue to see significant demand for our InteliSwab® COVID-19 Rapid Test, other companies are working to produce or have produced rapid tests for COVID-19 which may lead to the diversion of customers, including governmental and quasi-governmental entities, away from us and toward other companies. Moreover, the dangers posed by COVID-19 may subside over time. A number of preventative vaccines have recently been approved for use in human populations by regulatory agencies in the U.S. and around the world. The uptake of these vaccines will likely limit the spread of COVID-19 and potentially reduce the market size for COVID-19 testing.

We expect that, if and when the current COVID-19 pandemic subsides, there could be significantly reduced demand for testing, and thus, for our InteliSwab® COVID-19 Rapid Tests. There is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce our InteliSwab® COVID-19 Rapid Test in quantities to meet the demand. A significant decline in demand for our InteliSwab® COVID-19 Rapid Test without a corresponding increase in our other businesses could have a material, adverse effect on our results of operations, cash flow and financial position.

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

Although we have experienced heavy demand for our InteliSwab® tests and certain specimen collection devices for use in COVID-19 molecular testing as a result of the COVID-19 pandemic, which has had a positive impact on our performance, the duration and level of the demand for COVID-19 testing is highly uncertain. in addition, the COVID-19 pandemic has negatively impacted our ability to

provide our HIV self-tests in Southern and Eastern African countries due to logistics challenges and, in our Molecular Solutions segment, COVID-related disruptions in clinical and research work, particularly in the academic market, had reduced demand for our products. We believe the COVID-19 pandemic's continued impact on our consolidated results of operations, financial position and cash flows will be primarily driven by; (i) the severity and duration of the COVID-19 pandemic; (ii) the CCOVID-19 pandemic's impact on the U.S. healthcare system and the U.S. economy; (iii) the timing, scope and effectiveness of federal, state and local governmental responses to the COVID-19 pandemic, including the development and deployment of vaccine, and (iv) the COVID-19 pandemic's impact on global clinics, research markets and global logistics. Each of these factors are difficult to predict and the nature, length and severity of any adverse consequences as a result of any given factor are uncertain.

Management has closely monitored the impact of the COVID-19 pandemic, with a focus on the health and safety of the Company's employees and business continuity.

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

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

Marketing of Our COVID-19 Tests and Collection Kits Under EUAs From FDA Is Subject To Certain Limitations and We Are Required To Maintain Compliance With The Terms of The EUA, Among Other Things, And The Continuance of The EUAs Is Subject To Government Discretion.

On February 4, 2020, the U.S. Department of Health and Human Services ("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 Food, Drug, and Cosmetic Act ("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, our 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 we have separately obtained EUAs for these products. Several other laboratories are pursuing the inclusion of our specimen collection devices for use with their SARS-CoV-2 assays. In addition, we obtained three EUAs for our new COVID-19 Rapid Tests. Although there are certain regulatory requirements the FDA has waived for the duration of the EUAs, we remain 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 initiated the clinical studies as required by the condition of authorization. OraSure has successfully completed the clinical study in the pediatric population and the development of the InteliSwab® Connect app.

As with other FDA-regulated products, issues could emerge during the course of the marketing and use of our products under an EUA that could impact our 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 market our diagnostic products or collection kits for the purpose of detecting COVID-19, we 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 Quality System Regulation under 21 CFR Part 820. It is possible that we may not be able to obtain those clearances or approvals in a timely manner, or at all, and that one or more of our competitors may obtain the necessary clearances or approvals for their products before we do.

If Acceptance and Adoption of Oral Fluid Testing and Collection Products Does Not Continue, Our Future Results May Suffer.

We have made significant progress in gaining acceptance of oral fluid testing products, particularly for (i) HIV testing in the public health, hospital, insurance and other markets, and (ii) drugs-of-abuse testing in the workplace and criminal justice markets. Our subsidiary, DNAG, has also made significant progress in gaining acceptance of oral fluid collection products that are used with molecular testing applications including testing for SARS-CoV-2. However, the degree of acceptance for these products is uncertain, and one or more markets may resist the adoption of oral fluid products as a replacement for other testing or collection methods in use today. As a result, there can be no assurance that we will be able to expand the use of our 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. Our future sales will depend, in part, on our 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 we can demonstrate that our 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. In addition, demand for our new rapid tests for SARS-CoV-2 or PrEP adherence may not develop consistent with our expectations. Our failure to achieve and expand market acceptance of our rapid point-of-care diagnostic tests with customers would have a negative effect on our future sales growth.

We Expect to Face Increasing Competition From Other Providers of Diagnostic Tests, Sample Collection Products and Molecular Laboratory Services.

Our rapid point-of-care tests compete with other point-of-care products made by our competitors. This competition is particularly evident with respect to our OraQuick *ADVANCE*® HIV-1/2 test and our HIV Self-Test outside of the US. The Oragene® product line sold by our subsidiary, DNAG, competes against other molecular collection products, such as blood collection kits and buccal swabs and will likely face additional competition from collection devices similar in design and operation to our Oragene® and ORACollect® products. There are a number of products currently in or expected to enter the market for the detection of antigen to SARS-CoV-2 that will compete with our InteliSwab® COVID -19 diagnostic test.

Our genetic and microbiome laboratory services business is expected to face increasing competition, primarily from large commercial reference laboratories, hospital-based laboratories and specialty laboratories. We believe there is significant opportunity in the markets for these services, particularly the microbiome market which is still in the early stages. As these markets evolve and expand, we expect competition for genomic and microbiome laboratory services to intensify.

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

A number of our 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 we have. We also face competition from certain of our distributors or former customers that have created, or may decide to create, their own products to compete with ours. If our competitors take market share from our offerings through more effective marketing or competitive pricing, higher quality or technological superiority, our revenues, margins and operating results could be adversely affected. In addition, our revenues and operating results could be negatively impacted if some of our customers use internally developed or acquired sample collection devices or services in order to reduce costs.

Our Product Sales Cycles Can be Lengthy, and May Depend on Public Funding, Which Can Cause Variability and Unpredictability in Our Operating Results.

The sales cycles for certain of our 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 our 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 our OraQuick *ADVANCE*® HIV-1/2 test has been purchased through bulk procurement or other funding provided by governmental agencies. Our OraQuick® HCV test has been purchased by customers who receive government funding, and we believe increased funding from the CDC and other agencies will be required to substantially increase the volume of HCV testing, especially in the public health market. There can be no assurance that purchases or funding from these agencies will occur or continue. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions at all or on a schedule and in an amount consistent with our objectives.

Our Inability To Expand International Sales Could Adversely Affect Our Business and Results of Operations.

One of our strategic priorities is to substantially expand our product sales internationally. An opportunity to accomplish this objective is with the sale of our OraQuick® HIV Self-Test in support of large self-testing programs in certain African countries and elsewhere. We are also working to expand international sales of our professional HIV and HCV products and our molecular collection kits. We also believe there is a significant opportunity for international sales of our InteliSwab® COVID-19 Rapid Test once the necessary studies and registrations are complete.

While we believe 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 we are otherwise unable to expand international sales of our products, our revenues and results of operations could be negatively impacted.

In addition, market conditions in many countries often require that we sell our products at a price below our 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 our business. To the extent these international sales comprise a large or increasing part of our business, our gross margins will be negatively affected. In addition, we may have difficulty selling our 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 we are unable to obtain or continue this funding support at sufficient levels, or at all, our revenues and results of operations could be negatively affected.

Our International Presence May Increase Our Risks and Expose Our Business to Regulatory, Cultural or Other Restraints.

We seek to increase revenue derived from international sales of our products. Our international sales accounted for $45.3 million, or 24%, of consolidated net revenues in 2021, $40.9 million, or 24%, of consolidated net revenues in 2020 and $47.3 million, or 31%, of consolidated net revenues in 2019. In addition, our subsidiary DNAG, which accounted for $130.3 million or 56% of consolidated net revenues in 2021, is operated in Canada. In 2019 we also acquired Novosanis, a company based in Belgium, and we may acquire other foreign companies as part of our business development efforts.

A number of factors could adversely affect the performance of our business and/or cause us to incur substantially increased costs because of our international presence and sales, including 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 our 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 our products;
- Trade protection measures, additional trade sanctions and import/export licensing requirements;
- The inability to obtain or maintain ISO certification for our or our suppliers' manufacturing facilities;

- Our inability to identify international distributors and negotiate acceptable terms for distribution agreements;
- Diversion to the U.S. of our 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, 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 coronavirus outbreak on our business operations in geographic locations impacted by the outbreak and on the business operations of our 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 we offer for our products;
- Restrictions on our 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 our products; and
- Reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries.

In addition, we have contracted with a third party in Thailand for the manufacture of a portion of our OraQuick® HIV tests and a portion of the assembly of our InteliSwab® COVID-19 Rapid Tests, and all of DNAG's products are produced in Canada. We 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 our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us 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 our products in foreign countries. In addition, the ongoing coronavirus pandemic has resulted in increased government-imposed travel restrictions and extended shutdowns of certain businesses in the affected locations as well as logistics delays due to the global logistical crisis from the pandemic. These or any further political or governmental responses to pandemic diseases could result in social, economic and labor instability of foreign countries, which could have a material adverse effect on our business, results of operations and financial condition.

Our U.S. Government Contracts Require Compliance With Numerous Laws and Increases Our Risk and Liability.

From time to time, we receive funding from the U.S. government and we sell some of our products to the federal government. Historically, we have sold a number of our products to the government under contracts with the General Services Administration and the Veterans Administration.

During the third quarter of 2021, we entered into a contract with the Defense Logistics Agency ("DLA") for the procurement of our InteliSwab® COVID-19 Rapid Test for over-the-counter use, with an estimated value of $205 million. During the same quarter, we entered into a contract with the BARDA to provide us with up to $13.6 million in funding to obtain FDA 510(k) clearance and CLIA waiver for our InteliSwab® test. In September 2021, we entered into a contract with the U.S. Department of Defense, in coordination with the HHS for $109 million in funding to build additional manufacturing capacity in the United States for our InteliSwab® test.

As a result of our U.S. government funding and product sales to the U.S. government, we 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 us 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 we have not defaulted in any of our obligations.

As a U.S. government contractor, we are 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 our business and have an adverse effect on our consolidated financial performance.

A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our 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 our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our 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, we could suffer serious reputational harm and the value of our common stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Our Inability to Manufacture Products in Accordance with Applicable Specifications, Performance Standards or Quality Requirements Could Adversely Affect Our Business.

The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements. As a result, our 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 our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

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

In June 2021, we received three FDA EUAs for our InteliSwab® COVID-19 Rapid Tests. Although there has been significant demand for this product in 2021, we have experienced some challenges in the technology transfer of our test in accordance with applicable specifications. As a result, we have not been able to meet the demand for our product. While we have now implemented key process automation steps which have resolved prior issues, we are currently manufacturing InteliSwab® at rates well below our installed capacity as we are scaling up production. Therefore, significant variability in our output can be expected As a result, our future revenues with this test may not meet expectations and could be adversely affected.

Our Business Will Suffer if We Do Not Effectively Manage Challenges to Our Manufacturing Processes and We May be Unable to Successfully Scale-Up Manufacturing of Our Products in Sufficient Quality and Quantity to Meet Demand, Which Would Negatively Impact Revenue Expectations.

Challenges in the manufacture of our products in the face of significant demand for our InteliSwab® COVID-19 Rapid Tests have adversely affected, and could in the future adversely affect, our operating efficiency and results of operations. We have contracted with the U.S. Department of Defense to add additional manufacturing capacity of our InteliSwab® COVID-19 Rapid Tests, however, we face risks in scaling up and building new manufacturing facilities, including with respect to expanding our overall production capacity as well as moving production to new facilities, that could increase costs, divert management attention and reduce our operating results, with no guarantee of success. The expansion of our manufacturing and scale-up of additional commercial production and capacity involves significant risks and challenges, including, but not limited to, design and construction delays, implementation of new systems and expertise and cost overruns. There can be no assurance that our scale-up and manufacturing expansion will be operational, on time, or contribute the production capacity that we anticipate, and we cannot guarantee that any such scale-up will operate at costs acceptable to us or that demand for our products will remain at levels high enough to meet the return on investment necessary to justify our investment in these projects.

As we increase our manufacturing capacity to meet market demand or begin to manufacture new products at scale, we 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, we could experience delays in production as we increase our manufacturing capacity or begin to manufacture new products that may result in our inability to meet product demand as the products ordered by our customers being on back-order as initial production issues are addressed. If we experience production delays or inefficiencies, a deterioration in the quality of our products or other complications in managing changes to our manufacturing processes, including those

that are designed to increase capacity, enhance efficiencies and reduce costs or that relate to new products or technologies, we may not achieve the benefits that we anticipate from these actions when expected, or at all, and our operations could experience disruptions, our manufacturing efficiency could suffer and our business, financial condition and results of operations could be materially and adversely affected. Any such delays could allow our competitors to seize market advantage. In addition, global supply chain and workforce challenges related to the COVID-19 pandemic increase the risks in scaling-up manufacturing as global supply challenges may increase the difficulty in obtaining necessary materials and a dynamic and unpredictable labor market may make the necessary labor and staffing challenges more difficult. If we are unable to successfully meet our manufacturing challenges, we may be unable to meet the demand for our InteliSwab® COVID-19 Rapid Tests, which could have a material, adverse effect on our reputation, revenues, results of operations, cash flow and financial position.

Our Business Results Depend on our Ability to Manage Disruptions in our Domestic and Global Supply Chains and Distribution Channels.

Our ability to meet our customers needs and achieve our financial objectives depends on our ability to maintain key manufacturing, supply and distribution arrangements. The loss or disruption of such manufacturing and supply arrangements could, in the future, interrupt our ability to obtain necessary raw materials and manufacture our 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 our suppliers to timely provide us with raw materials and components and distribute our 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 our distributors to sell and deliver our products to customers. Recently, the global supply chain has experienced significant disruptions caused by the COVID-19 pandemic, 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 our products or delivery of our products to customers, particularly in international markets. This in turn could have an adverse impact on our business, financial condition, results of operations or cash flows.

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

Our Intercept i2®*he* collection device is manufactured and supplied under a long-term agreement with Thermo Fisher, the sole-source supplier for these products. If Thermo Fisher were unable or unwilling to supply the necessary components for the manufacture of the Intercept i2® *he* collection devices, we would be unable to produce this product or offer it to our customers. Any interruption in, or change in the cost or quality of, the supply of the necessary raw materials, manufacturing services, product and process development, or other materials necessary to manufacture the product could adversely impact the efficacy of the product and negatively affect our reputation with our customers. If our sole source supplier were to be acquired by a competitor, it may elect not to provide us with the product. If the sole source supplier were to otherwise cease supplying us, go out of business, or were unable to meet its obligations in a timely fashion or at an acceptable price, or at all, we may be forced to incur higher costs to obtain the necessary raw materials elsewhere, if we could even source such materials at all.

Our U.S. Government Contracts May Affect our Intellectual Property Rights.

Provisions in our U.S. government contracts may affect our intellectual property rights. Certain of our activities have been funded, and may in the future be funded, by the U.S. government, including our 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 our confidential information to third parties and to exercise “march-in” rights to use and allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail 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 our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

Our 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 our performance on government contracts, pricing practices, cost structure, and compliance with applicable laws, regulations and standards. They can also review our compliance with government regulations and policies and the adequacy of our internal control systems and policies, including our 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 our 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, we may be subjected to government scrutiny that could delay or otherwise adversely affect our ability to compete for or perform government contracts or collect our revenue in a timely manner. An unfavorable outcome of an audit of our government contracts could adversely affect our results of operations.

We May Not be Able to Fulfill Our Obligations Under Government Contracts, Which Could Result in Reduced Sales and Profits, Contract Penalties or Terminations, and Damages to Customer Relationships.

If we are unable to successfully scale-up our manufacturing of our InteliSwab® COVID-19 Rapid Tests, we may be unable to meet our obligations under our government contracts. Our inability to fulfill our obligations government contracts could result in reduced sales and profits, contract penalties or terminations, and damage to customer relationships, leading the government to turn to other companies to fulfill the contract.

Risks Relating to Our Industry, Business and Strategy

Our operations are subject to the general risks associated with acquisitions, divestitures, and other strategic transactions, including our ongoing, Board-led strategic review.

We have made several acquisitions and divestitures in recent years. We regularly review strategic opportunities to grow through acquisitions and to divest non-strategic assets. In January 2022, we announced that our Board of Directors intends to explore and evaluate a broad range of strategic alternatives with the goal of maximizing value for stockholders. This exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value. This process may also create a distraction and diversion of management's attention from other business concerns, or result in the loss of key employees, which could lead to uncertainty that may adversely affect our operating results, business or investor perceptions. Any or all of these risks could impact our financial results and business reputation.

Consolidation in the Healthcare Industry Could Adversely Affect Our 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. We may not be able to compete successfully in such a consolidated industry. We believe 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 our products.

Our Research, Development and Commercialization Efforts May Not Succeed and Our Competitors May Develop and Commercialize More Effective or Successful Offerings.

In order to remain competitive, we 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 we will not achieve our goals on a timely basis, or at all, and we may have to abandon a new or enhanced product or service in which we have 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 must be obtained before most products may be sold and additional development efforts on these products may be required before any regulatory authority will review them. Similarly, regulatory clearances or registrations, such as a CLIA certification, and compliance with industry guidelines, may be required in order to provide competitive laboratory services. As noted above, regulatory authorities may not issue such approvals, clearances or certifications or may substantially delay or condition such action. Even if a product or service is developed and all applicable regulatory approvals, clearance or certifications are obtained, there may be little or no market for the product or service and entry into or development of new markets for our products and services may require an investment of substantial resources, such as new employees, offices and manufacturing facilities. Moreover, we 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 our efforts include

our ability to manufacture products or provide laboratory services in a cost-effective manner and whether we can obtain necessary intellectual property rights and protection in the markets where the product or service is sold.
If we fail to develop and gain commercial acceptance for our 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 our products and services or may purchase and use products and services developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flow and business.

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

Since the beginning of 2019, we have acquired several companies through which we have gained access to new technologies, products and services which are complementary to our existing business and aligned with our long-term business strategy. We will likely continue to pursue strategic acquisitions or investments as a way to expand our business. These activities, and their impact on our 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 us or consistent with our objectives;
- We 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, our inexperience with new businesses or markets, general economic conditions and increased competition;
- We 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 our 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 our business;
- We may not be able to accurately forecast the performance or ultimate impact of an acquired business;
- We may have difficulties in coordinating geographically separate organizations;
- We 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 our 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 we agree to pay contingent consideration for an acquisition, if and how much of such consideration we are required to pay may be subject to dispute, resulting in the distraction of our 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 ours;
- An acquisition may result in employees not familiar with our 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 our earnings or our 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 our 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 our 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 us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business or otherwise achieve our financial and strategic objectives.

There Are Risks Relating To Our Acquisitions of Diversigen, Novosanis and UrSure.

The success of the acquisitions will depend, in part, on our ability to successfully combine and integrate our legacy business with those businesses acquired. The integration of the businesses with our existing business can be complex, costly and time-consuming processes. It is possible that a number of factors, including, without limitation, the loss of key employees, higher than expected costs, diversion of management attention and resources, the disruptions of ongoing businesses or inconsistencies in standards, controls, procedures and policies, could adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits and cost savings of the acquisitions. If we experience difficulties with the integration process, the anticipated benefits of the acquisitions may not be realized fully or at all, or may take longer to realize than expected. These integration matters could have an adverse effect on the Company for an undetermined period following the acquisitions.

As a general matter, the market for microbiome laboratory testing and analytical services provided by Diversigen is at an early stage and is still developing. In addition, the Colli-Pee® urine collection devices manufactured and sold by Novosanis are relatively new products that are not yet widely accepted by customers. There is no assurance that we will be successful in creating or expanding demand for these services and products. To the extent that the markets for these services and products fail to develop or increase, our revenues and results of operations could be adversely affected and we may not meet our growth objectives.

Our Revenues Could be Affected by Third-Party Reimbursement Policies and Potential Cost Constraints.

The end-users of certain of our products include hospitals, physicians and other healthcare providers. Use of our products could be adversely impacted if these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors. Our 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 our 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 our 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 our products or our ability to sell our products on a profitable basis. In addition, the reimbursement approval process may delay the market introduction of our products.

Changes in Healthcare Regulation Could Affect Our 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 U.S. government recently enacted legislation that eliminated what is known as the "individual mandate" under the Affordable Care Act and may enact other changes in the future. The ultimate content and timing of any of these types of changes in other healthcare reform legislation and the resulting impact on us are impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise have an adverse effect on our financial condition and results of operations.

New or Changed Testing Guidelines Could Affect Sales of Our Diagnostic Products.

From time to time, governmental agencies such as the Centers for Disease Control and Prevention, or CDC, issue diagnostic testing guidelines or recommendations, which can affect the usage of our 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 our 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 our 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 our products and our results of operations.

Reductions in Government Funding and Research Budgets Could Adversely Affect Our Business and Financial Results.

We sell our OraQuick *ADVANCE*® HIV-1/2 and OraQuick® HCV tests into the US public health market which consists of state, county and other governmental public health agencies, community based organizations, service organizations and similar entities. We also sell 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 our products. In international markets, we often sell products such as our OraQuick® HIV Self-Test to or through foreign governmental agencies or parties funded by such agencies.

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

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

Risks Relating to Our Reliance on Third Parties

The Use of Third Party Supply Sources For Critical Components of Our Products Could Adversely Affect Our Business.

We currently purchase certain critical components of our 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 our OraQuick® HIV, HCV and Ebola products are currently purchased from sole source suppliers. Our OraSure QuickFlu® test and the fully automated high-throughput drug assays sold with our Intercept i2® device are manufactured and supplied by sole source suppliers and the conjugates used in our MICROPLATE oral fluid drugs-of-abuse assays are obtained from third-party suppliers. We have 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, our subsidiary, DNAG, uses three third-party manufacturers to supply virtually all of its products, including its Oragene® and ORAcollect® lines of collection kits. Many of the raw materials and components used in its products are also purchased from third parties, a critical one of which is obtained from a sole source supplier.

The COVID-19 pandemic and the measures taken to contain the spread of the virus, have disrupted, and could continue to disrupt, the normal operations of our third-party suppliers. Our third-party suppliers may not have the personnel, raw materials, capacity or capability to manufacture our products according to our 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 our supply chain could have a material adverse effect on our results of operations. If our 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 our specifications, we may need to find another source and/or manufacturer. This could require that we 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. We may also need to obtain FDA or other regulatory approvals for the use of an alternative component or for changes to our 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 our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our

products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business.

Our Failure to Maintain Existing Distribution Channels, or Develop New Distribution Channels, May Result in Lower Revenues.

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. Our sales depend to a substantial degree on our ability to sell products to these customers and on the marketing and distribution abilities of the companies with which we collaborate.

Relying on distributors or others to market and sell our products could harm our business for various reasons, including:

- We may not be able to find suitable distributors to distribute our products on satisfactory terms, or at all;
- Our distributors or other customers may not fulfill their contractual obligations to us or otherwise market and distribute our products in the manner or at the levels we expect;
- We do not control the incentives provided by our distributors to their sales personnel and the effectiveness of these incentives could affect sales of our products;
- Agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the parties;
- We may not be able to renew existing distribution agreements on acceptable terms, or at all;
- Our distributors may not devote sufficient resources or priority to the sale of our products;
- Our distributors may prioritize their own private label products that compete with our products;
- Our existing distributor relationships or contracts may preclude or limit us from entering into arrangements with other distributors; and
- We may not be able to negotiate future distribution agreements on acceptable terms, or at all.

Although we will try to maintain and expand our 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, our revenues and business could be adversely affected.

We May Need Strategic Partners to Assist in Developing and Commercializing Some of Our Products.

Although we 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 our existing sales force may necessitate involving one or more strategic partners. Further, our ability to enter into agreements with additional strategic partners depends in part on convincing them that our products can help achieve and accelerate their goals and efforts. Our 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 our business for a number of reasons, including:

- We may be required to transfer material rights to such strategic collaborators, government agencies, licensees and others;
- Our collaborators may not devote sufficient resources or attach a sufficiently high priority to the success of our collaboration;
- Our collaborators may not obtain regulatory approvals necessary to continue the collaborations in a timely manner;
- We have limited access to our collaborator’s confidential corporate information and sudden unexpected changes in ownership or strategy or other material events affecting a collaborator of which we are not made aware of in a timely manner, or at all, could adversely impact our relationship;
- Our collaborators may be acquired by another company, sell the part of their business related to our collaboration, decide to terminate our collaborative arrangement or become insolvent;
- Our collaborators may develop technologies or components competitive with our products;
- Our 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
- We may not be able to negotiate future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms or at all.

While we generally expect that our 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 our 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

Our Success Depends on Our Ability to Protect Our Proprietary Technology.

Our 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. Our success depends, in part, on our 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 we cannot continue to develop, obtain and protect intellectual property rights, our revenues and profits could be adversely affected. Moreover, our current and future licenses or other rights to patents and other technologies may not be adequate for the operation of our business.

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

We also rely on trade secrets, know-how and continuing technological advancements to protect our proprietary technology. We have entered, and will continue to enter, into confidentiality agreements with our employees, consultants, advisors and collaborators. Our employees and third-party consultants also sign agreements requiring that they assign to us interests in inventions and original expressions and any patents or copyrights arising from their work. However, these parties may not honor these agreements.

We cannot guarantee that the process of filing patents, the laws governing trade secrets and proprietary information, or any agreements we enter into with employees, consultants, advisors or collaborators will provide adequate protection of our intellectual property rights. For example, our competitors may develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies. Employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our 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, we may decide not to file for patent, copyright or trademark protection outside of the U.S. Our trade secrets could become known through other unforeseen means. Although we have licensed certain technology for use in our microbiome laboratory services offerings and we have developed proprietary know-how that we use in this business, we do not currently hold any patents covering the laboratory processes and analytical methods offered to our customers. The absence of patent protection in this or other parts of our business may make it more difficult to protect our intellectual property. In addition, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology.

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

Some of our employees, including scientific and management personnel, were previously employed by competing companies. Although we encourage and expect all of our employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against us. In addition, some of these agreements may conflict with, or be subject to, the rights of third parties with whom our 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.

We may collaborate with universities and governmental research organizations or receive funding for our 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 our collaboration or funding relationship with them.

To facilitate development and commercialization of a proprietary technology base, we 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 we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded. Moreover, some licenses may be nonexclusive, and therefore our competitors may have access to the same technology licensed to us.

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

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

Our 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 we incorporate in our products or services. Accordingly, we may be subjected to substantial damages for past infringement or be required to modify our products or services or stop selling them if it is ultimately determined that our products or services infringe a third party's proprietary rights. In addition, governmental agencies could commence investigations or criminal proceedings against our employees or us relating to claims of misuse or misappropriation of another party's proprietary rights.

Intellectual property litigation is costly. As such, our 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 our 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 our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products or services;
- An adverse outcome could subject us to the loss of the protection of our 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 our future earnings;
- Governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us 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 us from selling our current products or services or other products or services we may develop or acquire;
- We may be required to alter our product or services, given the proprietary rights of others;
- The pendency of any litigation may in and of itself cause our distributors and customers to reduce or terminate purchases of our products or services; and
- A court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products or services.

We may indemnify some customers and strategic partners under our agreements with such parties if our products, services or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Further, our products or services may contain technology provided to us by other parties, such as universities, contractors, suppliers, customers or collaborators, and we 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 us in the event that an infringement or misappropriation claim is asserted against us.

We may also become involved in other types of disputes regarding intellectual property rights, including state, federal or foreign court litigation, and patent interference, patent reexamination, patent reissue, or trademark opposition proceedings in the United States Patent and Trademark Office. Opposition or revocation proceedings could be instituted in a foreign patent office as well. Under Federal law,

various forms of post issuance patent review proceedings have been authorized, including an inter-parties review process. These proceedings permit certain persons to challenge the validity of a patent on the grounds that it was known from the prior art. The filing of such proceedings, or the issuance of an adverse decision in such proceedings, could result in the loss of valuable patent rights that could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Regulatory Risks

The Need to Obtain Regulatory Approvals Could Increase Our Costs and Adversely Affect Our Financial Performance.

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

The process of obtaining required approvals, clearances, premarket authorizations 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. 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, 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 our 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 essential requirements of the IVDD through May 25th 2022. Beginning May 26th 2022, manufacturers will be required to comply with the in vitro diagnostic regulations (IVDR). Notified Bodies need to be designated to review and certify products based on codes. If a Notified Body is not designated to review a certain code, they will not be able to certify those products. Currently there are extensions published for certain product that have a declaration of conformity prior to May 26, 2022; however, class A non-sterile products are not included in the extension. We have obtained the CE mark for several of our existing products. We also intend to apply for CE marks for certain of our future products and are not aware of any material reason why we would be unable to obtain those marks. However, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark will be obtained or maintained for all products that we desire to sell in the EU. The failure to obtain or maintain the CE mark for one or more of our products could lead to the termination of strategic alliances and agreements for sales of those products in the EU.

In addition, we or our distributors are often required to obtain premarket authorization or product registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries. We may also be required to obtain WHO pre-qualification or endorsement in order to sell certain products in international markets or enable our customers to access interested funding sources for our products. We 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 our ability to market and sell our products in the relevant country. In addition, any change in our arrangement with a foreign distributor could result in the loss of or delay in transfer of any applicable product registrations, thereby interrupting our ability to sell those products in the affected markets.

Failure to Comply With FDA or Other Regulatory Requirements May Require Us to Suspend Production or Sale of Our 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 our operations, and the operations of our suppliers and distributors, including manufacturing, labeling, packaging, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are 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. We believe that our 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 we cannot be sure that the FDA or other regulators will agree with our 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 our or our 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 premarket clearance or PMA approval for devices, withdrawal of product registrations, marketing clearances or approvals, or criminal prosecution. The ability of our suppliers to supply critical components or materials and of our distributors to sell our 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 our revenues, costs and results of operations.

Some of our products, particularly those sold by DNAG, are sold for research purposes in the U.S. We do not promote these products for clinical diagnostic use and they are labeled “For Research Use Only”, or RUO. If the FDA were to disagree with our RUO designation of a product, we could be forced to stop selling the product until appropriate regulatory clearance or approval has been obtained.

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

Our Inability to Respond to Changes in Regulatory Requirements Could Adversely Affect Our Business.

We believe that our 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 our products, the QSR and ISO requirements, and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to our products, necessitate additional clinical trials or procedures, or make it impractical or impossible for us to market our 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 and/or impose new or additional requirements as part of the approval 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 our products. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

Our Inability to Manufacture Products in Accordance With Applicable Specifications, Performance Standards or Quality Requirements Could Adversely Affect Our Business.

The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers’ expectations and applicable regulatory requirements. As a result, our 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 our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

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

We Are Subject to Numerous Government Regulations in Addition to FDA Requirements, Which Could Increase Our Costs and Affect Our Operations.

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

We 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 we advertise our products. As a device manufacturer, we are required to report annually to the Centers for Medicare & Medicaid Services (“CMS”) any payments or transfers of value we have made to physicians and teaching hospitals and any

physician ownership or investment interest in the Company. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our 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 we do not comply, our business and results of operations could be adversely affected.

Failure to Comply With Privacy, Security and Breach Notification Regulations May Increase Our Costs.

In the past, the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") has generally affected us indirectly, as the Company is generally neither a Covered Entity nor a Business Associate, as further defined under HIPAA, to Covered Entities. We have 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 we do not comply with existing or new laws and regulations related to properly transferring data containing consumers' personal information, we 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, we 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 us is now greater, as the U.S. Department of Health and Human Services (HHS) can take action directly against Business Associates. Thus, while we believe we are 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 our business. For example, we 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 Our Costs.

The European Union ("EU") has adopted a comprehensive overhaul of its data protection regime from the prior national legislative approach to a single European Economic Area Privacy Regulation called the General Data Protection Regulation ("GDPR"), which came into effect on May 25, 2018. The new EU data protection regime extends the scope of the EU data protection law to all foreign companies processing data of EU residents. It provides for a harmonization of the data protection regulations throughout the EU, thereby making it easier for non-European companies to comply with these regulations. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "portability" of personal data. Although the GDPR will apply across the EU without a need for local implementing legislation, as had been the case under the prior data protection regime, local data protection authorities will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We are implementing a plan to ensure compliance with these new requirements. [AG4] Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to amend certain of our business practices. Further, we have no assurances that violations will not occur, particularly given the complexity of the GDPR, as well as the uncertainties that accompany new, comprehensive legislation.

We are also subject to the California Consumer Privacy Act of 2018 ("CCPA"), which took effect on January 1, 2020. The CCPA imposes extensive new requirements and protections on the processing of personal data, aimed at giving California consumers more visibility and control over their personal information. Failure to comply with the CCPA or other data processing or security laws, or any changes in these laws, could adversely impact our business and our business plans.

FDA Regulation of Laboratory-Developed Tests and Genetic Testing Could Affect Demand For Our 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, or 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. We cannot predict what policies will be adopted with respect to regulating LDTs. FDA has been working with regulatory advocacy groups (AdvaMed) to bring forward regulations specifically for in vitro diagnostic tests including LDTs called the VALID Act. In 2021, the VALID Act was introduced to Congress and will change IVDs and LDTs to in vitro clinical tests (IVCT). The proposed regulation will give FDA oversight of LDTs once it becomes law.

Our 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 our revenues.

In 2019, the Department of Justice ("DOJ") 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 our DNA collection devices.

Our International Sales Create Potential Exposure Under Anti-Corruption Laws.

We have a policy in place prohibiting our employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (the "FCPA") and similar foreign laws. In 2021, approximately $45.3 million of our consolidated net revenues were generated from sales in a variety of foreign countries. These international activities subject us 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. We have operations, enter into agreements with third parties, and make sales in countries known to experience corruption. Further international expansion, including the acquisition of foreign entities, may create increased exposure to such practices. Our activities in these countries create the risk of unauthorized payments or offers of payments by one of our 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 our control. It is our policy to implement safeguards to discourage these practices by our employees and distributors, including employee training, contracts requiring compliance with the FCPA and similar rules, and standard reviews of our distributors. However, our existing safeguards and any future improvements may not prove to be effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA and other laws may result in criminal or civil sanctions, which could be severe and we may be subject to other liabilities, which could negatively affect our reputation, business, results of operations and financial condition.

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

Economic Volatility and Disruption, Including Those Related To The COVID-19 Pandemic, Could Adversely Affect Our Business, Financial Performance, Results of Operations, Cash Flow and Financial Condition or Those of Our Customers and Suppliers.

Global and U.S. markets and economies have experienced extreme volatility and disruption following the global outbreak of COVID-19 that has continued throughout 2021. Many economists and major investment banks have expressed concern that the continued spread of the virus globally has led to a world-wide economic downturn. Volatile economic conditions may occur again or continue in the future.

Although the severity and duration of the COVID-19 pandemic cannot be reasonably estimated at this time, impacts that we may experience include, but are not limited to:

- a slowdown or stoppage in the supply chain of the raw materials and components used to manufacture our products;
- interruptions or delays in domestic and/or international shipment of our products to our distributors and customers;
- interruptions in normal operations of certain end-use customers that could result in reductions in demand for our products;
- disruptions to our operations, including a shutdown of our facilities or product lines; restrictions on our operations and sales, marketing and distribution efforts; and interruptions to our research and development, manufacturing, clinical/regulatory and other important business activities;
- shutdown or interruption of our manufacturing facilities due to contamination and costs incurred to clean and disinfect a facility following contamination;
- inefficiencies and increased costs in our production and shipping processes due to premium pay for manufacturing and certain other employees as well as social distancing and personal protective equipment requirements;

- limitations on employee resources and availability, including due to sickness, government restrictions, the desire of employees to avoid contact with large groups of people or mass transit disruptions;
- a fluctuation in foreign currency exchange rates or interest rates could result from market uncertainties;
- an increase in exposure to credit losses for customers adversely affected by the COVID-19 pandemic; and
- an increase in regulatory restrictions or continued market volatility could hinder our ability to execute strategic business activities, including acquisitions.

These conditions could adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could also adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. Many of our 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 our customers and suppliers, which, in turn, could adversely affect their ability to purchase and/or distribute our products or supply us with necessary equipment, raw materials or components. Any or all of these effects would have an adverse effect on our operations, business, financial condition and results of operations.

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

An Impairment of Goodwill and Intangible Assets Could Reduce our Earnings.

At December 31, 2021, our consolidated balance sheet reflected approximately $40.3 million of goodwill and approximately $14.3 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 us 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 our annual goodwill impairment testing based on the current circumstances of how we manage or business, this group of assets is the Company as a whole. If we determine that any of our goodwill or intangible assets were impaired, we will be required to take an immediate charge to earnings and our results of operations could be adversely affected.

We Have Experienced Losses in the Past and May Not Be Able To Maintain Profitable Operations.

We experienced annual net losses during the five years prior to 2015 and again in 2020 and 2021. In addition, as of December 31, 2021, the Company had an accumulated deficit of $120.5 million. Even though we achieved profitability in 2015 through 2019, there can be no assurance that we will be able to sustain his profitability in the future.

Our ability to continue profitable operations in the future will be dependent upon a number of factors including, without limitation, the following:

- Our ability to continue growing sales of our molecular collection products and related genomic and microbiome laboratory services;
- Our ability to produce and successfully commercialize our InteliSwab® COVID-19 Rapid Tests;
- Our ability to grow our OraQuick *ADVANCE*® HIV 1/2 test in the United States and expand sales of our OraQuick® HIV Self-Test internationally;
- Changes in customer buying patterns or a buildup of significant quantities in our distributors' inventories or distribution channels;
- The level of expenditures we are required to make in order to develop, obtain regulatory approvals for and successfully commercialize our new products;
- Our ability to expand our business through the acquisition of other companies or technologies or through internal development of new or improved products;

- Our ability to improve manufacturing efficiencies and reduce cost of goods sold;
- Our ability to successfully launch new products after receipt of required regulatory approvals or the acquisition of rights to those products;
- The degree to which our major distributors and customers comply with their contractual obligations, including minimum purchase commitments;
- Whether we are successful in obtaining and maintaining required regulatory approvals and registrations for our new products;
- The level of competition, including the degree to which competitors sell lower priced products or more attractive offerings to compete with our products;
- Changes in economic conditions in domestic or international markets, such as economic downturns, reduced demand, inflation and currency fluctuations;
- Failure to achieve our revenue growth targets; and
- The costs and results of patent infringement, product liability and other litigation or claims asserted by or against us.

Changes in Foreign Currency Exchange Rates Could Negatively Affect Our Operating Results.

Our financial statements are stated in U.S. Dollars and, historically, most of our international sales have also been denominated in U.S. Dollars. As a result, in the past our 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 our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets.

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

Exchange rate fluctuations may affect the revenues and expenses of our foreign subsidiaries and the translation of those financial results into U.S. dollars. Favorable movement in exchange rates have benefited us in prior periods. However, where there are unfavorable currency exchange rate fluctuations, our consolidated financial statements including our 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, we have not generally entered into hedging instruments to manage our currency exchange rate risk, but we may need to do so in the future. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavorable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

Risks Relating to Our Common Stock

Our Stock Price Could Continue to be Volatile.

Our 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 our Common Stock:

- The performance of our business, including our efforts to increase sales of our OraQuick® HIV, HCV and Molecular Solutions products and our OraQuick® In-Home HIV test and HIV Self-Test;
- Our efforts to expand sales of our genomic and microbiome laboratory service offerings;
- Our efforts to produce and commercialize our InteliSwab Covid-19 Rapid Tests;
- Future announcements concerning us and our products or services, including with respect to significant acquisitions, strategic collaborations and joint ventures;
- Ability to achieve the expected benefits, enhanced revenue growth and synergies from strategic acquisitions;
- Clinical results with respect to our products or services or those of our 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 us, our products or services, or one or more of our customers;
- The gain or loss of significant contracts and availability of funding for the purchase of our 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 our 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 us 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 our 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 our 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 we were subject to this type of litigation in the future, we could incur substantial costs and experience a subsequent diversion of our management's attention and resources, each of which could have a material adverse effect on our revenue and earnings. Any adverse determination in this type of litigation could also subject us to significant liabilities.

Future Sales of Our Common Stock by Existing Stockholders, Executive Officers or Directors Could Depress the Market Price of Our Common Stock and Make It More Difficult For Us to Sell Stock in the Future.

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

We have a number of institutional stockholders that own significant blocks of our 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 our Common Stock could be negatively affected. In addition, it is possible that one or more of our executive officers or non-employee members of our Board of Directors could sell shares of our Common Stock during an open trading window or pursuant to a 10b5-1 sales plan under our Insider Trading Policy. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price of our Common Stock.

Because We Do Not Intend to Pay Cash Dividends on Our Common Stock, an Investor in Our Common Stock Will Benefit Only if Our Stock Appreciates in Value.

We currently intend to retain our current earnings and future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our Common Stock in the foreseeable future. As a result, the success of an investment in our Common

Stock will depend entirely upon any future appreciation. There is no guarantee that our Common Stock will appreciate in value or even maintain the price at which investors purchased their shares.

Certain Provisions in Our Certificate of Incorporation and Bylaws and Under Delaware Law Could Make a Third-Party Acquisition of Us Difficult.

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

General Risk Factors

We May Face Product Liability Claims for Injuries Resulting From the Use of Our Products.

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

- Decreased demand for our products;
- Lost revenues;
- Damage to our 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.

We are selling the InteliSwab® Covid-19 Rapid Test and the OraQuick® In-Home HIV test in the United States OTC market, and we offer HIV Self-Tests to consumers internationally. We believe the sale of products for use by consumers increases our potential exposure to product liability and other claims.

Performance of Our Products May Affect Our Revenues, Stock Price and Reputation.

Our products are generally sold with labeling that contains performance claims approved or cleared by the FDA or other regulators. However, our products may not perform as expected. For example, a defect in one of our 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 our product properly. Identifying the root cause of a product performance or quality issue can be difficult and time consuming.

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

Our Ability to Sell Products Could be Adversely Affected by Competition From New and Existing Products and Services.

The markets we serve are highly competitive and rapidly changing and we expect competition to intensify as technological advances are made and become more widely known, and as new products and services reach the market. Many of our principal competitors have considerably greater financial, technical and marketing resources than we do. As new products and services enter the market, our 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 ours. In addition, there can be no assurance that our competitors will not succeed in obtaining

regulatory approval for new products and services that would render our technologies, products and services obsolete or otherwise commercially unattractive, or introduce or commercialize such products and services before we can do so. If we fail to convince our customers of the advantages and economic value of our products and services or otherwise maintain and enhance our competitive position, our 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 our business, financial condition and results of operations.

We also face 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 we may be forced to sell our 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 our products. We may also be required to increase our marketing efforts in order to compete effectively, which would increase our costs.

Failure to Achieve Our Financial and Strategic Objectives Could Have a Material Adverse Impact on Our Business Prospects.

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

If We Lose Our Key Personnel or Are Unable to Attract and Retain Qualified Personnel as Necessary, Our Business Could be Harmed.

Our success depends to a large extent upon the contributions of our executive officers, management and sales, marketing, operations and scientific staff. Our business may be harmed by the loss of a significant number of our executive officers or senior managers. We 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. Our ability to recruit such employees will depend on a number of factors, including compensation, benefits, work location, the prospects of our Company, and the possibility for advancement within our organization. We generally do not enter into employment agreements requiring our employees to work for us for any specified period.

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively produce, market and sell our products and services, to meet the demands of our strategic partners in a timely fashion, or to support research, development and clinical programs. Although we believe we 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 our ability to do so on acceptable terms.

If Our Essential Employees Who Are Unable To Telework Become Ill or Otherwise Incapacitated, Our Operations May Be Adversely Impacted.

As a medical device manufacturer, we fall within a “critical essential infrastructure” sector, specifically the “Healthcare/Public Health” sector, and are considered exempt under various stay at home/shelter in place orders. Accordingly, our employees may continue to work because of the importance of our operations to the health and well-being of citizens in the states in which we operate. Consistent with these Stay at Home Orders, we have implemented telework policies wherever possible for appropriate categories of “nonessential” employees. “Essential” employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering and increased sanitation standards. We are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and wellbeing of our “essential” employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

Increases in Demand for Our Products and Services Could Require Us to Expend Considerable Resources or Harm Our Customer Relationships if We Are Unable to Meet That Demand.

If we experience significant or unexpected increases in the demand for our products and services, we and our 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 our capital costs, which could adversely affect our earnings. Our 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 our products or provide laboratory services. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products and services could be adversely affected.
If we are unable to develop necessary manufacturing or laboratory capabilities in a timely manner, our sales could be adversely affected. If we fail to increase these capabilities in a cost effective manner or if we experience lower than anticipated yields or production or performance problems as a result of changes that we make in our manufacturing or laboratory processes to meet increased demand, we could experience delays or interruptions and increased costs, which could also have a material adverse effect on our revenues and profitability.

Unexpected increases in demand for our products may require us 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. We have long-term supply agreements with certain of these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of raw materials and components and our 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 us. Any shortfall in our supply of raw materials and components, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our ability to meet increased demand for our products. This could negatively affect our total revenues or cost of sales and related profits.

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

We Rely on Information Technology in Our Operations and Any Material Failure, Inadequacy, Interruption or Security Breach of that Technology Could Harm Our Ability to Efficiently Operate Our Business.

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

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

Security Breaches and Other Disruptions Could Compromise Our Information, Expose Us To Liability and Harm Our Reputation and Business.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our employees in our data centers and on our networks. Secure maintenance and transmission of this information is critical to our operations business strategy. We generally rely on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive date.

Cyber-attacks could result in unauthorized access to our computer systems or our third party IT service provider’s systems and, if successful, misappropriate personal or confidential information. The Company has been victimized by a spear phishing attack, and such attacks are an ongoing threat. If successful, these activities could lead to the disclosure of intellectual property or personally identifiable information, which could lead to financial harm and cause reputational damage. We have taken additional steps designed to improve the security of our networks and computer systems.

In addition, a contractor or other third party with whom we do business may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. While we will continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third party training, monitoring of networks and systems and maintenance of back up of protective systems) which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, voyeur or malfeasance.

Even the most well protected IT networks, systems and facilities remain potentially vulnerable because the techniques used in attempted security breaches 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 our or our third party's IT service providers' data security and access, public disclosure, or loss of personal 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 our operations, require significant management attention and resources to remedy any damages that result, and damage our reputation and customers willingness to transact business with us, any of which could adversely affect our business.

As our activities continue to evolve and expand, we 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 our business either directly or indirectly. Our failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact our business and future business plans.

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

We are 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 we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

We May Experience Fluctuations in Our Financial Results or Fail to Meet Our Financial Projections.

Our operating results can fluctuate from quarter to quarter and year to year, which could cause our growth or financial performance to fall below the expectations of investors and securities analysts. Our financial projections for future periods are based on a number of assumptions, including estimated demand for our products. However, sales to our 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 our financial results.

Customers in certain of the markets we serve 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 our sales from year-to-year. This can make it difficult to accurately forecast whether we will achieve our quarterly sales forecasts and can cause variability in our operating results.

In addition, our products provide different contributions to our gross margin. Accordingly, our 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 our reputation and the price of our Common Stock.

We May Require Future Additional Capital.

Our future liquidity and ability to meet our 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 we gain or expand market acceptance for existing, new or enhanced products and services;
- The costs and timing of the expansion of our manufacturing and laboratory capacity;
- The success of our 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, we 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 us on satisfactory terms, or at all.

Terrorist Attacks, Natural Disasters, Public Health Crises, Political Unrest or Other Catastrophic Events Outside of Our Control May Adversely Affect Our Business.

Terrorist attacks, natural disasters, including disasters attributable to climate change impacts, public health crises, political unrest or other catastrophic events outside of our 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 our products. For example, the COVID-19 outbreak has led to, and for an unknown period of time will continue to lead to, disruptions in local, regional, national and global markets and economies affected thereby, including the United States. This outbreak has resulted in, and until fully resolved is likely to continue to result in, among other things: (i) restrictions on travel, government mandated social distancing measures, and the temporary closure of many corporate offices, retail stores, and manufacturing facilities and factories; (ii) significant disruption to the business of many companies, including our customers and suppliers, as well as layoffs of employees; (iii) reduction or termination by public health and other customers of infectious disease testing programs, including for HIV and HCV, and a reallocation of personnel and monetary resources from these programs to programs intended to address COVID-19; (iv) reduction or termination of clinical and research studies by academic and other entities that use our molecular collection products and laboratory services; and (v) rapidly evolving proposals and actions by state and federal governments to address the problems being experienced by markets, businesses and the economy in general, which may have unintended consequences or may not adequately address such problems. These events have disrupted, and threaten to continue to disrupt, our normal operation, the operations of our customers and suppliers and eliminate, reduce or delay our customers' ability to purchase and use our products and our suppliers' ability to provide raw materials and finished products. Despite our efforts to manage and mitigate the impact of these events on us, it is impossible to predict the precise nature and consequences of these events, or of any political or policy decisions and regulatory changes occasioned by emerging events or uncertainty under applicable laws or regulations that impact us. It is clear that these types of events are impacting and will, for at least some time, continue to impact our product development and operation and in many instances the impact may be adverse and may be material. Any potential impact to our results of operations will depend to a large extent on future developments and new information that could emerge regarding the duration and severity of the COVID-19 pandemic and the actions taken by authorities and other entities to contain the spread or treat its impact, all of which are beyond our control. These potential impacts, while uncertain, could adversely affect our business and results of operation. In addition, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China or escalation in conflict between Russia and Ukraine, including any resulting sanctions, export controls or other restrictive actions that may be imposed by the US 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 our business or ability to access the capital markets.

Various types of disasters, including earthquakes, fires, floods, riots, acts of terrorism and pandemics, may also affect our manufacturing facilities and computer systems, and increase our cybersecurity risks. Although we have business interruption insurance, our facilities,

including some pieces of manufacturing equipment and our computer systems, may be difficult to replace and could require substantial replacement lead-time. In the event our existing manufacturing facilities or computer systems are affected by man-made or natural disasters, including pandemics, we may have difficulty operating our business and may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or shut down entirely, it would seriously harm our business. Moreover, we may incur incremental costs following an unforeseen event which could adversely affect our results of operation.

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

Future sales of a substantial number of our 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 our Common Stock, and could impair our 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 our Common Stock.

ITEM 1B. Unresolved Staff Comments.

None

ITEM 2. Properties.

We own a 48,000 square foot facility which is OraSure's primary corporate office and manufacturing facility, a 31,700 square foot facility that houses our sales and marketing, research and development, human resources, and regulatory and quality offices, and a 33,500 square foot facility which is used for manufacturing activities. Each of these facilities is located in Bethlehem, Pennsylvania. We also rent additional warehouse space on an as-needed basis, including a 70,000 square foot warehouse in Bethlehem Township, Northampton County, Pennsylvania. Additionally, in January 2022, we entered into an agreement to lease a 96,010 square foot facility in York, Pennsylvania, which is scheduled to commence during the first quarter of 2022 and will be used for manufacturing activities. Our subsidiary, DNAG, also leases a 35,883 square foot facility in Ottawa, Canada, which is used as its primary corporate office and houses sales and marketing, manufacturing, distribution, research and development, and regulatory and quality operations. Our other subsidiaries, Diversigen and Novosanis, also lease facilities for their operations.

We believe that the facilities described above are adequate for our current requirements.

ITEM 3. Legal Proceedings.

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

In March 2021, we 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 has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. We believe Spectrum's counterclaims are without merit and we filed a motion to dismiss both claims in October 2021. We are seeking injunctive relief and damages in this matter. In January 10, 2022, the Court assigned a new judge to preside over the matter, which vacated all dates for the trial. Spectrum filed their reply to our motion to dismiss on January 11, 2022. Though all other dates are pending, the Court has set the hearing for the motion to dismiss for March 30, 2022.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

Our Common Stock is listed for trading on the Global Select Market tier of The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "OSUR". On February 21, 2022, there were 293 holders of record and approximately 40,810 holders in street name of our Common Stock, and the closing price of our Common Stock was $7.97 per share.

Dividends

We have never paid any cash dividends and our Board of Directors does not anticipate paying cash dividends in the foreseeable future. We intend to retain any future earnings to provide funds for the operation and expansion of our business.

Share Repurchases and Retirements

Period	Total number of shares purchased		Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs [1, 2]
October 1, 2021 - October 31, 2021	—	[3]	$ —	—	11,984,720
November 1, 2021 - November 30, 2021	323	[3]	9.98	—	11,984,720
December 1, 2021 - December 31, 2021	21,027		8.81	—	11,984,720
	21,350			—	

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

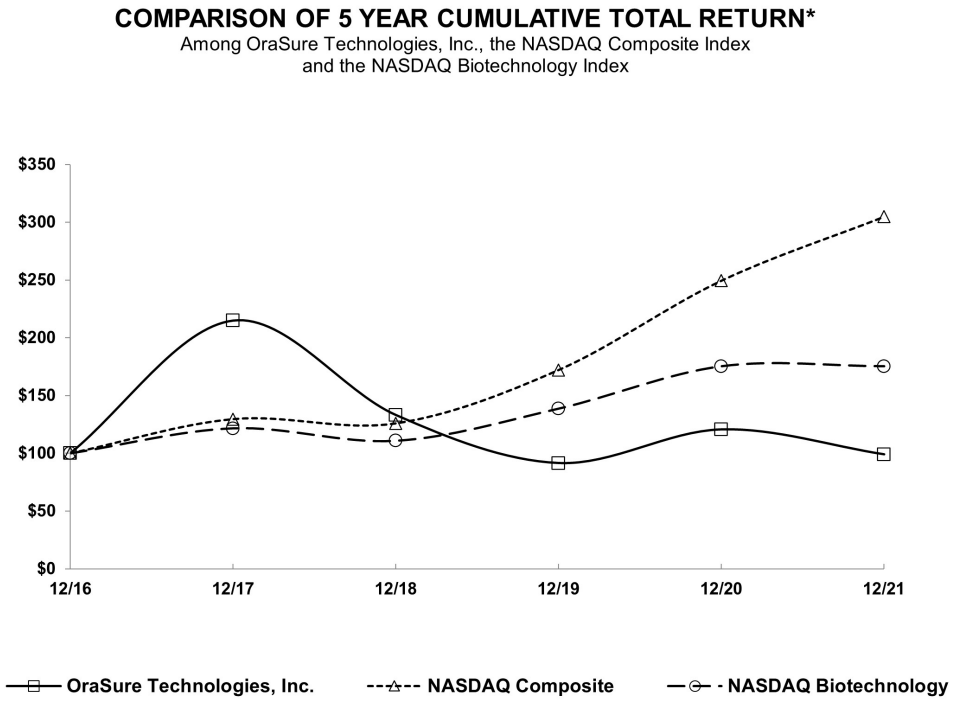
(2) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. We have made no commitment to purchase any shares under this plan.

Performance Graph

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

The following graph compares the cumulative total returns to investors in the Company's Common Stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index for the period from December 31, 2016 through December 31, 2021. The graph assumes that $100 was invested on December 31, 2016 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 Biotechnology Index was chosen because it includes a number of our competitors. 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 12/31/16 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	Fiscal year ending December 31,					
	2016	2017	2018	2019	2020	2021
OraSure Technologies, Inc.	**100.00**	**214.81**	**133.03**	**91.46**	**120.56**	**98.97**
NASDAQ Composite	**100.00**	**129.64**	**125.96**	**172.17**	**249.51**	**304.85**
NASDAQ Biotechnology	**100.00**	**121.63**	**110.85**	**138.69**	**175.33**	**175.37**

Securities Authorized for Issuance Under Equity Compensation Plans

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

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. Our 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 us, 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. We undertake 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, 2021 (this "Annual Report") generally discusses 2021 and 2020 items and year-to-year comparisons between 2021 and 2020. Discussion of 2019 items and year-to-year comparisons between 2020 and 2019 that are not included in this Form 10-K 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, 2020.

Overview and Business Segments

The overall goal of our Company is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our "Diagnostics" segment and our "Molecular Collection Systems" segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests 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. Our HIV product is also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and as a self-test to individuals in a number of other countries. Our Diagnostics business includes the operations of UrSure, Inc. ("UrSure"), which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient's urine or blood, as well as point-of-care products currently in development. In 2020, we began developing a rapid antigen self-test for COVID-19 and a COVID-19 antibody enzyme-linked immunosorbent assay ("ELISA") for use in laboratory settings. In June 2021, we received three Emergency Use Authorizations ("EUA") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab® COVID-19 Rapid Tests for non-prescription OTC, professional point-of-care and prescription use. We began recording revenues on the sales of our InteliSwab® COVID-19 Rapid Tests during the third quarter of 2021. Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we decided to no longer pursue an EUA for the ELISA laboratory antibody test. We have, however, continued to offer the product for research use to labs and other parties interested in COVID antibody surveillance and research applications.

Our Molecular Solutions business is operated by our wholly-owned subsidiaries, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen"), and Novosanis NV ("Novosanis"). In our Molecular Solutions business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Three of our collection devices are used in connection with COVID-19 molecular testing. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, Inc. ("CoreBiome"), a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

Recent Developments

Impact of COVID-19

The COVID-19 pandemic continues to impact our business operations and it is not possible for us to predict the duration or magnitude of the outbreak's effects on our business or results of operations. During 2020, traditional HIV and HCV testing programs and drug testing in the workplace market were reduced or terminated as a result of the various "stay-at-home" orders and social distancing guidelines issued by federal, state and local governments to contain the spread of the COVID-19 pandemic and we continued to see this impact our business in early 2021. However, during the second and third quarters of 2021, we saw a resumption of HIV and HCV testing in the U.S. as domestic sales of our non-COVID diagnostic products began returning to pre-pandemic levels. On the international front, professional HIV and HCV testing in Europe and Asia also started to pick up. More recently we have experienced logistics and distribution delays, which have impacted our ability to provide our HIV self-tests in Southern and Eastern African countries due to the COVID-19 pandemic. In our Molecular Solutions segment, COVID-related disruption in clinical and research work, particularly in the academic market, had reduced demand for our products in 2020 and early 2021, but demand levels started to return to normal in the second and third quarters of 2021. Although the negative trends that materially impacted our results of operations during 2020 and early 2021 are starting to abate, it is impossible to predict if this improvement will continue and these negative trends may adversely impact certain parts of our business in future periods and for an indeterminate time period, depending on the duration and severity of the COVID-19 pandemic, the impact of COVID-19 variants and the scope and success of vaccination programs globally.

We also have experienced significant opportunities, and continue to believe there are potentially more significant opportunities, for increased revenues as a result of the COVID-19 pandemic. In 2020, we began selling our saliva collection devices for use in molecular COVID-19 testing. In 2021, we generated revenues of approximately $54.2 million from sales of our molecular collection devices related to COVID-19 testing. In the U.S., public health customers purchased increased quantities of our OraQuick® In-Home HIV Test in order to permit continued HIV testing while allowing clients and patients to adhere to "stay-at-home" and social distancing requirements. In addition, we saw increased demand for our molecular collection products from customers who conduct both saliva and blood-based testing. As it became more difficult to collect blood in clinics or healthcare settings, these customers increasingly relied on the saliva collection alternative. However, demand for molecular COVID-19 testing during 2021 began to decline primarily due to the availability of vaccines and other testing options. We believe this trend will continue in future periods.

In June 2021, we received three Emergency Use Authorizations ("EUAs") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab® COVID-19 Rapid Tests for non-prescription OTC, professional point-of-care (Clinical Laboratory Improvements Amendment of 1988, "CLIA" waived) and prescription use. These lateral flow, rapid antigen diagnostic tests are designed to detect active COVID-19 infection with a simple, easy-to-use workflow, using samples self-collected from the lower nostrils. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution. No instrumentation, batteries, smart phone or laboratory analysis is needed to read the result, which appears on the test stick a short time later. During the second half of 2021, we recorded $22.4 million of InteliSwab® sales.

Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we decided to no longer pursue an EUA for a COVID-19 antibody enzyme-linked immunosorbent assay ("ELISA") for use in laboratory settings. We are, however, continuing to offer this product for research use only to labs and other parties interested in COVID antibody surveillance and research applications.

Exploration of Strategic Alternatives

The COVID-19 pandemic has provided us an opportunity to fundamentally transform into a higher growth, more innovative and efficient organization with broader customer reach, both within and outside the United States. We believe we are well positioned to address current public health challenges and capitalize on diagnostic trends in the market and enhance its operational and competitive profile. Against this backdrop, our Board of Directors is exploring and evaluating a broad range of strategic alternatives with the goal of maximizing value for stockholders. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

DLA Procurement Contract

In September 2021, we entered into a contract with the Defense Logistics Agency ("DLA") for the procurement of our OTC InteliSwab® COVID-19 Rapid Test, which the DLA estimated to have a value of $205 million. Under the terms of the contract, the Company will provide its InteliSwab® COVID-19 Rapid Test to up to 25,000 sites throughout the United States. The contract will run from October 2021 through September 2022. We recognized revenue of $1.9 million during the fourth quarter of 2021 related to this arrangement.

BARDA 510(k) Funding

In September 2021, we entered into an agreement with the Biomedical Advanced Research Development Authority ("BARDA"), which is part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services

("HHS"), pursuant to which BARDA will provide up to $13.6 million in funding for us to obtain 510(k) clearance and CLIA waiver of our InteliSwab® COVID-19 rapid test from the U.S. Food and Drug Administration ("FDA").

DOD Manufacturing Capacity Funding

In September 2021, we also entered into an agreement for $109 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 our InteliSwab® COVID-19 Rapid Tests as part of the nation's pandemic preparedness plan. Under this agreement, the funding will be used to expand our production capacity by 100 million tests annually. Funding will be paid to the Company based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment, as set forth in the agreement. We began receiving funds from the DOD in January 2022 and had received $15.4 million as of the date of this report.

Current Consolidated Financial Results

During the year ended December 31, 2021, our consolidated net revenues increased 36% to $233.7 million, compared to $171.7 million for the year ended December 31, 2020. Net product and services revenues during the year ended December 31, 2021 also increased 36% when compared to the same period of 2020, largely due to increased revenues across all product lines, other than our international HIV self-test. Other revenues for the year ended December 31, 2021 were $6.8 million compared to $5.3 million in the same period of 2020. This increase was largely due to increased research and development funding for our COVID-19 tests and higher royalty income.

Our consolidated net loss for the year ended December 31, 2021 was $23.0 million, or $(0.32) per share on a fully diluted basis, compared to a consolidated net loss of $14.9 million, or $(0.22) per share on a fully diluted basis, for the year ended December 31, 2020. Results for the full-year 2021 reflect the negative impact of inefficiencies in our InteliSwab® manufacturing process as we worked through our tech transfer issues and scale up and increased spending on research and development of COVID-19 products as well as higher sales and marketing spend to get our new COVID-19 product to market.

Cash used by operating activities during the years ended December 31, 2021 was $35.4 million compared to cash provided by operating activities for the year ended December 31, 2020 of $5.8 million. The use of cash in 2021 reflected the significant investment in inventory purchases in anticipation of future demand of our COVID-19 testing products. As of December 31, 2021, we had $170.0 million in cash, cash equivalents, and available-for-sale securities, compared to $257.1 million at December 31, 2020.

Results of Operations

YEAR ENDED DECEMBER 31, 2021 COMPARED TO DECEMBER 31, 2020

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total net revenues (dollars in thousands) generated by each of our business segments.

	For the Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2021	2020	% Change	2021	2020
Diagnostics	$ 87,030	$ 63,601	37 %	37 %	37 %
Molecular Solutions	139,867	102,780	36	60	60
Net product and services revenues	226,897	166,381	36	97	97
Other	6,777	5,340	27	3	3
Net revenues	$ 233,674	$ 171,721	36 %	100 %	100 %

Consolidated net product and services revenues increased 36% to $226.9 million for the year ended December 31, 2021 from $166.4 million for 2020 due to increased revenues across all product lines, other than our international HIV self-test. Other revenues for the year ended December 31, 2021 were $6.8 million compared to $5.3 million in 2020. This increase was largely due to increased research and development funding for our COVID-19 tests and higher royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $45.3 million and $40.9 million, or 19% and 24% of total net revenues, during the years ended December 31, 2021 and 2020, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

Diagnostics Segment

The table below shows the amount of total net revenues (dollars in thousands) generated by our Diagnostics segment.

	For years Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
Market	2021	2020	% Change	2021	2020
Infectious disease testing	$ 54,645	$ 54,407	0 %	61 %	83 %
COVID-19	22,707	—	NM	25	0
Risk assessment testing	9,678	9,194	5	11	14
Net product revenues	87,030	63,601	37	97	97
Other	3,010	1,639	84	3	3
Net revenues	$ 90,040	$ 65,240	38 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market remained largely flat at $54.6 million in 2021 compared to $54.4 million in 2020. What difference there was resulted from increased world-wide sales of our OraQuick® HCV products and higher domestic sales of our OraQuick® HIV products partially offset by lower international sales of our OraQuick® HIV products.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during 2021 and 2020.

	Years ended December 31,		
Market	2021	2020	% Change
Domestic HIV	$ 16,641	$ 15,184	10 %
International HIV	25,503	29,040	(12)
Net HIV revenues	42,144	44,224	(5)
Domestic HCV	6,881	4,793	44
International HCV	4,902	3,655	34
Net HCV revenues	11,783	8,448	39
Net OraQuick® revenues	$ 53,927	$ 52,672	2 %

Domestic OraQuick® HIV sales increased 10% to $16.6 million for the year ended December 31, 2021 from $15.2 million for the year ended December 31, 2020. This increase was primarily the result higher sales of our OraQuick® In-Home HIV test used in a Centers for Disease Control and Prevention ("CDC") initiative to drive increased in-home testing and the increased number of stores from which this product is sold. Domestic HIV sales into the public health, hospital, and physicians markets also increased due to the recovery of these markets post the COVID-19 pandemic impact in 2020.

International sales of our OraQuick® HIV products during 2021 decreased 12% to $25.5 million from $29.0 million in 2020. This decrease was largely due to the expiration of the Gates Foundation subsidy for certain international tests and challenges presented by the COVID-19 pandemic causing shipping delays and staffing issues at our customers.

Domestic OraQuick® HCV sales increased 44% to $6.9 million in 2021 from $4.8 million in 2020 due to the re-opening of testing programs previously closed as a result of the COVID-19 pandemic and as resources used for COVID-19 testing and vaccinations were starting to be redirected back to HCV testing.

International OraQuick® HCV sales increased 34% to $4.9 million in 2021 from $3.7 million in 2020 as sales into certain international markets continued to return to pre-pandemic levels.

COVID-19 Testing Market

During the year ended December 31, 2021, COVID-19 revenues were $22.7 million driven by the first time sales of our InteliSwab® COVID-19 Rapid Test which we began shipping to customers in August.

Risk Assessment Market

Sales to the risk assessment market increased 5% to $9.7 million for the year ended December 31, 2021 from $9.2 million for the year ended December 31, 2020 due to hiring increases driven by the economic recovery from the COVID-19 pandemic.

Other revenues

Other revenues for the year ended December 31, 2021 increased 84% to $3.0 million from $1.6 million for the year ended December 31, 2020 largely due to higher research and development funding for our COVID-19 tests and the inclusion of royalty income under the terms of a new licensing agreement related to our proprietary buffer solution used for the preservation and stabilization of oral fluid specimens.

Molecular Solutions Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Molecular Solutions segment for the year ended December 31, 2021 and 2020.

	Years ended December 31,		
Market	**2021**	**2020**	**% Change**
Genomics	$ 63,350	$ 36,878	72 %
Microbiome	7,944	5,474	45
COVID-19	54,167	50,747	7
Laboratory services	11,840	8,746	35
Other product and service revenues	2,566	935	174
Net molecular product and services revenues	$ 139,867	102,780	36
Other	3,767	3,701	2
Net molecular product and services revenues	$ 143,634	$ 106,481	35 %

Sales of our genomics products increased 72% to $63.4 million in 2021 compared to $36.9 million in 2020 as we continued to see our customers' businesses recover from the COVID-19 pandemic and strong organic growth from customers in the commercial animal markets.

Microbiome revenues increased 45% to $7.9 million in 2021 compared to $5.5 million in 2020 due to a recovery in the market from the COVID-19 pandemic.

Sales of our molecular sample collection kits for COVID-19 testing increased 7% to $54.2 million in 2021 compared to $50.7 million in 2020 due to increased demand as the COVID-19 pandemic began late in the first quarter of 2020 and testing ramped up in the second and third quarters of 2020 and continued into the first half of 2021 contributing to the revenue growth for the full year period. Demand for COVID-19 PCR testing, in which our product is used, has shown declines in the second half of 2021 as a result of the increased availability of rapid tests.

Laboratory services revenues increased 35% to $11.8 million in 2021 compared to $8.7 million in 2020, due to customers resuming activities delayed by the COVID-19 pandemic.

Other revenues in 2021 remained largely flat at $3.8 million in 2021 compared to $3.7 million in 2020 since it is largely made up of royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 50% for the year ended December 31, 2021 compared to 59% for 2020. The decrease in gross profit percentage was primarily due to increased scrap expense, including adjustments to inventory due to excess inventory or

obsolescence, lower labor utilization, lower subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation, and a less favorable product mix as a result of the decline in sales of higher gross profit percentage product, partially offset by lower payroll taxes as result of applying for an Employee Retention Credit under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which increased gross profit by $2.5 million.

Consolidated operating loss in 2021 was $10.2 million, which was a $5.0 million increase from the $5.2 million of operating loss reported in 2020. Results in 2021 were negatively impacted by the decline in gross margin described above coupled with increased operating expenses described below.

OPERATING INCOME BY SEGMENT

Diagnostic Segment

The gross profit percentage of the Diagnostics business was 29% in 2021 compared to 42% in 2020. This decrease was due to an increase in scrap costs associated with production and tech transfer issues associated with our InteliSwab® test and the recording of adjustments for COVID-19 antibody inventory which will not be sold, lower absorption of labor costs due to production inefficiencies, and the lower subsidies received from the Gates Foundation, partially offset by a more favorable product mix of higher gross profit percentage product sales, and lower payroll taxes resulting from the Employee Retention Credit under the CARES act.

Research and development expenses increased 13% to $24.1 million in 2021 from $21.3 million in 2020, due to higher staffing costs as a result of increased headcount and increased COVID-19 product development expenses.

Sales and marketing expenses increased 27% to $28.5 million in 2021 from $22.4 million in 2020, due to higher marketing spending associated with the introduction of our InteliSwab® test into the market, higher commissions directly related to the increase in revenues and increased consulting costs associated with business strategy planning. These increases were partially offset by a decline in our reserve for uncollectible accounts associated primarily with one of our distributors located in Africa who has paid its over-due balance.

General and administrative expenses increased 16% to $32.6 million in 2021 from $28.1 million in 2020 largely due to higher staffing costs associated with increased headcount and higher consulting costs. These increases were partially offset by lower legal fees, lower employee bonuses, a lower allocation of building costs as administrative space was repurposed for manufacturing, and increased intercompany services fees allocated to the Molecular Solutions segment.

All of the above contributed to the Diagnostics segment’s operating loss of $57.2 million for the year ended December 31, 2021, which included non-cash charges of $4.3 million for depreciation and amortization and $4.7 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax benefit of $1.5 million associated with the change in the fair value of acquisition-related contingent consideration.

Molecular Solutions Segment

The gross profit percentage of the Molecular Solutions segment was 63% in 2021 compared to 70% in 2020. This decrease is due to a less favorable product mix associated with increased sales of lower gross profit percentage products, increased costs at our third party contract manufacturers and an increase in inventory adjustments associated with expiring or excess inventory levels.

Research and development expenses increased 4% to $10.1 million in 2021 from $9.8 million in 2020 due to increased staffing and consulting costs.

Sales and marketing expenses increased 35% to $16.3 million in 2021 compared to $12.0 million in 2020 largely due to higher staffing costs, increased consulting costs associated with business strategy planning, and an increase in our reserve for uncollectible accounts.

General and administrative expenses increased 22% to $17.7 million in 2021 compared to $14.6 million in 2020, due higher legal fees, increased intercompany service fees allocated from the Diagnostics segment, increased sales tax costs, and higher staffing costs.

All of the above contributed to operating income of $47.0 million for 2021, which included non-cash charges of $7.3 million for depreciation and amortization and $673,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the year ended December 31, 2021 and 2020, we recorded income tax expense of $13.7 million and $11.4 million, respectively. Our overall tax expense recorded in both periods is largely comprised of foreign tax expense associated with our Canadian subsidiary.

Liquidity and Capital Resources

	December 31, 2021	December 31, 2020
	(In thousands)	
Cash and cash equivalents	$ 116,762	$ 160,802
Available for sale securities	53,288	96,317
Working capital	220,367	242,404

Our cash and cash equivalents and available-for-sale securities decreased to $170.0 million at December 31, 2021 from $257.1 million at December 31, 2020. Our working capital decreased to $220.4 million at December 31, 2021 from $242.4 million at December 31, 2020.

During the year ended December 31, 2021, net cash used in operating activities was $35.4 million. Our net loss of $23.0 million included non-cash charges for depreciation and amortization expense of $11.7 million, stock-based compensation expense of $7.8 million, an inventory reserve of $6.7 million, deferred income tax expense of $1.0 million and other non-cash expense of $456,000. Operating activities also included a benefit for the change in the estimated fair value of acquisition-related contingent consideration of $1.5 million and a $142,000 contingent consideration payment representing the excess of the total contingent consideration payment made during the year ended December 31, 2021 over the fair value of the liability estimated at the time of acquisition. Cash used to fund our working capital accounts included an increase in inventory of $27.9 million to meet anticipated demand to support COVID-19 testing programs, an increase in prepaid expenses and other assets of $8.7 million due to an asset recorded to reflect the future receipt of an Employee Retention Credit filed with the U.S. Government under the CARES Act in 2021 and prepayments made on a manufacturing contract, an increase in accounts receivable of $6.5 million due to orders placed late in the quarter and a decrease in deferred revenue of $1.9 million due to the recognition of revenue from customer prepayments. Offsetting these uses of cash were an $3.2 million increase in accounts payable due to the timing of invoices received and payments made and an increase in accrued expenses and other liabilities of $3.3 million.

Net cash used in investing activities was $5.5 million for the year ended December 31, 2021, which reflects proceeds from the maturities and redemptions of investments of $67.9 million, offset by $25.8 million used to purchase investments. Investing activities also include $36.6 million to acquire property and equipment largely to increase our manufacturing capacity and $10.9 million used to build additional manufacturing capacity as required by the $109 million agreement with the DOD. This cash outlay will be reimbursed in 2022 and represents the timing of cash used in the fourth quarter of 2021 and submitted for reimbursement.

Net cash used in financing activities was $2.8 million for the year ended December 31, 2021, which reflects $2.1 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to our employees, payments of lease liabilities of $686,000 and payment of our contingent consideration obligation of $264,000, partially offset by proceeds from stock option exercises of $246,000.

We expect current balances of cash and cash equivalents and available-for-sale securities to be sufficient to fund our current and foreseeable operating and capital needs. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the timing of reimbursement under our $109 million DOD contract, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures including continued investment to expand our capacity to manufacture products for COVID-19 testing, 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. In addition, $135.8 million, or 80%, of our $170.0 million in cash, cash equivalents and available-for-sale securities belongs to our Canadian subsidiary. In 2022, we repatriated $65 million of such cash into the United States and will be required to pay withholding taxes to the Canada Revenue Agency. It is still our intention going forward to continue to permanently reinvest the historical undistributed earnings of our foreign subsidiaries.

Critical Accounting Policies and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses our 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 we make judgements 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. We base our 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.

Our significant accounting policies are described in Note 2 of the Notes to the consolidated financial statements included in Item 15 of this Annual Report. We consider the following accounting policies, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our 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 we are entitled to, net of allowances for any discounts or rebates.

We generally do not grant product return rights to our customers, except for (i) warranty returns, (ii) return rights on sales of our OraQuick® In-Home HIV test and (iii) return rights on some of the sales of our InteliSwab®COVID-19 Rapid Test to the retail trade.

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Service Revenues. Service revenues represent microbiome laboratory testing and analytical services. We recognize revenues when we satisfy our performance obligation for services rendered.

Arrangements with multiple-performance obligations. In arrangements involving more than one performance obligation, which largely applies to our 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.

Other revenues. Other revenues consist primarily of royalty income, funding of research and development efforts and cost reimbursements under a charitable support agreement. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Funding and charitable support reimbursements are recorded as the activities are being performed in accordance with the respective agreements.

Inventories.

Our 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 our inventories are subject to expiration dating, which can be extended in certain circumstances. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based on prior experience as well as estimated forecasts of product sales. We reserve for unidentified scrap or spoilage based on historical write-off rates. We also consider items identified through specific identification procedures in assessing the adequacy of our reserve. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Deferred Tax Assets and Liabilities.

At December 31, 2021, we had federal Net Operating Loss ("NOL") carryforwards of $188.0 million. The net deferred tax assets, before the valuation allowance, associated with these NOLs and other temporary differences were $46.8 million at December 31, 2021. Net operating losses will begin to expire in 2022. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs

and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment.

We currently have a full valuation allowance recorded against our total U.S. deferred tax asset as we had determined in 2008 that it was more likely than not that we would not realize the benefits associated with our deferred tax assets. Each year, we continue to reevaluate our valuation allowance position and believe that it is more likely than not that our U.S. deferred income tax asset will not be realized. As such, we maintain a full valuation allowance as of December 31, 2021 and 2020 against our deferred tax assets associated with the operations subject to income tax in the U.S.

The Tax Reform Act of 1986 contains provisions under Internal Revenue Code ("IRC") Section 382 that limit the annual amount of federal and state NOLs available to be used in any given year in the event of a significant change in ownership. Our ability to use our federal and state NOL carryforwards to offset future federal income tax obligations could be limited by changes in the ownership of our stock. The Company does not believe, however, that there is a Section 382 limitation that will impair our future ability to utilize NOLs to offset our future taxable income and the Company continues to review ownership changes on an annual basis.

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 our recent acquisitions, 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 certain intangible assets and contingent consideration include:

- future expected cash flows from sales and acquired developed technologies;
- the acquired company's trade name and customer relationships as well as assumptions about the period of time the acquired trade name and customer relationships will continue to be used in the combined company's portfolio;
- 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.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

As of December 31, 2021, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.4% of our total revenues for the year ended December 31, 2021. We do have foreign currency exchange risk related to our operating subsidiaries in Canada and in Belgium. The principal foreign currencies in which we conduct 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. Our foreign subsidiaries had net assets, subject to translation, of $198.0 million in U.S. Dollars, which are included in the Company’s consolidated balance sheet as of December 31, 2021. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have increased our comprehensive loss by approximately $19.8 million in the year ended December 31, 2021.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in our Consolidated Financial Statements included under Item 15 of this Annual Report on Form 10-K.

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, Interim Chief Financial Officer and Chief Accounting Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2021. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2021 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 we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer, Interim 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 our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our 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 our evaluation under the framework, our management concluded that our 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, 2021.

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

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

(c) Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2021 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.

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

Opinion on Internal Control Over Financial Reporting

We have audited OraSure Technologies, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements), and our report dated March 1, 2022 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 1, 2022

ITEM 9B. Other Information.

Not applicable.

ITEM 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2021Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed within 120 days after the end of our fiscal year pursuant to Regulation 14A.

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 of Form 10-K will be included in our 2022 Proxy Statement and is incorporated herein by reference. Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and principal accounting officer, as well as to the members of our Board of Directors and our other officers and employees. This Code of Business Conduct and Ethics is available on our website at www.orasure.com. We intend 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 our website.

ITEM 11. Executive Compensation.

The information required by this Item 11 of Form 10-K will be included in our 2022 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 of Form 10-K will be included in our 2022 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 of Form 10-K will be included in our 2022 Proxy Statement and is incorporated herein by reference.

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item 14 of Form 10-K will be included in our 2022 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Consolidated Financial Statement Schedules.

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

(a)(3). Exhibits.

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of OraSure Technologies, Inc. is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.2	Bylaws of OraSure Technologies, Inc., as amended and restated as of February 19, 2018, are incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.
4.1	Description of Securities is incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year-ended December 31, 2019.
10.1	Employment Agreement dated as of January 3, 2018, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D., is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 4, 2018.*
10.2	Transition Agreement dated as of January 2, 2022, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D. is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-k filed January 6, 2022*
10.3	Employment Agreement, dated as of May 4, 2018, between the Company and Roberto Cuca is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 4, 2018.*
10.4	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Jack E. Jerrett, is incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.5	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed December 19, 2008.*
10.6	Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.7	Amendment No. 3 to Employment Agreement, dated as of March 27, 2015, between the Company and Jack E. Jerrett is incorporated by reference to Exhibit 99.3 to the Company's current Report on Form 8-K filed March 31, 2015.*
10.8	Retirement Agreement, dated as November 9, 2021, between OraSure Technologies, Inc. and Jack E. Jerrett is incorporated by reference to Exhibit 10.1 to the Company's Current Report on For 8-K filed November 9, 2021.*
10.9	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.*
10.10	Amendment No. 1 to Employment Agreement, dated as of December 20, 2021, between Kathleen G. Weber, DNA Genotek, Inc. and OraSure Technologies, Inc.
10.11	Employment Agreement, dated as of May 11, 2020, between OraSure Technologies, Inc. and Lisa Nibauer is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on form 10-Q for the quarter ended June 30, 2020.*
10.12	Employment Agreement, dated as of November 29, 2021, between OraSure Technologies, Inc. and Agnieszka M. Gallagher.*
10.13	Severance Letter Agreement, dated August 25, 2021, between OraSure Technologies, Inc. and Michele M. Miller.*
10.14	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.*

10.15	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.*
10.16	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.*
10.17	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.*
10.18	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.*
10.19	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. *
10.20	Form of Restricted Unit Award Agreement (Executive Officers-Employment Agreements) for 2021 awards.*
10.21	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.*
10.22	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.*
10.23	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.*
10.24	Description of the OraSure Technologies, Inc. 2021 Incentive Plan is incorporated by reference to the Company's Current Report on Form 8-K filed August 13, 2021.*
10.25	Description of Long-Term Incentive Policy and 2021 Award Performance Measures is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed August 13, 2021.*
10.26	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.*
10.27	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.*
10.28	Amended and Restated Code of Business Conduct and Ethics of OraSure Technologies, Inc. is incorporated by reference to Exhibit 14.1 to the Company's Current Report on Form 8-K filed August 14, 2019.
10.29	$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.
10.30	Industrial Lease between Core5 at Laughman Farms Phase 1, LLC as Landlord and OraSure Technologies, Inc. as Tenant, dated January 3, 2022.
21	Subsidiaries of the Company are incorporated by reference to Exhibit 21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
23	Consent of KPMG LLP.
24	Powers of Attorney.
31.1	Certification of Stephen S. Tang, Ph.D. required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Scott Gleason required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Stephen S. Tang, Ph.D. 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 Scott Gleason 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.
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.

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* Management contract or compensatory plan or arrangement.

ITEM 16. Form 10-K Summary.

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 1, 2022.

ORASURE TECHNOLOGIES, INC.

By: */s/ Stephen S. Tang*
Stephen S. Tang, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 1, 2022, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ Stephen S. Tang Stephen S. Tang, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Scott Gleason Scott Gleason	Interim Chief Financial Officer & Senior Vice President of Investor Relations and Corporate Communications (Principal Financial Officer)
/s/ Michele Miller Michele Miller	Chief Accounting Officer (Principal Accounting Officer)
*MARA ASPINALL Mara Aspinall	Director
*MICHAEL CELANO Michael Celano	Director
*JAMES A. DATIN James A. Datin	Director
*NANCY J. GAGLIANO Nancy J. Gagliano	Director
*EAMONN P. HOBBS Eamonn P. Hobbs	Director
*RONNY B. LANCASTER Ronny B. Lancaster	Director
*LELIO MARMORA Lelio Marmora	Director
*DAVID J. SHULKIN, M.D. David J. Shulkin, M.D.	Director
*ANNE C. WHITAKER Anne C. Whitaker	Director

*By: */s/Agnieszka M. Gallagher*
Agnieszka M. Gallagher
(Attorney-in-Fact)

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 1, 2022 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matter

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

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

As discussed in Notes 2 and 6 to the consolidated financial statements, the Company has inventories with a carrying value of $53,138 thousand as of December 31, 2021. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The majority of the inventories are subject to expiration dating, which can be extended in certain circumstances. The Company continually evaluates quantities on hand and the carrying value of inventories to determine the need for net realizable value adjustments for excess and obsolete inventories, based on prior experience as well as estimated forecasts of product sales. The Company reserves for unidentified scrap or spoilage based on historical write-off rates. The Company also considers items identified through specific identification procedures in assessing the adequacy of the reserve.

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

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's process for determining net realizable value adjustments for inventory excess or obsolescence, which included controls related to the review of the specific identification procedures. For a selection of inventory items, we compared the Company's historic estimates of net realizable value adjustments for excess and obsolescence to the actual physical inventory disposals to evaluate the Company's ability to accurately estimate the net realizable value adjustments. We evaluated the Company's ability to forecast sales by comparing prior period sales forecasts to actual results. In addition, we selected inventory items from the underlying data used in the Company's analysis and evaluated the Company's determination of net realizable value adjustments for those items by comparing forecasted inventory consumption to historic inventory consumption. We also selected inventory items from the underlying data used in the Company's analysis and evaluated the ability to extend the expiration dates by inspecting relevant supporting documentation.

/s/ KPMG LLP

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

Philadelphia, Pennsylvania
March 1, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 116,762	$ 160,802
Short-term investments	36,279	48,599
Accounts receivable, net of allowance for doubtful accounts of $3,418 and $3,654	45,323	38,835
Inventories	53,138	31,863
Prepaid expenses	7,939	3,860
Other current assets	28,990	4,934
Total current assets	288,431	288,893
Noncurrent Assets:		
Property, plant and equipment, net	88,164	51,860
Operating right-of-use assets, net	9,056	4,461
Finance right-of-use assets, net	2,493	1,312
Intangible assets, net	14,343	17,904
Goodwill	40,279	40,351
Long-term investments	17,009	47,718
Other noncurrent assets	1,215	1,973
Total noncurrent assets	172,559	165,579
TOTAL ASSETS	**$ 460,990**	**$ 454,472**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 28,024	$ 17,407
Deferred revenue	2,936	4,811
Accrued expenses and other current liabilities	33,778	22,227
Finance lease liability	939	517
Operating lease liability	2,181	1,125
Acquisition-related contingent consideration obligation	206	402
Total current liabilities	68,064	46,489
Noncurrent Liabilities:		
Finance lease liability	1,952	895
Operating lease liability	7,202	3,591
Acquisition-related contingent consideration obligation	354	2,049
Other noncurrent liabilities	651	1,682
Deferred income taxes	2,234	1,195
Total noncurrent liabilities	12,393	9,412
TOTAL LIABILITIES	80,457	55,901
Commitments and contingencies (Note 15)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 72,069 and 71,738 shares issued and outstanding	—	—
Additional paid-in capital	511,063	505,123
Accumulated other comprehensive loss	(10,077)	(9,097)
Accumulated deficit	(120,453)	(97,455)
Total stockholders' equity	380,533	398,571
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 460,990**	**$ 454,472**

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,		
	2021	2020	2019
NET REVENUES:			
Products and services	$ 226,897	$ 166,381	$ 148,073
Other	6,777	5,340	6,532
	233,674	171,721	154,605
COST OF PRODUCTS AND SERVICES SOLD	116,074	69,853	60,022
Gross profit	117,600	101,868	94,583
OPERATING EXPENSES:			
Research and development	34,170	31,032	19,629
Sales and marketing	44,751	34,459	31,869
General and administrative	50,328	42,653	35,287
Change in the estimated fair value of acquisition-related contingent consideration	(1,485)	(1,099)	(664)
Gain on sale of business	—	—	(10,149)
	127,764	107,045	75,972
Operating income (loss)	(10,164)	(5,177)	18,611
OTHER INCOME	872	1,653	2,720
Income (loss) before income taxes	(9,292)	(3,524)	21,331
INCOME TAX EXPENSE	13,706	11,398	4,675
NET INCOME (LOSS)	$ (22,998)	$ (14,922)	$ 16,656
INCOME (LOSS) PER SHARE:			
BASIC	$ (0.32)	$ (0.22)	$ 0.27
DILUTED	$ (0.32)	$ (0.22)	$ 0.27
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:			
BASIC	71,981	67,505	61,675
DILUTED	71,981	67,505	62,170

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,		
	2021	2020	2019
NET INCOME (LOSS)	$ (22,998)	$ (14,922)	$ 16,656
OTHER COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments	(894)	3,273	5,767
Unrealized gain (loss) on marketable securities	(86)	(234)	803
COMPREHENSIVE INCOME (LOSS)	$ (23,978)	$ (11,883)	$ 23,226

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2021, 2020 and 2019
(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
Balance at January 1, 2019	61,276	—	401,273	(18,706)	(99,189)	283,378
Common stock issued upon exercise of options	27	—	196	—	—	196
Vesting of restricted stock	717	—	—	—	—	—
Purchase and retirement of common shares	(289)	—	(3,712)	—	—	(3,712)
Stock-based compensation	—	—	4,057	—	—	4,057
Net income	—	—	—	—	16,656	16,656
Currency translation adjustments	—	—	—	5,767	—	5,767
Unrealized gain on marketable securities	—	—	—	803	—	803
Balance at December 31, 2019	61,731	$ —	$ 401,814	$ (12,136)	$ (82,533)	$ 307,145
Common stock issued upon exercise of options	402	—	3,222	—	—	3,222
Vesting of restricted stock and performance stock units	653	—	—	—	—	—
Purchase and retirement of common shares	(248)	—	(2,088)	—	—	(2,088)
Issuance of common stock in connection with public offering, net of commissions and expenses of $6,200	9,200	—	95,036	—	—	95,036
Stock-based compensation	—	—	7,139	—	—	7,139
Net loss	—	—	—	—	(14,922)	(14,922)
Currency translation adjustments	—	—	—	3,273	—	3,273
Unrealized loss on marketable securities	—	—	—	(234)	—	(234)
Balance at December 31, 2020	71,738	$ —	$ 505,123	$ (9,097)	$ (97,455)	$ 398,571
Common stock issued upon exercise of options	33	—	246	—	—	246
Vesting of restricted stock and performance stock units	451	—	—	—	—	—
Purchase and retirement of common shares	(153)	—	(2,113)	—	—	(2,113)
Stock-based compensation	—	—	7,807	—	—	7,807
Net loss	—	—	—	—	(22,998)	(22,998)
Currency translation adjustments	—	—	—	(894)	—	(894)
Unrealized loss on marketable securities	—	—	—	(86)	—	(86)
Balance at December 31, 2021	72,069	$ —	$ 511,063	$ (10,077)	$ (120,453)	$ 380,533

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,		
	2021	**2020**	**2019**
OPERATING ACTIVITIES:			
Net loss	$ (22,998)	$ (14,922)	$ 16,656
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Stock-based compensation	7,807	7,139	4,057
Depreciation and amortization	11,658	9,387	7,339
Other non-cash amortization	837	327	391
Provision for doubtful accounts	(253)	941	2,248
Inventory reserve	6,731	736	(280)
Unrealized foreign currency (gain) loss	(210)	269	385
Interest expense on finance leases	82	72	36
Deferred income taxes	1,026	(392)	(1,457)
Loss on sale of fixed assets	—	114	147
Gain on sale of product line	—	(225)	—
Gain on sale of business	—	—	(10,149)
Change in the estimated fair value of acquisition-related contingent consideration	(1,485)	(1,099)	(664)
Payment of acquisition-related contingent consideration	(142)	(496)	—
Changes in assets and liabilities			
Accounts receivable	(6,451)	(2,324)	(2,210)
Inventories	(27,941)	(9,343)	(1,044)
Prepaid expenses and other assets	(8,674)	(104)	200
Accounts payable	3,234	7,379	(1,537)
Deferred revenue	(1,891)	1,051	(297)
Accrued expenses and other liabilities	3,288	7,297	(4,017)
Net cash (used in) provided by operating activities	(35,382)	5,807	9,804
INVESTING ACTIVITIES:			
Purchases of investments	(25,822)	(90,137)	(92,173)
Proceeds from maturities and redemptions of investments	67,925	107,718	93,491
Purchases of property and equipment	(36,622)	(26,674)	(9,314)
Purchase of property and equipment under government contracts	(11,495)	—	—
Proceeds from funding under government contract	531	—	—
Purchase of patent and product rights	—	(2,250)	—
Acquisition of businesses, net of cash acquired	—	(3,037)	(23,801)
Proceeds from sale of business	—	—	12,000
Other investing activities	(18)	351	—
Net cash used in investing activities	(5,501)	(14,029)	(19,797)
FINANCING ACTIVITIES:			
Repayments of loans	—	—	(724)
Cash payments for lease liabilities	(686)	(687)	(442)
Issuance of common stock in connection with public offering, net	—	95,036	—
Proceeds from exercise of stock options	246	3,222	196
Payment of acquisition-related contingent consideration	(264)	(3,004)	—
Repurchase of common stock	(2,113)	(2,088)	(3,712)
Net cash (used in) provided by financing activities	(2,817)	92,479	(4,682)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(340)	830	1,952
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(44,040)	85,087	(12,723)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	160,802	75,715	88,438
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 116,762	$ 160,802	$ 75,715

See accompanying notes to the consolidated financial statements.

1. THE COMPANY:

The overall goal of OraSure Technologies, Inc. ("OraSure" or "the Company") is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our "Diagnostics" segment, and our "Molecular Solutions" segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. Our 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 as a self-test to individuals in a number of other countries. Our Diagnostics business also includes the operations of UrSure, Inc. ("UrSure"), which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient's urine or blood, as well as point-of-care products currently in development. In 2020, we began developing a rapid antigen self-test for COVID-19 and a COVID-19 antibody enzyme-linked immunosorbent assay ("ELISA") for use in laboratory settings. In June 2021, we received three Emergency Use Authorizations ("EUA") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab® COVID-19 Rapid Tests for non-prescription OTC, professional point-of-care (Clinical Laboratory Improvements Amendment of 1988, or "CLIA," waived) and prescription use. We began recording revenues on the sales of our InteliSwab® COVID-19 Rapid Tests during the third quarter of 2021. Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we decided to no longer pursue an EUA for the ELISA antibody test. We have, however, continued to offer the product for research use to labs and other parties interested in COVID antibody surveillance and research applications.

Our Molecular Solutions business is operated by our subsidiaries, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen"), and Novosanis NV ("Novosanis"). In our Molecular Solutions business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Three of our collection devices are used in connection with COVID-19 molecular testing. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, Inc. ("CoreBiome"), a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation and Basis of Presentation

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

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the 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 intangible assets and goodwill, as well as

calculations related to accruals, taxes, contingent consideration and performance-based compensation expense, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Employee Retention Credit

In December 2021, we applied for the Employee Retention Credit for payroll taxes paid in the first and second quarters of 2021 as provided by the Coronavirus Aid, Relief and Economic Security Act. The amount due from the Internal Revenue Service of $5,728 is recorded in other current assets in our consolidated balance sheet as of December 31, 2021. The credit is reported in our consolidated statement of operations, for the year ended December 31, 2021, within cost of products and services sold, research and development, sales and marketing and general and administrative costs in the amounts of $2,536, $1,134, $924, and $1,134, respectively

Supplemental Cash Flow Information

In 2021, 2020 and 2019, we paid income taxes of $13,727, $9,263 and $10,611, respectively.

In 2021, 2020 and 2019, we recorded through the consolidated statements of operations an increase (decrease) in our allowance for doubtful accounts of $(253), $941 and $2,248 respectively. We had write-offs of $115, $501 and $110 in 2021, 2020, and 2019, respectively.

As of December 31, 2021, 2020 and 2019, we had accruals for purchases of property and equipment of $8,166 $802, and $660, respectively.

Investments

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

We record an allowance for credit loss for our available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, we review 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. During 2021, we recognized a provision for expected credit losses for our available-for-sale securities of $98.

The following is a summary of our available-for-sale securities as of December 31, 2021 and 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2021				
Guaranteed investment certificates	$ 33,249	$ —	$ —	$ 33,249
Corporate bonds	20,473	—	(434)	20,039
Total available-for-sale securities	$ 53,722	$ —	$ (434)	$ 53,288
December 31, 2020				
Guaranteed investment certificates	$ 25,132	$ —	$ —	$ 25,132
Corporate bonds	71,533	135	(483)	71,185
Total available-for-sale securities	$ 96,665	$ 135	$ (483)	$ 96,317
At December 31, 2021, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 36,386	$ —	$ (107)	$ 36,279
Greater than one year	$ 17,336	$ —	$ (327)	$ 17,009

Fair Value of Financial Instruments

As of December 31, 2021 and 2020, 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).

All of our available-for-sale debt securities are measured as Level 2 instruments as of December 31, 2021 and 2020. Our guaranteed investment certificates are measured as Level 1 instruments as of December 31, 2021 and 2020.

Included in cash and cash equivalents at December 31, 2021 and 2020, was $1,160 and $71,489 invested in government money market funds. These funds have investments in government securities and are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds. The fair value of the plan assets as of December 31, 2021 and 2020 was $1,763 and $2,565, 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.

As further discussed in Note 3, Business Combinations, we have identified our contingent consideration obligations as Level 3 liabilities due to significant inputs that are required to measure the fair value of these obligations.

The following table represents the change in contingent consideration:

Balance as of January 1, 2019	$	—
Addition related to acquisition (initial measurement)		4,350
Change in fair value during the period		(664)
Currency translation adjustment		(74)
Balance as of December 31, 2019		3,612
Addition related to acquisition (initial measurement)		3,440
Payments made during the period		(3,500)
Change in fair value during the period		(1,099)
Currency translation adjustment		(2)
Balance as of December 31, 2020		2,451
Payments made during the period		(406)
Change in fair value during the period		(1,485)
Balance as of December 31, 2021	$	560

Accounts Receivable

Accounts receivable have 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 our customers and our historical experience related to write-offs.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating, which can be extended in certain

circumstances. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based on prior experience as well as estimated forecasts of product sales. We reserve for unidentified scrap or spoilage based on historical write-off rates. We also consider items identified through specific identification procedures in assessing the adequacy of our reserve. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates.

Property, Plant and Equipment

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

Intangible Assets

Intangible assets consist of customer relationships, patents and product rights, acquired technology and tradenames. 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 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. We assess the recoverability of our 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, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these 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 our assumptions about selling prices, volumes, costs and market conditions over a reasonable period of time.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the carrying value of a reporting unit is greater than its fair value, then we 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.

We performed our annual impairment assessment as of July 31, 2021 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our reporting units is greater than their carrying value. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting units. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs.

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 we are entitled to, net of allowances for any discounts or rebates.

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

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Service revenues. Service revenues represent microbiome laboratory testing and analytical services. We recognize revenues when we satisfy our performance obligations for services rendered.

Arrangements with multiple-performance obligations. In arrangements involving more than one performance obligation, which largely applies to our 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 services 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 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.

Other revenues. Other revenues consist primarily of royalty income, funding of research and development efforts and cost reimbursements under a charitable support agreement. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Funding of research and development efforts and charitable support reimbursements are recorded as the activities are being performed in accordance with the respective agreements.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2021 and 2020 included customer prepayments of $1,843 and $3,216, respectively. Deferred revenue as of December 31, 2021 and 2020 also included $1,093 and $1,595, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of contract was determined based on expected revenues and revenue is recognized at that rate when the product is delivered to the customer.

Financing and Payment. Our payment terms vary by the type and location of our 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, we 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, we defer the cost of the commission and expense it over the life of the related sales contract.

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

	Years ended December 31,		
	2021	2020	2019
Infectious disease testing	$ 54,645	$ 54,227	$ 58,016
Risk assessment testing	9,678	9,194	12,189
Cryosurgical systems	-	-	7,054
Genomics [(1)]	63,350	36,878	56,200
Microbiome [(1)]	7,944	5,474	7,172
COVID-19 [(1)]	76,874	50,927	-
Laboratory services	11,840	8,746	6,767
Other product and service revenues	2,566	935	675
Net product and services revenues	226,897	166,381	148,073
Royalty income	4,420	3,432	5,116
Other non-product revenues	2,357	1,908	1,416
Other revenues	6,777	5,340	6,532
Net revenues	$ 233,674	$ 171,721	$ 154,605

(1) 2020 Genomics, Microbiome, and COVID-19 revenues were reclassified to reflect the correct classification of the product line sales. The reclassification increased (decreased) the product line revenues for the year ended December 31, 2020 by $(263), $(682), and $945, respectively.

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

	Years ended December 31,		
	2021	2020	2019
United States	$ 188,383	$ 130,835	$ 107,279
Europe	13,799	12,068	11,752
Other regions	31,492	28,818	35,574
	$ 233,674	$ 171,721	$ 154,605

Customer and Vendor Concentrations. We had no customers that accounted for more than 10% of our accounts receivable as of December 31, 2021. We had one customer that accounted for 11% of our accounts receivable as of December 31, 2020. The same customer accounted for approximately 15% of our net consolidated revenues for the year ended December 31, 2019. We had no customers that accounted for more than 10% of our consolidated net revenues for the years ended December 31, 2021 and 2020.

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

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. We are actively seeking to qualify other suppliers that can manufacture and supply the raw materials and components for the DNAG products.

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 standard. As part of our consideration for the recent acquisitions, 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 certain intangible assets and contingent consideration include:

- future expected cash flows from sales and acquired developed technologies;
- the acquired company's trade name and customer relationships as well as assumptions about the period of time the acquired trade name and customer relationships will continue to be used in the combined company's portfolio;
- 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.

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 2021, 2020, and 2019, we incurred $5,103, $1,126, and $468, respectively, in advertising expenses.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the fair value method. We recognize 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. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options, issuance of restricted stock, or redemption of performance-based restricted stock units, we issue new shares rather than purchase shares in the open market.

Income Taxes

We follow 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.

We assess the realizability of our 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, we reduce our 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 our net operating loss carryforwards.

Foreign Currency Translation

The assets and liabilities of our 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 our consolidated statements of operations in the period in which the change occurs. Net foreign exchange losses resulting from foreign currency transactions that are included in other income in our consolidated statements of operations were $(667), $(337), and $(1,339) for the years ended December 31, 2021, 2020, and 2019, 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 antidilutive. 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.

The computations of basic and diluted earnings (loss) per share are as follows:

	Years ended December 31,		
	2021	2020	2019
Net income (loss)	$ (22,998)	$ (14,922)	$ 16,656
Weighted-average shares of common stock outstanding:			
Basic	71,981	67,505	61,675
Dilutive effect of stock options, restricted stock, and performance stock units	—	—	495
Diluted	71,981	67,505	62,170
Earnings (loss) per share:			
Basic	$ (0.32)	$ (0.22)	$ 0.27
Diluted	$ (0.32)	$ (0.22)	$ 0.27

For the years ended December 31, 2021 and 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 769 and 984 shares, respectively, were excluded from the computation of diluted loss per share.

For the year ended December 31, 2019 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 768 were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive.

Accumulated Other Comprehensive Loss

We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our consolidated balance sheets.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and we have defined the Euro as the functional currency of our Belgian subsidiary, Novosanis. The results of operations are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at December 31, 2021 consists of $9,643 of currency translation adjustments and $434 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investments portfolio. Accumulated other comprehensive loss at December 31, 2020 consists of $8,749 of currency translation adjustments and $348 of net unrealized losses on marketable securities.

Recent Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, The purpose of this update is to improve transparency by requiring business entities to disclose information about certain types of government assistance they receive in their financial statements . Required disclosures include i) the nature of the transactions and related accounting policy used, ii) the financial statement line items affected and amounts thereof and iii) significant terms and conditions of the transactions. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, with early application permitted. We have adopted this guidance within this 2021 Form 10-K. See Note 5 for required disclosures.

3. BUSINESS COMBINATIONS

UrSure

On July 22, 2020, the Company acquired all of the outstanding stock of UrSure, Inc. ("UrSure"), pursuant to the terms of a merger agreement. The initial aggregate purchase price of this transaction was $3,000, adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement.

During the year ended December 31, 2020, we incurred a total of $393 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 expense in the consolidated statement of operations for the year ended December 31, 2020.

Pursuant to our acquisition agreement, we may pay up to an additional $28,000 of contingent consideration over the three years following the acquisition date based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, and the achievement of certain clinical milestones associated with the development of certain new technology. The Company, with the assistance of an independent valuation specialist, determined the estimated acquisition-date fair value of the acquisition-related contingent consideration of $3,440. The fair value was determined using a probability-weighted model based on our assessment of the likelihood that the benchmarks will be achieved. The probability-weighted payments were then discounted using a discount rate based on an internal rate of return analysis using the probability-weighted cash flows. The fair value measurement was based on significant inputs, including the likelihood of the achievement of clinical milestones and revenue forecasts, not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy.

The following table represents the change in contingent consideration:

Estimated fair value of contingent consideration as of acquisition date	$	3,440
Change in fair value during the period		(989)
Balance as of December 31, 2020		2,451
Payments made during the period		(406)
Change in fair value during the period		(1,485)
Balance as of December 31, 2021	$	560

The change in fair value during the years ended December 31, 2021 and 2020 is a result of delays in achieving certain product development milestones and a decrease in associated revenue forecasts as result of these delays.

Revenues from UrSure primarily consist of grant money received to fund the development of certain new technology. Effective as of July 22, 2020, the financial results of UrSure are included in our Diagnostics segment.

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

Assets Acquired		
Accounts receivable	$	285
Other current assets		24
Other assets		6
Intangibles		3,600
Goodwill		3,586
Total assets acquired		7,501
Liabilities Assumed		
Current liabilities		335
Deferred tax liability		689
Total liabilities assumed		1,024
Net Assets Acquired		6,477
Estimated fair value of contingent consideration		(3,440)
Net Cash Paid (net of cash acquired of $111)	$	3,037

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 principally included developed technology, which is subject to amortization on a straight-line basis and is being amortized over a ten year estimated useful life.

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets of UrSure. 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 useful lives of the intangible assets were estimated based on the expected future economic benefit of the assets and are being amortized over the estimated useful life in proportion to the economic benefits consumed using the straight-line method.

The amortization of intangible assets is not deductible for income tax purposes.

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. We believe the goodwill related to the acquisition was a result of gaining a complementary product offering that will enable us to leverage those products with existing and new customers. The goodwill is not deductible for income tax purposes. All of the goodwill identified above has been allocated to our Diagnostics segment.

We continue to evaluate the fair value of certain assets acquired and liabilities assumed, related to the acquisition. Additional information that existed as of the acquisition date, but was at that time unknown to us, 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.

Diversigen

On November 8, 2019, the Company acquired all of the outstanding stock of Diversigen pursuant to the terms of a merger agreement. The aggregate purchase price for this transaction was $12,000, adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement noted above.

During the year ended December 31, 2019, we incurred a total of $1,198 of acquisition related costs, including investment banking fees and 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, 2019.

Pursuant to the merger agreement, we were to pay up to an additional $1,500 of contingent consideration in 2020 based on the achievement of certain 2019 revenue metrics as defined under the agreements which did not occur.

Revenues from Diversigen primarily consist of microbiome laboratory services that provide metagenomics sequencing, bioinformatics and statistical analysis for the study of the microbiome. Effective as of November 8, 2019, the financial results of Diversigen are included in our Molecular Solutions segment.

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

Assets Acquired		
Accounts receivable	$	1,234
Other current assets		45
Property, plant, and equipment, net		1,916
Acquired intangible assets		3,560
Goodwill		6,317
Total assets acquired		13,072
Liabilities Assumed		
Current liabilities		1,123
Deferred tax liability		598
Other long-term liabilities		893
Total liabilities assumed		2,614
Net Assets Acquired		10,458
Estimated fair value of contingent consideration		-
Net Cash Paid (net of cash acquired of $479)	$	10,458

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 customer relationships and tradenames, all of which are subject to amortization on a straight-line basis and are being amortized over estimated useful lives as summarized below:

Description	Estimated Useful Life (in years)	Amount
Customer relationships	10	2,900
Tradenames	9	660
Total acquired intangibles		$ 3,560

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets of Diversigen. 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 useful lives of the intangible assets were estimated based on the expected future economic benefit of the assets and are being amortized over the estimated useful life in proportion to the economic benefits consumed using the straight-line method.

The amortization of intangible assets is not deductible for income tax purposes.

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. We believe the goodwill related to the acquisitions was a result of providing us a complementary service and product offering that will enable us to leverage those services and products with existing and new customers. The goodwill is not deductible for income tax purposes. All of the goodwill identified above has been allocated to our Molecular Solutions segment.

CoreBiome and Novosanis

On January 4, 2019, the Company acquired all of the outstanding stock of CoreBiome, pursuant to the terms of a merger agreement, dated January 3, 2019. CoreBiome has subsequently been merged into Diversigen in December 2020. Also on January 4, 2019, the Company, through a wholly-owned subsidiary, acquired all of the outstanding stock of Novosanis, pursuant to a share purchase agreement, dated January 3, 2019. We began operating these entities as of the January 4, 2019 closing date. The aggregate purchase price for both of these transactions was $13,320 adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into escrow accounts for a limited period after closing, in order to secure the potential payment of certain indemnification obligations of the selling stockholders under each agreement noted above.

During the year ended December 31, 2019, we incurred a total of $639 of acquisition-related costs in connection with these acquisitions, including success-based investment banking fees and accounting, legal and other professional fees, related to both acquisitions, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of operation.

Pursuant to our acquisition agreements, we were to pay up to an additional $32,400 of contingent consideration over three years based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, the achievement of a large customer contract, and the development of certain new technology. The Company, with the assistance of an independent valuation specialist, utilized a Monte Carlo simulation to determine the estimated acquisition-date fair value of the acquisition-related contingent consideration of $4,350. The simulation calculated the probability-weighted payments based on our assessment of the likelihood that the benchmarks will be achieved. The probability-weighted payments were then discounted using a discount rate based on an internal rate of return analysis using the probability-weighted cash flows. The fair value measurement was based on significant inputs, including revenue forecasts, not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration obligation changed from $4,350 as of the acquisition date to $3,612 as of December 31, 2019. This change was a result of changes in our estimated revenue forecasts and an amendment to one of the agreements, entered into in October 2019, in which management agreed to settle the contingent consideration associated with one of the acquisition's 2019 results for $3,500. The fair value of the contingent consideration obligation changed from $3,612 as of December 31, 2019 to $0 as of December 31, 2020. This change is a result of a $3,500 payment made in the first quarter of 2020, changes in our estimated revenue forecasts and an amendment to one of the agreements.

Revenues from CoreBiome primarily consist of microbiome laboratory services that utilize optimal analytical algorithms to deliver speed and scalability in the lab with precise analytics. Revenues from Novosanis primarily consist of the sale of its Colli-Pee collection device which was designed for the standard collection of first-void urine used in the liquid biopsy and sexually transmitted infection screening market. Effective as of January 4, 2019, the financial results of CoreBiome and Novosanis are included in our Molecular Solutions segment.

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

Assets Acquired		
Accounts receivable	$	791
Inventories		310
Other current assets		82
Property, plant, and equipment, net		414
Other assets		5
Acquired intangible assets		8,400
Goodwill		10,368
Total assets acquired		20,370
Liabilities Assumed		
Current liabilities		1,180
Notes payable, short-term		730
Deferred tax liability		819
Other long-term liabilities		74
Total liabilities assumed		2,803
Net Assets Acquired		17,567
Estimated fair value of contingent consideration		(4,350)
Net Cash Paid (net of cash acquired of $103)	$	13,217

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 principally included developed technology, customer relationships, and tradenames, all of which are subject to amortization on a straight-line basis and are being amortized over estimated useful lives as summarized below:

Description	Estimated Useful Life (in years)	Amount
Developed Technology	10	$ 5,000
Customer relationships	10	2,200
Tradenames	8.34	1,200
Total acquired intangibles		$ 8,400

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets of CoreBiome and Novosanis. 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 useful lives of the intangible assets were estimated based on the expected future economic benefit of the assets and are being amortized over the estimated useful life in proportion to the economic benefits consumed using the straight-line method.

The amortization of intangible assets is not deductible for income tax purposes.

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. We believe the goodwill related to the acquisitions was a result of providing us a complementary service and product offering that will enable us to leverage those services and products with existing and new customers. The goodwill is not deductible for income tax purposes. All of the goodwill identified above has been allocated to our Molecular Solutions segment.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the UrSure, Diversigen, CoreBiome and Novosanis acquisitions as if they had been consummated as of January 1, 2019. The unaudited pro forma results include the amortization associated with acquired intangible assets and the estimated tax effect of adjustments to income before income taxes but do not include changes in the fair value of our 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, 2019.

	Year Ended December 31,	
	2020	2019
Revenue	$ 172,563	$ 159,632
Net income (loss)	(14,937)	16,261
Net income (loss) per share, basic	(0.22)	0.26
Net income (loss) per share, diluted	(0.22)	0.26

4. SALE OF CRYOSURGICAL BUSINESS

On August 16, 2019, we sold all rights and title to the assets necessary to operate our cryosurgical systems line of business to a third party for $12,000. This business consisted of medical devices used for the removal of benign skin lesions by cryosurgery or freezing. The products were sold in both the professional and OTC markets in North America, Europe, Central and South America and Australia. We also entered into a transition services agreement with CryoConcepts in which both parties agreed to provide certain transition services beginning after the closing. The Company recorded a gain on sale of business of $10,149 reflected in our statement of operations for the year ended December 31, 2019. The gain includes the $12,000 of proceeds net of the fair value of the assets sold, which consisted entirely of inventory and fully-depreciated fixed assets, the legal fees associated with the transaction, and a value attributed to the transition services.

5. GOVERNMENT CAPITAL CONTRACTS:

In September 2021, we entered into an agreement for $109,000 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 our InteliSwab® COVID-19 Rapid Tests as part of the nation’s pandemic preparedness plan. Funding will be paid to the Company based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment, as set forth in the agreement. In accordance with the milestone payment schedule, 15% of the total will not be funded until the completion of the final validation testing, which is scheduled to occur in late 2023 and early 2024. We began making payments to vendors for the capital project during the fourth quarter of 2021. We began receiving funds from the DOD in January 2022 and had received $15,428 as of the date of this report.

Additionally, during 2021, we received $531 in funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development, for the purchase of machinery and equipment as part of an expansion of manufacturing operations in Pennsylvania. All related purchases were completed in 2021.

Activity for these capital contracts is accounted for pursuant to International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. Funding earned 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 in excess of our expected cost of the project for project management are recognized straight-line in other income over the term of the government contract. We recognized $561 of such income, which is reported as other income in our consolidated statement of operations for the year ended December 31, 2021.

The balances corresponding to government contracts included in our consolidated balance sheet as of December 31, 2021, are as follows:

	December 31, 2021
Other current assets:	
Billed receivables	$ 9,913
Unbilled receivables	9,716
Total other current assets	19,629
Property, plant and equipment, net:	
Cost of assets	11,495
Reduction for funding earned, not yet received	(10,964)
Reduction for funding received	(531)
Total property, plant and equipment, net	-
Accrued expenses and other current liabilities	(8,103)

6. INVENTORIES:

	December 31,	
	2021	2020
Raw materials	$ 33,168	$ 15,425
Work in process	2,252	2,572
Finished goods	17,718	13,866
	$ 53,138	$ 31,863

During 2021, 2020, and 2019, we recorded adjustments to inventory which had a cost of $13,400, $2,564, and $1,318, respectively. The adjustments in 2021 included a write-off of $3,008 of COVID-19 antibody inventory, which we do not believe we can sell as a result of the decision to no longer pursue an EUA for the ELISA antibody test. Additionally, a significant portion of our 2021 adjustments were related to production and tech-transfer issues associated with our COVID-19 rapid test.

7. PROPERTY, PLANT AND EQUIPMENT:

	December 31,	
	2021	2020
Land	$ 1,118	$ 1,118
Buildings and improvements	35,420	26,480
Machinery and equipment	57,919	36,878
Computer equipment and software	14,700	13,024
Furniture and fixtures	4,228	3,545
Construction in progress	35,936	24,419
	149,321	105,464
Less accumulated depreciation	(61,157)	(53,604)
	$ 88,164	$ 51,860

Depreciation expense was $7,498, $5,514, and $4,421 for 2021, 2020, and 2019, respectively.

8. GOODWILL AND OTHER INTANGIBLE ASSETS:

The following table represents total goodwill by operating segment:

	December 31,	
	2021	2020
Diagnostics	$ 3,604	$ 3,586
Molecular Solutions	36,675	36,765
	$ 40,279	$ 40,351

The changes in goodwill are as follows:

	December 31,	
	2021	2020
Balance as of January 1	40,351	36,201
Goodwill acquired during the year	—	3,586
Purchase price adjustment	18	(126)
Change related to foreign currency translation	(90)	690
Balance as of December 31	$ 40,279	$ 40,351

Intangible assets consist of the following:

		December 31, 2021		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer relationships	10	$ 15,016	$ (11,205)	$ 3,811
Patents and product rights	5	7,785	(6,241)	1,544
Developed technology	7-10	16,293	(9,725)	6,568
Tradename	5-15	5,661	(3,241)	2,420
		$ 44,755	$ (30,412)	$ 14,343

		December 31, 2020		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer relationships	10	$ 14,997	$ (9,685)	$ 5,312
Patents and product rights	5	7,766	(5,792)	1,974
Developed technology	7-10	16,603	(8,880)	7,723
Tradename	5-15	5,645	(2,750)	2,895
		$ 45,011	$ (27,107)	$ 17,904

Amortization expense for 2021, 2020, and 2019 was $3,260, $3,246, and $2,522, respectively.

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

2022	2,305
2023	2,305
2024	2,265
2025	2,012
2026	1,630
Beyond	3,826
	$ 14,343

9. ACCRUED EXPENSES:

	December 31,	
	2021	2020
Payroll and related benefits	$ 15,570	$ 14,769
Commitment to purchase under government contract	8,103	—
Professional fees	3,335	978
Sales tax payable	2,227	2,400
Other	4,543	4,080
	$ 33,778	$ 22,227

10. LEASES:

We determine whether an arrangement is a lease at inception. We have operating and finance leases for corporate offices, warehouse space and equipment (including vehicles). As of December 31, 2021, we are the lessee in all agreements. Our leases have remaining

lease terms of 1 to 7 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year.

As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

We have lease agreements that contain both lease and non-lease components (e.g., common-area maintenance). For these agreements, we account for lease components separate from non-lease components. During 2021, we entered into various purchase agreements for our molecular solutions business which include a finance lease component for the use of specialized molds made and used by the vendor for purposes of manufacturing the goods to be purchased. We recorded an aggregate ROU asset and offsetting lease liability of $2,074 upon commencement of these contracts. The consideration to be paid under the agreements is variable based on the amounts purchased with a fixed amount charged if specified purchase minimums are not met. Only the fixed amount has been included in the measurement of the finance right-of-use asset and lease liability and the variable costs are recognized as purchases are made within cost of products and services sold in our consolidated statements of operations. The consideration for the contract has been allocated between the lease and non-lease components based on their relative estimated stand-alone selling prices.

The components of lease expense are as follows:

	Years ended December 31,		
	2021	2020	2019
Operating lease cost	$ 2,226	$ 1,291	$ 964
Variable lease cost	201	—	—
Finance lease cost:			
Amortization of right-of use assets	900	627	410
Interest on lease liabilities	82	72	36
Total finance lease cost	982	699	446
Total lease cost	$ 3,409	$ 1,990	$ 1,410

Supplemental cash flow information related to leases is as follows:

	Years ended December 31,		
	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 3,733	$ 1,280	$ 937
Operating cash flows from financing leases	82	72	33
Financing cash flows from financing leases	686	687	442
Non-cash activity:			
Right-of-use assets obtained in exchange for operating lease obligations	6,480	498	1,829
Right-of-use assets obtained in exchange for finance lease obligations	2,074	46	2,069

Supplemental balance sheet information related to leases is as follows:

	December 31,	
	2021	2020
Operating Leases		
Right-of-use assets	$ 9,056	$ 4,461
Lease liabilities:		
Current lease liabilities	2,181	1,125
Non-current lease liabilities	7,202	3,591
Total operating lease liabilities	$ 9,383	$ 4,716

Finance Leases		
Right-of-use assets	$ 2,493	$ 1,312
Lease liabilities:		
Current lease liabilities	939	517
Non-current lease liabilities	1,952	895
Total finance lease liabilities	$ 2,891	$ 1,412

Weighted Average Remaining Lease Term		
Weighted-average remaining lease term—operating leases	5.26 years	4.45 years
Weighted-average remaining lease term—finance leases	2.21 years	2.67 years
Weighted Average Discount Rate		
Weighted-average discount rate—operating leases	3.90%	4.28%
Weighted-average discount rate—finance leases	3.57%	4.35%

As of December 31, 2021, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2022	815	2,494
2023	946	1,775
2024	1,275	1,807
2025	—	1,442
2026	—	1,215
Thereafter	—	1,592
Total minimum lease payments	3,036	10,325
Less: imputed interest	(145)	(942)
Present value of lease liabilities	$ 2,891	$ 9,383

In January 2022, we entered into an operating lease for warehouse space, which is scheduled to commence during the first quarter of 2022. The agreement stipulates escalating fixed rent payments aggregating $7,154 to be paid over a lease term of 124 months.

11. INCOME TAXES:

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

	Years Ended December 31,		
	2021	2020	2019
United States	$ (60,500)	$ (47,995)	$ 3,106
Foreign	51,208	44,471	18,225
	$ (9,292)	$ (3,524)	$ 21,331

The components of income tax expense are as follows:

	Years Ended December 31,		
	2021	2020	2019
Current			
Federal	$ —	$ —	$ —
State	163	(106)	1,033
Foreign	12,517	11,896	5,099
	12,680	11,790	6,132
Deferred			
Federal	(10,318)	(20,946)	3,568
State	(965)	(1,053)	125
Foreign	(151)	(410)	(697)
	(11,434)	(22,409)	2,996
Increase (decrease) in valuation allowance	12,460	22,017	(4,453)
	1,026	(392)	(1,457)
Total income tax expense	$ 13,706	$ 11,398	$ 4,675

For the years ended December 31, 2021, 2020, and 2019 we recorded foreign income tax expense of $13,543, $12,185, and $4,607, respectively.

The Tax Cuts and Jobs Act imposed a U.S. tax on GILTI that is earned by certain foreign affiliates owned by a U.S. shareholder effective in 2018. GILTI is generally intended to impose tax on the earnings of a foreign corporation that are deemed to exceed a certain threshold return relative to the underlying tangible property. The Company has made a policy election related to its treatment of GILTI and will treat it as a current period expense in the reporting period in which the tax is incurred.

Final GILTI regulations were released in 2020. Among the changes was a GILTI “High-Tax Exception,” which allows foreign income deemed taxed at a sufficient effective rate to be excluded from a US owner’s GILTI income. All foreign income in 2021 and 2020 fell under this exception. It is expected that foreign income will continue to qualify for the exception in future years.

A reconciliation of the statutory United States federal income tax rate to our effective tax rate for each of the years ended December 31, 2021, 2020, and 2019 is as follows:

	2021	2020	2019
Statutory U.S. federal income tax rate	21.0 %	21.0 %	21.0 %
GILTI tax	—	—	16.9
Nondeductible executive compensation	(6.1)	(0.9)	0.4
Impact of share-based payment awards	(3.3)	(12.4)	(5.3)
Tax effect of foreign items	(30.8)	(70.7)	4.5
State income taxes, net of federal benefit	6.8	26.0	4.0
U.S. and foreign tax credits	2.5	34.9	(1.1)
Nondeductible transaction costs	-	(2.8)	1.6
Nondeductible expenses and other	(4.0)	(2.6)	0.4
NOL adjustment due to change in GILTI regulations	—	308.9	—
Change in valuation allowance, federal and state	(133.6)	(624.8)	(20.5)
Effective tax rate	(147.5) %	(323.4) %	21.9 %

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 our deferred tax assets (liabilities) as of December 31, 2021 and 2020 are as follows:

	2021	2020
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 44,191	$ 31,701
Inventories	4,642	1,593
Capitalized research and development costs	453	746
Accruals and reserves currently not deductible	3,245	3,200
Acquired intangible assets	(3,117)	(3,870)
Depreciation and amortization	(8,536)	(2,804)
Right-of-use assets	(2,777)	(2,415)
Lease liabilities	2,957	2,524
Stock-based compensation	1,891	1,354
Tax credit carryforwards	3,855	3,354
Net deferred tax asset	46,804	35,383
Valuation allowance	(49,038)	(36,578)
Net deferred tax liability	$ (2,234)	$ (1,195)

In assessing the realizability of our deferred tax asset, we consider 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 prior to the expiration of the NOL carryforwards. In 2008, we established a full valuation allowance against our U.S. deferred tax asset, and management believes the full valuation allowance is still appropriate as of December 31, 2021 and 2020 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal income tax benefit was recorded for the years ended December 31, 2021, 2020, and 2019.

Our Federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2022 - 2032	$ 38,444
2033 - 2037	26,631
Non-Expiring	122,920
	$ 187,995

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. We do not believe that there is a Section 382 limitation that will impair our future ability to utilize NOLs to offset our future taxable income. We continue to review ownership changes on an annual basis and we do not believe we have had a subsequent ownership change that would impact the NOLs.

In January 2022, approximately $65,000 was repatriated from our Canadian subsidiary as a one-time event. It is still our intention to continue to permanently reinvest the historical undistributed earnings of our foreign subsidiary to the extent that we 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, 2021.

As of December 31, 2021, our gross unrecognized tax benefits totaled $805, and based upon the valuation allowance for our U.S. operations, the recognition of any tax benefit would not impact our effective tax rate. We record interest and penalties related to unrecognized tax benefits as a component of income tax expense. Interest and penalties were immaterial in 2021, 2020, and 2019. As a result of our net operating loss carryforward position, we are subject to audit by the Internal Revenue Service since our inception, as well as by several state jurisdictions for the years ended September 30, 1998 through December 31, 2021.

A reconciliation of our unrecognized tax benefits is as follows:

	2021	2020	2019
Balance as of January 1	$ 1,172	$ 1,308	$ 1,676
Additions for tax positions of prior periods	1	1	4
Reductions for tax positions of prior periods	(368)	(137)	(372)
Balance as of December 31	$ 805	$ 1,172	$ 1,308

12. STOCKHOLDERS' EQUITY:

Stock-Based Awards

We grant 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, 2021, 4,613 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 our 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:

	Years Ended December 31,		
Black-Scholes Option Valuation Assumptions	**2021**	**2020**	**2019**
Risk-free interest rate[1]	0.47 %	1.33 %	2.52 %
Expected dividend yield	—	—	—
Expected stock price volatility[2]	50 %	42 %	41 %
Expected life of stock options (in years)[2]	4	5	5

(1) Based on the constant maturity interest rate of U.S. Treasury securities whose term is consistent with the expected life of our stock options.
(2) Based upon historical experience.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2021, 2020 and 2019 was $6.14, $2.79 and $5.19, respectively.

Compensation expense recognized in the financial statements related to stock options was as follows:

	Years Ended December 31,		
	2021	**2020**	**2019**
Total compensation cost during the year	$ 1,063	$ 892	$ 1,161
Amounts capitalized into inventory during the year	(538)	(466)	(343)
Amounts recognized in cost of products sold for amounts previously capitalized	502	360	405
Amounts charged against income	$ 1,027	$ 786	$ 1,223

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $130, $3,117, and $92, 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, 2021	1,232	$ 10.12		
Granted	366	13.68		
Exercised	(33)	7.50		
Expired	(88)	15.80		
Forfeited	(67)	10.67		
Outstanding on December 31, 2021	1,410	$ 10.73	6.88	$ 1,113
Vested or expected to vest as of December 31, 2021	1,378	$ 10.68	6.84	$ 1,081
Exercisable on December 31, 2021	786	$ 10.39	5.43	$ 729

As of December 31, 2021, there was $2,571 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.8 years.

Net cash proceeds from the exercise of stock options were $246, $3,222 and $196 for the years ended December 31, 2021, 2020 and 2019, respectively. As a result of our 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, 2021:

	Options outstanding			Options exercisable	
Range of exercise prices	Number Outstanding	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Exercise Price Per Share	Number Exercisable	Weighted-Average Exercise Price Per Share
$5.37-$8.24	588	6.7	$ 6.92	353	$ 6.75
$8.87-$13.31	437	6.4	10.59	282	10.67
$14.95-$22.43	385	7.8	16.70	151	18.37
	1,410	6.9	$ 10.73	786	$ 10.39

The Stock Plan also permits us to grant restricted shares and restricted units of our common stock to eligible employees, including officers, and our outside directors. Generally, these shares or units are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by our 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 $4,094 $4,094 and $2,979 related to restricted shares was recognized during the years ended December 31, 2021, 2020 and 2019, 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, 2021	659	$ 9.95
Granted	454	13.23
Vested	(328)	10.84
Forfeited	(84)	11.02
Issued and unvested, December 31, 2021	701	$ 11.53
Issued and expected to vest, December 31, 2021	638	$ 11.32

As of December 31, 2021, there was $4,640 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 1.9 years.

In connection with the vesting of restricted shares during the years ended December 31, 2021, 2020 and 2019, we purchased and immediately retired 107, 127 and 76 shares with aggregate values of $1,417, $1,219 and $949, respectively, in satisfaction of minimum tax withholding and exercise obligations.

We grant 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 our service for three years from the grant date. Prior to 2021, performance during the one-year period was based on a one-year income before tax target. Performance during the three-year period was based on achievement of a three-year compound annual growth rate for consolidated revenues. In 2021, 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 our 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 200% of the target number of performance share units granted. Upon grant of the PSUs, we recognize compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Compensation cost of $2,650, $2,153 and $(83) related to the PSUs was recognized during the years ended December 31, 2021, 2020 and 2019, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2021	651	$ 11.30
Granted [1]	182	10.99
Performance adjustment [2]	41	N/A
Vested	(123)	16.66
Forfeited	(129)	14.28
Issued and unvested, December 31, 2021	622	$ 9.88
Issued and expected to vest, December 31, 2021	470	$ 9.56

(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, 2021, there was $2,349 of unrecognized compensation expense related to unvested performance stock units that is expected to be recognized over a weighted average period of 1.8 years.

In connection with the vesting of performance stock units during the year ended December 31, 2021, 2020 and 2019, we purchased and immediately retired 46, 121, and 213 shares with aggregate values of $696, $869 and $2,763, respectively.

Public Offering

On June 1, 2020, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Evercore Group LLC, as representatives of several underwriters, relating to the issuance and sale of 8,000 shares of our common stock. The price to the public in the offering was $11.00 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,200 shares of common stock. On June 3, 2020, we announced the full exercise by the underwriters of their option to purchase these additional shares.

The offering was made pursuant to an effective registration statement on Form S-3 (File No. 333-228877) we had previously filed with the SEC, and a prospectus supplement thereunder. The net proceeds from the offering were approximately $95,000 after deducting underwriting discounts and offering expenses paid by the Company.

Share Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired in 2021, 2020, and 2019.

13. 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 is expected to end on March 31, 2022. Pursuant to the Transition Agreement, as of December 31, 2021, a severance accrual of $1,569 is included in the consolidated financial statements.

14. BUSINESS SEGMENT INFORMATION:

Our business consists of two segments, which are described in Note 1: our “Diagnostics” segment and our “Molecular Solutions” segment.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income. We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues and inter-segment expenses have been eliminated.

The following table summarizes operating segment information for the years ended December 31, 2021, 2020, and 2019, and asset information as of December 31, 2021 and 2020:

	Years ended December 31,		
	2021	2020	2019
Net revenues:			
Diagnostics	$ 90,040	$ 65,240	$ 78,225
Molecular Solutions	143,634	106,481	76,380
Total	$ 233,674	$ 171,721	$ 154,605
Operating income (loss):			
Diagnostics	$ (57,177)	$ (43,156)	$ 154
Molecular Solutions	47,013	37,979	18,457
Total	$ (10,164)	$ (5,177)	$ 18,611
Depreciation and amortization:			
Diagnostics	$ 4,325	$ 3,345	$ 3,039
Molecular Solutions	7,333	6,042	4,300
Total	$ 11,658	$ 9,387	$ 7,339
Capital expenditures:			
Diagnostics[(1)]	$ 26,994	$ 17,860	$ 6,073
Molecular Solutions	9,628	8,814	3,241
Total	$ 36,622	$ 26,674	$ 9,314

(1) Excludes $11,495 for purchases of property and equipment under government contracts for the year ended December 31, 2021.

	December 31,	
	2021	2020
Total assets:		
Diagnostics	$ 209,674	$ 242,613
Molecular Solutions	251,316	211,859
Total	$ 460,990	$ 454,472

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

	December 31,	
	2021	2020
United States	$ 76,232	$ 36,897
Canada	11,003	10,616
Other regions	929	4,347
	$ 88,164	$ 51,860

15. COMMITMENTS AND CONTINGENCIES:

Purchase Commitments

As of December 31, 2021, we had outstanding non-cancelable purchase commitments related to inventory, supplies, capital expenditures, and other goods or services as follows:

2022	36,721
2023	25,429
2024	16,934
2025	8,667
2026	—
	$ 87,751

Additionally, we have entered into manufacturing agreements with certain third party vendors, in which minimum purchase commitments are required. If the minimum commitments are not achieved, we will be required to make annual penalty payments over

the next three years. Based on current forecasts, these penalties aggregate to approximately $2,209 for the three-year period. These estimated penalties can fluctuate based on changes in forecasted demand.

Employment Agreements

Under terms of employment agreements with certain employees, which extend through 2024, we are required to pay each individual a base salary for continuing employment with us as follows:

2022	$	2,911
2023		821
2024		426
2025		—
2026		—
	$	4,158

Litigation

From time to time, we are 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 our future financial position or results of operations.

Spectrum Patent Litigation

In March 2021, we 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 has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. We believe Spectrum's counterclaims are without merit and we filed a motion to dismiss both claims in October 2021. We are seeking injunctive relief and damages in this matter. On January 10, 2022, the Court assigned a new judge to preside over the matter, which vacated all dates for the trial. Spectrum filed their reply to our motion to dismiss on January 11, 2022. Though all other dates are pending, the Court has set the hearing for the motion to dismiss for March 30, 2022.

16. RETIREMENT PLANS:

Substantially all of our 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 us to match employee contributions up to $4 per year. We contributed $1,295, $994 and $754 to the 401(k) Plan, net of forfeitures, in 2021, 2020, and 2019, respectively.

In addition to our 401(k) plan, we offer 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. We 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, 2021 and 2020, the value of the assets associated with this plan was $1,763 and $2,565, respectively, and is included in current assets and other assets in our consolidated balance sheets. Our obligation related to the deferred compensation plan is included in accrued expenses and other liabilities in our consolidated balance sheets. As of December 31, 2021 and 2020, our total obligation under this plan was $1,763 and $2,565, 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 Revenue Canada. The RRSP also provides for DNAG to match employee contributions up to $4 per year. We contributed $448, $366 and $184 to the RRSP in 2021, 2020, and 2019, respectively.

EXHIBIT 10.10

AMENDMENT NO. 1
TO
EMPLOYMENT AGREEMENT

This Amendment No. 1 to Employment Agreement entered into as of December 20, 2021 (this "Amendment"), by and among Kathleen G. Weber, DNA Genotek, Inc. and OraSure Technologies, Inc.

WHEREAS, the parties have previously entered into an Employment Agreement, dated as of January 1, 2019 (the "Employment Agreement"), and desire to amend the Employment Agreement as more fully set forth herein.

NOW, THEREFORE, intending to be legally bound, the parties hereby agree as follows:

1. **Definitions**. Unless otherwise specifically defined herein, capitalized terms used in this Amendment shall have the meanings set forth in the Employment Agreement.

2. **Duties**. Notwithstanding Section 1.2 (Duties) of the Employment Agreement, Employee's primary place of work shall move from DNA Genotek's headquarters located in Ottawa, Ontario Canada to a Company location in the United States to be mutually determined by Employee and the Company. Such relocation shall occur on or before December 31, 2022 (the "Relocation Date"); provided that the Relocation Date may be extended to February 28, 2023 if determined by Employee and the Company to be reasonably necessary to accommodate the business needs of the Company. Following such relocation, Employee shall continue to serve in the Position as provided by the Employment Agreement.

3. **Employee Benefits**. Following Employee's relocation to the United States, Employee shall be entitled to receive or participate in employee benefits as provided in Section 3.4 of the Employment Agreement (Employee Benefits), which may from time-to-time be made available by the Company to other senior executives of the Company in the United States. To the extent that the specific benefits described in Sections 3.4.1 through 3.4.10 no longer apply due to Employee's relocation to the United States, such benefits shall be deemed to be terminated with respect to the period beginning immediately after the Relocation Date; provided that the foregoing termination shall not affect the Company's obligation to provide such benefits to the extent related to the period on or prior to the Relocation Date.

4. **Housing Expenses**. Beginning January 1, 2022, the aggregate reimbursement amount required by Section 3.4.4 of the Employment Agreement (Housing Expenses) shall be increased to $3,438.00 USD per month.

5. **Tax Equalization/Tax Services**. Section 3.4.5 of the Employment Agreement (Tax Equalization/Tax Services) is hereby restated in its entirety to read as follows:

> "3.4.5 *Tax Equalization/Tax Services*. Because during the Term Employee will be a United States citizen performing services in Canada, Employee may be subject to aggregate personal income tax in the United States and

Canada on compensation and benefits earned from the Company ("**Company Compensation**") and on other income ("**Other Income**") that may be greater than the personal income tax that Employee would have been required to pay had Employee remained working in the United States (such tax that Employee would have been required to pay had Employee remained working in the United States, the "**Theoretical U.S. Tax**," and the actual tax that Employee will owe in both the United States and Canada, the "**Actual Tax**"). For the avoidance of doubt, it is understood and agreed that "Other Income" includes all of Employee's income not reported on a Form W-2 or similar Canadian form issued by the Company, including, but not limited to any capital gains attributable to the sale of OraSure stock. In order to protect Employee from incurring the additional cost of the Actual Tax over and above the Theoretical U.S. Tax (the "**Supplemental Tax**"), the Company will pay (i) the full amount of the Supplemental Tax with respect to the Company Compensation, (ii) up to a maximum of $30,000.00 USD per year of Supplemental Tax with respect to the Other Income and (iii) any additional tax necessary to put the Employee in the same after-tax position that Employee would have been in (taking into account any and all applicable federal, state, local and foreign income and employment taxes) had the Company not provided the amounts described in items (i) and (ii) (the amount determined under items (i) through (iii) of this sentence, the "**Tax Equalization Benefit**"). In order to process the Tax Equalization Benefit, an accounting firm selected and paid for by the Company will assist in preparing and filing Employee's income tax returns required in the United States and Canada. In addition, this accounting firm will, at the Company's cost, assist with the preparation and filing of Employee's Canadian tax return, if required, for a period of three years after the date of the notice of assessment received for the last tax year Employee will be physically working in Canada, such assistance to include responding to any audits of Employee's Canadian or US tax returns. Each year during the Term, the Company will make actual payments of income taxes for Employee in the United States and Canada. During the Term, the Company will deduct from Employee's salary each pay period an amount that the Company, acting in good faith, determines is required by law to be withheld from the Company Compensation by taxing authorities in the United States and Canada. Following the end of each taxable year, the Company will provide Employee with a statement of tax liability that will indicate the amount of the Theoretical U.S. Tax, the Actual Tax and the Tax Equalization Benefit. If such statement indicates that the Company owes Employee additional Supplemental Tax or that Employee owes the Company any additional tax, the party owing such tax will remit it to the other party within 60 days. Any determination required under this Section 3.4.5 shall be made by the Company in its sole discretion."

6. **Other Employee Benefits**. The following new provision is hereby added to Section 3.4 of the Employment Agreement (Employee Benefits):

3.4.11 *Departure Tax*. In connection with Employee's relocation to the United States, the Company shall pay or reimburse Employee for any liability under the "departure" tax rules in Canada; provided that the Company's liability therefor shall not exceed $25,000.00 CDN in total.

7. Effect of Amendment. Except as amended hereby, the Employment Agreement shall remain in full force and effect.

8. Counterparts and Facsimiles. This Amendment may be executed, including execution by facsimile or electronic signature, in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

9. Governing Law. This Amendment shall be governed by, and enforced in accordance with, the laws of the Province of Ontario without regard to the application of the principles of conflicts of laws.

The parties have executed this Amendment as of the date indicated above.

ORASURE TECHNOLOGIES, INC.

/s/ Kathleen G. Weber
Kathleen G. Weber

By: */s/ Stephen S. Tang, Ph.D.*
Stephen S. Tang
Title: President and Chief Executive Officer

DNA GENOTEK, INC.

By: */s/ Stephen S. Tang, Ph.D.*
Stephen S. Tang
Title: Chief Executive Officer

EXHIBIT 10.12

EMPLOYMENT AGREEMENT

This Employment Agreement (this "**Agreement**") is entered into as of November 29, 2021 (the "**Effective Date**"), between Agnieszka M. Gallagher ("**Employee**") and OraSure Technologies, Inc. ("**OraSure**" or the "**Company**").

WHEREAS, the parties wish to set forth the terms of their relationship and to enter into this Agreement and a confidentiality agreement of even date herewith (the "Confidentiality Agreement").

NOW, THEREFORE, in consideration of the mutual promises made herein, intending to be legally bound, the parties hereby agree as follows:

1. **Services.**

1.1 **Employment.** Subject to the terms hereof, the Company agrees to employ Employee as the Company's Executive Vice President, General Counsel, Chief Compliance Officer and Secretary (the "**Position**"), and Employee hereby accepts such employment in accordance with the terms and conditions of this Agreement. Employee shall begin her employment with the Company on the Effective Date.

1.2 **Duties.** Upon the Effective Date, Employee shall have such powers and duties that are (a) commensurate with the Position, (b) set forth in Exhibit A attached to this Agreement, and (c) otherwise determined from time to time by the Board of Directors of OraSure (the "**Board of Directors**") or the Chief Executive officer of OraSure (the "**CEO**"). Employee's primary place of work shall be the Company's headquarters, at its present location in Bethlehem, Pennsylvania; provided that Employee may work remotely from her home and shall travel to the Company's headquarters when required, as mutually determined by Employee and the CEO, to meet the business needs of the Company.

1.3 **Outside Activities.** Employee shall obtain the consent of the Board of Directors or the CEO before she engages, either directly or indirectly, in any other professional or business activities that may require an appreciable portion of Employee's time.

1.4 **Direction of Services.** Employee shall at all times report directly to, and discharge her duties in consultation with and under the supervision and direction of, the CEO.

2. **Term.** The initial term of this Agreement shall begin as of the Employment Date and end on the third anniversary of the Employment Date, unless Employee's employment is sooner terminated in accordance with Section 6 below (the "**Initial Term**"). Thereafter, this Agreement shall automatically renew and Employee's employment shall continue for successive one-year terms (each, a "**Renewal Term**" and together with the Initial Term, the "**Term**") unless the Company gives Employee written notice of the Company's intent not to renew this Agreement at least 90 days before the expiration of the Initial Term or any Renewal Term, or Employee's employment under this Agreement is terminated in accordance with Section 6 below.

3. **Compensation and Expenses.**

3.1 **Salary.** As compensation for services under this Agreement, the Company shall pay to Employee a base salary of $465,000 per annum. Such salary will be subject to review by the Board of Directors on an annual basis and may be increased from time to time in the discretion of the Board of Directors. Any reduction shall be subject to the provisions of Good Reason (as defined below) and Section 6 below. Payment shall be made in accordance with the Company's normal payroll practices as in effect

from time to time, less all amounts required by law or authorized by Employee to be withheld or deducted. For all purposes under this Agreement, the term "salary" shall mean the regular annual base salary of Employee payable under this Section 3.1, as increased.

3.2 **Bonus.** In addition to the salary described in Section 3.1 above, Employee shall be entitled to participate in the incentive plan established by OraSure each year for the payment of cash bonuses to senior executive officers of OraSure and its subsidiaries (each, a "**Bonus Plan**"), on such terms as may be approved by the Board of Directors or its compensation committee (the "**Compensation Committee**") in its sole discretion each Bonus Plan. With respect to each Bonus Plan, (a) Employee shall have a target bonus amount as determined by the Board of Directors or Compensation Committee which is at least equal to 45% of Employee's salary and (b) cash bonuses payable to Employee shall be determined in the same manner as the cash bonuses paid to other senior executive officers of the Company under the applicable Bonus Plan with respect to the same time period. Employee shall be eligible for a bonus as provided above in February 2022 along with the Company's other senior executives under the Company's 2021 Incentive Plan and such bonus shall not be subject to pro-ration to reflect the actual duration of Employee's service during 2021.

3.3 **Long-Term Incentive Awards.** Employee shall be entitled to participate in the Long-Term Incentive Policy or comparable long-term incentive equity policy or plan that may from time to time be adopted by the Board of Directors or the Compensation Committee, in its sole discretion (an "**LTIP**") and, with respect to each LTIP, (a) Employee shall be entitled to annual awards ranging from between 95% to 155% of her salary (with the target set at a minimum of 125% of her salary), as determined by the Board of Directors or its Compensation Committee and (b) equity awards or other benefits provided to Employee under any such LTIP shall be determined in the same manner as the awards or other benefits provided under such policies or plans to other senior executive officers of the Company with respect to the same time period. All equity awards granted to Employee on or after the Effective Date, including the award provided for in Section 4, shall, to the extent then unvested, immediately vest (i) in the event of a Change of Control (as defined herein) or (ii) in the event Employee's employment is terminated for Good Reason (as defined herein) pursuant to Section 6.4 or without Cause (as defined herein) pursuant to Section 6.5 during a Change of Control Period (as defined herein), and 50% of such awards shall, to the extent then unvested, immediately vest in the event Employee's employment is terminated for death or Disability (as defined herein) pursuant to Section 6.1, Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 during any period other than a Change of Control Period (as defined herein). Employee shall be eligible for an annual LTIP award as provided above in February 2022 along with the Company's other senior executives and such award shall not be subject to pro-ration to reflect the actual duration of Employee's service during 2021.

3.4 **Employee Benefits.** Employee shall be entitled to receive or participate in any additional benefits, including without limitation medical and dental insurance programs, qualified and non-qualified profit sharing or pension plans, disability plans, medical reimbursement plans, and life insurance programs, which may from time to time be made available by the Company to other senior executive officers of the Company. The Company may change or discontinue such benefits at any time in its sole discretion; provided that the benefits provided to Employee shall be determined in the same manner as the benefits provided to other senior executive officers of the Company under such plans with respect to the same time period.

3.5 **Expenses.** The Company shall reimburse Employee for all reasonable and necessary expenses incurred in carrying out her duties under this Agreement, subject to compliance with the Company's reasonable policies relating to expense reimbursement. Expenses subject to reimbursement under this Section 3.5 shall include, but not be limited to, the cost of business-related travel, lodging and meals and the fees and expenses incurred by Employee to maintain her membership in professional

associations and obtain continuing professional education reasonably required in connection with Employee's performance of her duties under this Agreement. All reimbursements under this Section 3.5 will be made as soon as practicable after submission of any required documentation, in compliance with the Company's reasonable policies relating to expense reimbursement.

3.6 **Fees.** From and after the Effective Date, all compensation earned by Employee, other than pursuant to this Agreement, as a result of services performed on behalf of the Company or as a result of or arising out of any work done by Employee in any way related to the scientific or business activities of the Company shall belong to the Company. Employee shall pay or deliver such compensation to the Company promptly upon receipt. For the purposes of this provision, "compensation" shall include, but is not limited to, all professional and nonprofessional fees, lecture fees, expert testimony fees, publishing fees, royalties, and any related income, earnings, or other things of value; and "scientific or business activities of the Company" shall include, but not be limited to, any project or projects in which the Company is involved and any subject matter that is directly or indirectly researched, tested, developed, promoted, or marketed by the Company.

4. **Onboarding Compensation.** On or as soon as practicable after the Effective Date, Employee shall be granted an equity award under the Company's Stock Award Plan having an aggregate value of $1,000,000 and consisting of (i) $250,000 of time-vested restricted stock, with cliff vesting for the entire award occurring five years after the grant date, (ii) $250,000 of time-vested restricted stock, with vesting in equal annual amounts over the three years following the grant date, and (iii) $500,000 of options to purchase the Company's common stock, with the first 25% of such award vesting after one year and the remaining 75% vesting on a monthly basis over the next three years following the first anniversary of the grant date. The other terms for the awards described above shall reflect the requirements set forth in this Agreement and shall otherwise be consistent with similar equity awards granted to senior executives of the Company.

5. **Confidentiality Agreement.** Employee's compliance with the terms of the Confidentiality Agreement is a material requirement of this Agreement. Any breach of the Confidentiality Agreement that is materially detrimental to the Company and that, if capable of being cured, is not cured within 30 days of written notice thereof from the Company to Employee shall constitute a material breach of this Agreement. Notwithstanding the foregoing, (i) nothing in this Agreement or the Confidentiality Agreement shall prohibit the Employee from reporting possible violations of law or a regulation to any governmental agency or entity or self-regulatory organization or making disclosures that are protected under law, including the whistleblower provisions of U.S. federal law or regulation; and (ii) in accordance with the U.S. Defend Trade Secrets Act of 2016, Employee shall not be held criminally or civilly liable under any U.S. federal or state trade secret law for the disclosure of a trade secret that: (A) is made (i) in confidence to a U.S. federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

6. **Termination.**

6.1 **Termination Upon Death or Disability.** Employee's employment under this Agreement shall terminate immediately upon Employee's death or Disability. The term "**Disability**" means Employee is (a) unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months; or (b) by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company.

6.2 **Termination by Employee.** Employee may terminate her employment under this Agreement by ninety (90) days' written notice to the Company.

6.3 **Termination by the Company for Cause.** Employee's employment under this Agreement may be terminated by the Company at any time for Cause. Only the following actions, failures, or events by or affecting Employee shall constitute "**Cause**" for termination of Employee by the Company: (i) willful and continued failure by Employee to substantially perform her duties provided herein after a written demand for substantial performance is delivered to Employee by the CEO or the Board of Directors, which demand identifies with reasonable specificity the manner in which Employee has not substantially performed her duties, and Employee's failure to comply with such demand within a reasonable time, which shall not be less than thirty (30) days after Employee's receipt of such demand; (ii) the engaging by Employee in gross misconduct or gross negligence materially injurious to the Company, which if capable of being cured, is not cured within 30 days of written notice thereof from the CEO or the Board of Directors to Employee; (iii) the commission of any act in direct competition with or materially detrimental to the best interests of the Company, which if capable of being cured, is not cured within 30 days of written notice thereof from the CEO or the Board of Directors to Employee; or (iv) Employee's conviction of having committed a felony. Notwithstanding the foregoing, Employee shall not be deemed to have been terminated by the Company for Cause unless and until there shall have been delivered to her a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the entire membership of the Board of Directors finding that, in the good faith opinion of the Board of Directors, the Company has Cause for the termination of the employment of Employee as set forth in any of clauses (i) through (iv) above and specifying the particulars thereof in reasonable detail.

6.4 **Termination by Employee With Good Reason.** Employee may terminate her employment under this Agreement for Good Reason; provided that (i) Employee gives written notice to the Board of Directors within sixty (60) days of the event constituting Good Reason; (ii) the Company has not cured the event giving rise to such notice within thirty (30) days of receipt of Employee's notice; and (iii) Employee resigns her employment within thirty (30) days following the expiration of such cure period. The term "**Good Reason**" shall mean any of the following actions that are taken without Employee's prior written consent: (a) a material breach of this Agreement by the Company (or its successor); (b) a material diminution in Employee's base compensation or authority, duties or responsibilities; (c) a material change in Employee's reporting obligation from the CEO to another employee of the Company; or (d) a relocation of Employee's principal worksite that increases Employee's one-way commute by more than 30 miles.

6.5 **Termination by the Company Without Cause.** The Company may terminate Employee's employment under this Agreement without Cause by ninety (90) days' written notice to Employee. In the event the Company fails to renew this Agreement pursuant to Section 2, such failure shall be deemed to be a termination of Employee's employment by the Company without Cause.

6.6 **Definitions.** For purposes of this Agreement, the term "**Change of Control Period**" shall mean the period which begins sixty (60) days prior to the occurrence of a Change of Control and ends eighteen (18) months thereafter. For purposes of this Agreement, the term "**Change of Control**" shall mean a change of control of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A pursuant to the U.S. Securities Exchange Act of 1934 (the "**Exchange Act**"); provided, however, that a change of control shall only be deemed to have occurred at such time as (i) any person, or more than one person acting as a group within the meaning of Section 409A of the Internal Revenue Code (the "**Code**") and the regulations issued thereunder, acquires ownership of stock of the Company that, together with stock held by such person or group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the stock of the Company; (ii) any person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the twelve (12) month period ending on the date of the most

recent acquisition) ownership of stock of the Company possessing thirty percent (30%) or more of the total voting power of the Company's stock; (iii) a majority of the members of the Board of Directors is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors before the date of the appointment or election; or (iv) a person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition) assets from the Company that have a total gross fair market value equal to or more than 40 percent of the total gross fair market value of all the assets of the Company immediately before such acquisition or acquisitions.

6.7 **Compensation Upon Termination.**

6.7.1 **Termination Upon Death or Disability, by Employee (Other Than for Good Reason) or for Cause.**

In the event of a termination of Employee's employment under Sections 6.1, 6.2 or 6.3, all salary and benefits shall cease on the date of termination, subject to the terms of any benefit plans then in force and applicable to Employee, and the Company shall have no further liability or obligation hereunder by reason of such termination, save and except as stated herein. In the event of a termination of Employee's employment under Sections 6.1, 6.2 or 6.3, Employee or her estate, as applicable, shall be paid all salary earned under Section 3.1 through the date of termination on the next regularly scheduled payroll date following the termination date ("**Accrued Salary and Benefits**"). With respect to terminations under Sections 6.1 and 6.2 only, Employee or her estate, as applicable, shall receive, in addition to the foregoing, any bonus that has been approved by the Board of Directors or Compensation Committee prior to the date of termination but not yet paid (the "**Accrued Bonus**"), payable at the time that cash bonuses are or would otherwise be payable to other officers of the Company in respect of such year. In the event of a termination under Sections 6.1 or 6.2 that occurs after June 30 in any given year, Employee or her estate, as applicable, shall receive a prorated portion of any cash bonus, at Employee's target bonus percentage of base salary (subject to adjustment for bonus pool funding as determined by the Board of Directors), for the calendar year in which termination occurs (calculated based on the number of days in the calendar year that have passed prior to Employee's termination), payable at the time that cash bonuses are or would otherwise be payable to other officers of the Company in respect of such year (the "**Prorated Bonus**"). For greater certainty, in the event a termination under Sections 6.1 or 6.2 occurs on or before June 30 in any given year, Employee or her estate, as applicable, shall not receive a Prorated Bonus. The Accrued Salary and Benefits and Prorated Bonus (if any) are herein referred to collectively as the "**Accrued Obligations**."

6.7.2 **Termination Without Cause or Upon Good Reason.** In the event of a termination of Employee's employment under Sections 6.4 or 6.5 of this Agreement, the following shall occur:

(i) Employee shall receive the Accrued Obligations;

(ii) Employee shall receive: (A) if such termination does not occur during a Change of Control Period, a lump sum payment (less applicable withholdings) equivalent to twelve (12) months of Employee's annual salary; or (B) if such termination occurs during a Change of Control Period, a lump sum payment (less applicable withholdings) equivalent to twenty-four (24) months of the Employee's annual salary;

(iii) Employee shall receive, as a component of severance, a cash bonus for the calendar year in which termination occurs equal to Employee's target bonus for such year established pursuant to Section 3.2;

(iv) if Employee validly elects to receive continuation coverage under OraSure's group health plan pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), and if such termination is for Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 and does not occur during a Change of Control Period, the Company shall reimburse Employee for the applicable premium otherwise payable for COBRA continuation coverage for such coverage for a period of twelve (12) months after the date of termination, but only with respect to the portion of such premium that exceeds the monthly amount charged to active employees of the Company for the same coverage. If such termination is for Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 and occurs during a Change of Control Period, the Company shall reimburse Employee for the applicable premium otherwise payable for COBRA continuation coverage for such coverage for a period for the shorter of either (x) twenty-four (24) months after the date of termination; or (y) the date Employee is no longer eligible for COBRA, but only with respect to the portion of such premium that exceeds the monthly amount charged to active employees of the Company for the same coverage; and

(v) Employee shall receive accelerated vesting as described in Section 3.3 herein.

The amounts payable under clauses (ii), (iii) and (iv) are collectively referred to as "severance." Subject to Section 6.8, all severance payments will be made (or commence) under this Section 6.7.2 on the 90th day after termination of employment hereunder. As a condition to receipt of severance under this Section 6.7.2, within forty-five (45) days following termination of Employee's employment, Employee shall sign, deliver and not revoke a release agreement, in the form and substance set forth in Exhibit B hereto, releasing all claims related to Employee's employment, other than those that cannot be released as a matter of law. The severance shall be in lieu of and not in addition to any other severance arrangement maintained by the Company, and shall be offset by any monies Employee may owe to the Company. The Company's obligation to pay the amounts stated in clauses (ii), (iii) and (iv) of this Section 6.7.2 shall terminate if, during the period commencing on termination of employment and continuing until all severance payments have been made by the Company, Employee fails to comply with Sections 9 or 13 of this Agreement or with the Confidentiality Agreement.

6.7.3 **Parachute Payment.** In the event that (i) Employee becomes entitled to any payments or benefits hereunder or otherwise from the Company or any of its affiliates which constitute a "parachute payment" as defined in Code Section 280G (the "**Total Payments**") and (ii) Employee is subject to an excise tax imposed under Code Section 4999 (the "**Excise Tax**"), then, if it would be economically advantageous for Employee, the Total Payments shall be reduced by an amount (including zero) that results in the receipt by Employee on an after tax basis (including the applicable U.S. federal, state and local income taxes, and the Excise Tax) of the greatest Total Payments, notwithstanding that some or all of the portion of the Total Payments may be subject to the Excise Tax. If a reduction in Total Payments is required pursuant to the preceding sentence, the reduction will occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Total Payments being subject to taxes pursuant to Code Section 409A (as defined below) that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification will preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), will be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A will be reduced (or eliminated) before Payments that are not deferred compensation within

the meaning of Section 409A. All calculations hereunder shall be performed by a nationally recognized independent accounting firm selected by the Company, with the full cost of such firm being borne by the Company. Any determinations made by such firm shall be final and binding on Employee and the Company.

6.8 **Section 409A.** This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("**Code Section 409A**") (to the extent applicable) and the parties hereto agree to interpret, apply and administer this Agreement in the least restrictive manner necessary to comply therewith and without resulting in any increase in the amounts owed hereunder by the Company. Notwithstanding any other provision of this Agreement to the contrary, if Employee is a "specified employee" within the meaning of Section 409A of the Internal Revenue Code, as amended (the "**Code**") at the time of Employee's termination of employment and any payment under this Section 6 would otherwise subject Employee to any tax, interest or penalty imposed under Code Section 409A (or any regulation promulgated thereunder) if the payment or benefit would commence as set forth in this Section 6, then the payment due under this Section 6 shall not be made (or commence) until the first day which is at least six (6) months after the date of the Employee's termination of employment. All payments, which would have otherwise been required to be made to Employee over such six (6) month period, shall be paid to Employee in one lump sum payment as soon as administratively feasible after the first day which is at least six months after the date of Employee's termination of employment with the Company. For purposes of the application of Code Section 409A, each payment in a series of payments will be deemed a separate payment. Notwithstanding anything herein to the contrary, except to the extent any expense, reimbursement or in-kind benefit provided to the Employee does not constitute "nonqualified deferred compensation" within the meaning of Code Section 409A, and its implementing regulations and guidance, (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Employee during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Employee in any other calendar year, (ii) the reimbursements for expenses for which the Employee is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iii) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

7. **Indemnification.** The Company agrees that if Employee is made a party (or is threatened to be made a party to) any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "**Proceeding**"), by reason of her service (including past service) as an officer, director, employee, agent, or the like of the Company, or is or was serving at the request of the Company as an officer, director, employee, agent, or the like of another entity, including, without limitation, as a fiduciary of an employee benefit plan sponsored or established by the Company (any such service for a subsidiary, affiliate, joint venture or other entity in which the Company has an ownership or other financial interest, or as a fiduciary of any employee benefit plan sponsored by the Company or any such other entity, shall be presumed to be at the request of the Company), whether or not the basis of such Proceeding is an act or omission alleged to have occurred while Employee was acting in an official capacity as a director, officer, employee, agent, or the like, then Employee shall be indemnified and held harmless by the Company to the fullest extent authorized by applicable law (including for all reasonable attorneys' fees and costs incurred by Employee), and such indemnification shall continue even if Employee has ceased to be a director, officer, employee, agent, or the like of the Company for any reason.

8. **Insurance.** During the Term and for a period of six (6) years thereafter (regardless of the reason for the termination of Employee's employment), the Company shall maintain suitable directors and officers insurance coverage for Employee in her respective roles and shall name Employee as an additional insured under such insurance policies, which policies shall be no less favorable to Employee than such insurance policies that cover OraSure's directors during such time period.

9. **Non-Competition.** In consideration of the severance payable hereunder, during the Term and for a period of one (1) year thereafter, Employee agrees that, unless she obtains written agreement from the CEO or the Board of Directors, Employee covenants to not:

(a) recruit, solicit, or hire any executive or employee of the Company;

(b) induce or solicit any current or prospective customer, client, or supplier of the Company to cease being a customer, client or supplier or divert Company business away from any customer, client, or supplier of the Company; or

(c) own, manage, control, work for, or provide services to any entity which competes with the Company in the market for rapid point-of-care, oral fluid diagnostic testing in the United States (the "Protected Business"); provided, however, that this Section 9: (i) shall not prevent Employee from accepting a position with and working for any other entity which competes with the Company in the Protected Business, if such business is diversified, Employee is employed in a department, division or other unit of the business that is not engaged in the Protected Business and Employee does not, directly or indirectly, provide any assistance, services, advice, consultation or information with respect to rapid point-of-care, oral fluid diagnostic testing to the department, division or unit of the business engaged in the Business; and (ii) shall not prevent Employee from purchasing or owning less than five percent (5%) of the stock or other securities of any entity, provided that such stock or other securities are traded on any national or regional securities exchange or are actively traded in the over-the-counter market and registered under Section 12(g) of the Securities Exchange Act of 1934, as amended. The parties acknowledge that the non-competition agreement set forth in this Section 9 is intended to replace and supersede the non-competition provision set forth on page 1 of the Confidentiality Agreement executed contemporaneously herewith.

10. **Remedies.** The respective rights and duties of the Company and Employee under this Agreement are in addition to, and not in lieu of, those rights and duties afforded to and imposed upon them by law or at equity.

11. **Severability of Provisions.** The provisions of this Agreement are severable, and if any provision hereof is held invalid or unenforceable, it shall be enforced to the maximum extent permissible, and the remaining provisions of the Agreement shall continue in full force and effect.

12. **Non-Waiver.** Failure by either party at any time to require performance of any provision of this Agreement shall not limit the right of the party failing to require performance to enforce the provision. No provision of this Agreement may be waived by either party except by a writing signed by that party. A waiver of any breach of a provision of this Agreement shall be construed narrowly and shall not be deemed to be a waiver of any succeeding breach of that provision or a waiver of that provision itself or of any other provision.

13. **Non-Disparagement.** Both during and after her employment, Employee agrees not to disparage the Company or any of the stockholders, directors, officers, or employees of the Company. The Company agrees not to disparage, and will not direct its directors, officers and employees to disparage, Employee. Employee and the Company agree not to make any statement or engage in any conduct that might affect adversely the business or professional reputation of the other party or, in the case of the Company, any of the stockholders, directors, officers or employees of the Company. Any breach of this Section 13 by a director, officer or employee of the Company shall be deemed to be a breach by the Company.

14. **Other Agreements.** Employee represents, warrants and, where applicable, covenants to the Company that:

(a) There are no restrictions, agreements or understandings whatsoever to which Employee is a party which would prevent or make unlawful Employee's execution of this Agreement or Employee's employment hereunder, or which is or would be inconsistent or in conflict with this Agreement or Employee's employment hereunder, or would prevent, limit or impair in any way the performance by Employee of her obligations hereunder;

(b) Employee's execution of this Agreement and Employee's employment hereunder shall not constitute a breach of any contract, agreement or understanding, oral or written, to which Employee is a party or by which Employee is bound; and

(c) Employee is free to execute this Agreement and to be employed by the Company as an employee pursuant to the provisions set forth herein.

15. **Successors and Assigns.** This Agreement shall inure to the benefit of and be binding upon the Company and Employee and their respective successors, executors, administrators, heirs and/or permitted assigns; *provided*, *however*, that neither Employee nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party, except that, without such consent, the Company may assign this Agreement to any successor to all or substantially all the business or assets of the Company by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise and Employee may transfer this Agreement by will or the laws of descent and distribution. The Company will require any successor (whether direct or indirect, by merger, consolidation, transfer of assets, or otherwise) acquiring all or substantially all of the business and/or assets of the Company (whether such assets are held directly or indirectly) to assume expressly and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. As used in this Agreement, "**Company**" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

16. **Non-exclusivity of Rights.** Nothing in this Agreement shall prevent or limit Employee's continuing or further participation in any benefit, bonus, incentive, stock-based or other plan or program provided by the Company and for which Employee may qualify. Except as otherwise provided herein, amounts and benefits which are vested benefits or which Employee is otherwise entitled to receive at or subsequent to the date of termination shall be payable in accordance with such plan or program.

17. **Entire Agreement; Amendments.** This Agreement and the Confidentiality Agreement contain the entire agreement and understanding of the parties hereto relating to the subject matter hereof and thereof, and supersede all prior and contemporaneous discussions, agreements and understandings of every nature relating to the employment of Employee by the Company. This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

18. **Consent to Suit.** Any legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and Employee and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that Employee or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

19. **Cooperation.** Employee further agrees that during and after her employment with the Company, subject to reimbursement of her reasonable expenses, she will cooperate fully with the Company and its counsel with respect to any matter (including, without limitation, litigation, investigations, or governmental proceedings) in which the Employee was in any way involved during her employment with the Company. Employee shall render such cooperation in a timely manner on reasonable notice from the Company, so long as the Company, following Employee's termination of employment, exercises commercially reasonable efforts to schedule and limit its need for Employee's cooperation under this paragraph so as not to interfere with Employee's other personal and professional commitments.

20. **Counterparts and Facsimiles.** This Agreement may be executed, including execution by facsimile signature, in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

21. **Governing Law.** This Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania without regard to the application of the principles of conflicts of laws.

The parties have executed this Employment Agreement as of the date stated above.

ORASURE TECHNOLOGIES, INC.

/s/ Agnieszka M. Gallaher
Agnieszka M. Gallagher

By: */s/ Stephen S. Tang, Ph.D.*
Stephen S. Tang

Title: President and Chief Executive Officer

EXHIBIT A

Specific Duties of Employee as
Executive Vice President, General Counsel, Chief Compliance Officer and Secretary

Employee, as the Executive Vice President, General Counsel, Chief Compliance Officer and Secretary of the Company or the surviving entity in the event of a Change of Control, shall have duties commonly performed by the chief legal officer and chief compliance officer of a company with capital stock that is publicly traded on a national stock exchange, including, without limitation, being the individual primarily responsible for (i) overseeing all legal matters affecting the Company or such surviving entity; (ii) advising senior management and the Board of Directors of the Company or such surviving entity regarding commercial, corporate, intellectual property, M&A, labor and employment, litigation, real estate, securities, disclosure, governance and other legal matters; (iii) attending meetings of and preparing minutes for, and providing legal advice to, the Board of Directors (and Committees of the Board) of the Company or such surviving entity; and (iv) overseeing all compliance matters, including regulatory affairs, quality assurance, compliance with the Company's Code of Conduct and other principal policies and other legal compliance.

EXHIBIT B

RELEASE AGREEMENT

THIS RELEASE AGREEMENT (the "**Agreement**") is entered into on this __ day of _____, 20__, by and between Agnieszka M. Gallagher ("**Executive**") and OraSure Technologies, Inc., a Delaware corporation, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, directors, officers, Executives, attorneys and agents, whether present or former (collectively "**OraSure**");

WHEREAS, Executive is entitled to receive severance under an Employment Agreement ("**Employment Agreement**"), dated _____, 2021 between Employee and OraSure; and

WHEREAS, Executive agrees to execute this Agreement as consideration for such severance; and

WHEREAS, capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in the Employment Agreement.

NOW, THEREFORE, the parties agree as follows, in consideration of the mutual covenants and obligations contained herein, and intending to be legally held bound:

1. Employment Termination; Consideration. Executive's employment with OraSure shall terminate on _____ (the "**Termination Date**"). In consideration for Executive's receipt of severance as provided in the foregoing Employment Agreement, Executive is willing to enter into this Agreement and provide the release set forth herein.

2. Executive's Release. Executive, on behalf of Executive, Executive's heirs, executors, successors, assigns and representatives hereby unconditionally and irrevocably releases settles and forever discharges OraSure, together with each and every one of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, and all of their directors, officers, executives, attorneys and agents, and benefit plans (and the administrators, fiduciaries and agents of such plans), whether present or former (collectively the "**Releasees**"), from any and all suits, causes of action, complaints, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown, suspected or unsuspected (hereinafter "Claims"), which the Executive ever had or now has arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. Except as otherwise expressly provided in this Agreement, the Claims released by Executive specifically include, but are not limited to:

a. any and all claims for wages and benefits including, without limitation, salary, stock, options, commissions, royalties, license fees, health and welfare benefits, separation pay, vacation pay, incentives, and bonuses (collectively "wage related claims") other than wage related claims that cannot be released as a matter of law;

b. any and all claims for wrongful discharge, breach of contract (whether express or implied), or for breach of the implied covenant of good faith and fair dealing;

c. any and all claims for alleged employment discrimination on the basis of age, race, color, religion, sex, national origin, veteran status, disability and/or handicap and any and all other claims in violation of any federal, state or local statute, ordinance, judicial precedent or executive order,

including but not limited to claims under the following statutes: Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. §2000e et seq., the Civil Rights Act of 1866, 42 U.S.C. §1981, the Age Discrimination in Employment Act, 29 U.S.C. §621 et seq., the Older Workers Benefit Protection Act, 29 U.S.C. §626(f) (together with the Age Discrimination in Employment Act, the "**ADEA**"), the Americans with Disabilities Act, 42 U.S.C. §12101 et seq., the Family and Medical Leave Act of 1993, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974, or any comparable statute of any other state, country, or locality except as required by law, but excluding claims for vested benefits under OraSure's pension plans;

d. any and all claims under any foreign, federal, state or local statute or law;

e. any and all claims in tort (including but not limited to any claims for misrepresentation, defamation, interference with contract or prospective economic advantage, intentional or negligent infliction of emotional distress, duress, loss of consortium, invasion of privacy and negligence);

f. any and all claims for attorneys' fees and costs; and

g. any and all other claims for damages of any kind.

It is the intention of Executive and OraSure that the language relating to the description of released claims in this Section shall be accorded the broadest possible interpretation. Notwithstanding the foregoing, nothing contained in this paragraph shall apply to, or shall release OraSure from, (i) any obligation of OraSure under this Agreement or the Employment Agreement; (ii) any accrued or vested benefit of Executive pursuant to any employee benefit plan of OraSure, including any benefit not yet due and payable; (iii) any obligation of OraSure under existing stock options, restricted stock or other stock awards; or (iv) any right to indemnification under this Agreement, the By-Laws or Certificate of Incorporation of OraSure or any subsidiary or any insurance policy maintained by the Company or any subsidiary or other entity. Further, Executive does not waive any rights or claims under the ADEA or otherwise that may arise after the date of Executive's execution of this Agreement.

3. Acknowledgment. Executive understands that her release in Section 2 extends to all of the aforementioned Claims and potential Claims which arose on or before the date of this Agreement, whether now known or unknown, suspected or unsuspected, and that this constitutes an essential term of this Agreement. Executive further understands and acknowledges the significance and consequence of this Agreement and of each specific release and waiver, and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands, obligations, and causes of action, if any, as well as those relating to any other claims, demands, obligations or causes of action hereinabove specified.

4. Remedies. All remedies at law or in equity shall be available to OraSure for the enforcement of this Agreement. This Agreement may be pleaded as a full bar to the enforcement of any claim that Executive may assert against OraSure in violation of this Agreement.

5. Promise Not To Sue.

a. Executive agrees and covenants not to file, initiate, or join any lawsuit (individually, with others, or as part of a class), in any forum, pleading, raising, or asserting any claim(s) barred or released by this Agreement. If Executive does so, and the action is found to be barred in whole or in part by this Agreement, Executive agrees to pay the attorneys' fees and costs, or the proportions thereof, incurred by the applicable Releasees in defending against those claims that are found to be barred by this Agreement. While this Agreement will serve to release any ADEA claims, the attorneys' fees/cost

shifting provision set forth in this paragraph will not apply to any claims challenging the validity of the release contained in this Agreement under the ADEA.

b. Notwithstanding any of the foregoing to the contrary, nothing in this Agreement or otherwise shall prohibit Executive from (a) reporting possible violations of federal law or regulation to any governmental agency or entity or self-regulatory organization (including but not limited to the Department of Justice, the Securities and Exchange Commission, Congress and any agency Inspector General), or making other disclosures that are protected under the whistleblower provisions of federal law or regulations (it being understood that Executive does not need the prior authorization of OraSure to make any such reports or disclosures or to notify OraSure that Executive has made such reports or disclosures), or (b) providing truthful testimony or statements to the extent, but only to the extent, required by applicable law, rule, regulation, legal process or by any court, arbitrator, mediator or administrative, regulatory, judicial or legislative body (including any committee thereof) with apparent jurisdiction (provided, however, that in such event, except as set forth in the foregoing clause (a) above, Executive will give OraSure prompt written notice thereof prior to such disclosure so that OraSure may seek appropriate protection for such information). However, Executive acknowledges and agrees that Executive shall not seek or accept and waives any rights to any relief obtained on Executive's behalf in any proceeding by any government agency (including the Equal Employment Opportunity Commission), private party, class, or otherwise with respect to any claims covered by the release in Section 2 of this Agreement.

6. No Admissions. Neither the execution of this Agreement by the Company, nor the terms hereof, constitute or should be construed to constitute any admission or evidence of any wrongdoing, liability or violation of any federal, state or local law or the common law on the part of the Company.

7. Confidentiality. To the extent not otherwise made public by OraSure and except as permitted by this Section, Executive shall not disclose or publicize the terms or fact of this Agreement, directly or indirectly, to any person or entity, except to Executive's attorney and spouse, provided that Executive's attorney and spouse agree to keep the information confidential, and to others as required by law. Executive is specifically prohibited from disclosing the facts or terms of this Agreement to any former or present executive of OraSure except as required by law. Executive further agrees that in the event Executive receives a subpoena, order, or other legal process seeking disclosure of the information referred to in this Agreement, within five (5) business days of such receipt then Executive shall immediately notify OraSure's General Counsel of such subpoena, request or order and cooperate with OraSure in any efforts to oppose such disclosure.

8. Non-Disparagement. Executive agrees not to disparage or encourage others to disparage OraSure, as well as any of the other Releasees, their products, missions or businesses or any of the Releasees' officers, directors, attorneys, and employees, and Executive agrees not to initiate any contact with or respond to any inquiry by the press or other media regarding the Releasees. For the purpose of this Agreement, "disparage" includes, without limitation, comments or statements to any person or entity, including but not limited to the press and/or media, employees, contractors, or advisors of OraSure or any entity with which OraSure has a business relationship, which would adversely affect in any manner (a) the conduct of the business of OraSure or any of the Releasees (including but not limited to any business plans or prospects) or (b) the reputation of OraSure, OraSure's officers, directors or any of the Releasees. For the avoidance of doubt, nothing in this Agreement precludes Executive from supplying truthful information to any governmental authority or in response to any lawful subpoena or other legal process.

9. Entire Agreement. This Agreement, together with the terms of the Employment Agreement and the Confidentiality Agreement, contain the entire agreement of the parties with respect to the subject matter hereof, supersede any prior agreements or understandings with respect to the subject matter hereof, and shall be binding upon their respective heirs, executors, administrators, successors and

assigns. The Executive agrees that the obligations contained in this Agreement and the other agreements referenced herein are in addition to, and not in lieu of, any obligations Executive may have.

10. Severability. If any term or provision of this Agreement shall be held to be invalid or unenforceable for any reason, the validity or enforceability of the remaining terms or provisions shall not be affected, and such term or provision shall be deemed modified to the extent necessary to make it enforceable.

11. Advice of Counsel; Revocation Period. Executive is hereby advised to seek the advice of counsel. Executive acknowledges that she is acting of her own free will, that she has been afforded a reasonable time to read and review the terms of this Agreement, and that Executive is voluntarily entering into this Agreement with full knowledge and understanding of its provisions and effects. Executive understands and agrees that she is waiving rights or claims, including, but not limited to, possible claims under the ADEA, in exchange for consideration in addition to anything of value to which Executive is already entitled. Executive agrees that this Agreement shall not be deemed void or avoidable by claims of duress, deception, mistake of fact, or otherwise. Nor shall the principle of construction whereby all ambiguities are to be construed against the drafter be employed in the interpretation of this Agreement. There is absolutely no agreement or reservation that is not clearly expressed in this Agreement. This Agreement should not be construed for or against any party. Executive further acknowledges that she has been given at least twenty-one (21) days within which to consider this Agreement and that if Executive decides to execute this Agreement before the twenty-one (21) day period has expired, Executive does so voluntarily and waives the opportunity to use the full review period. Executive acknowledges and agrees that changes made to this Agreement, whether or not material, do not restart the aforementioned twenty-one (21) day period. Executive also acknowledges that she has seven (7) days following her execution of this Agreement to revoke acceptance of this Agreement, with the Agreement not becoming effective until the revocation period has expired without Executive having revoked. Executive acknowledges that to be effective any revocation must be in writing, signed by the Executive, and received by OraSure prior to the expiration of the revocation date. If Executive chooses to revoke her acceptance of this Agreement, she should provide written notice to:

Chief Executive Officer
OraSure Technologies, Inc.
220 East First Street
Bethlehem, Pennsylvania 18015

12. Amendments. Neither this Agreement nor any term hereof may be orally changed, waived, discharged, or terminated, and may be amended only by a written agreement between the parties hereto.

13. Governing Law. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to the conflict of law principles of any jurisdiction.

14. Legally Binding. The terms of this Agreement contained herein are contractual, and not a mere recital.

IN WITNESS WHEREOF, the parties, acknowledging that they are acting of their own free will, have caused the execution of this Agreement as of this day and year written below.

OraSure Technologies, Inc.

By: _____

Name: _____

Title: _____

Dated: _____

_____

Agnieszka M. Gallagher

Dated: _____

OraSure Technologies, Inc.

EXHIBIT 10.13

August 25, 2021

Ms. Michele M. Miller
Vice President, Finance and Controller

Re: Severance Benefit

Dear Michele:

As a valued employee of OraSure Technologies, Inc. (the "Company"), the Company would like to provide you with certain compensation in the event that your employment is terminated by the Company without Cause (as defined below) or by you for Good Reason (as defined below), in either case, during the one year period following the date of a Change of Control (as defined below) (a "Covered Termination"). Specifically, in the event of a Covered Termination, and subject to your execution and non-revocation of a release of claims and covenant not to sue in form and substance reasonably satisfactory to the Company (the "Release") such that the Release is effective and irrevocable within 60 days after the date of a Covered Termination, the Company will provide you an amount equal to one (1) year of your base salary at the rate in effect immediately prior to your termination of employment, or if you terminate your employment for Good Reason as the result of a reduction in your base salary, at the rate in effect immediately prior to such reduction (the "Severance Payment").

The Severance Payment will be paid in substantially equal installments during the one (1) year period commencing on your termination date in accordance with the Company's normal payroll practices as in effect at the time, provided that the first payment shall be made on the first payroll date after the effective date of the Release and shall include a catch-up for any payments that would have been made had the Release been effective on your termination date. Notwithstanding the foregoing, to the extent required by Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), if the 60 day Release period overlaps two calendar years, then any portion of the Severance Payment that otherwise would have been made in the first calendar year instead shall be withheld and paid on the first payroll date in the second calendar year with all remaining payments to be made as if no such delay had occurred.

For purposes of this Agreement, the terms "Cause," "Change of Control" and "Good Reason" have the following meanings:

1. "Cause" shall mean your (i) willful and continued failure to substantially perform your duties to the Company consistent with your job title; (ii) engaging in gross misconduct or gross negligence materially injurious to the Company; (iii) commission of any act in direct competition with or materially detrimental to the best interests of the Company; (iv)

conviction of, or plea of guilty or no contest to, a felony; or (v) engaging in willful and serious misconduct that would reasonably be expected to harm the reputation of the Company or any of its affiliates or which would reasonably be expected to lead to unwanted or unfavorable publicity to the Company or its affiliates; provided, however, that the Company provides you with written notice of the event alleged to constitute Cause within 60 days after the Company first becomes aware of the occurrence thereof and you fail to cure such event (if capable of cure) within 30 days after your receipt of such written notice. Such written notice to you must describe the alleged events constituting Cause in reasonable detail.

2. "Change of Control" means a change of control of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A pursuant to the U.S. Securities Exchange Act of 1934 (the "Exchange Act"); provided, however, that a change of control shall only be deemed to have occurred at such time as (i) any person, or more than one person acting as a group within the meaning of Section 409A of the Code and the regulations issued thereunder, acquires ownership of stock of the Company that, together with stock held by such person or group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the stock of the Company; (ii) any person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition) ownership of stock of the Company possessing thirty percent (30%) or more of the total voting power of the Company's stock; (iii) a majority of the members of the Board of Directors of the Company is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors before the date of the appointment or election; or (iv) a person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition) assets from the Company that have a total gross fair market value equal to or more than 40 percent of the total gross fair market value of all the assets of the Company immediately before such acquisition or acquisitions.

3. "Good Reason" means any of the following actions that are taken without your prior written consent: (i) a material diminution in your base compensation or authority, duties or responsibilities; (ii) a material change in your reporting obligation from the Chief Financial Officer of the Company to another employee of the Company; or (iii) a relocation of your principal worksite that increases your one-way commute by more than 30 miles. Notwithstanding the foregoing, Good Reason shall not be deemed to exist unless (x) you give the Company written notice within thirty (30) days after you first have knowledge of the occurrence of the event which you believe constitutes the basis for Good Reason, specifying the particular act or failure to act which you believe constitutes the basis for Good Reason, (y) the Company fails to cure such act or failure to act within thirty (30) days after receipt of such notice and (z) you terminate your employment within thirty (30) days after the end of the period specified in clause (y).

This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, applied without reference to principles of conflicts of law.

Any legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and you and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that you or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

This Agreement may not be amended or modified otherwise than by a written agreement executed by you (or your legal representative) and the Company (or its successor).

The terms and provisions of this Agreement are intended to be separate and divisible provisions and if, for any reason, any one or more of them is held to be invalid or unenforceable, neither the validity nor the enforceability of any other provision of this Agreement shall thereby be affected.

This Agreement may be executed in counterparts and delivered by facsimile transmission or electronic transmission in "portable document format," each of which shall be an original and which taken together shall constitute one and the same document.

The Company may assign its rights and/or delegate its obligations under this Agreement to any successor of the Company, whether by operation of law, agreement or otherwise (including, without limitation, any person or entity who acquires all or a substantial portion of the business of the Company and its subsidiaries (whether direct or indirect and whether structured as a stock sale, asset sale, merger, recapitalization, consolidation or other transaction)) and, in connection with any such delegation of its obligations hereunder (but only so long as such assignee or delegee has consented in writing to be bound by the obligations hereunder) shall be released from such obligations hereunder. This Agreement may not be assigned by you. Except as otherwise provided herein, this Agreement shall bind and inure to the benefit of and be enforceable by you, the Company, your legal representatives and the Company's successors and permitted assigns.

If you agree to the terms of this Agreement, please sign below and return your signed copy of this Agreement to me.

OraSure Technologies, Inc.	Acknowledged and Agreed:
By: */s/ Stephen S. Tang, Ph.D.*	*/s/ Michele M. Miller*
Stephen S. Tang	Michele M. Miller
President and Chief Executive Officer	

EXHIBIT 10.20

RESTRICTED UNIT AWARD AGREEMENT

(Performance-Vested)

(OSUR Executives –Employment Agreements)

This Restricted Unit Award Agreement ("Agreement") is entered into as of February 1, 2021 between **OraSure Technologies, Inc.**, a Delaware corporation ("OraSure" or the "Company"), and **NAME** ("Participant").

The OraSure Technologies, Inc. Stock Award Plan (the "Plan") is administered by the Compensation Committee (the "Committee") of the Board of Directors (the "Board") of OraSure. This Agreement evidences the Committee's grant of an Award of Restricted Units to Participant under the Plan. Capitalized terms not otherwise defined in this Agreement have the meanings given in the Plan.

OraSure and Participant agree as follows:

1. **Grant of Restricted Units**. Subject to the terms and conditions of this Agreement and the Plan, OraSure hereby issues to Participant a total of # OF UNITS Restricted Units, all of which shall, subject to adjustment by the Applicable Percentage (as defined below), Vest based on Participant's continued employment by OraSure or its Subsidiaries until the Vesting Date (as defined below) and the achievement of the Modified Revenue Amount (as defined below). As further described in Section 2.2 below, Participant will be issued an applicable percentage (the "Applicable Percentage") of the total number of Restricted Units, based on the actual level of achievement of the Modified Revenue Amount.

2. **Terms of Restricted Units**. The Restricted Units shall be subject to all the provisions of the Plan and to the following terms and conditions:

2.1 **Transfer Restrictions**. Except as expressly provided in Sections 2.2 through 2.4, none of the Restricted Units, or any rights under this Agreement, may be sold, assigned, transferred, pledged, encumbered or otherwise disposed of, voluntarily or involuntarily, by Participant. The foregoing restrictions are in addition to any other restrictions on transfer of the Restricted Units arising under federal or state securities laws or other agreements with OraSure. Any purported sale, assignment, transfer, pledge, encumbrance, or other disposition of Restricted Units in violation of this Agreement shall be null and void and may and will be enjoined.

2.2 **Vesting of Restricted Units**. Subject to Participant's continued employment by OraSure or its Subsidiaries and except as otherwise provided in Sections 2.3 and 2.4, the Applicable Percentage of the Restricted Units shall become Vested on the Vesting Date based on the actual level of achievement of the Modified Revenue Amount, in accordance with the table below and shall be settled in accordance with Section 2.5:

Modified Revenue Amount	Percentage of Restricted Units to become Vested
Threshold: $ 695 million	50%
Target: $ 921.2 million	100%
Maximum: $1,297.5 million or more	150%

The actual number of Restricted Units that become Vested if the Modified Revenue Amount achieved falls between the levels set forth in the preceding table shall be determined using linear interpolation. No portion of the applicable Restricted Units shall become Vested if the Modified Revenue Amount is less than the Threshold amount shown above, and in such event the affected Restricted Units shall be forfeited to OraSure with no payment or issuance of shares to Participant. To the extent the Modified Revenue Amount exceeds the Maximum amount shown above, the Applicable Percentage shall remain at 150%.

2.3 Change of Control. Subject to Participant's continuing employment by OraSure or its Subsidiaries, 100% of the Restricted Units shall become Vested immediately prior to the consummation of a Change of Control (as defined below) and be settled in accordance with Section 2.5, with the Modified Revenue Amount being deemed to have been achieved at the 100% level.

2.4 Termination of Employment.

(a) *Death or Disability* - If Participant's employment by OraSure and its Subsidiaries is terminated by the Company due to Participant's death or Disability (as defined below), 100% of the Restricted Units shall become Vested upon the date of such termination of employment and be settled in accordance with Section 2.5, with the Modified Revenue Amount being deemed to have been achieved at the 100% level.

(b) *Without Cause or For Good Reason* - If Participant's employment with OraSure and its Subsidiaries is terminated by the Company without Cause (as defined below) or by Participant for Good Reason (as defined below), then (i) 100% of the unvested Restricted Units shall become Vested upon the date of such termination of employment and be settled in accordance with Section 2.5, if such termination occurs during a Change of Control Period (as defined below), with the Modified Revenue Amount being deemed to have been achieved at the 100% level, and (ii) 50% of the Restricted Units shall become Vested upon the date of such termination of employment and be settled in accordance with Section 2.5 if such termination does not occur during a Change of Control Period, with the Modified Revenue Amount being deemed to have been achieved at the 100% level.

(c) *Retirement* – If Participant's employment with OraSure and its Subsidiaries is terminated due to Participants' Retirement (as defined below), the Restricted Units shall Vest on the Vesting Date and be settled in accordance with Section 2.5, on a pro-rata basis through the date of Retirement based on the actual level of achievement of the Modified Revenue Amount during the Performance Period.

(d) *Other* - If Participant's employment by OraSure and its Subsidiaries is terminated for any reason other than as specified in Sections 2.4(a), (b) or (c), all of the Restricted Units that are not then Vested shall be forfeited to OraSure on the date of such termination with no payment or issuance of shares to Participant.

2.5 Settlement of Restricted Units. On or as soon as reasonably practicable following the date on which the Restricted Units have become Vested (but no later than 30 days thereafter), OraSure shall issue to Participant one share of OraSure common stock in

settlement of each such Vested Restricted Unit. The terms of this Agreement, including, but not limited to, the number of such Restricted Units which shall become Vested in accordance with this Agreement and the shares of common stock underlying the Restricted Units, shall be subject to adjustment pursuant to Section 13.2 of the Plan.

3. **No Rights as Stockholder; Dividend Equivalents**. Participant shall not be entitled to any of the rights of a stockholder with respect to the shares of OraSure common stock underlying the Restricted Units issued hereunder unless and until such shares of OraSure common stock are issued to Participant in settlement of the Restricted Units. Notwithstanding the foregoing, Participant shall be entitled to dividend equivalents in an amount equal to any stock dividends paid and additional shares issued as a result of stock splits occurring during the vesting period with respect to the shares of OraSure common stock underlying any Restricted Units issued hereunder that subsequently become Vested Restricted Units, which dividend equivalent or stock split amount shall be paid or issued to participant in cash or additional shares of common stock, at the discretion of the Committee, at the time such shares of common stock are issued to Participant in settlement of such Vested Restricted Units.

4. **Withholding Taxes**. Participant shall pay to OraSure, or permit OraSure to withhold from other amounts payable to Participant, as compensation or otherwise, an amount sufficient to satisfy all federal, state, and local withholding tax requirements or tax liability with respect to the Vesting of the Restricted Units and the issuance of shares of OraSure common stock in settlement of such Vested Restricted Units. Alternatively, Participant may, by written notice to the Committee that complies with any applicable timing restrictions imposed pursuant to Rule 16b-3 under the Exchange Act, elect to satisfy all or a part of the withholding tax obligations incident to the Vesting of the Restricted Shares and the issuance of shares of OraSure common stock in settlement of such Vested Restricted Units by having OraSure withhold a portion of the shares of OraSure common stock that would otherwise be issuable to Participant. Such shares will be valued based on their Fair Market Value on the date the tax withholding is required to be made. Any stock withholding with respect to Participant will be subject to such limitations as the Committee may impose to comply with the requirements of the Exchange Act.

5. **Other Documents**. Participant agrees to furnish OraSure any documents or representations OraSure may require related to the Restricted Units or this Agreement to assure compliance with applicable laws and regulations.

6. **Certain Defined Terms**. When used in this Agreement, the following terms have the meanings specified below:

6.1 "**Beginning Price**" means, with respect to the Company and any other company within the Comparison Group, the average of the closing market prices of such company's common stock on the NASDAQ Stock Market for the twenty (20) consecutive trading days beginning with the first trading day of the Performance Period. For the purpose of determining Beginning Price, the value of dividends and other distributions shall be determined by treating them as reinvested in additional shares of stock at the closing market price on the applicable ex-dividend date.

6.2 "**Cause**" shall have the meaning set forth in the Employment Agreement.

6.3 "**Change of Control**" shall have the meaning set forth in the Employment Agreement.

6.4 "**Change of Control Period**" shall have the meaning set forth in the Employment Agreement.

6.5 "**Comparison Group**" means the Company and each other company included in the NASDAQ Health Care Index on the first day of the Performance Period and, except as provided below, the common stock (or similar equity security) of which is continually listed or traded on the NASDAQ Stock Market from the first day of the Performance Period through the last trading day of the Performance Period. In the event a member of the Comparison Group files for bankruptcy or liquidates due to an insolvency, such company shall continue to be treated as a Comparison Group member, and such company's Ending Price will be treated as $0 if the common stock (or similar equity security) of such company is no longer listed or traded on the NASDAQ Stock Market on the last trading day of the Performance Period (and if multiple members of the Comparison Group file for bankruptcy or liquidate due to an insolvency, such members shall be ranked in order of when such bankruptcy or liquidation occurs, with earlier bankruptcies/liquidations ranking lower than later bankruptcies/liquidations). In the event of a formation of a new parent company by a Comparison Group member, substantially all of the assets and liabilities of which consist immediately after the transaction of the equity interests in the original Comparison Group member or the assets and liabilities of such Comparison Group member immediately prior to the transaction, such new parent company shall be substituted for the Comparison Group member to the extent (and for such period of time) as its common stock (or similar equity securities)are listed or traded on the NASDAQ Stock Market but the common stock (or similar equity securities) of the original Comparison Group member are not. In the event of a merger or other business combination of two Comparison Group members (including, without limitation, the acquisition of one Comparison Group member, or all or substantially all of its assets, by another Comparison Group member), the surviving, resulting or successor entity, as the case may be, shall continue to be treated as a member of the Comparison Group, provided that the common stock (or similar equity security) of such entity is listed or traded on the NASDAQ Stock Market through the last trading day of the Performance Period. With respect to the preceding two sentences, the applicable stock prices shall be equitably and proportionately adjusted to the extent (if any) necessary to preserve the intended incentives of the awards and mitigate the impact of the transaction.

6.6 "**Disability**" shall have the meaning set forth in the Employment Agreement.

6.7 "**Employment Agreement**" means the Employment Agreement dated as of DATE OF EMPLOYMENT AGREEMENT, as amended, between the Company and Participant.

6.8 "**Ending Price**" means, with respect to the Company and any other company within the Comparison Group, the average of the closing market prices of such company's common stock on the NASDAQ Stock Marekt for the twenty (20) consecutive trading days ending on the last trading day of the Performance Period. For the purpose of determining Ending Price, the value of dividends and other distributions shall be determined by treating them as reinvested in additional shares of stock at the closing market price on the applicable ex-dividend date.

6.9 **"Good Reason"** shall have the meaning set forth in the Employment Agreement.

6.10 "**Modified Revenue Amount**" shall mean the Revenue Amount multiplied by the TSR Modifier.

6.11 "**Performance Period**" shall mean the three (3) year period beginning on January 1, 2021 and ending December 31, 2023.

6.12 "**Relative TSR**" shall mean the Company's TSR relative to the TSR of each of the other companies in the Comparison Group. Relative TSR will be determined by ranking the Company and each of the companies in the Comparison Group from highest to lowest according to their respective TSRs. After this ranking, the percentile performance of the Company relative to the Comparison Group will be determined as follows:

$$P=1-\frac{R-1}{N-1}$$

Where:

"P" represents the percentile performance which will be rounded, if necessary, to the nearest whole percentile by application of regular rounding.

"N" represents the number of companies in the Comparison Group including the Company.

"R" represents the Company's ranking among the Comparison Group.

Example: If there are 101 companies in the Comparison Group (including the Company), and the Company ranked 26th, the performance would be at the 75th percentile: 1- ((26-1)/(101-1)).

Relative TSR shall be determined by the Committee in its sole and absolute discretion.

6.13 "Retirement" shall mean the date when Participant terminates employment and retires from the Company and its Subsidiaries after having achieved at least ten (10) years of cumulative service with the Company and/or its Subsidiaries and reached the age of 57 years or older.

6.14 " **Revenue Amount**" shall mean OraSure's aggregate consolidated revenues, as reported in OraSure's audited financial statements for the Performance Period and shall include any revenue resulting from any mergers or acquisitions during the Performance Period.

6.15 "**TSR**" shall be expressed as a percentage and determined, with respect to the Company and any other company within the Comparison Group, by dividing: (a) the sum of (i) the difference obtained by subtracting the applicable Beginning Price from the applicable Ending Price plus (ii) all dividends and other distributions during the Performance Period by (b) the applicable Beginning Price and subtracting one from the quotient. Any noncash distributions shall be valued at fair market value. For the purpose of determining TSR, the value of dividends and other distributions shall be determined by treating them as reinvested in additional shares of stock at the closing market price on the applicable ex-dividend date. The TSR for the Company and each other member of the Comparison Group shall be determined by the Committee in its sole and absolute discretion.

6.16 "**TSR Modifier**" shall be determined based on the Company's Relative TSR for the Performance Period, as follows:

Company Relative TSR	TSR Modifier
75th percentile or more	1.15
55th percentile	1.00
25th percentile or less	0.85

To the extent the Company's Relative TSR falls in between the 75th and 55th percentiles, or between the 55th and 25th percentiles, the TSR Modifier shall be determined using linear interpolation. The TSR Modifier shall be determined by the Committee in its sole and absolute discretion.

6.17 "**Vesting Date**" shall mean February 1, 2024 (the third anniversary of the date of this Agreement).

7. **No Employment Contract**. Neither the Plan nor this Agreement constitutes a contract of employment of Participant by OraSure or its Subsidiaries.

8. **Conflicts**. To the extent the terms of this Agreement are inconsistent or in conflict with the terms of the Employment Agreement, the terms of this Agreement shall control.

9. **Notices**. Any notices under this Agreement shall be in writing and shall be effective when actually delivered personally or, if mailed, when deposited as certified mail, directed to OraSure at its principal offices, to Participant at the address maintained in OraSure's records, or to such other address as either party may specify by notice to the other party.

10. **Choice of Law**. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to any contrary conflicts of laws rules.

11. **Successorship**. Subject to the restrictions on transferability of the Restricted Shares set forth in this Agreement and the Plan, this Agreement shall be binding upon and benefit the parties, their successors and assigns.

ORASURE TECHNOLOGIES, INC.

_____
NAME

By: _____

Name: Stephen S. Tang

Title: President and Chief Executive Officer

Exhibit 10.30

INDUSTRIAL LEASE

BETWEEN

CORE5 AT LAUGHMAN FARMS PHASE 1, LLC

AS LANDLORD

AND

ORASURE TECHNOLOGIES, INC.

AS TENANT

LEASE INDEX

INDUSTRIAL LEASE

THIS INDUSTRIAL LEASE (the "**Lease**") is made as of the Lease Date (defined below) by and between CORE5 AT LAUGHMAN FARMS PHASE 1, LLC, a Delaware limited liability company ("**Landlord**"), and ORASURE TECHNOLOGIES, INC., a Delaware corporation ("**Tenant**") (the words "Landlord" and "Tenant" to include their respective legal representatives, successors and permitted assigns where the context requires or permits).

W I T N E S S E T H:

1. Basic Terms. This Section 1 contains the basic terms of this Lease. Capitalized terms used in this Lease will have the meanings given them in this Section 1 and elsewhere in this Lease, including **Schedule A** hereto.

(a) Premises/Demised Premises: That portion of the Building depicted on **Exhibit A** attached hereto, containing approximately 96,010 square feet and commonly known as 222 Morgan Lane, Building C, York, Pennsylvania.

(b) Building: The building depicted on **Exhibit A** hereto and containing approximately 182,410 square feet.

(c) Project: Laughman Farm, York, Pennsylvania, York County

(d) Base Rent:

Months		Price Per SF Net	Monthly Rental	Annual Rental
1	4	Free		
5	16	$6.50	$52,005.42	$624,065.04
17	28	$6.70	$53,565.58	$642,786.99
29	40	$6.90	$55,172.55	$662,070.60
41	52	$7.10	$56,827.73	$681,932.72
53	64	$7.32	$58,532.56	$702,390.70
65	76	$7.54	$60,288.54	$723,462.42
77	88	$7.76	$62,097.19	$745,166.29
89	100	$7.99	$63,960.11	$767,521.28
101	112	$8.23	$65,878.91	$790,546.92
113	124	$8.48	$67,855.28	$814,263.33

*Provided no Event of Default shall have occurred and be continuing beyond any applicable cure and/or notice period, Tenant shall be conditionally excused of its obligation for the payment of Base Rent for the initial four (4) months of the Primary Term ("**Base Rent Credits**"). However, Tenant shall pay all other charges due pursuant to the terms hereof commencing on the Base Rent Commence Date.

**(Plus the prorated amount for any Fractional Month, if applicable.)

(e) Lease Commencement Date: The date of Base Building Substantial Completion of Landlord's Base Building Work (estimated to be March 1, 2022) or any earlier date upon which Tenant commences business operations from the Premises. Any delay in delivery of the Premises which is not caused by Tenant Delay shall extend the Lease Commencement Date day for day. For purposes of this Lease, the term "Base Building Substantial Completion" (or any variation thereof) shall mean completion of construction of Landlord's Base Building Work in accordance with

the Base Building Plans and Specifications set forth on Exhibit B, attached hereto, subject only to Punchlist items established pursuant to subsection (b), above, as established by a Certificate of Substantial Completion on Standard AIA Form G-704 certified by Landlord's architect. In the event Base Building Substantial Completion is delayed because of Tenant Delay, then for the purpose of establishing the Lease Commencement Date and any other date tied to the date of Base Building Substantial Completion, Base Building Substantial Completion shall be deemed to mean the date when Substantial Completion would have been achieved but for such Tenant Delay.

(f) Base Rent Commencement Date: The date that is four (4) months after the Lease Commencement Date.

(g) Expiration Date: The last day of the one hundred twenty-fourth (124th) full calendar month occurring after the Lease Commencement Date, as expressly may be extended hereby.

(h) Primary Term: As defined in Section 3.

(i) Tenant's Percentage Share: 52.63%

(j) Security Deposit: $52,005.42

(k) Permitted Use: Manufacturing, distribution, warehouse, fulfillment, and ancillary office use.

(l) Address for notice:

Landlord: Core5 at Laughman Farms Phase 1, LLC
c/o Core5 Industrial Partners LLC
1230 Peachtree Street, NE, Suite 3560
Atlanta, Georgia 30309
Attn: CFO

Tenant: OraSure Technologies, Inc.
c/o SVP of Operations
220 E. First Street
Bethlehem, PA 18015

(m) Address for rental payments:

Core5 at Laughman Farms Phase 1, LLC
c/o Core5 Industrial Partners LLC
1230 Peachtree Street, NE, Suite 3560
Atlanta, Georgia 30309
Attn: CFO

(n) Broker(s): CBRE, Inc.

(o) Guarantor: N/A

2. Premises. For and in consideration of the rent reserved herein and the mutual covenants contained herein, Landlord hereby leases to Tenant and Tenant hereby leases and accepts the Premises from Landlord, for the Term and upon all the terms and provisions of this Lease. Landlord and Tenant agree that the square footage of each of the Premises and the Building has been conclusively determined using BOMA Industrial -2012 Method B (Dripline Method) and is not subject to remeasurement or any form of contest by

either party. Tenant will have a non-exclusive right to use the Building Common Area along with other tenants of the Building.

3. Term. To have and to hold the Premises for a primary term (the "**Primary Term**") commencing on the Lease Commencement Date and ending on the Expiration Date, as such dates may be revised pursuant to this Lease (the Primary Term, together with all renewals and extensions thereof, if any, is sometimes referred to in this Lease as the "**Term**"). The term "**Lease Year**" means the 12-month period commencing on the Base Rent Commencement Date, and each 12-month period thereafter during the Term; *provided, however,* that if the Base Rent Commencement Date is a day other than the first day of a calendar month, the first Lease Year shall include the period from and including the Base Rent Commencement Date to and including the last day of the calendar month in which the Base Rent Commencement Date occurs (the "**Fractional Month**") and shall extend through the end of the twelfth (12th) full calendar month following the Base Rent Commencement Date.

4. Base Rent. Tenant shall pay the Annual Base Rent in the Monthly Base Rent Installments to Landlord at the address set forth in Section 1(m), as the Base Rent for the Premises, commencing on the Base Rent Commencement Date and continuing through the Primary Term, in lawful money of the United States, payable in advance, without demand, on the first day of each calendar month during the Term; provided, however, that the first month's Base Rent shall be paid to Landlord upon Tenant's execution of this Lease. If the Base Rent Commencement Date falls on a day other than the first day of a calendar month, the Base Rent shall be apportioned pro rata on a per diem basis for the resulting Fractional Month (which pro rata payment shall be due and payable on the Base Rent Commencement Date). Landlord shall receive the Rent from Tenant without any abatement (except as set forth in Section 18 and Section 19), reduction, set-off, counterclaim, defense or deduction whatsoever. No endorsement or statement on any check or any letter accompanying any check or payment of Rent shall be deemed an accord and satisfaction. Landlord may accept any such check as payment without prejudice to Landlord's right to recover the balance of such installment or payment of Rent or pursue any other remedies available to Landlord.

5. Security Deposit. Upon Tenant's execution of this Lease, Tenant will pay the Security Deposit to Landlord as security for the full and faithful performance by Tenant of each and every term, covenant and condition of this Lease. If the Security Deposit is a Letter of Credit: (a) it shall be an irrevocable letter of credit and in a form and from a financial institution acceptable to Landlord, and (b) Tenant shall, upon demand, pay directly or reimburse Landlord for all expenses incurred by Landlord in connection with the Letter of Credit, including, but not limited to, any transfer fee due upon the transfer of the Letter of Credit upon a sale of the Building by Landlord. The acceptance by Landlord of the Security Deposit shall not render this Lease effective unless and until Landlord shall have executed and delivered to Tenant a fully executed copy of this Lease. Any cash Security Deposit will be commingled with Landlord's other funds and will not bear interest. If an Event of Default occurs, Landlord may retain the Security Deposit for the payment of any sum due Landlord or which Landlord may expend by reason of the Event of Default; provided, however, that any such retention by Landlord shall not be deemed to be an election of remedies by Landlord or viewed as liquidated damages, it being agreed that Landlord shall have the right to pursue any and all other remedies available to it under the terms of this Lease or otherwise. In the event all or any portion of the Security Deposit is so retained by Landlord, Tenant shall, within five (5) days after written demand therefor from Landlord, replenish the Security Deposit in full. In the event that Tenant complies with all of the terms, covenants and conditions of this Lease, the Security Deposit shall be returned to Tenant within thirty (30) days after the later of (a) the Expiration Date or (b) the date that Tenant delivers possession of the Premises to Landlord. In the event of a sale of the Building, Landlord shall transfer the Security Deposit to the purchaser and, upon any such transfer, Landlord shall be released from all liability for the return of the Security Deposit. Tenant shall not assign or encumber the Security Deposit, and neither Landlord nor its successors or assigns shall be bound by any such assignment or encumbrance.

6. Operating Expenses and Additional Rent.

(a) Tenant agrees to pay as Additional Rent Tenant's Percentage Share of Operating Expenses in the manner described in this Section 6. "**Operating Expenses**" are defined as all reasonable expenses for operation, repair, maintenance and replacement as necessary to keep the Building and the

Building Common Area fully operational and in good order, condition and repair, including but not limited to: (i) the cost of all utilities for the Building Common Area, (ii) expenses associated with the driveways and parking areas (including sealing and restriping, and trash, and, if applicable, snow and ice removal) and truck ramps, (iii) expenses associated with the maintenance and repair of the roof and roof drainage system of the Building (but not the expense of replacing the roof or roof drainage system that would be treated as a capital improvement), (iv) expenses associated with the periodic maintenance of the exterior walls of the Building, including, without limitation, caulking and painting, (v) expenses associated with sprinkler systems, security systems, fire detection and prevention systems and lighting facilities, (vi) expenses associated with landscaped areas, walkways, directional signage, curbs, drainage lines and facilities and sewer lines, (vii) all charges assessed against or attributed to the Building pursuant to any applicable easements, covenants, restrictions, agreements, declaration of protective covenants or development standards (including, without limitation, assessments charged by owners' associations) (the "**Covenants**"), (ix) property management fees (not to exceed three percent (3%) of gross rental for the applicable year), (x) all real property taxes, payment-in-lieu of taxes, special assessments and similar charges imposed upon the Building, the Building Common Area and the land on which the Building and the Building Common Area are constructed, and (xi) all costs of insurance paid by Landlord with respect to the Building and the Building Common Area (including, without limitation, commercially reasonable deductibles). Operating Expenses shall not include expenses for the costs of any maintenance and repair required to be performed by Landlord at its own expense under Section 8(b). Notwithstanding the foregoing, as to property management fees, Tenant shall pay Landlord the property management fees directly attributable to the Rent payable with respect to the Premises, and not Tenant's Percentage Share of the management fees payable on the entire Building. Notwithstanding the foregoing, Landlord shall, in Landlord's reasonable discretion, have the right to adjust Tenant's proportionate share of individual components of Operating Expenses if Tenant's Percentage Share thereof would not equitably allocate to Tenant its share of such component of Operating Expenses in light of Tenant's particular use of, manner of use of and/or level of tenant improvements in the Premises. Prior to or promptly after the beginning of each calendar year during the Term, Landlord shall estimate the total amount of Operating Expenses to be paid by Tenant during each such calendar year and Tenant shall pay to Landlord one-twelfth (1/12) of such sum on the first day of each calendar month during each such calendar year, or part thereof, during the Term. From time to time during any calendar year, Landlord may revise Landlord's estimate and adjust Tenant's monthly payments to reflect such revised estimate. Within a reasonable time after the end of each calendar year, Landlord shall submit to Tenant a statement of the actual amount of Operating Expenses for such calendar year, and the actual amount owed by Tenant, and within thirty (30) days after receipt of such statement, Tenant shall pay any deficiency between the actual amount owed and the estimates paid during such calendar year. In the event of overpayment, Landlord shall credit the amount of such overpayment toward the next installment of Operating Expenses owed by Tenant or, if the Term has expired or has been terminated and no Event of Default has occurred hereunder, remit such overpayment to Tenant. The obligations in the immediately preceding two sentences shall survive the expiration or any earlier termination of this Lease. Tenant's proportionate share of the Operating Expenses for any partial calendar year at the beginning or end of the Term shall be apportioned prorata.

(b) Tenant's obligations to pay Additional Rent shall begin to accrue on the Lease Commencement Date regardless of the Base Rent Commencement Date. If applicable in the jurisdiction where the Premises are located, Tenant shall pay and be liable for all rental, margin, sales, use and inventory taxes or other similar taxes, if any, on the amounts payable by Tenant hereunder levied or imposed by any city, state, county or other governmental body having authority. Such payment shall be made by Tenant directly to such governmental body if billed to Tenant, or if billed to Landlord, such payment shall be paid concurrently with the payment of the Base Rent, Additional Rent, or such other charge upon which the tax is based, all as set forth herein. Further, Tenant shall be liable for all taxes and assessments of any kind or nature levied against personal property and trade fixtures placed by Tenant in the Premises. If any such taxes are levied against Landlord or Landlord's property and if Landlord elects to pay the same or if the assessed value of Landlord's property is increased by inclusion of personal property and trade fixtures placed by Tenant in the Premises and Landlord elects to pay the taxes based on such increase, Tenant shall pay to Landlord upon demand that part of such taxes for which Tenant is liable hereunder as Additional Rent.

(c) Beginning after the second (2nd) full calendar year during the Primary Term, in the event that the amount of Operating Expenses for the Building attributable to all items other than taxes,

utilities, insurance (including any commercially reasonable deductibles), snow removal, capital expenditures, including Code Modifications (as allowed under this Lease), management fees and charges assessed against or attributed to the Building pursuant to any applicable declaration of protective covenants (Operating Expenses attributable to all such other items being referred to collectively herein as "Controllable Expenses") in any calendar year exceeds the amount attributable to Controllable Expenses for the Building during the immediately preceding calendar year by more than five percent (5%) (the "Cap"), then the amount attributable to Controllable Expenses for the Building, for purposes of determining the amount of Tenant's Percentage Share of Operating Expenses only (as Tenant's Percentage Share may have been adjusted to account for any changes in the size of the Premises due to expansions or contractions), shall be limited to the amount attributable to Controllable Expenses for the Building for the immediately preceding calendar year multiplied by the sum of one hundred percent (100%) and the Cap. If the Building was not fully leased during such immediately preceding calendar year, then Operating Expenses for the Building shall be "grossed-up" (as if the Building had been fully leased for the entirety of such immediately preceding calendar year) on such basis as Landlord may reasonably determine for purposes of determining the application of this Section 6(c).

(d) Within three (3) months after Tenant's receipt of the statement for the actual amount of Operating Expenses for any Lease Year, Tenant (or an independent certified accountant selected by Tenant) may, at Tenant's sole cost and expense, inspect Landlord's records. Such inspection, if any, shall be conducted no more than once each Lease Year, during Landlord's normal business hours and at Landlord's offices, upon first furnishing Landlord at least ten (10) business days prior written notice. Any errors disclosed by the review and agreed upon in good faith by Landlord and Tenant shall be promptly corrected by Landlord. In the event the results of the review of records (taking into account, if applicable, the results of any additional review caused by Landlord) reveal that Tenant has overpaid obligations for a preceding period, the amount of such overpayment shall be credited against Tenant's subsequent installment of Base Rent, Additional Rent or other payments due to Landlord under the Lease. In the event that such results show that Tenant has underpaid its obligations for a preceding period, the amount of such underpayment shall be paid by Tenant to Landlord with the next succeeding installment obligation of estimated Tenant's Percentage Share of Operating Expenses. If the results show that Tenant's actual Percentage Share of Operating Expenses for any given Lease Year was improperly computed and that Tenant's actual Percentage Share of Operating Expenses was overstated by more than ten percent (10%), Landlord shall reimburse Tenant up to $2,500.00 for the reasonable fees and expenses of Tenant's independent professionals, if any, conducting said audit. All of the information obtained through Tenant's inspection with respect to financial matters (including, without limitation, costs, expenses, income) and any other matters pertaining to Landlord, the Premises or the Building as well as any compromise, settlement, or adjustment reached between Landlord and Tenant relative to the results of the inspection, shall be held in strict confidence by Tenant and its officers, agents, and employees; and Tenant shall cause its independent professionals and any of its officers, agents or employees to be similarly bound. The obligations within this subsection (c) shall survive the expiration or earlier termination of the Lease.

7. Utilities. All Utilities, except sewer and water, will be separately metered and billed directly to Tenant by the utility provider. Tenant shall establish an account with the utility provider for each of the separately metered Utilities and pay all charges for such Utilities prior to delinquency. Sewer and water will not be separately metered and will be billed to Tenant by Landlord, at Landlord's actual cost, as part of Operating Expenses. Tenant's obligation for payment of all Utilities shall commence on the earlier of the Lease Commencement Date or the date of Tenant's actual occupancy of all or any portion of the Premises, including any period of occupancy prior to the Lease Commencement Date, regardless of whether or not Tenant conducts business operations during such period of occupancy. In the event Tenant's use of water is in excess of the average use by other tenants, as reasonably determined by Landlord, Landlord shall have the right to install a separate water meter for Tenant, at Tenant's expense, and bill Tenant for Tenant's actual use of water.

8. Maintenance and Repairs.

(a) Tenant shall, at its own cost and expense, maintain in good condition and repair and replace as necessary the Premises, including, but not limited to, the HVAC Systems, glass, windows and

doors, all plumbing and sewage systems, fixtures, interior walls, floors (including floor slab), dock areas, dock ramps, ceilings, storefronts, plate glass, skylights, all electrical facilities and equipment (including, without limitation, lighting fixtures, lamps, fans and any exhaust equipment and systems and electrical motors), and all other appliances and equipment (including, without limitation, dock levelers, dock shelters, dock seals and dock lighting) of every kind and nature located in, upon or about the Premises, except as to such maintenance, repair and replacement as is the obligation of Landlord pursuant to Section 8(b). During the Term, Tenant shall maintain in full force and effect a service contract for the maintenance of the HVAC Systems with an entity reasonably acceptable to Landlord; provided, however, that for new HVAC Systems, during the one year period following the Lease Commencement Date, such service contract shall be maintained with the contractor that installed the HVAC Systems and shall provide for at least two preventive maintenance service calls during such one year period. Tenant shall deliver to Landlord (i) a copy of said service contract prior to the Lease Commencement Date, and (ii) thereafter, a copy of a renewal or substitute service contract within thirty (30) days prior to the expiration of the existing service contract. If Tenant fails to carry such service contract, Landlord shall have the option to enter into such service contract for and on behalf of Tenant and Tenant shall reimburse Landlord, as Additional Rent, all of Landlord's reasonable costs incurred in connection with such service contract, as well as Landlord's actual costs of repair and maintenance of the HVAC Systems together with an administrative fee payable to Landlord (or, at Landlord's election, to a Landlord's Affiliate designated by Landlord) equal to 5% of the amount of the service contract and any associated repairs. Tenant's obligation shall exclude any maintenance, repair or replacement required because of the negligence or willful misconduct of Landlord or Landlord's Affiliates, which shall be the responsibility of Landlord.

(b) (i) Landlord shall, at its own cost and expense, (1) maintain in good condition and repair the foundation (beneath the floor slab) and structural frame of the Building (i.e. steel columns, bar joists and girders, and concrete wall panels (excluding painting and caulking) and (2) replace the roof and roof drainage systems. Landlord's obligation shall exclude the cost of any maintenance or repair required because of the act or negligence of Tenant or any of Tenant's Affiliates, the cost of which shall be the responsibility of Tenant.

(ii) Landlord shall maintain the Building Common Area (including, but not limited to, the roof and roof drainage systems), subject to Tenant's obligation to pay Tenant's Percentage Share of Operating Expenses pursuant to Section 6. Except as required by this Section 8(b) or as otherwise specifically provided for in this Lease, Landlord shall be responsible for no other services whatsoever. Landlord shall never have any obligation to repair, maintain or replace any Tenant Alteration.

(c) Unless the same is caused solely by the gross negligence or willful misconduct of Landlord or Landlord's Affiliates (and is not covered by the insurance required to be carried by Tenant pursuant to the terms of this Lease), Landlord shall not be liable to Tenant or to any other person for any damage (1) occasioned by failure in any utility system or by the bursting or leaking of any vessel or pipe in or about the Premises, (2) occasioned by water coming into the Premises or (3) arising from the acts or negligence of occupants of adjacent property or the public.

9. Use of Premises. The Premises shall be used for the Permitted Use (and for no other purpose) and in compliance with applicable Governmental Requirements and Covenants. Tenant shall be responsible for satisfying itself that Tenant's use of, and operation of its business from, the Premises is permissible under applicable Governmental Requirements and Covenants. Tenant will permit no liens of any nature to attach or exist against the Premises (to the extent such liens arise by, through or under Tenant), and shall not commit any waste. Tenant will not allow, suffer, or permit any vibration, noise, odor, light or other effect to occur within or around the Premises that could constitute a nuisance or trespass with respect to Landlord, any occupant of the Building or any adjoining building or any of the customers, agents, or invitees of any such occupant.

10. Insurance.

(a) From and after the Lease Commencement Date or any earlier date upon which Tenant enters or occupies the Premises or any portion thereof, Tenant will carry and maintain, at its sole cost and expense, the following:

(i) Liability insurance (including Broad Form Contractual Liability coverage or reasonable equivalent thereto) covering the Premises and related dock areas (including the dock ramps) and Tenant's use thereof against claims for bodily injury or death, property damage and product liability occurring upon, in or about the Premises, such insurance to (1) be written on an occurrence basis (not a claims made basis), with primary Commercial General Liability limits of not less than $1,000,000 per occurrence/$1,000,000 aggregate and “following form” umbrella liability limits of not less than $10,000,000 per occurrence/$10,000,000 aggregate for each policy year, and (2) extend to liability of Tenant arising out of the indemnities by Tenant in Section 11.

(ii) Commercial Automobile Liability insurance to insure Tenant for operations of all owned, hired, and non-owned vehicles with limits for each accident of not less than $1,000,000 combined single limit with respect to bodily injury, death and property damage.

(iii) (1) Workers’ compensation statutory coverage for the state in which the Building is located; and (2) Employer’s Liability coverage as required by law with limits of not less than $1,000,000 each accident, $1,000,000 each employee, and $1,000,000 policy limit. Such coverage shall include a waiver of subrogation provision in favor of Landlord, Lender and Landlord’s property manager.

(iv) “Special Form” property insurance (including terrorism coverage and coverage for the perils of earthquake and flood, regardless of the quake or flood zone) covering (1) any and all Tenant Alterations (as hereinafter defined) in an amount not less than one hundred percent (100%) of their full replacement value from time to time during the Term, as reasonably determined by Landlord, and (2) Tenant's trade fixtures, merchandise and personal property from time to time located in, on or upon the Premises, in an amount not less than one hundred percent (100%) of their full replacement value from time to time during the Term. Tenant’s deductible shall not exceed Fifty Thousand dollars ($50,000) per occurrence. The coverage described in Section 10(a)(iv)(1) above relating to the Tenant Alterations shall also name Landlord and, if applicable, Lender as "loss payee"; such provision shall be for the sole benefit of Landlord and Lender and shall not apply to any other party without the written approval of Landlord and Lender. Any policy proceeds from insurance relating to the Tenant Alterations shall be used solely for the repair, construction and restoration or replacement of the Tenant Alterations which are damaged or destroyed, unless this Lease shall terminate under the provisions of Section 20.

(b) All policies of the insurance provided for in Section 10(a) shall be issued in form reasonably acceptable to Landlord by insurance companies with a rating of not less than "A," and financial size of not less than Class X, in the most current available "Best's Insurance Reports", and licensed to do business in the state in which the Building is located. Each and every such policy:

(i) shall name Landlord, Landlord’s property manager, Lender and any other party reasonably designated by Landlord, as an additional insured on a primary and non-contributory basis, with the exception of coverage required in Section 10(a)(iii) and Section 10(a)(iv);

(ii) shall be delivered to Landlord through a certificate of insurance on an Acord form 25, 27, or 28, as applicable, evidencing the required lines of coverage, insurance limits and coverage endorsements set forth in this Lease, and otherwise in a form acceptable to Landlord, prior to the Lease Commencement Date or any earlier entry into the Premises by Tenant or Tenant’s Affiliates and thereafter at least thirty (30) days prior to the expiration of each such policy, and, as often as any such policy shall expire or terminate. Renewal or additional policies shall be procured and maintained by Tenant in like manner and to like extent; and

(iii) shall contain a provision that the insurer will give to the first named insured at least thirty (30) days advance written notice of policy cancellation for reasons other than non-payment of premium and ten (10) days advance written notice of policy cancellation for non-payment of premium. If

Tenant intends to provide substitute coverage or voluntarily change the terms of any policy of insurance provided by Tenant pursuant to this Section 10, Tenant shall give to Landlord at least thirty (30) days advance written notice of any such substitution or change. Tenant will provide to Landlord, within three (3) days after receipt, a copy of any notice of cancellation or change of coverage sent to Tenant by any carrier providing any of the insurance policies provided by Tenant pursuant to this Section 10.

(c) Tenant shall comply with the requirements and conditions of all policies of insurance at any time in force with respect to the Premises. If Tenant shall fail to carry and maintain the insurance coverage required by this Section 10, Landlord may, upon ten (10) days advanced written notice to Tenant (unless such coverage will lapse, in which event no such notice shall be necessary), procure such policies of insurance and Tenant shall promptly reimburse Landlord therefor. In addition, if such coverage is procured by Landlord, Tenant shall pay to Landlord (or, at Landlord's election, to a Landlord's Affiliate designated by Landlord) an administrative fee equal to 10% of the associated insurance premiums for the coordination of coverage.

(d) In addition to the foregoing insurance requirements, Landlord reserves the right to require Tenant to procure insurance in amounts and against such other risks as Landlord may reasonably require to cover such risks as may be customarily insured from time to time during the Term by prudent owners of similar properties.

(e) Notwithstanding anything to the contrary contained in this Lease, Landlord hereby releases Tenant, and Tenant hereby releases Landlord, Lender and their respective partners, principals, members, officers, shareholders, directors, agents, employees and affiliates from any and all liability for loss, damage or injury to the property of the other, whether located in or about the Premises or elsewhere which is caused by or results from a peril, event or happening which is covered by insurance actually carried and in force at the time of the loss (or which would have been covered but for a failure to maintain insurance coverage that was required to be maintained under this Lease) by the party sustaining such loss. Each of Landlord and Tenant hereby waives all rights of subrogation of its insurers and shall cause its insurance policies to be endorsed such that said waiver of subrogation shall not affect the right of the insured to recover thereunder.

11. Indemnity.

(a) Landlord shall not be liable to Tenant for any damage to, or loss or theft of, any property or for any bodily or personal injury, illness or death of any person in, on or about the Premises arising at any time and from any cause whatsoever, except to the extent caused by the gross negligence or willful misconduct of Landlord. To the fullest extent permitted by law, Tenant waives all claims against Landlord arising from any liability described in this Section 11(a).

(b) Tenant shall be solely liable for, and agrees to indemnify and defend Landlord against and hold Landlord harmless from, all claims, demands, liabilities, damages, losses, costs and expenses, including reasonable attorneys' fees and disbursements, arising from or related to Tenant's use or occupancy of the Premises, any condition of the Premises arising out of Tenant's use or occupancy of the Premises or for which Tenant is otherwise responsible or any failure by Tenant to perform its obligations under this Lease, or any damage to any property (including property of employees and invitees of Tenant) or any bodily or personal injury, illness or death of any person (including employees and invitees of Tenant) occurring in, on or about the Premises or any part thereof or any part of the Building or the land on which the Building is located (except to the extent caused by the gross negligence or willful misconduct of Landlord) or occurring outside the Premises when such damage, bodily or personal injury, illness or death is caused by any act or omission of Tenant or Tenant's Affiliates. This Section 11(b) shall survive the termination of this Lease with respect to any damage, bodily or personal injury, illness or death occurring prior to such termination. The waiver by Tenant in Section 11(a) and the indemnity by Tenant in this Section 11(b) are intended to exculpate and indemnify Landlord from and against any liability of Landlord based on any applicable doctrine of strict liability.

12. Tenant's Fixtures. Tenant may install in the Premises racking and trade fixtures required by Tenant for conducting the Permitted Use; provided that the location and manner of installation of all such

racking and trade fixtures are subject to the prior approval of Landlord, which will not be unreasonably withheld, delayed or conditioned. All racking and trade fixtures so installed by Tenant shall, not later than the date of termination or expiration of this Lease, be removed by Tenant at its expense; provided, however, that Tenant shall comply with the Rules and Regulations in performing such removal and shall, in any event, repair and restore any damage to the Premises (to the condition in which the Premises existed prior to such installation, reasonable wear and tear only excepted) caused by the installation or removal of all racking and trade fixtures; and provided further that Tenant shall not be required to remove, in any way, the HVAC system or related equipment.

13. Signs. No sign, advertisement or notice shall be inscribed, painted, affixed or displayed on the windows or exterior walls of the Premises or on any public area of the Building, except in such places, numbers, sizes, colors and styles as are approved in advance in writing by Landlord, and which conform to all applicable Governmental Requirements and covenants affecting the Premises. Any and all signs installed or constructed by or on behalf of Tenant pursuant hereto shall be installed and maintained by Tenant during the Term and, prior to the end of the Term, be removed by Tenant, all at Tenant's sole cost and expense, provided, however, that Tenant shall comply with the Rules and Regulations in performing such removal and shall, in any event, repair and restore any damage to the Premises, the Building and the Building Common Area (to the condition in which the Premises, the Building and the Building Common Area existed prior to such installation, reasonable wear and tear only excepted) caused by the installation or removal of all signs.

14. Governmental Requirements. Tenant shall promptly comply throughout the Term, at Tenant's sole cost and expense, with all Governmental Requirements relating to all or any part of the Premises or the use or manner of use of the Premises and the Building Common Area. Without limiting the foregoing, if as a result of one or more Governmental Requirements, it is necessary, from time to time during the Term, to perform a Code Modification which is made necessary as a result of a Tenant Alteration or the specific use being made by Tenant of the Premises, then such Code Modification shall be the sole and exclusive responsibility of Tenant in all respects. Any such Code Modification shall be promptly performed by Tenant at its expense in accordance with the applicable Governmental Requirement and with Section 17. If as a result of one or more Governmental Requirements it is necessary from time to time during the Term to perform a Code Modification which would be characterized as a capital expenditure under generally accepted accounting principles and is not made necessary as a result of the specific use being made by Tenant of the Premises (as distinguished from an alteration or modification which would be required to be made by the owner of any warehouse-office building comparable to the Building irrespective of the use thereof by any particular occupant) or a Tenant Alteration, then (a) Landlord shall have the obligation to perform the Code Modification at its expense, (b) the cost of such Code Modification shall be amortized at an interest rate, and over the useful life of the item in question, all as reasonably determined by Landlord, and (c) Tenant shall be obligated to pay (as Additional Rent, payable in the same manner and upon the same terms and conditions as the Base Rent) for (i) Tenant's Percentage Share of the portion of such amortized costs attributable to the remainder of the Term, including any extensions thereof, with respect to any Code Modification respecting the Building or the Building Common Area and (ii) the entire portion of such amortized costs attributable to the remainder of the Term, including any extensions thereof, with respect to any Code Modification respecting the Premises. Tenant shall promptly send to Landlord a copy of any written notice received by Tenant requiring a Code Modification.

15. Environmental Matters.

(a) Tenant covenants that all the activities of Tenant and Tenant's Affiliates, in or at the Premises, the Building, or the Project during the Term will be conducted in compliance with Environmental Laws. Tenant warrants that it has obtained, or will obtain prior to the Lease Commencement Date, all permits, licenses or approvals required by any applicable Environmental Laws necessary for Tenant's operation of its business at the Premises.

(b) Tenant shall not cause or permit any Hazardous Substances to be brought upon, kept or used in or about the Premises, the Building or the Project without the prior written consent of Landlord; provided, however, that the consent of Landlord shall not be required for the use at the Premises of cleaning supplies, toner for photocopying machines and other similar materials, in containers and quantities

reasonably necessary for and consistent with normal and ordinary use by Tenant in the routine operation or maintenance of Tenant's office equipment or in the routine janitorial service, cleaning and maintenance for the Premises.

(c) Tenant shall not cause or permit the release of any Hazardous Substances by Tenant or Tenant's Affiliates into any environmental media such as air, water or land, or into or on the Premises, the Building or the Project in any manner that violates any Environmental Laws. If such release occurs, Tenant shall (i) take all steps reasonably necessary to contain and control such release and any associated Contamination, (ii) investigate and clean up or otherwise remedy such release and any associated Contamination to the extent required by, and take any and all other actions required under, applicable Environmental Laws and (iii) notify and keep Landlord reasonably informed of such release and response.

(d) Tenant shall not cause or permit (i) any activity on the Premises which would cause the Premises to become subject to regulation as a hazardous waste treatment, storage or disposal facility under applicable Environmental Laws (including, without limitation, RCRA), (ii) the discharge of Hazardous Substances into the storm sewer system serving the Building or the Project or (iii) the installation of any underground storage tank or underground piping on or under the Premises.

(e) Tenant shall, and hereby does, indemnify Landlord and hold Landlord harmless from and against any and all expense, loss, and liability suffered by Landlord (except to the extent arising out of Landlord's own negligence or willful act), by reason of the storage, generation, release, handling, treatment, transportation, disposal, or arrangement for transportation or disposal, of any Hazardous Substances by Tenant or Tenant's Affiliates or by reason of Tenant's breach of any of the provisions of this Section 15. Such expenses, losses and liabilities shall include, without limitation, (i) any and all expenses that Landlord may incur to comply with any Environmental Laws; (ii) any and all costs that Landlord may incur in studying or remedying any Contamination at or arising from the Premises, the Building or the Project; (iii) any and all costs that Landlord may incur in studying, removing, disposing or otherwise addressing any Hazardous Substances; (iv) any and all fines, penalties or other sanctions and any liens or claims, including but not limited to natural resource damages claims, assessed upon Landlord; and (v) any and all legal and professional fees and costs incurred by Landlord in connection with the foregoing. The indemnity contained herein shall survive the expiration or earlier termination of this Lease.

16. Landlord's Work. Landlord will perform Landlord's Base Building Work in accordance with **Exhibit B -** Construction Addendum hereto.

17. Tenant Alterations.

(a) Except with respect to Cosmetic Alterations (as hereinafter defined), Tenant shall not make or permit to be made any alterations, improvements or additions to the Premises (each a "**Tenant Alteration**" and collectively "**Tenant Alterations**"), without first obtaining on each occasion Landlord's prior written consent (which consent will not be unreasonably withheld or conditioned, except as hereinafter provided to the contrary). As part of its approval process, Landlord may require that Tenant submit plans and specifications to Landlord. All Tenant Alterations shall be performed in accordance with all applicable Governmental Requirements and in a good and workmanlike manner with first-class materials. Tenant shall maintain (and shall require its contractors performing work on behalf of the Tenant to maintain) insurance reasonably satisfactory to Landlord during the construction of all Tenant Alterations. If Landlord, at the time of giving its approval to any Tenant Alteration, notifies Tenant in writing that approval is not conditioned upon removal of the Tenant Alteration at the termination of expiration of this Lease, then Tenant shall not be required to remove the applicable Tenant Alteration at the termination or expiration of this Lease; provided, however, that, absent a written confirmation that approval is not conditioned on removal, then Tenant shall, at its sole cost and expense and upon the termination or expiration of this Lease, remove the same and restore the Premises to its condition prior to such Tenant Alteration. No Tenant Alteration may be structural in nature or impair the structural strength of the Building or reduce its value, and any such proposed structural Tenant Alteration may be disapproved by Landlord in its absolute discretion. Any proposed Tenant Alteration which will affect in any way the exterior walls or roof of the Building, including, without limitation, any penetration of the exterior walls or roof of the Building or placement of any equipment of any nature on the

exterior walls or roof of the Building, will conclusively be deemed to be structural in nature. Tenant shall pay the full cost of any Tenant Alteration and shall give Landlord such reasonable security as may be requested by Landlord to insure payment of such cost. Except as otherwise provided in Section 12 and in this Section 17, all Tenant Alterations and all repairs and all other property attached to or installed on the Premises by or on behalf of Tenant shall immediately upon completion or installation thereof be and become part of the Premises and the property of Landlord without payment therefor by Landlord and shall be surrendered to Landlord upon the expiration or earlier termination of this Lease. Notwithstanding the foregoing, Tenant shall be permitted to make non-structural Tenant Alterations without Landlord's prior consent, to the extent that such Alterations (i) do not affect the exterior appearance of the Building or the structural aspects of the Building, (ii) significantly affect the mechanical, electrical and plumbing systems and related equipment of the Building or (iii) cost more than $50,000 in the aggregate for such Alteration ("Cosmetic Alterations").

(b) Tenant shall not permit the Premises to become subject to any mechanics', laborers' or materialmen's lien on account of labor, material or services furnished to Tenant or claimed to have been furnished to Tenant in connection with work of any character performed or claimed to have been performed at the Premises by, or at the direction or sufferance of, Tenant. Tenant agrees to indemnify Landlord against, hold Landlord harmless from, and defend Landlord and the Premises against (with legal counsel acceptable to Landlord) all liens, claims, liabilities and costs (including, without limitation, reasonable attorneys' fees actually incurred) of every kind, nature and description which may be suffered or incurred by Landlord and arise out of, or in any way be connected with, such work or a failure by Tenant to meet its obligations under this Section 17. If any such liens are filed against the Premises, Tenant shall discharge the same by payment or bonding within five (5) business days after Tenant has actual knowledge of the existence of the lien or receipt of written notice from Landlord of the existence of the lien, whichever occurs first. If Tenant fails timely to accomplish such discharge, Landlord may, without investigation of the validity of the lien claim, discharge such lien and Tenant shall reimburse Landlord upon demand for all costs and expenses incurred by Landlord in connection therewith, including, without limitation, reasonable attorneys' fees and expenses, including litigation through all trial and appellate levels. Nothing contained in this Lease shall be construed as a consent or authorization by Landlord to allow any person claiming through or under Tenant to file or otherwise subject the Premises to any lien claim of any nature under any lien law of the state in which the Premises are located, whether existing on the Lease Date or adopted at any time during the Term.

18. Fire and Other Casualty. If the Premises are damaged by fire or other casualty insured by Landlord, Landlord agrees to restore and repair the Premises promptly at Landlord's expense, including the Tenant Alterations to be insured by Tenant (but only to the extent Landlord receives insurance proceeds therefor, including the proceeds from the insurance required to be carried by Tenant on the Tenant Alterations). Notwithstanding the foregoing, if the Premises are (a) in the reasonable opinion of Landlord, so destroyed that they cannot be repaired or rebuilt within two hundred seventy (270) days after the later of (i) the date of such damage or (ii) the date all tenants, including Tenant, vacate the necessary portions of the Building to allow Landlord to commence said repair; or (b) destroyed by a casualty which is not covered by Landlord's insurance, or if such casualty is covered by Landlord's insurance but Lender or other party entitled to insurance proceeds fails to make such proceeds available to Landlord in an amount sufficient for restoration of the Premises, then Landlord shall give written notice to Tenant of such determination (the "**Determination Notice**") within sixty (60) days after such casualty. Either Landlord or Tenant may terminate and cancel this Lease by giving written notice to the other within twenty (20) days after Tenant's receipt of the Determination Notice. Upon the giving of such termination notice, all obligations hereunder with respect to periods from and after the date of receipt by Landlord or Tenant, as applicable, of the termination notice shall thereupon cease and terminate. If no such termination notice is given, Landlord shall, to the extent of the available insurance proceeds, repair and restore the Premises to the approximate condition existing immediately prior to such casualty, promptly and in such manner as not to interfere unreasonably with Tenant's use and occupancy of the Premises (if Tenant is still occupying the Premises). Rent shall abate during the time that the Premises or any part thereof are unusable, by reason of any casualty damage, in proportion to the loss of use of the Premises actually suffered by Tenant. Notwithstanding anything in this Lease to the contrary, in no event shall Tenant be entitled to an abatement of Rent or right to terminate this Lease as provided in this Section 18 if the Premises are damaged by fire or other casualty caused by Tenant or Tenant's Affiliates.

19. Condemnation.

(a) If all of the Premises is taken or condemned by any authority having the power of eminent domain, or if a material portion of the Premises is so taken or condemned and the remaining portion thereof is not usable by Tenant for the Permitted Use, this Lease shall terminate as of the earlier of the date title to the condemned real estate vests in the condemnor or the date on which Tenant is deprived of possession of the Premises. In such event, the Rent shall be apportioned and paid in full by Tenant to Landlord through that date, all Rent prepaid for periods beyond that date shall be repaid by Landlord to Tenant, and neither party will thereafter have any liability hereunder, except that any obligation or liability of either party, actual or contingent, under this Lease which has accrued on or prior to such termination date shall survive.

(b) If only part of the Premises is taken or condemned by an authority with the power of eminent domain and this Lease does not terminate pursuant to Section 19(a), Landlord shall, to the extent of the award it receives, restore the Premises to a condition as nearly comparable as reasonably practicable to the condition thereof immediately prior to the taking, and there shall be an equitable adjustment to the Rent based on the actual loss of use of the Premises suffered by Tenant from the taking.

(c) Landlord shall receive the entire award in any proceeding with respect to any taking described in this Section 19, without deduction therefrom for any estate vested in Tenant by this Lease, and Tenant shall receive no part of such award. Nothing contained herein shall be deemed to prohibit Tenant from making a separate claim against the condemnor, to the extent permitted by law, for the value of Tenant's moveable trade fixtures, machinery and moving expenses, provided that the making of such claim does not diminish Landlord's award.

20. Tenant's Default.

(a) The occurrence of any one or more of the following events shall constitute an "**Event of Default**" of Tenant under this Lease:

(i) if Tenant fails to pay Base Rent or any Additional Rent as and when such Rent becomes due and such failure shall continue for more than five (5) days after Landlord gives written notice to Tenant of such failure;

(ii) if Tenant fails to pay Base Rent or any Additional Rent on time more than two (2) times in any period of twelve (12) months, notwithstanding that such payments have been made within the applicable cure period;

(iii) if Tenant fails to discharge any lien against the Premises or the Building in accordance with Section 17(b);

(iv) if Tenant fails to maintain in force all policies of insurance required by this Lease and such failure shall continue for more than ten (10) days after Landlord gives Tenant written notice of such failure;

(v) if any petition is filed by or against Tenant or any guarantor of this Lease under any present or future section or chapter of the Bankruptcy Code, or under any similar law or statute of the United States or any state thereof (which, in the case of an involuntary proceeding, is not permanently discharged, dismissed, stayed, or vacated, as the case may be, within sixty (60) days of commencement), or if any order for relief shall be entered against Tenant or any guarantor of this Lease in any such proceedings;

(vi) if Tenant or any guarantor of this Lease becomes insolvent or makes a transfer in fraud of creditors or makes an assignment for the benefit of creditors;

(vii) if a receiver, custodian, or trustee is appointed for the Premises or for all or substantially all of the assets of Tenant or of any guarantor of this Lease, which appointment is not vacated within sixty (60) days following the date of such appointment;

(viii) if Tenant fails to vacate the Premises, upon expiration of the Term of this Lease, in accordance with Section 28(b); or

(ix) if Tenant fails to perform or observe any other term of this Lease and such failure shall continue for more than thirty (30) days after Landlord gives Tenant written notice of such failure, or, if such failure cannot be corrected within such thirty (30) day period, if Tenant does not commence to correct such default within said thirty (30) day period and thereafter diligently prosecute the correction of same to completion within a reasonable time (but in no event later than ninety (90) days after Landlord's notice of default).

(b) Upon the occurrence of any one or more Events of Default, Landlord may, at Landlord's option, without any demand or notice whatsoever (except as expressly required in this Section 20):

(i) Terminate this Lease by giving Tenant notice of termination, in which event this Lease shall expire and terminate on the date specified in such notice of termination and all rights of Tenant under this Lease and in and to the Premises shall terminate. Tenant shall remain liable for all obligations under this Lease arising up to the date of such termination, and Tenant shall surrender the Premises to Landlord on the date specified in such notice; or

(ii) Terminate this Lease as provided in Section 20(b)(i) hereof and recover from Tenant all damages Landlord may incur by reason of Tenant's default, including, without limitation, an amount which, at the date of such termination, is calculated as follows: (1) the value of the excess, if any, of (A) the Base Rent, Additional Rent and all other sums which would have been payable hereunder by Tenant for the period commencing with the day following the date of such termination and ending with the Expiration Date had this Lease not been terminated (the "**Remaining Term**"), over (B) the aggregate reasonable rental value of the Premises for the Remaining Term (which excess, if any shall be discounted to present value at the "Treasury Yield" as defined below for the Remaining Term); plus (2) the costs of recovering possession of the Premises and all other expenses incurred by Landlord due to Tenant's default, including, without limitation, reasonable attorney's fees; plus (3) the unpaid Base Rent and Additional Rent earned as of the date of termination plus any interest and late fees due hereunder, plus other sums of money and damages owing on the date of termination by Tenant to Landlord under this Lease or in connection with the Premises. The amount as calculated above shall be deemed immediately due and payable. The payment of the amount calculated in subparagraph (ii)(1) shall not be deemed a penalty but shall merely constitute payment of liquidated damages, it being understood and acknowledged by Landlord and Tenant that actual damages to Landlord are extremely difficult, if not impossible, to ascertain. "**Treasury Yield**" shall mean the rate of return in percent per annum of Treasury Constant Maturities for the length of time specified as published in document H.15(519) (presently published by the Board of Governors of the U.S. Federal Reserve System titled "**Federal Reserve Statistical Release**") for the calendar week immediately preceding the calendar week in which the termination occurs. If the rate of return of Treasury Constant Maturities for the calendar week in question is not published on or before the business day preceding the date of the Treasury Yield in question is to become effective, then the Treasury Yield shall be based upon the rate of return of Treasury Constant Maturities for the length of time specified for the most recent calendar week for which such publication has occurred. If no rate of return for Treasury Constant Maturities is published for the specific length of time specified, the Treasury Yield for such length of time shall be the weighted average of the rates of return of Treasury Constant Maturities most nearly corresponding to the length of the applicable period specified. If the publishing of the rate of return of Treasury Constant Maturities is ever discontinued, then the Treasury Yield shall be based upon the index which is published by the Board of Governors of the U.S. Federal Reserve System in replacement thereof or, if no such replacement index is published, the index which, in Landlord's reasonable determination, most nearly corresponds to the rate of return of Treasury Constant Maturities. In determining the aggregate reasonable rental value pursuant to subparagraph (ii)(1)(B) above, the parties hereby agree that, at the time Landlord seeks to enforce this remedy, all relevant factors should be considered, including, but not limited to, (a) the length of time remaining in the Remaining Term,

(b) the then current market conditions in the general area in which the Building is located, (c) the likelihood of reletting the Premises for a period of time equal to the remainder of the Term, (d) the net effective rental rates then being obtained by landlords for similar type space of similar size in similar type buildings in the general area in which the Building is located, (e) the vacancy levels in the general area in which the Building is located, (f) current levels of new construction that will be completed during the Remaining Term and how this construction will likely affect vacancy rates and rental rates and (g) inflation; or

(iii) Without terminating this Lease, in its own name but as agent for Tenant, enter into and upon and take possession of the Premises or any part thereof. Any property remaining in the Premises may be removed and stored in a warehouse or elsewhere at the cost of, and for the account of, Tenant without Landlord being deemed guilty of trespass or becoming liable for any loss or damage which may be occasioned thereby unless caused by Landlord's negligence. Thereafter, Landlord may, but shall not be obligated to (except as required to meet any duty to mitigate its damages in accordance with applicable law), lease to a third party the Premises or any portion thereof as the agent of Tenant upon such terms and conditions as Landlord may deem necessary or desirable in order to relet the Premises. The remainder of any rentals received by Landlord from such reletting, after the payment of any indebtedness due hereunder from Tenant to Landlord, and the payment of any costs and expenses of such reletting, shall be held by Landlord to the extent of and for application in payment of future rent owed by Tenant, if any, as the same may become due and payable hereunder. If such rentals received from such reletting shall at any time or from time to time be less than sufficient to pay to Landlord the entire sums then due from Tenant hereunder, Tenant shall pay any such deficiency to Landlord. Notwithstanding any such reletting without termination, Landlord may at any time thereafter elect to terminate this Lease for any such previous default provided same has not been cured; or

(iv) Pursue such other remedies as are available at law or equity.

(c) If this Lease shall terminate as a result of, or while there exists, an Event of Default, any funds of Tenant held by Landlord may be applied by Landlord to any damages payable by Tenant (whether provided for herein or by law) as a result of such termination or Event of Default.

(d) Neither the commencement of any action or proceeding, nor the settlement thereof, nor entry of judgment thereon shall bar Landlord from bringing subsequent actions or proceedings from time to time, nor shall the failure to include in any action or proceeding any sum or sums then due be a bar to the maintenance of any subsequent actions or proceedings for the recovery of such sum or sums so omitted.

(e) No agreement to accept a surrender of the Premises and no act or omission by Landlord or Landlord's agents during the Term shall constitute an acceptance or surrender of the Premises unless made in writing and signed by Landlord. No re-entry or taking possession of the Premises by Landlord shall constitute an election by Landlord to terminate this Lease unless a written notice of such intention is given to Tenant. No provision of this Lease shall be deemed to have been waived by either party unless such waiver is in writing and signed by the party making such waiver. Landlord's acceptance of Base Rent or Additional Rent in full or in part following an Event of Default hereunder shall not be construed as a waiver of such Event of Default. No custom or practice which may grow up between the parties in connection with the terms of this Lease shall be construed to waive or lessen either party's right to insist upon strict performance of the terms of this Lease, without a written notice thereof to the other party.

(f) If an Event of Default shall occur, Tenant shall pay to Landlord, on demand, all expenses incurred by Landlord as a result thereof, including reasonable attorneys' fees, court costs and expenses actually incurred.

(g) The various rights, remedies and elections available to Landlord under this Lease because of the occurrence and existence of an Event of Default are intended to be cumulative and no such right, remedy or election shall be or be deemed to be exclusive of any of the others or exclusive of any other rights or remedies which may at any time be available Landlord under applicable law.

(h) Whenever an Event of Default has occurred, any payment of Rent by Tenant, any other payment of any nature tendered by Tenant to Landlord and any other amount of money collected or received

by Landlord from any reletting of the Premises pursuant to this Section 20 shall be applied in such order as Landlord may elect toward payment of all amounts due from Tenant to Landlord pursuant to this Lease.

(i) If an Event of Default shall occur, the sum of the Base Rent Credits shall immediately become due and payable to Landlord; provided, however, that such payment by Tenant shall not be viewed as liquidated damages, it being agreed that Landlord shall have the right to pursue any and all other remedies available to it under the terms of this Lease or otherwise in connection with such Event of Default.

(j) CONFESSION OF JUDGMENT.

(i) CONFESSION OF JUDGMENT FOR RENT. TENANT HEREBY EMPOWERS ANY PROTHONOTARY OR ATTORNEY OF ANY COURT OF RECORD TO APPEAR FOR TENANT AFTER AN EVENT OF DEFAULT IN ANY AND ALL ACTIONS WHICH MAY BE BROUGHT FOR BASE RENT AND ADDITIONAL RENT, OR HEREIN AGREED TO BE PAID BY TENANT AND TO SIGN FOR TENANT AN AGREEMENT FOR ENTERING IN ANY COMPETENT COURT AN ACTION OR ACTIONS FOR RECOVERY OF SUCH RENT OR OTHER CHARGES OR EXPENSES, AND IN SAID SUITS OR IN SAID ACTION OR ACTIONS TO CONFESS JUDGMENT AGAINST TENANT FOR ALL OR ANY PART OF THE RENT SPECIFIED IN THIS LEASE THEN DUE AND UNPAID, AND OTHER CHARGES, PAYMENTS, COSTS AND EXPENSES RESERVED AS RENT, TOGETHER WITH AN ATTORNEY'S COMMISSION OF FIVE PERCENT (5%) OF THE AMOUNT DUE (BUT NOT LESS THAN $15,000). SUCH AUTHORITY SHALL NOT BE EXHAUSTED BY ONE EXERCISE THEREOF, BUT JUDGMENT MAY BE CONFESSED AS AFORESAID FROM TIME TO TIME AFTER SUBSEQUENT EVENTS OF DEFAULT.

(ii) CONFESSION OF JUDGMENT FOR POSSESSION. UPON AN EVENT OF DEFAULT OR THE EXPIRATION OF THE TERM, IT SHALL BE LAWFUL FOR ANY ATTORNEY OF ANY COURT OF RECORD TO APPEAR AS ATTORNEY FOR TENANT AS WELL AS FOR ALL PERSONS CLAIMING BY, THROUGH OR UNDER TENANT AND TO SIGN AN AGREEMENT FOR ENTERING IN ANY COMPETENT COURT AN ACTION IN EJECTMENT AGAINST TENANT AND ALL PERSONS CLAIMING BY, THROUGH OR UNDER TENANT AND THEREIN CONFESS JUDGMENT FOR THE RECOVERY BY LANDLORD OF POSSESSION OF THE PREMISES, FOR WHICH THIS LEASE SHALL BE ITS SUFFICIENT WARRANT, WHEREUPON, IF LANDLORD SO DESIRES, A WRIT OF POSSESSION OR OTHER APPROPRIATE WRIT UNDER THE PENNSYLVANIA RULES OF CIVIL PROCEDURE THEN IN EFFECT MAY ISSUE FORTHWITH, WITHOUT ANY PRIOR WRIT OR PROCEEDINGS; PROVIDED, HOWEVER, IF THIS LEASE IS TERMINATED AND POSSESSION OF THE PREMISES REMAIN IN OR BE RESTORED TO TENANT, LANDLORD SHALL HAVE THE RIGHT FOR THE SAME EVENT OF DEFAULT AND UPON ANY SUBSEQUENT EVENT OF DEFAULT OR EVENTS OF DEFAULT, TO BRING ONE OR MORE FURTHER ACTION OR ACTIONS AS HEREINBEFORE SET FORTH TO RECOVER POSSESSION OF THE DEMISED PREMISES AND CONFESS JUDGMENT FOR THE RECOVERY OF POSSESSION OF THE DEMISED PREMISES AS HEREIN ABOVE PROVIDED.

(iii) PROCEEDINGS. IN ANY ACTION OF EJECTMENT, LANDLORD SHALL FIRST CAUSE TO BE FILED IN SUCH ACTION AN AFFIDAVIT MADE BY IT OR SOMEONE ACTING FOR IT, SETTING FORTH THE FACTS NECESSARY TO AUTHORIZE THE ENTRY OF JUDGMENT, AND, IF A TRUE COPY OF THIS LEASE (AND OF THE TRUTH OF THE COPY SUCH AFFIDAVIT SHALL BE SUFFICIENT EVIDENCE) BE FILED IN SUCH ACTION, IT SHALL NOT BE NECESSARY TO FILE THE ORIGINAL AS A WARRANT OF ATTORNEY, ANY RULE OF COURT, CUSTOM OR PRACTICE TO THE CONTRARY NOTWITHSTANDING. TENANT RELEASES TO LANDLORD AND TO ANY AND ALL ATTORNEYS WHO MAY APPEAR FOR TENANT, ALL PROCEDURAL ERRORS IN SAID PROCEEDINGS AND ALL LIABILITY THEREOF. IF PROCEEDINGS SHALL BE COMMENCED BY LANDLORD TO RECOVER POSSESSION UNDER THE PENNSYLVANIA ACTS OF ASSEMBLY AND RULES OF CIVIL PROCEDURE UPON AN EVENT OF DEFAULT, TENANT SPECIFICALLY WAIVES THE RIGHT TO THE FIFTEEN (15) OR THIRTY (30) DAYS

NOTICE REQUIRED BY THE PENNSYLVANIA LANDLORD AND TENANT ACT OF 1951, AS AMENDED, OR ANY SIMILAR OR SUCCESSOR PROVISION OF LAW, AND AGREES THAT FIVE (5) DAYS NOTICE SHALL BE SUFFICIENT IN EITHER OR ANY SUCH CASE.

(iv) ACKNOWLEDGMENT OF CONFESSION OF JUDGMENT. TENANT CONFIRMS TO LANDLORD THAT (I) THIS LEASE AND THE FOREGOING WARRANTS OF ATTORNEY HAVE BEEN NEGOTIATED AND AGREED UPON IN A COMMERCIAL CONTEXT; (II) TENANT IS A BUSINESS ENTITY AND ITS PRINCIPALS ARE KNOWLEDGEABLE IN COMMERCIAL MATTERS; (III) TENANT HAS CONSULTED WITH ITS OWN SEPARATE COUNSEL REGARDING THIS LEASE; (IV) ON THE ADVICE OF ITS OWN SEPARATE COUNSEL, TENANT HAS AGREED TO THE AFORESAID WARRANT OF ATTORNEY TO CONFESS JUDGMENT AGAINST TENANT; AND (V) TENANT UNDERSTANDS THAT IT IS WAIVING CERTAIN RIGHTS WHICH IT WOULD OTHERWISE POSSESS.

21. Landlord's Right of Entry. Tenant shall permit Landlord and the authorized representatives of Landlord and Lender to enter the Premises at all reasonable times for the purposes of inspecting the Premises, assessing Tenant's compliance with this Lease and performing Landlord's obligations under this Lease; provided that, except in the case of an emergency, Landlord shall give Tenant not less than 24 hours prior written or electronic notice of Landlord's intended entry into the Premises. Nothing herein shall imply any duty of Landlord to do any work required of Tenant under this Lease and the performance of any such work by Landlord shall not constitute a waiver of Tenant's default in failing to perform it. Landlord shall not be liable for inconvenience, annoyance, disturbance or other damage to Tenant by reason of making such repairs or the performance of such work in the Premises or on account of bringing materials, supplies and equipment into or through the Premises during the course thereof, and the obligations of Tenant under this Lease shall not thereby be affected; provided, however, that Landlord shall use reasonable efforts not to disturb or otherwise interfere with Tenant's operations in the Premises in making such repairs or performing such work. Landlord also shall have the right to enter the Premises at all reasonable times to exhibit the Premises to any Lender, any prospective purchaser, investor or lender, and during the last six (6) months of the Term, any prospective tenant.

22. Lender's Rights.

(a) This Lease and all rights of Tenant hereunder are and shall be subject and subordinate to any Mortgage and foreclosure of any Mortgage. If, in connection with foreclosure of a Mortgage or other taking of possession of the Premises pursuant to a Mortgage, a Lender (or a nominee of the Lender or other purchaser at foreclosure) shall elect to succeed to the rights of Landlord under this Lease, Tenant shall attorn to and recognize such successor as landlord under this Lease, without change in the terms and provisions of this Lease, and shall promptly execute and deliver any instrument that may be reasonably required by such successor to evidence such attornment; provided, however, that such successor shall not be bound by (i) any payment of Base Rent or Additional Rent more than one month in advance, except prepayments in the nature of security for the performance by Tenant of its obligations under this Lease, and then only if such prepayments have been deposited with and are under the control of such successor, (ii) any provision of any amendment to this Lease to which Lender has not consented or (iii) the defaults of any prior landlord under this Lease, including, without limitation, any offset against Rent arising out of the defaults of any prior landlord under this Lease. Tenant shall, in confirmation of the subordination and attornment set forth in this Section 22 and notwithstanding that such subordination and attornment is self-operative, upon written demand by Landlord, execute and deliver to Landlord or to any Lender any instrument reasonably requested by either of them to evidence such subordination and attornment.

(b) At any time during the Term, any Lender may, by written notice to Tenant, make this Lease superior to the lien/security title of its Mortgage. If requested by Lender, Tenant shall, upon demand, at any time or times, execute, acknowledge and deliver to Lender, any and all instruments that may be necessary to make this Lease superior to the lien/security title of any Mortgage.

23. Estoppel Certificate and Financial Statement.

(a) During the Term, each of Landlord and Tenant agrees to execute, acknowledge and deliver within fifteen (15) days after written request from the other, a statement in recordable form to the requesting party and/or its designee certifying that: (i) this Lease is unmodified and in full force and effect (or, if there have been modifications, that the same is in full force and effect, as modified), (ii) the dates to which Base Rent and Additional Rent have been paid, (iii) whether or not, to its knowledge, there exists any failure by the requesting party to perform any term, covenant or condition contained in this Lease, and, if so, specifying each such failure, (iv) (if such be the case) Tenant has unconditionally accepted the Premises and is conducting its business therein, and (v) as to such additional factual matters relating to this Lease as may be requested, it being intended that any such statement delivered pursuant hereto may be relied upon by the requesting party and by any party that has, or is contemplating having, a direct or indirect interest in Landlord or the Premises, Building or Project.

(b) If Landlord desires to finance, refinance, or sell the Building, Tenant and all guarantors, if any, of Tenant’s obligations under this Lease, shall deliver to Lender and any prospective Lender or purchaser designated by Landlord such financial statements of Tenant and such guarantors as may be reasonably required by such lender or purchaser, including but not limited to Tenant's financial statements for the past three (3) years. All such financial statements shall be received by Landlord and such Lender or purchaser in confidence and shall be used only for the purposes herein set forth.

24. Landlord Liability. NO OWNER OF THE PREMISES, WHETHER OR NOT NAMED HEREIN, SHALL HAVE LIABILITY HEREUNDER AFTER IT CEASES TO HOLD TITLE TO THE PREMISES. NEITHER LANDLORD NOR ANY OFFICER, DIRECTOR, SHAREHOLDER, SECURITY HOLDER, MEMBER, MANAGER, EQUITY HOLDER, TRUSTEE, PARTNER OR PRINCIPAL OF LANDLORD, WHETHER DISCLOSED OR UNDISCLOSED, SHALL HAVE ANY PERSONAL LIABILITY WITH RESPECT TO ANY OF THE PROVISIONS OF THIS LEASE. IN THE EVENT LANDLORD IS IN BREACH OR DEFAULT WITH RESPECT TO LANDLORD'S OBLIGATIONS OR OTHERWISE UNDER THIS LEASE, TENANT SHALL LOOK SOLELY TO THE EQUITY OF LANDLORD IN THE BUILDING FOR THE SATISFACTION OF TENANT'S REMEDIES. IT IS EXPRESSLY UNDERSTOOD AND AGREED THAT LANDLORD'S LIABILITY UNDER THE TERMS, COVENANTS, CONDITIONS, WARRANTIES AND OBLIGATIONS OF THIS LEASE SHALL IN NO EVENT EXCEED LANDLORD'S EQUITY INTEREST IN THE BUILDING.

25. Notices. Any notice required or permitted by the provisions of this Lease shall be in writing and either (a) personally delivered or (b) delivered by a nationally recognized overnight delivery service providing proof of delivery, to the appropriate address set forth in Section 1(l) (as the same may be changed by the affected party to any other address in the continental United States by giving written notice at least ten (10) business days in advance of the effective date of the change). Notice will be deemed to have been given on the date of personal delivery or the date placed in the possession of the overnight delivery service, as applicable, but any time period provided in this Lease for a response to the notice will not commence until the date of receipt. Any refusal to accept delivery or inability to make delivery because of a change of address as to which no timely notice was given will conclusively constitute receipt of the notice on the date given. Any notice required or permitted to be given by Landlord or Tenant may be given by either an agent, law firm or attorney acting on behalf of Landlord or Tenant.

26. Brokers. Landlord and Tenant represent and warrant to each other that, except for the Broker(s), it has not engaged or had any conversations or negotiations with any broker, finder or other third party concerning the leasing of the Premises to Tenant who would be entitled to any commission or fee based on the execution of this Lease. Landlord and Tenant hereby indemnify the other against and from any claims for any brokerage commissions (except those payable to the Broker(s), all of which are payable by Landlord pursuant to a separate agreement) and all costs, expenses and liabilities in connection therewith, including, without limitation, reasonable attorneys' fees and expenses, for any breach of the foregoing. The foregoing indemnification shall survive the expiration or termination of this Lease.

27. Assignment and Subleasing.

(a) No Transfer shall be permitted without the prior written consent of Landlord, which consent Landlord shall not unreasonably withhold, condition, or delay. If Tenant desires to Transfer this Lease (other than in connection with a Change in Control, which shall be governed by the provisions of subsection (b) below), Tenant shall give Landlord written notice no later than thirty (30) days in advance of the proposed effective date of the proposed Transfer, specifying (i) the name and business of the other party to the proposed transaction, (ii) the proposed effective date and duration of the Transfer and (iii) the proposed rent or consideration to be paid to Tenant by the other party to the proposed transaction. In the event of a sublease or any other proposed agreement to Transfer less than Tenant's entire interest in the Premises, Tenant's notice to Landlord shall also specify the amount and location of the space within the Premises that is the subject of the proposed transaction. In addition, Tenant shall promptly supply Landlord with financial statements and other information as Landlord may reasonably request to evaluate any Transfer.

(b) If Tenant desires to effectuate a Change in Control, Tenant shall give Landlord written notice no later than thirty (30) days in advance of the proposed effective date of any proposed Change in Control, specifying (i) the name of the proposed entity acquiring the direct or indirect interest in (or assets of) Tenant and (ii) the proposed effective date of such Change in Control. Tenant shall promptly supply Landlord with financial statements and other information as Landlord may reasonably request to evaluate the proposed Change in Control.

(c) For all Transfers, Landlord shall have a period of fifteen (15) days following Landlord's receipt of the notice and information from Tenant required above within which to notify Tenant in writing that Landlord elects: (1) to permit the Transfer, either with or without reasonable conditions specified by Landlord or (2) to refuse, in Landlord's reasonable discretion (taking into account all relevant factors including, without limitation, the factors set forth below), to consent to the Transfer and to continue this Lease in full force and effect as to the entire Premises. If Landlord fails to notify Tenant in writing of such election within the aforesaid fifteen (15) day period, Landlord shall be deemed to have elected option (2) above. For purposes of this Section 27, by way of example and not limitation, Landlord shall be deemed to have reasonably withheld consent if Landlord determines (i) that the creditworthiness of the prospective transferee (or, in the instance of a Change in Control, the creditworthiness of Tenant after the Change in Control) will not equal or exceed the creditworthiness of Tenant as of the Lease Date, (ii) that the proposed use of the Premises by such prospective transferee, when compared to Tenant's use, as permitted by the Permitted Use, will increase the risk of Contamination, increase wear and tear on the Premises or the Building, will necessitate any modifications of either the Premises or the Building, will increase the cost of, or risk exposure under, insurance carried by Landlord or otherwise negatively affect the value or marketability of the Building or the Project, or (iv) in the instance of any Transfer other than a Change in Control, that the prospective transferee is a current tenant in the Project or is a bona-fide third-party prospective tenant.

(d) Tenant agrees to reimburse Landlord for reasonable legal fees and any other reasonable costs incurred by Landlord in connection with any requested Transfer, and such payments shall not be deducted from the Additional Rent owed to Landlord pursuant to provisions below. Tenant shall deliver to Landlord copies of all transfer documents executed by Tenant and the transferee in connection with any Transfer. If the transferee is to pay rent or other consideration to Tenant, and the rent rate (or other consideration) agreed upon between Tenant and its proposed transferee is greater than the rent rate that Tenant must pay Landlord hereunder for the Premises (or the applicable portion thereof), then one half (1/2) of such excess rent and consideration (after payment of brokerage commissions, attorneys' fees and other disbursements reasonably incurred by Tenant for such Transfer, if acceptable evidence of such disbursements is delivered to Landlord) shall be considered Additional Rent to be paid to Landlord by Tenant.

(e) No acceptance by Landlord of any rent or any other sum of money from any assignee, sublessee or other category of transferee shall be deemed to constitute Landlord's consent to any Transfer. Permitted subtenants, assignees or other transferees shall become liable directly to Landlord for all obligations of Tenant hereunder, without, however, relieving Tenant (or any guarantor of this Lease) of any of its liability hereunder. No such Transfer shall be deemed a release of transferring Tenant from the further

performance by Tenant of Tenant's obligations under this Lease. Any Transfer consented to by Landlord shall not relieve Tenant (or its transferee) from obtaining Landlord's consent to any subsequent Transfer.

28. Termination or Expiration; Holdover.

(a) No termination of this Lease prior to the normal ending thereof, by lapse of time or otherwise, shall affect Landlord's right to collect Rent for the period prior to termination.

(b) At the expiration or earlier termination of this Lease, Tenant shall surrender the Premises (including the Improvements, but not including any trade fixtures, signage or Tenant Alteration which Tenant is obligated to remove pursuant to Section 12, Section 13 and Section 17, respectively), and all keys therefor, to Landlord, clean and neat, in compliance with the Rules and Regulations and otherwise in the same condition as when delivered to Tenant pursuant to this Lease, excepting only normal wear and tear, condemnation and casualty (other than casualty required by this Lease to be insured against by Tenant).

(c) If Tenant remains in possession of the Premises after expiration of the Term, with or without Landlord's acquiescence and without a written agreement of the parties, after thirty (30) days from the expiration date Tenant shall be a tenant-at-sufferance at 150% of the Base Rent in effect at the end of the Term (. Tenant shall also continue to pay all other Additional Rent due hereunder. Notwithstanding the foregoing, there shall be no renewal of this Lease by operation of law or otherwise, and, in addition to and without limiting such rights and remedies as may be available to Landlord at law or in equity as a result of Tenant's holding over beyond the Term, Landlord shall be entitled to exercise any and all rights and remedies available to Landlord by virtue of an Event of Default (it being agreed that any such holdover shall be deemed an immediate Event of Default, without notice or opportunity to cure). In addition to the foregoing, if Tenant holds over at the Premises for a period in excess of thirty (30) days, Tenant shall be liable for all damages, direct and consequential, incurred by Landlord as a result of such holdover. No receipt of money by Landlord from Tenant after the termination of this Lease or Tenant's right of possession of the Premises shall reinstate, continue or extend the Term or Tenant's right of possession. The provisions of this subsection (c) shall survive the expiration of the Term.

29. Late Payments. In the event any installment of Rent is not paid within five (5) days after the date when due, Tenant shall pay a one-time administrative fee (the "**Administrative Fee**") equal to five percent (5%) of such past due amount, in order to defray the additional expenses incurred by Landlord as a result of such late payment. If any past due installment of Rent, plus the Administrative Fee, is not paid in full within thirty (30) days after the original due date thereof, then the past due installment, plus the Administrative Fee, will, after expiration of such thirty (30) days and until paid in full, accrue interest at the lesser of (i) one percent (1.0%) per month, compounded monthly or (ii) the maximum interest rate allowed by law (the "**Interest Rate**"). The Administrative Fee and accrual of interest at the Interest Rate are in addition to, and not in lieu of, any of the Landlord's remedies under this Lease for non-payment of Rent.

30. Rules and Regulations. Tenant shall abide by the rules and regulations set forth on **Exhibit D** hereto, as well as other rules and regulations reasonably promulgated by Landlord from time to time, so long as such other rules and regulations do not materially and adversely affect the rights of Tenant hereunder.

31. Quiet Enjoyment. So long as Tenant is in full compliance with all the provisions of this Lease and no Event of Default has occurred and is continuing, Tenant shall have the right to quiet enjoyment of the Premises during the Term by anyone claiming by, through or under Landlord.

32. Miscellaneous.

(a) Tenant certifies, represents, warrants and covenants that: (i) it is not acting and will not act, directly or indirectly, for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department as a terrorist, "**Specially Designated National and Blocked Person**", or other banned or blocked person, entity, nation or transaction pursuant to any law, order, rule, or regulation that is enforced or administered by the Office of Foreign Assets Control; and (ii) it is not engaged in this transaction, directly or indirectly on behalf of, or instigating or facilitating this transaction, directly or

indirectly on behalf of, any such person, group, entity or nation. Tenant agrees to defend (with counsel reasonably acceptable to Landlord), indemnify and hold harmless Landlord and the Landlord's Affiliates from and against any and all claims arising from or related to any such breach of the foregoing certifications, representations, warranties and covenants.

(b) This Lease contains the entire agreement of the parties hereto as to the subject matter of this Lease and no prior representations, inducements, letters of intent, promises or agreements, oral or otherwise, between the parties not embodied herein shall be of any force and effect. Any future amendment to this Lease must be in writing and signed by the parties hereto. Any masculine or neuter pronoun used in this Lease will, as the context requires, include the masculine, feminine and neuter gender. Use of a singular pronoun will, as the context requires, be construed to include the plural. If any clause or provision of this Lease is determined to be illegal, invalid or unenforceable under applicable law, then (i) all remaining provisions of this Lease will remain in full force and effect and (ii) it is the intention of Landlord and Tenant that, in lieu of such illegal, invalid or unenforceable clause or provision, there shall be substituted a clause or provision as similar to such illegal, invalid or unenforceable clause or provision as may be possible and be legal, valid and enforceable.

(c) All rights, powers, and privileges conferred hereunder upon the parties hereto shall be cumulative, but not restrictive to those given by law.

(d) TIME IS OF THE ESSENCE OF THIS LEASE.

(e) No failure of Landlord or Tenant to exercise any power given Landlord or Tenant hereunder or to insist upon strict compliance by Landlord or Tenant with its obligations hereunder, and no custom or practice of the parties at variance with the terms hereof shall constitute a waiver of Landlord's or Tenant's rights to demand exact compliance with the terms hereof.

(f) This contract shall create the relationship of landlord and tenant between Landlord and Tenant; no estate shall pass out of Landlord. Tenant has a usufruct, not subject to levy and sale, and not assignable by Tenant except as expressly set forth herein.

(g) Under no circumstances shall Tenant have the right to record this Lease or a memorandum thereof.

(h) This Lease may be executed in multiple counterparts, each of which shall constitute an original, but all of which taken together shall constitute one and the same agreement. Delivery of a pdf or other electronic counterpart of this Lease executed by a party hereto shall be deemed to constitute delivery of an original hereof executed by such party.

(i) All matters relating to the interpretation, construction, validity and enforcement of this Lease, including all claims (whether in contract or tort) that may be based upon, arise out of or relate to this Lease or the negotiation, execution or performance of this Lease or the transactions contemplated thereby, shall be governed by and construed in accordance with the domestic laws of the state where the Premises are located, without giving effect to any choice of law or conflict of law provision or rule (whether of such state or of any other jurisdiction) that would cause the application of laws of any jurisdiction other than such state.

(j) The captions of this Lease are for convenience only and are not a part of this Lease, and do not in any way define, limit, describe or amplify the terms or provisions of this Lease or the scope or intent thereof. The parties acknowledge that this Lease is the result of negotiations between the parties, and in construing any ambiguity hereunder no presumption shall be made in favor of either party. No inference shall be made from any item which has been stricken from this Lease other than the deletion of such item.

(k) The parties hereto waive trial by jury in any action, proceeding or counterclaim brought by any party(ies) against any other party(ies) on any matter arising out of or in any way connected with this Lease or the relationship of the parties hereunder.

(l) Notwithstanding anything contained in this Lease to the contrary, neither Tenant nor Landlord shall have any liability to the other for any consequential, incidental, indirect, special, exemplary or punitive damages, whether proximately or remotely related to such party's default, except as the same relates to hold over in the Premises or to a party's indemnification obligations as set forth in this Lease.

33. Special Stipulations. The Special Stipulations, if any, attached hereto as **Exhibit C**, are incorporated herein and made a part hereof and, to the extent of any conflict between the foregoing provisions and the Special Stipulations, the Special Stipulations shall govern and control.

34. Authority. Tenant certifies to Landlord that (i) Tenant is duly organized, validly existing and in good standing under the laws of the State of Delaware and duly qualified to do business in the State of Pennsylvania, (ii) Tenant is authorized by all required corporate or partnership action to enter into this Lease, and (iii) the individual(s) signing this Lease on behalf of Tenant are each authorized to bind Tenant to its terms.

35. Prevailing Party. In the event of a dispute between Landlord and Tenant regarding the terms of this Lease, including any dispute regarding the enforcement of this Lease or the interpretation of any provision of this Lease, whether arising in a lawsuit filed by either Landlord or Tenant, an arbitration, bankruptcy or otherwise, the prevailing party in such dispute will be entitled to recover from the other its reasonable attorney's fees and costs actually incurred in connection with such dispute.

36. Force Majeure Delay. Each party shall be excused (excluding Tenant's rent and other monetary obligations hereunder) for delay in the performance of either party's obligations hereunder which is not within the direct control of such party; "Force Majeure Delay" includes without limitation delays resulting from the failure of permits, licenses and approvals to be issued in timely manner, pandemic (e.g., the COVID-19 pandemic), epidemic, strikes or other labor troubles, governmental restrictions and limitations, war or other national emergency, non-availability of materials or supplies, delay in transportation, accidents, floods, fire, damage or other casualties, weather, or delays by utility companies in bringing utility lines to the Premises.

37. No Offer Until Executed. The submission of this Lease by Landlord to Tenant for examination or consideration does not constitute an offer by Landlord to lease the Premises and this Lease shall become effective, if at all, only upon the execution and delivery thereof by Landlord and Tenant. Execution and delivery of this Lease by Tenant to Landlord constitutes an offer to lease the Premises on the terms contained herein. The offer by Tenant will be irrevocable until 6:00 p.m. Eastern time for fifteen (15) days after the date of execution of this Lease by Tenant and delivery to Landlord.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands under seals, the day and year first above written.

LANDLORD:

Date: January 3, 2022

CORE5 AT LAUGHMAN FARMS PHASE 1, LLC, a Delaware limited liability company

By: */s/ Timothy J. Gunter* (SEAL)
Name: Timothy J. Gunter
Title: President and Chief Executive Officer

TENANT:

Date: December 30, 2021

ORASURE TECHNOLOGIES, INC., a Delaware corporation

By: */s/ Stephen S. Tang* (SEAL)
Name: Stephen S. Tang
Title: Chief Executive Officer

TENANT ACKNOWLEDGES THAT SECTION 20(j) OF THIS LEASE CONTAINS THE RIGHT OF LANDLORD TO CONFESS JUDGMENT AGAINST TENANT

SCHEDULE A

"Additional Rent": Any amount other than Base Rent required to be paid by Tenant pursuant to this Lease and any cost or expense incurred by Landlord on behalf of Tenant under the terms of the Lease, including, without limitation, any amount advanced by Landlord to cure a default by Tenant under this Lease.

"Administrative Fee": Defined in Section 29.

"Building Common Area": Areas of the Building and the lot on which the Building is located, including driveways and parking areas associated with the Building which are not designated by Landlord for exclusive use by a particular tenant of the Building, which either serve or are available for use by multiple tenants in the Building, including, without limitation, landscaped areas, sidewalks, pump rooms and electrical panels. Landlord, from time to time, may change the size, location, nature, and use of any of the Building Common Area, convert Building Common Area into leasable areas, construct additional parking facilities in the Common Areas, and increase or decrease Common Area land or facilities so long as Tenant's use of the Premises is not adversely affected in any material way.

"**Change in Control**": Either (a) the transfer of fifty percent (50%) or more of the direct or indirect equity or controlling interests in Tenant in one or more transactions occurring in a twelve (12) month period, whether by sale, merger, consolidation or other transfers of shares, membership, partnership or other equity interests of any kind (by operation of law or otherwise) or (b) the sale or other transfer or disposition of all or substantially all of the assets of Tenant. The transfer of any direct or indirect interests in Tenant which are publically traded on any recognized national or international securities exchange shall not be deemed a Change in Control.

"Change Order": Defined in Exhibit E.

"Code Modification": Any alteration or modification of the Premises, the Building or the Building Common Area required during the Term by Governmental Requirements.

"Contamination": The presence of, or release of, Hazardous Substances into any environmental media from, upon, within, below, into or on any portion of the Premises, the Building, the Building Common Area or the Project so as to require remediation, cleanup or investigation under any Environmental Law.

"Construction Addendum": The Construction Addendum attached hereto as **Exhibit E**.

"Determination Notice": Defined in Section 18.

"Environmental Laws": All federal, state, and local laws, regulations, orders, permits, ordinances or other requirements, which exist now or as may exist after the Lease Date, concerning protection of human health, safety and the environment, all as may be amended from time to time, including, without limitation, the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9601 et seq. ("CERCLA") and the Resource Conservation and Recovery Act, 42 U.S.C. 6901 et seq. ("RCRA"). "Environmental Law" means any one of the Environmental Laws.

"Event of Default": Defined in Section 20(a).

"Federal Reserve Statistical Release": Defined in Section 20(b)(ii).

"Fractional Month": Defined in Section 3.

"Governmental Requirements": All present and future laws, regulations, orders, permits, ordinances, rules and other requirements of federal, state, municipal and local governments and governmental authorities. "Governmental Requirement" means any one of the Governmental Requirements.

“Hazardous Substances”: Any hazardous or toxic substance, material, chemical, pollutant, contaminant or waste, as those terms are defined by any applicable Environmental Law, and any solid wastes, polychlorinated biphenyls, urea formaldehyde, asbestos, radioactive materials, radon, explosives, petroleum products and oil.

“HVAC System”: A heating, ventilation and air conditioning system.

“Interest Rate”: Defined in Section 29.

“Landlord”: Defined in the preamble.

“Landlord’s Affiliates”: The employees, agents and contractors of Landlord.

“Landlord’s Base Building Work”: All of the work and improvements installed or constructed by Landlord in accordance with the Exhibit B.

“Lease”: Defined in the preamble.

“Lease Date”: The later date on which this Lease is signed by Landlord or Tenant, as indicated next to their signatures on this Lease.

“Lease Year”: Defined in Section 3.

“Lender”: The holder of any Mortgage.

“Mortgage”: Each and every deed to secure debt, mortgage, deed of trust or other comparable instrument which may now or hereafter affect or encumber the title of Landlord to the Building, and any amendments, modifications, extensions or renewals thereof.

“Operating Expenses”: Defined in Section 6(a).

“Primary Term”: Defined in Section 3.

“Remaining Term”: Defined in Section 20(b)(ii).

“Rent”: The aggregate amount of Base Rent and Additional Rent.

“Specially Designated Blocked Person”: Defined in Section 32.

“Term”: Defined in Section 3.

“Tenant”: Defined in the preamble.

“Tenant’s Affiliates”: The subsidiaries and affiliates of Tenant and all agents, contractors, employees, vendors, licensees or invitees of Tenant and such subsidiaries and affiliates.

“Tenant Alteration” and “Tenant Alterations”: Defined in Section 17(a).

“Tenant Delay”: Delay in completion of Landlord’s Base Building Work (or other work to be performed by Landlord) resulting from (a) Change Orders or (b) by any other act or omission of Tenant or Tenant’s Affiliates.

“**Transfer**”: Any assignment, mortgage, pledge, encumbering, granting of a license to occupy, subleasing or other transfer of this Lease, or any interest hereunder. A Change in Control shall also be deemed a Transfer.

“Treasury Yield”: Defined in Section 20(b)(ii).

“Utilities”: All natural gas, fuel, electricity, telephone, steam, water, sewer and any and all other utility services provided to the Premises by any public or private utility supplier.

EXHIBIT A

Depiction of Building and Premises

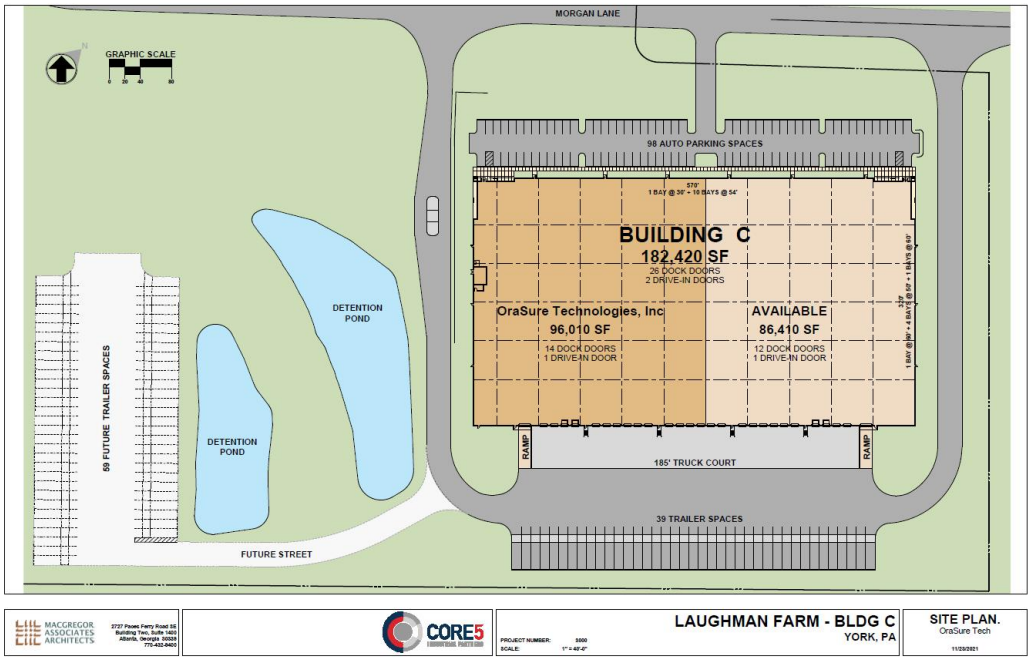

EXHIBIT B

Preliminary Plans and Specifications/Base Building Work

Laughman Farms Building C MEP Drawings

Drawing	Description	Page Number
H-1	Partial Floor Plan HVAC	1 of 18
H-2	Partial Floor Plan HVAC	2 of 18
H-3	Enlarged Floorplan Schedule and Details HVAC	3 of 18
H-4	Specifications HVAC	4 of 18
SE-1	Partial Floor Plan-Lighting	5 of 18
E-1	Partial Floor Plan-Lighting	6 of 18
E-2	Partial Floor Plan-Lighting	7 of 18
E-3	Partial Floor Plan- Power	8 of 18
E-4	Partial Floor Plan- Power	9 of 18
E-5	Schedule and Details Electrical	10 of 18
E-6	Specifications Electrical	11 of 18
E-7	Specifications Electrical	12 of 18
P-1	Plumbing	13 of 18
P-2	Plumbing	14 of 18
P-3	Plumbing	15 of 18
P-4	Plumbing	16 of 18
P-5	Plumbing	17 of 18
P-6	Plumbing	18 of 18

Architectural and Structural

SHEET INDEX

TOTAL SHEETS: 23

ARCHITECTURAL

A0.1	TITLE SHEET
A0.1a	PROJECT DATA
A0.2	GENERAL NOTES
A0.3	ACCESSIBILITY DETAILS
A0.3a	ACCESSIBILITY DETAILS
A0.5	OCCUPANCY AND EGRESS PLAN
A1.0	OVERALL SITE PLAN
A1.1	ENLARGED SITE PLAN
A2.1	FLOOR PLAN
A2.2	OVERALL REFLECTED CEILING PLAN - WAREHOUSE
A3.1	ROOF PLAN
A4.1	EXTERIOR ELEVATIONS
A5.0	BUILDING SECTIONS
A5.1	ENLARGED ELEVATION, PLAN AND WALL SECTIONS
A5.2	ENLARGED ELEVATION, PLAN AND WALL SECTIONS
A6.1	ENLARGED RESTROOM PLANS & ELEVATIONS
A7.1	DOOR SCHEDULE AND DETAILS
A9.2a	GENERAL NOTES
A9.1	DETAILS
A9.2	DETAILS
A9.3	DETAILS
A9.4	DETAILS
A9.5	DETAILS

ARCHITECTURAL SHEET COUNT: 23

STRUCTURAL

S100	GENERAL STRUCTURAL DATA
S200	FOUNDATION PLAN
S201	ENLARGED FOUNDATION PLAN
S210	FOUNDATION DETAILS
S211	FOUNDATION DETAILS
S300	ROOF FRAMING PLAN
S301	TYPICAL FRAMING ELEVATION
S302	MECH/ELECTRICAL ROOM FRAMING
S310	ROOF FRAMING DETAILS
S311	ROOF FRAMING DETAILS
S400	WALL PANEL KEY PLAN
S401	WALL PANEL DETAILS
S410	WALL PANEL LAYOUT
S411	WALL PANEL LAYOUT
S412	WALL PANEL LAYOUT
S413	WALL PANEL LAYOUT
S414	WALL PANEL LAYOUT
S415	WALL PANEL LAYOUT
S416	WALL PANEL LAYOUT
S500	WALL PANEL REINFORCING
S501	WALL PANEL REINFORCING
S502	WALL PANEL REINFORCING
S503	WALL PANEL REINFORCING
S504	WALL PANEL REINFORCING
S505	WALL PANEL REINFORCING
S506	WALL PANEL REINFORCING
S700	STANDARD FABRICATION DETAILS

STRUCTURAL SHEET COUNT: 27

EXHIBIT C

Special Stipulations

The Special Stipulations set forth herein are hereby incorporated into the body of the Lease and to the extent of any conflict between these Special Stipulations and the preceding language, these Special Stipulations shall govern and control.

1. Option to Extend Term.

(a) Landlord hereby grants to Tenant two (2) options to extend the Term for a period of five (5) years each, such option to be exercised by Tenant giving written notice of its exercise to Landlord in the manner provided in this Lease at least two hundred seventy (270) days prior to (but not more than three hundred sixty five (365) days prior to) the expiration of the Term, as it may have been previously extended. No extension option may be exercised by Tenant if an Event of Default has occurred and is then continuing or any facts or circumstances then exist which, with the giving of notice or the passage of time, or both, would constitute an Event of Default either at the time of exercise of the option or at the time the applicable Term would otherwise have expired if the applicable option had not been exercised.

(b) If Tenant exercises its options to extend the Term, Landlord shall, within thirty (30) days after the receipt of Tenant's notice of exercise, notify Tenant in writing of Landlord's reasonable determination of the Base Rent for the Demised Premises for the applicable five (5) year option, which amount shall be based on the greater of (i) the market rate for such space or (ii) the Annual Base Rent rate to be in effect immediately prior to the commencement of such option period. Tenant shall have thirty (30) days from its receipt of Landlord's notice to notify Landlord in writing that Tenant does not agree with Landlord's determination of the Base Rent and that Tenant elects to determine the Prevailing Market Rate (as defined and calculated below). If Tenant does not notify Landlord of such election within thirty (30) days of its receipt of Landlord's notice, Base Rent for the Demised Premises for the applicable extended term shall be the Base Rent set forth in Landlord's notice to Tenant. The phrase "Prevailing Market Rate" shall mean the then prevailing market rate for base minimum rental calculated on a per square foot basis for leases covering buildings comparable to the Building (as adjusted for any variances between such buildings and the Building) located in the area of York, Pennsylvania (hereinafter referred to as the "Market Area"). The Prevailing Market Rate shall be determined by an appraisal procedure as follows:

In the event that Tenant notifies Landlord that Tenant disagrees with Landlord's determination of the market rate and that Tenant elects to determine the Prevailing Market Rate, then Tenant shall specify, in such notice to Landlord, Tenant's selection of a real estate appraiser who shall act on Tenant's behalf in determining the Prevailing Market Rate. Within twenty (20) days after Landlord's receipt of Tenant's selection of a real estate appraiser, Landlord, by written notice to Tenant, shall designate a real estate appraiser, who shall act on Landlord's behalf in the determination of the Prevailing Market Rate. Within twenty (20) days of the selection of Landlord's appraiser, the two (2) appraisers shall render a joint written determination of the Prevailing Market Rate, which determination shall take into consideration any differences between the Building and those buildings comparable to the Building located in the Market Area, including without limitation age, location, setting and type of building. If the two (2) appraisers are unable to agree upon a joint written determination within said twenty (20) day period, the two appraisers shall select a third appraiser within such twenty (20) day period. Within twenty (20) days after the appointment of the third appraiser, the third appraiser shall render a written determination of the Prevailing Market Rate by selecting, without change, the determination of one (1) of the original appraisers as to the Prevailing Market Rate and such determination shall be final, conclusive and binding. All appraisers selected in accordance with this subparagraph shall have at least ten (10) years prior experience in the commercial leasing market of the Market Area and shall be members of the American Institute of Real Estate Appraisers or similar professional organization. If either Landlord or Tenant fails or refuses to select an appraiser, the other appraiser shall alone determine the Prevailing Market Rate. Landlord and Tenant agree that they shall be

bound by the determination of Prevailing Market Rate pursuant to this paragraph. Landlord shall bear the fee and expenses of its appraiser; Tenant shall bear the fee and expenses of its appraiser; and Landlord and Tenant shall share equally the fee and expenses of the third appraiser, if any.

Notwithstanding anything to the contrary contained herein, in the event the Prevailing Market Rate as determined herein is less than the Annual Base Rent to be in effect immediately prior to the commencement of such option period, the Base Rent during the applicable extension Term shall equal the Annual Base Rent in effect during the last year of the Term.

(c) Except for the Base Rent, which shall be determined as set forth in subparagraph (b) above, leasing of the Demised Premises by Tenant for the applicable extended term shall be subject to all of the same terms and conditions set forth in this Lease, including Tenant's obligation to pay Tenant's share of Operating Expenses as provided in this Lease; provided, however, that any improvement allowances, termination rights, rent abatements or other concessions applicable to the Demised Premises during the initial Term shall not be applicable during any such extended term, nor shall Tenant have any additional extension options unless expressly provided for in this Lease. Landlord and Tenant shall enter into an amendment to this Lease to evidence Tenant's exercise of its renewal option. If this Lease is guaranteed, it shall be a condition of Landlord's granting the renewal that Tenant deliver to Landlord a reaffirmation of the guaranty in which the guarantor acknowledges Tenant's exercise of its renewal option and reaffirms that the guaranty is in full force and effect and applies to said renewal.

2. **Building Signage**. As long as no Event of Default shall have occurred and be continuing hereunder, and Tenant is occupying the entire Premises, Tenant shall have the non-exclusive right, at Tenant's sole cost and expense, to place Tenant's graphics identifying the name of Tenant and Tenant's logo (“Tenant’s Building Signage”) on the exterior portion of the Building. The location, size, design and color of Tenant's Building Signage, and the method of attachment thereto, shall be subject to the prior written approval of Landlord. If Tenant shall cease to occupy all of the Premises, or if an Event of Default occurs and shall be continuing hereunder (beyond applicable notice and cure periods), Landlord may cause the removal of Tenant’s Building Signage at Tenant's expense. If the removal of Tenant’s Building Signage causes damage or defacement to the Building, Tenant shall be responsible for the reasonable cost of repair of such damage or defacement. Such obligation shall survive any expiration or termination of the Lease. The Building signage rights set forth in this subparagraph (b) are personal to OraSure Technologies, Inc., and may not be assigned or transferred to any other party without the prior written consent of Landlord.

EXHIBIT D

Rules And Regulations

These Rules and Regulations have been adopted by Landlord for the mutual benefit and protection of all the tenants of the Building in order to insure the safety, care and cleanliness of the Building and Building Common Area and the preservation of order therein.

1. The sidewalks shall not be obstructed or used for any purpose other than ingress and egress. No tenant and no employees of any tenant shall go upon the roof of the Building without the consent of Landlord.

2. No awnings or other projections shall be attached to the outside walls of the Building without the prior written consent of Landlord.

3. The plumbing fixtures shall not be used for any purpose other than those for which they were constructed, and no sweepings, rubbish, rags or other substances, including Hazardous Substances, shall be thrown therein.

4. No tenant shall cause or permit any objectionable or offensive odors to be emitted from the Premises. Smoking is prohibited within the Building and in outdoor areas located within twenty-five (25) feet of entry-ways, outdoor intakes and operable windows.

5. The Premises shall not be used for (i) an auction, "fire sale", "liquidation sale", "going out of business sale" or any similar such sale or activity or (ii) lodging or sleeping.

6. No tenant shall make, or permit to be made any unseemly or disturbing noises, sounds or vibrations or disturb or interfere with tenants of this or neighboring buildings or premises or those having business with them.

7. Each tenant must, upon the termination of this tenancy, return to the Landlord all keys of stores, offices, and rooms, either furnished to, or otherwise procured by, such tenant, and in the event of the loss of any keys so furnished, such tenant shall pay to the Landlord the cost of replacing the same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such change.

8. Canvassing, soliciting and peddling in the Building and the Project are prohibited and each tenant shall cooperate to prevent such activity.

9. Landlord will direct electricians as to where and how telephone, telegraph, computer and other wires and cables (collectively, “Wires”) are to be introduced. No boring or cutting for Wires or stringing of Wires will be allowed without written consent of Landlord. The location of telephones, call boxes and other office equipment affixed to the Premises shall be subject to the approval of Landlord. Tenant shall remove all Wires from the Premises by the end of the Term.

10. Parking spaces associated with the Building are intended for the exclusive use of passenger automobiles. Except for intermittent deliveries, no vehicles other than passenger automobiles may be parked in a parking space (other than spaces expressly designated for such purpose by Landlord for truck parking) without the express written permission of Landlord. Trucks may be parked only in truck dock positions and in other paved areas expressly designated for such purpose by Landlord. Trailers may be parked only in paved areas expressly designated for such purpose by Landlord. Neither trucks nor trailers may be parked or staged in (i) areas adjacent to truck docks, serving any portion of the Building, which are intended by Landlord for truck maneuvering or (ii) any driveway, drive aisle or other paved area which provides ingress or egress for cars or trucks to or from any portion of the Building or any street adjoining the Building. Tenants may only use that portion of the truck court for truck and trailer parking or staging that is contiguous to the Premises (i.e. the truck court area that would be included in the area if the sidewalls of the Premises were extended into the truck court).

11. No tenant shall use any area within the Project for storage purposes other than the interior of the Premises, unless otherwise expressly consented to in writing by Landlord.

12. Tenant will have the right to stripe or mark the floor of the Building only in compliance with this rule. Landlord strongly encourages Tenant to stripe or otherwise mark the floor of the Building only with 3M floor striping tape. If Tenant elects to paint stripes or other markings on the floor of the Building, all such paint must, prior to expiration or termination of this Lease, be removed by Tenant at its expense in accordance with this rule. Paint on the floor of the Building must be removed only by use of a chemical paint remover; provided that the chemical used for removal must be permissible for such use under Environmental Laws and other Governmental Requirements and the chemical must be used (and all chemicals and removed paint must be disposed of) in accordance with Environmental Laws and other Governmental Requirements. Under no circumstances may paint be removed from the floor of the Building by grinding, scraping or shot-blasting. After paint has been chemically removed in accordance with this rule, the floor must be thoroughly cleaned to remove completely any chemical residue which might be present as a result of the removal process.

13. If Tenant installs any racking, equipment or machinery in the Building which requires installation of bolts in the floor of the Building, Tenant must, prior to expiration or termination of this Lease, at the expense of Tenant, remove all such bolts in accordance with this rule. All bolts will be cut or ground so that the top of the remaining portion of the bolt is at least one-quarter inch below the surface of the floor. All holes created by such removal of bolts must be filled with 100% epoxy, which meets the standards set by the American Concrete Institute and which is color-matched to the floor being filled.

EXHIBIT E

CONSTRUCTION ADDENDUM

1. Tenant shall be responsible for constructing the interior improvements within the Premises (the "**Leasehold Improvements**"). Tenant's proposed architect/engineer and construction contractor is subject to Landlord's prior approval, which approval shall not be unreasonably withheld or delayed. Tenant shall, at its sole cost and expense, and no later than April 1, 2022, prepare and submit to Landlord for Landlord's written approval or disapproval (which approval will not be unreasonably withheld or conditioned) a complete set of plans and specifications and construction drawings (collectively, the "**Tenant Work Plans and Specifications**") covering all work to be performed by Tenant in constructing the Leasehold Improvements. The Tenant Work Plans and Specifications shall be in such detail as Landlord may reasonably require and shall be in compliance with all applicable statutes, ordinances and regulations; provided, however, that Landlord's approval of the Tenant Plans and Specifications shall not be deemed to be a warranty or representation that the Tenant Plans and Specifications comply with all applicable statutes, ordinances and regulations. Landlord shall review the Tenant Plans and Specifications and indicate requested changes, if any, by written notice to Tenant, within fifteen (15) days after receipt of the Tenant Plans and Specifications by Landlord.

2. Before starting construction of any Leasehold Improvements, Tenant shall procure, and provide Landlord with copies of, all permits, licenses, consents, notices and other approvals necessary to commence such work from all public and quasi-public authorities with jurisdiction (collectively, the "**Construction Permits**"). In connection with completion of any of the Leasehold Improvements, Tenant shall: (i) procure, and provide Landlord with copies of, all necessary permits, licenses, consents and other approvals, including without limitation a certificate of occupancy; and (ii) comply with all Governmental Requirements.

3. Tenant or its contractor shall use reasonable speed and diligence to construct the Leasehold Improvements in a good, first-class, workmanlike and timely manner and in accordance with the Tenant Plans and Specifications and Tenant shall not unreasonably interfere with Landlord's completion of Landlord's Base Building Work at the Premises. Tenant shall carry, or cause its contractor to carry, insurance reasonably satisfactory to Landlord throughout the construction of the Leasehold Improvements. Regardless of whether or not Tenant is able to Substantially Complete the Leasehold Improvements or commence business operations from the Premises by the date of Substantial Completion of Landlord's Base Building Work, Tenant's obligation to pay Base Rent and Additional Rent hereunder shall nevertheless begin in accordance with the terms of this Lease.

4. Upon Substantial Completion of the Leasehold Improvements, a representative of Landlord and a representative of Tenant together shall inspect the Premises and generate a punchlist of defective or uncompleted items relating to the completion of construction of the Leasehold Improvements. Tenant shall, within a reasonable time after such punchlist is prepared and agreed upon by Landlord and Tenant, complete such incomplete work and remedy such defective work as are set forth on the punchlist.

5. Landlord shall reimburse Tenant for Tenant's costs (as defined in subsection (d) below) incurred in constructing the Leasehold Improvements, up to an amount of Four Hundred Eighty Thousand Fifty and 00/100 Dollars ($480,050.00)) (the "**Tenant Allowance**") as follows:

(a) Landlord shall pay the Tenant Allowance to Tenant at such time that Tenant's contractor has:

(i) substantially completed the Leasehold Improvements and received a certificate of occupancy from the applicable governing authority;

(ii) delivered to Landlord lien waivers and affidavits from Tenant's contractor, all subcontractors, and all laborers or materials suppliers having performed any work at the Premises relating to the Leasehold Improvements, together with any other evidence reasonably required by Landlord to satisfy Landlord's title insurer that

there are no parties entitled to file a lien against the real property underlying the Building in connection with such work; and

(iii) delivered to Landlord all invoices, receipts and other evidence reasonably required by Landlord to evidence the cost of the Leasehold Improvements.

(b) Tenant's costs for construction of the Leasehold Improvements shall include all “hard” and “soft” costs associated with the construction of the Leasehold Improvements, which shall include without limitation, the cost of the Tenant Work Plans and Specifications, Construction Permits and all tenant buildout.

(c) The Tenant Allowance must be used within twelve (12) months following the Lease Commencement Date or shall be deemed forfeited with no further obligation by Landlord with respect thereto, time being of the essence with respect thereto,

(d) Tenant shall be responsible for all costs of construction of the Leasehold Improvements in excess of the Tenant Allowance.

6. Landlord and Tenant acknowledge that Landlord will install a 2,000 amp main electrical panel at the Building. Tenant shall be able to utilize up to 1,000 amps of electrical service from such panel. Any electrical service requirements by Tenant in excess of 1,000 amps and costs related thereto will be subject to deduction from the Tenant Improvement Allowance or paid directly by Tenant to Landlord upon demand.

Exhibit 23

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-262633 and No. 333-2288) on Form S-3 and registration statements (No. 333-248424, No. 333-220148, No. 333-118385, No. 333-102235, No. 333-50340, No. 333-138814, No. 333-151077, No. 333-176315 and No. 333-198237) on Form S-8 of OraSure Technologies, Inc. of our reports dated March 1, 2022, with respect to the consolidated financial statements of OraSure Technologies, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 1, 2022

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ Mara G. Aspinall
Signature

Mara G. Aspinall
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ Michael Celano
Signature

Michael Celano
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ James. A. Datin
Signature

James A. Datin
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

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

Nancy J. Gagliano, M.D.
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ Eamonn P. Hobbs
Signature

Eamonn P. Hobbs
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022..

/s/Ronny B. Lancaster
Signature

Ronny B. Lancaster
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher** 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, 2021, 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 10, 2022.

/s/ Lelio Marmora
Signature

Lelio Marmora
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher** 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, 2021, 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 10, 2022.

/s/ David J. Shulkin
Signature

David J. Shulkin
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ Stephen S. Tang, Ph.D.
Signature

Stephen S. Tang, Ph.D.
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Agnieszka M. Gallagher,** 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, 2021, 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 10, 2022.

/s/ Anne C. Whitaker
Signature

Anne C. Whitaker
Print Name

Exhibit 31.1

Certification

I, Stephen S. Tang, Ph.D., 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 1, 2022

/s/ Stephen S. Tang
Stephen S. Tang, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Scott Gleason, 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 1, 2022

/s/ Scott Gleason
Scott Gleason
Interim Chief Financial Officer & Senior Vice President of Investor Relations and Corporate Communications
(*Principal Financial 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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen S. Tang, Ph.D., 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/ Stephen S. Tang
Stephen S. Tang, Ph.D.
President and Chief Executive Officer

March 1, 2022

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Gleason, Interim Chief Financial Officer and Senior Vice President of Investor Relations and Corporate Communications 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/ Scott Gleason
Scott Gleason
Interim Chief Financial Officer and Senior Vice President of Investor Relations and Corporate Communications

March 1, 2022