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, 2020

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 **(State or Other Jurisdiction of Incorporation or Organization)**	**36-4370966** **(I.R.S. Employer Identification No.)**
220 East First Street **Bethlehem, Pennsylvania** **(Address of Principal Executive Offices)**	**18015** **(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, 2020)**:** $829,039,107

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 22, 2021: 71,945,502 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

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This Report contains certain "forward-looking statements," within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, losses, expenses or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, expected manufacturing performance, 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: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; 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; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collection 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; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; 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 ("CDC") or other agencies; ability to fund research and development and other products and operations; 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; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; 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; ability to attract and retain qualified personnel; 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 are made as of the date of this Annual Report and we undertake no duty to update these statements.

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.

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.

PART I

ITEM 1. Business.

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 is made up of two principal segments. The first is our Diagnostics business, previously named "OSUR", which consists primarily 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. Our diagnostic products include 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., which we acquired and merged into OraSure in 2020. This part of the business develops and commercializes products that determine adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV infection. These products include laboratory-based tests that can measure levels of the medication in a patient's urine or blood, as well as point-of-care products currently in development.

The second segment is our Molecular Solutions business, previously named "DNAG," which is operated primarily through our subsidiaries, DNA Genotek Inc. ("DNAG"), a company based in Ottawa, Canada, Diversigen, Inc. ("Diversigen") and Novosanis NV ("Novosanis"). In the Molecular Solutions business, we manufacture and sell kits that are used to collect, stabilize, transport and store biological samples 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. Included in the disease risk management area are pharmacogenomics testing, hereditary disease screening, prenatal or cancer screening, population health initiatives and other molecular testing using DNA or RNA for diagnosis of acute disease. We also sell research use only collection products into the microbiome market. We also 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.

Additional information about us can be found on our website, www.orasure.com. We make available free of charge through a link provided at such website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and our other filings with the Securities and Exchange Commission ("SEC"), as well as any amendments to those Reports and filings. These Reports and filings are made available as soon as reasonably practicable after they are filed with or furnished to the SEC. Our website and the information contained in or connected to that website are not intended to be incorporated by reference into this Annual Report.

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:

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. We have also received a CE mark for the OraQuick® In-Home HIV test, although this product is not currently sold in the European Union. 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 at a lower cost to meet the needs of those markets. This product has received WHO pre-qualification and is eligible for procurement by purchasing entities entitled to access funding and other resources from the Global Fund, UNITAID and other agencies.

OraQuick® HCV Rapid Antibody Test

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

We have received FDA 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 or 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 ("Thermo Fisher"). Under the Thermo Fisher agreement, we intend to obtain FDA 510(k) clearance of our device for use with a 12-assay panel of the Thermo Fisher assays that will meet the oral fluid drug testing guidelines issued by the Substance Abuse and Mental Health Services Administration ("SAMHSA").

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 a number of genomic products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA and/or RNA from human and animal biologic 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 different configurations and contain proprietary chemical solutions that are 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 simply hold the product close to their mouth and spit into the collection device. When the container is closed, the reagents stored in the lid of the container 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 results in 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, use of simple non-invasive collection methods, the ability to store and transport collected samples for extended periods at ambient temperatures and 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 Products

During 2020, we 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 very broad spectrum of microbiome activity spanning bacteria to viruses and 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. Unlike nasopharyngeal and oropharyngeal swabs which cannot be self-administered easily, our products are optimized for self-collection. That means healthcare providers, retailers, and online vendors could ship our kits directly to an individual's home, eliminating unnecessary trips to hospitals, doctors' offices and testing facilities. Self-collection would also support the social distancing guidelines already in place in many communities, reduce the burden on testing sites and healthcare facilities, and provide 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 usability and form factor of these products are conducive to use in at-home or clinic settings.

As a result, during 2020 we began selling 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.

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 environment fluctuations. In order to optimize and standardize sample results, a reliable method that captures and preserves ("snapshots") the microbiome after collection until analysis is required. 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 clinical laboratory and research settings. Current methodologies for gut microbiome profiling have distinct shortcomings due to the introduction of bias, leading to a lack of reproducibility in the field. Our product ensures that the fecal sample is fully stabilized immediately upon collection and maintains an accurate and reliable bacterial profile for weeks at room temperature. We have also begun marketing other microbiome collection kits for skin, vaginal and oral 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 services of our CoreBiome and 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, to unleash the translational potential of the microbiome and provide fast and information-rich characterizations of microbial diversity and function paired with expert analytics. We also provide comprehensive microbiome and metagenomics services focused on solutions to improve human, animal and environmental health. Diversigen has extensive experience with highly diverse microbiome sample types and provides full project life cycle consulting services, including pre-project consulting, study design, extraction and sequencing to complete bioinformatics analysis. Diversigen is at the forefront for setting quality standards for this industry and is in the process of obtaining College of American Pathologists ("CAP") accreditation at its laboratory facilities. We are also in the process of integrating the services offered through GenoFIND™, CoreBiome and Diversigen into a unified offering and brand for our customers.

Regulatory Approvals.

Our Molecular Solutions products historically have been sold primarily as Class I medical devices for use by research and academic institutions. We have received FDA 510(k) clearance of the Oragene® • DX product for use with the eSensor® Warfarin sensitivity saliva test. A separate 510(k) clearance permits self-collection by consumers when the sample is to be tested with either an exempt or 510(k) cleared molecular test. More recently, we received a generic 510(k) clearance for this product, which we believe will further broaden the use of our Oragene®• DX device. Our ORAcollect® product similarly received 510(k) clearance from the FDA. We have also received CE mark approval for the Oragene® • DNA, ORAcollect® and OMNIgene® • GUT collection kits. Diversigen provides molecular services in CLIA-certified laboratories and as noted above, and is in the process of obtaining CAP accreditation.

With respect to COVID testing, our collection devices have been included in FDA Emergency Use Authorizations ("EUAs") granted to a number of third parties for use with COVID-19 molecular test offerings. These EUAs permit the use of our devices in healthcare settings or in some cases in at-home or unsupervised settings for the collection of samples. Our DNA Genotek subsidiary also received FDA EUAs for the use of its OMNIgene® •ORAL and ORAcollect® •RNA collection devices in COVID-19 testing which allows for the unsupervised use of these devices at home or in healthcare settings when used as part of an approved or validated at-home test kit. With these FDA authorizations, the OMNIgene® • ORAL and ORAcollect® •RNA devices can be used for the self-collection, transport and laboratory testing of saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), without the presence of a healthcare professional, before sending the sample to a lab for analysis. These products are also CE marked for in vitro diagnostic use, including for COVID-19 testing, in the European Union.

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 monitoring, rapid tests for diseases other than HIV and HCV and drug testing. In 2020, significant time and resources were dedicated to the development of our COVID-19 Rapid Antigen Self-Test. Subject to regulatory approvals, the Company intends to introduce its antigen test to the market for three different uses:

- **Professional Test** 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 have completed development of the COVID-19 Rapid Antigen Self-Test and have collected all clinical study data to submit both the Prescription Self-Test and the Professional Test versions of this product for EUA at the same time, which is expected to occur in the first quarter of 2021. Subject to receipt of EUA, this product would test for active COVID-19 infection using nasal samples self-collected from the lower nostril. After we submit the Professional Test and Prescription Self-Test for EUA, we intend to continue plans to pursue an OTC claim.

During the third quarter of 2020, limit of detection studies for the assay were completed with live coronavirus in a certified third party analytical laboratory, with results comparable to that of another EUA approved, instrument-free, rapid antigen test. The results from the limit of detection comparison provides further confidence that the proprietary chemistries incorporated on OraSure's lateral flow test strip will deliver the analytical sensitivity needed. Although the timing of EUA approval is subject to FDA review, the Company will be prepared to launch the test, subject to authorization, without delay following such approval. Subject to receipt of EUA, this product would test for active COVID-19 infection using nasal samples collected from the lower nostril. Results would be available at the point of collection, with no special instrumentation needed to interpret result.

In addition to a rapid antigen self-test, we are developing a lab-based oral fluid microplate SARS-CoV-2 antibody enzyme-linked immunosorbent assay ("ELISA"). The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies (including IgM/IgA/IgG) to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device. To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. Oral sample collection is quick, painless, non-invasive and requires less human contact in comparison to a blood draw, minimizing the need for personal protective equipment and exposure to potentially infected patients. With this test, individuals would use a collection pad to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the OraSure oral antibody collection device buffer for storage and transport, and then later dispensed onto the ELISA microplate for testing in a laboratory. The lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Antibody tests are well suited for community surveillance and seroprevalence studies to identify people in a population or community that have antibodies against an infectious disease such as COVID-19. In addition, the OraSure SARS-COV-2 Antibody ELISA can detect antibodies developed from vaccination.

In October 2020, the Company submitted an EUA application to the FDA for its SARS-CoV-2 Antibody ELISA test and in December 2020, the FDA requested additional information as part of its review of our EUA submission. At the FDA's request, we are performing additional analytical studies on sample collection and stability and, after data from these studies have been obtained, we intend to resubmit two separate EUAs – one for the ELISA and one for the collection device.

During 2020, a significant amount of time was also devoted to the oral fluid drug assay development efforts with Thermo Fisher. Another development area focused on increasing the number of country registrations for our HIV Self-Test. Finally, we are also working to develop a rapid point-of-care assay to determine HIV drug adherence to be sold in the same markets where we currently sell our HIV diagnostic products.

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 RNA collection and stabilization. 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. We are also evolving the physical design and features of our products to further enable high throughput processing through improved interoperability with automated platforms.

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 technology, as well as providing new and relevant services to our customers. These development goals are being pursued while we also leverage new sequencing technologies and methodologies to enable scalability for our business.

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 $130.8 million, $107.3 million and $136.8 million in 2020, 2019 and 2018, respectively. Consolidated net revenues attributable to international customers amounted to $40.9 million, $47.3 million and $44.9 million, or 24%, 31% and 25% of our total revenues, in 2020, 2019 and 2018 respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Notes 2 and 13 to our consolidated financial statements included elsewhere in this Annual Report.

Diagnostics - Professional

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 directly to hospitals in the U.S. primarily through distributors. We also use distributors to sell our OraQuick ADVANCE® test into the U.S. physician office market and to retail clinics operated by pharmacies. 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 OraQuick® In-Home test in the U.S. retail or consumer market. Retailers carrying the product include CVS, Walgreens, Rite Aid and Walmart. 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 expires in 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® 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. Under our Thermo Fisher agreement, we intend to obtain FDA 510(k) clearance of our Intercept i2® device for use with the NIDA-5 assay panel, along with an additional six fully-automated high-throughput assays in order to expand sales of this product line into the workplace testing market and other markets that require 510(k) cleared drug tests. These products are expected to meet recent oral fluid drug testing guidelines issued by SAMHSA, which will enable us to expand sales into markets where employee drug testing is federally regulated.

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 and 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 to establish itself as the leader 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 so that we can now provide a single-integrated offering to our customers 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,		
	2020	2019	2018
Genomics	$37,141	$56,200	$79,765
OraQuick® HIV	44,224	43,092	41,457
COVID-19	49,802	—	—

One of our customers accounted for approximately 15% and 24% of our net consolidated revenues in 2019 and 2018, respectively. We had no customers in 2020 that accounted for more than 10% of our net consolidated revenues.

Supply and Manufacturing

We manufacture all of our OraQuick *ADVANCE*® HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraQuick® Ebola test, OraSure®, Intercept® and Intercept i2® collection devices, AUTOLYTE and MICRO-PLATE assays and QED® 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® HIV device and the OraQuick® HIV Self-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 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 intend to manufacture our COVID-19 Rapid Antigen Self-Test and OraSure SARS-CoV-2 Antibody ELISA in our Bethlehem, Pennsylvania facilities. In addition, we plan to manufacture our COVID-19 Rapid Antigen Self-Test at a third party in Thailand in order to supply certain international markets. We made significant capital investments during 2020 and will continue to invest to add the manufacturing capacity needed to meet the expected demand for these products. Specifically, we plan to add capacity of 70 million tests per year (which includes tests for HIV, HCV and Ebola) to meet demand for the COVID-19 Rapid Antigen Self-Test in the U.S. by the third quarter of 2021, and capacity for an additional 50 million tests per year by the second quarter of 2022 to support sales of this product outside of the U.S. We expect to add capacity of 20 million tests per year (including existing products) to meet demand for our OraSure SARS-CoV-2 Antibody ELISA by the fourth quarter of 2021.

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® collection device are manufactured and supplied under a long-term agreement with Thermo Fisher. There is no other supply source for these products.

DNAG has three long-term contract manufacturing relationships to supply virtually all of its products, including the Oragene® product line. Many of the raw materials and components used in these products are also purchased from third parties, including one critical component that is purchased from a sole source supplier. We believe there are other suppliers that can manufacture and supply the raw materials and components for the DNAG products. We are increasing capacity for our molecular collection kits to meet demand for COVID molecular testing to 80 million kits per year (including non-COVID kits) by the third quarter of 2021.

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, 2020, we had 570 full-time employees, which compares to 472 employees as of December 31, 2019. The increase in employees during 2020 was primarily the result of the need to add manufacturing capacity for our COVID-19 Rapid Antigen Self-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 2020, in response to the COVID-19 pandemic, we implemented 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 modified the way we conduct many aspects of our business to reduce the number of in-person interactions. For example, we significantly expanded the use of virtual interactions in all aspects of our business, including customer facing activities. Many of our administrative and operational functions during this time have required modification as well, including much of our workforce working remotely.

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.

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.

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

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.

Several companies market or have announced plans to market oral specimen collection devices and tests both within and outside the United States. We expect the number of devices competing with our OraQuick®, OraSure®, Intercept® and Intercept i2® devices to increase as the benefits of oral fluid-based testing become more widely accepted.

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 point-of-care rapid blood tests, automated laboratory-based blood tests, or other oral fluid-based tests. Our competitors sell both a rapid oral fluid HIV test and a rapid HIV antigen/antibody test that are both FDA approved and CLIA waived. 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 competitors in the domestic infectious disease testing market include medical diagnostic companies and specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions. Competing tests are often sold at a lower price than we charge for our products. This competition can result in lost sales and degradation of the price (and therefore the applicable profit margins) we can charge for our HIV and HCV tests.

Outside the U.S., our rapid HIV and HCV tests compete against other rapid and laboratory-based tests. Significant sales of these products in Europe have not materialized principally because of differences in European healthcare systems compared to U.S. systems. Unlike in the U.S., adoption of rapid point-of-care diagnostics is not widespread in Europe because laboratory testing is entrenched and healthcare systems are structured around centralized testing models. In addition, many competing tests in international markets are sold at very low prices. We intend to continue to build awareness and develop strategies to expand sales of our OraQuick® HIV and HCV tests in European and other international markets.

Our OraQuick® In-Home HIV oral fluid test is the only rapid HIV test approved by the FDA for sale in the U.S. OTC market. We compete against one other non-rapid HIV blood test available in the OTC market, which requires consumers to self-collect a blood sample and then send it to a laboratory for testing. We expect that other non-rapid HIV blood tests will eventually compete with our product. The OraQuick® HIV Self-Test that we sell in certain international markets is facing competition from other blood-based rapid HIV self-tests.

In the United States there are currently four rapid COVID-19 self-tests on the market that are expected to compete against our COVID-19 Rapid Antigen Self-Test. There are several other Professional point of care COVID-19 antigen tests with EUA in the United States which are expected to compete with the Professional use version of our antigen test. In addition, there are a number of COVID-19 blood-based antibody tests sold in the U.S. market that are expected to compete against our OraSure SARS-CoV-2 Oral

Fluid Antibody ELISA. We also expect additional rapid COVID-19 antigen tests and COVID-19 antibody tests to enter the market both in the U.S. and in international markets that will compete against our COVID-19 assays.

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.

There are at least two competitors that sell fully-automated high-throughput oral fluid drug testing products in unregulated settings in the United States. These competitors sell these assays for use with either their own oral fluid collector or a collector manufactured by another party. These offerings compete against our Intercept® and Intercept i2® collection devices and related oral fluid assays.

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. These tests provide strong competitive pressure because they provide the benefits of automation, including lower costs and short turn-around times.

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, these tests are qualitative tests that are believed to be substantially 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 four 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 May 2021 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 two pending patents in the United States for our COVID-19 Rapid Antigen Self-Test and we expect to file additional patent applications for this product in certain international markets.

We hold, through our subsidiary, DNAG, twenty-two 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 March 2035.

We hold through our subsidiary, Novosanis, one granted United States patents 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®, OraQuick®, OraQuick *ADVANCE*®, OraSure QuickFlu®, Q.E.D.®, Oragene®, DNA Genotek™, OMNImet™, ORAcollect®, OMNIgene®, Diversigen®, Colli-Pee®, 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 downclassified 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 EUA. FDA may grant an EUA application 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 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 postmarket 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 postmarket 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 postmarket 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 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. Manufacturers of currently approved medical devices will have until May 2021 to meet the requirements of the EU MDR and until May 2022 to meet the EU IVDR. 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 June 2019.

We have obtained WHO pre-qualification for our OraQuick® HIV Self-Test and OraQuick® HCV test and we will likely seek WHO pre-qualification or endorsement for certain other products sold into international markets.

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

Below is a summary of the principal factors that could adversely affect our business, operations and financial results. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this summary, and other risks that we face, 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 has significantly and adversely affected our consolidated results of operations, financial position and cash flows and may continue to do so.
- 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 U.S. government contracts may affect our intellectual property rights.
- Our U.S. government contracts and related administrative processes are subject to audits and cost adjustments by the federal government.

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 Collaborators

- 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 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, together with all of the other information included in this Annual Report and our other SEC filings, in considering our business and prospects. 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 ancestry testing which offers products and services to consumers to provide them with genealogical information. The ancestry market is maturing and sales to this market have declined in recent periods. Our genomics revenues have been reduced, primarily due to a change in promotional strategies and purchasing patterns by our largest customer which serves the consumer ancestry and genetic testing market. This trend in the ancestry testing market is continuing and is expected to adversely affect our revenues and results of operations in future periods.

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 market, we believe there is significant growth opportunity for our genomics products in the area of disease risk management ("DRM"). However, during 2019, the U.S. Department of Justice ("DOJ") investigated several telemedicine companies and individuals for allegedly submitting fraudulent insurance claims to Medicare for cancer genetic screening and pharmacogenomics testing. Several of our customers were included in the DOJ investigation. These activities have had a negative impact on our revenues and to the extent such allegedly fraudulent insurance billing practices continue, our future genomic revenues could be adversely affected.

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

We believe successful new product and service introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product or service and are reluctant to switch thereafter. Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as our in-home antigen pan-SARS-coronavirus self-test ("Coronavirus Self-Test"), laboratory-based oral fluid SARS-CoV-2 antibody test ("Coronavirus Antibody Test"), 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 substantial marketing efforts and spend significant funds to complete product development and clinical studies and 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. It is also possible that governmental funding may be limited for new products, such as our Coronavirus Self-Test and Coronavirus Antibody Test or the new sample collection and stabilization products being commercialized by DNAG. Also, we are still in the process of developing and seeking regulatory authorization for the Coronavirus Self-Test and Coronavirus Antibody Test and validating the use of existing products for pan-SARS-coronavirus testing, 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, clearances or EUAs 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. In addition, it is possible that our expenses to develop and market any such products, including, without limitation our Coronavirus Self-Test and Coronavirus Antibody Test, will exceed any benefit in revenues, which may be short-lived, or that other products that compete with ours achieve commercial acceptable earlier than we do.

We May Not Realize Anticipated Revenue From Our COVID-19 Diagnostic Assays.

We are developing assays to detect antigen and antibodies to the coronavirus, which causes the infectious disease known as COVID-19. While we expect to see significant demand for our COVID-19 assays, other companies are working to produce or have produced 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 Europe. The anticipated effectiveness 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 may be a significantly reduced demand for ongoing testing, and thus, for our COVID-19 assays. There is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce our COVID-19 assays in quantities to meet the demand. A significant decline in demand for our COVID-19 assays 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 Has Significantly And Adversely Affected Our Consolidated Results of Operations, Financial Position and Cash Flows, and May Continue To Do So.

Although we have experienced heavy demand for 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 molecular testing is uncertain. We believe the COVID-19 pandemic's adverse impact on its 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 COVID-19 pandemic's impact on the U.S. healthcare system and the U.S. economy; and (iii) the timing, scope and effectiveness of federal, state and local governmental responses to the COVID-19 pandemic, including the development and deployment of vaccines.

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 intend to obtain EUAs for our new COVID-19 Rapid Antigen Self-Test and OraSure SARS-CoV-2 antibody ELISA. 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 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 EUA's 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. We expect that clinical reference and other hospital-based laboratories will continue to compete vigorously against our rapid point-of-care 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 similar 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. 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 antibodies or antigen to SARS-CoV-2 that will compete with our COVID -19 diagnostic products once completed and authorized for sale.

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, to create rapid tests for COVID-19. Many of these entities have substantially greater resources (including capital and personnel) than we do. In addition, some of these entities are or may be further ahead in the development and commercialization of tests than we are. Even if we are successful in developing and marketing tests for COVID-19, 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. We also sold large quantities of our OraQuick® HCV test to foreign governments and agencies for use in broad-based or country-wide HCV elimination programs. 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 believe there is a significant opportunity for international sales of our SARS-CoV-2 diagnostic products once these products are available for sale.

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 other cheaper 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 $40.9 million or 24% of consolidated net revenues in 2020, $47.3 million or 31% of consolidated net revenues in 2019 and $44.9 million or 25% of consolidated net revenues in 2018. In addition, our subsidiary DNAG, which accounted for $97.3 million or 57% of consolidated net revenues in 2020, is operated in Canada. In 2019 we also recently 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;
- Multiple jurisdictions and differing tax laws, 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® 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. 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. 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. 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 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 the Biomedical Advanced Research and Development Authority ("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.

Risks Relating to Our Industry, Business and Strategy

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.

Starting in 2020, we have been investing significant time and resources in developing two diagnostic products for SARS-CoV-2 and pursuing EUA for these products from the FDA. If these efforts are successful we believe these products could contribute significant revenues once commercialized. We are also investing significantly to expand our manufacturing capacity to ensure we can satisfy the expected demand for these products.

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. Additionally, if we are not successful in commercializing our planned SARS-CoV-2 assays, the investment in expanded manufacturing capacity may not be fully utilized.

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. 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 CoreBiome and 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. Although we are optimistic about the prospects for these new businesses, 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.

The Future results of Acquired Companies May Be Adversely Impacted if We Do Not Effectively Manage Our Expanded Operations.

Following the completion of recent acquisitions, the size of our business has increased and these acquisitions are expected to enhance our growth in future periods. Our ability to successfully manage this expanded business will depend, in part, upon management's ability to design and implement strategic initiatives that address not only the integration of the two companies, but also the increased scale and scope of the combined businesses with its associated increased costs and complexity. There can be no assurances that we will be successful and the acquisitions may have an adverse effect on the Company.

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, domestic professional OraQuick® HIV sales 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 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 Collaborators

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 a third party in Thailand for 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, could 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:

- As is common with major litigation, 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.

We are developing and are or will be seeking EUA for a rapid pan-SARS coronavirus antigen self-test and a lab-based SARS-CoV-2 oral fluid antibody test. There is no assurance that we will obtain an EUA for either or both of these products. Failure to do so could result in the loss of potential future revenues and adversely affect our business 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. 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 recently completed a merger of our wholly owned subsidiary, UrSure, Inc. Given that UrSure, Inc. collects certain protected health information, or PHI, it is a Business Associate subject to HIPAA. As a result of the merger, the PHI collected cannot be walled off from the Company and the Company is now subject to HIPAA. 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. 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.

Given the recent integration of UrSure, we now collect, process or maintain sensitive information, such as patient data and other personal information, on a limited basis. If we do use or not adequately safeguard that information in compliance with applicable requirements under state, federal and international laws, or if it were disclosed to persons or entities that should not have access to it, our business could be materially impaired, our reputation could suffer and we could be subject to fines, penalties and litigation. In the event of a data security breach, we may be subject to notification obligations, litigation and governmental investigation or sanctions, and may suffer reputational damage, which could have an adverse impact on our business. We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including: (a) HIPPA and the regulations thereunder, which establish (i) a complex regulatory framework including requirements for safeguarding protected health information and (ii) comprehensive federal standards regarding the uses and disclosures of protected health information.

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.

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 LDT's 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 ("CGx") 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 2020, approximately $40.9 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 began in December 2019. Many economists and major investment banks have expressed concern that the continued spread of the virus globally has led or will lead 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 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.

The duration of the COVID-19 pandemic is 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, 2020, our consolidated balance sheet reflected approximately $40.4 million of goodwill and approximately $17.9 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. In addition, as of December 31, 2020, the Company had an accumulated deficit of $96.9 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 successfully commercialize a rapid pan-SARS coronavirus antigen self-test and a lab-based SARS-CoV-2 oral fluid antibody test;
- Our ability to mitigate declining sales of 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; and
- 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;
- 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;
- 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 commercialize a rapid pan-SARS coronavirus antigen test and a lab-based SARS-CoV-2 oral fluid antibody test;
- 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 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 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. Spear phishing has occurred and is a growing threat that the Company is facing. 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 shut downs 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 or Other Catastrophic Events Outside of Our Control May Adversely Affect Our Business.

Terrorist attacks, natural disasters, public health crises 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.

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.

Not Applicable.

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. In addition, our subsidiary, DNAG, 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.

On February 6, 2017, DNAG entered into a settlement and license agreement (the "Settlement Agreement") in order to settle certain patent infringement and breach of contract litigation against Ancestry.comDNA, LLC ("Ancestry") and its contract manufacturer. This litigation was related to a saliva DNA collection device sold by Ancestry that was similar to products sold by DNAG. Under the terms of the Settlement Agreement, DNAG and Ancestry agreed to certain procedures for considering whether future versions of Ancestry's saliva DNA collection product are covered by the DNAG patents licensed to Ancestry (the "Licensed Patents") and thus subject to ongoing royalties under the Settlement Agreement. A dispute arose among the parties regarding whether certain new Ancestry products are covered by the Licensed Patents. Pursuant to the terms of the Settlement Agreement, a binding arbitration proceeding was commenced to resolve the dispute. In February 2020, an arbitration panel issued a decision finding that the future Ancestry products do not infringe the DNAG patents asserted in the arbitration and would no longer be subject to the royalties under the Settlement Agreement.

Following the completion of the arbitration, a new patent was issued to DNAG that is a continuation of a patent licensed to Ancestry and is thus a Licensed Patent under the Settlement Agreement. DNAG notified Ancestry of this new patent and following discussions between the parties, Ancestry initiated a new arbitration proceeding during the third quarter of 2020 pursuant to the Settlement Agreement with respect to the applicability of the new patent to the future Ancestry products and the validity of that patent. Following the initiation of the arbitration by Ancestry, DNAG filed a statement of defense and an objection to the arbitration on the basis that a dispute between the parties has not yet occurred and therefore the alleged dispute is not sufficiently ripe to arbitrate. An arbitration panel has been appointed. The parties have since engaged in settlement discussions and the commencement of the arbitration has been delayed.

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 22, 2021, there were 305 holders of record and approximately 37,295 holders in street name of our Common Stock, and the closing price of our Common Stock was $10.83 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, 2020- October 31, 2020	—	—	—	$ 11,984,720
November 1, 2020 - November 30, 2020	—	—	—	$ 11,984,720
December 1, 2020 - December 31, 2020	1,083	11.60	—	$ 11,984,720
	1,083		—	

(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.

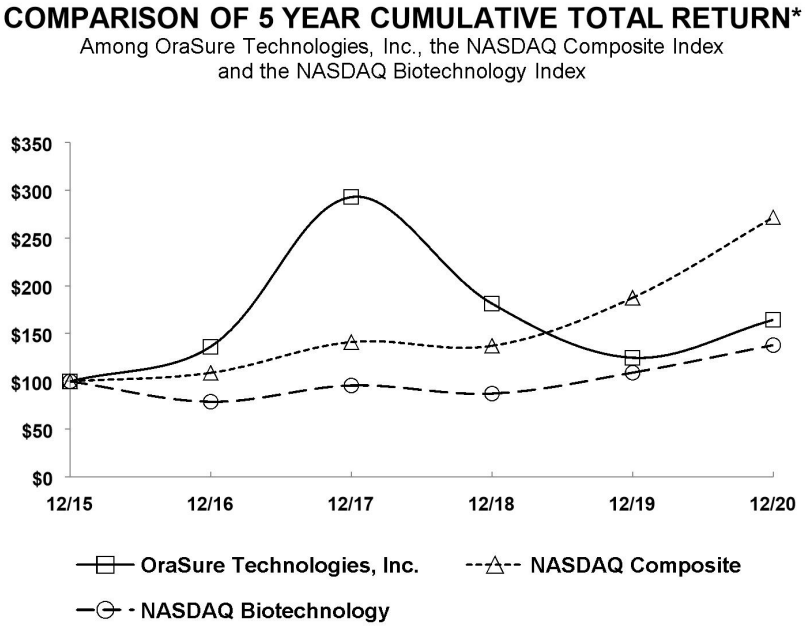
Performance Graph

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, 2015 through December 31, 2020. The graph assumes that $100 was invested on December 31, 2015 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 12/31/15 in stock or index, including reinvestment of dividends.



	Fiscal year ending December 31,					
	2015	2016	2017	2018	2019	2020
OraSure Technologies, Inc.	**100.00**	**136.34**	**292.86**	**181.37**	**124.69**	**164.36**
NASDAQ Composite	**100.00**	**108.87**	**141.13**	**137.12**	**187.44**	**271.64**
NASDAQ Biotechnology	**100.00**	**78.65**	**95.67**	**87.19**	**109.08**	**137.90**

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 Form 10-K generally discusses 2020 and 2019 items and year-to-year comparisons between 2020 and 2019. Discussion of 2018 items and year-to-year comparisons between 2019 and 2018 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, 2019.

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, which was previously named "OSUR" and our "Molecular Collection Systems" segment, which was previously named "DNAG." 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. Our Molecular Solutions business consists of the manufacture and sale of kits that are used to collect, stabilize, transport and store biological samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, infectious disease diagnostics, pharmacogenomics, personalized medicine, microbiome and animal genetics markets. Our collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets and in the sexually transmitted infection screening market. In addition, our Molecular Solutions business provides microbiome laboratory and bioinformatics services.

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 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 medication in a patient's urine or blood, as well as point of care products currently in development. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. We sold the assets associated with our cryosurgical systems business to a third party in August 2019.

Our Molecular Solutions business is operated by our subsidiaries, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen") and Novosanis NV ("Novosanis"). In this business, we manufacture and sell kits that are used to collect, stabilize, transport and store 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. Included in the disease risk management area are pharmacogenomics testing, hereditary disease screening, prenatal or cancer screening, population health initiatives and other molecular testing using DNA or RNA for diagnosis of acute disease. 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

In March 2020, the World Health Organization declared the novel coronavirus ("COVID-19") a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, economies, and financial markets globally, leading to an economic downturn. It is not possible for us to predict the duration or magnitude of the outbreak's effects on our business or results of operations at this time. 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 in the United States. On the international front, we experienced some reductions and stoppages of professional HIV and HCV testing in Europe and Asia due to the pandemic and delays with international shipments due to a reduction of customs and transportation personnel, a reduced number of air flights and shipping congestion. In our molecular segment, clinical and research work during the year, particularly in the academic market, has reduced demand for our products. These trends had a material impact on our results of operations during 2020 and we believe they will continue to have a material and adverse impact on the revenues of certain parts of our business for an indeterminate time period, depending on the duration and severity of the COVID-19 pandemic.
We also believe there are potentially significant opportunities for increased revenues as a result of the pandemic. During 2020, we began selling our saliva collection devices for use in molecular COVID-19 testing. In addition, we are developing and will be seeking EUA of a rapid COVID-19 antigen test and a laboratory-based oral fluid SARS-CoV-2 antibody test. A description of these products can be found in the "Business" section of Part I one of this Annual Report.

In 2020, we generated additional revenues of approximately $49.8 million from sales of our molecular collection devices related to COVID-19 testing during the year. In the U.S., public health customers are purchasing 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 are seeing increased demand for our molecular collection products from customers who conduct both saliva and blood-based testing. As it becomes increasingly difficult to collect blood in clinics or healthcare settings, these customers are increasingly relying on the saliva collection alternative. However, the degree to which these and other opportunities will offset the negative trends caused by the COVID-19 pandemic in future periods cannot be predicted with certainty.
Public Offering

In June 2020, the Company completed the issuance and sale of 9,200,000 shares of its Common Stock. The price to the public in the offering was $11.00 per share, with net proceeds from the offering equaling approximately $95.0 million after deducting underwriting discounts and offering expenses paid by the Company.

UrSure Acquisition

On July 22, 2020, the Company acquired all of the outstanding stock of UrSure, pursuant to the terms of a merger agreement. Subsequently in December 2020, UrSure was merged into OraSure. The activities of this line of business are described in the "Business" section of Part I of this Annual Report. The acquisition of UrSure supports our strategy of expanding our product offerings to include additional diagnostic products particularly point-of-care tests, that complement our current infectious disease portfolio and pipeline. We used cash of $3.0 million to pay for this acquisition and have incurred a total of $393,000 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 income for the year ended December 31, 2020.

Current Consolidated Financial Results

During the year ended December 31, 2020, our consolidated net revenues increased 11% to $171.7 million, compared to $154.6 million for the year ended December 31, 2019. Net product and services revenues during the year ended December 31, 2020 increased 12% when compared to the same period of 2019, due to the inclusion of product revenues associated with COVID-19 testing, higher international sales of our OraQuick® HIV Self-Test, and higher laboratory services revenues. Partially offsetting these increases were lower sales of our genomics, HCV, risk assessment, domestic HIV and microbiome products and the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019. Other revenues for the year ended December 31, 2020 were $5.3 million compared to $6.5 million in the same period of 2019. This decline was largely due to lower royalty income partially offset by increased revenues from funded research and development associated with the development of our adherence tests and COVID-19 products.

Our consolidated net loss for the year ended December 31, 2020 was $14.9 million, or $(0.22) per share on a fully diluted basis, compared to consolidated net income of $16.7 million, or $0.27 per share on a fully diluted basis, for the year ended December 31, 2019. Results for the year ended December 31, 2020 included a $1.1 million non-cash pre-tax gain associated with the change in the fair value of acquisition-related contingent consideration and $393,000 of acquisition related transaction costs associated with the UrSure acquisition, which together accounted for approximately $0.01 per share. Results for the year ended December 31, 2019 included a pre-tax gain on the sale of our cryosurgical systems business of $10.2 million, $664,000 of non-cash pre-tax income associated with the change in the fair value of acquisition-related contingent consideration and $1.8 million of acquisition-related transaction costs. The combined net impact of these items increased earnings per share by approximately $0.14 in 2019. Results for the full-year 2020 also reflect the significant increase in spending associated with the development of our COVID-19 products.

Cash provided by operating activities during the years ended December 31, 2020 and 2019 was $5.8 million and $9.8 million, respectively. As of December 31, 2020, we had $257.1 million in cash, cash equivalents, and available-for-sale securities, compared to $189.8 million at December 31, 2019.

Results of Operations

YEAR ENDED DECEMBER 31, 2020 COMPARED TO DECEMBER 31, 2019

CONSOLIDATED NET REVENUES

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

	Years Ended December 31,					
	Dollars			Percentage of Total Net Revenues		
	2020	2019	% Change	2020	2019	
Diagnostics	$63,601	$77,259	(18) %	37 %	50 %	
Molecular Solutions	102,780	70,814	45	60	46	
Net product and service revenues	166,381	148,073	12	97	96	
Other	5,340	6,532	(18)	3	4	
Net revenues	$171,721	$154,605	11 %	100 %	100 %	

Consolidated net product and services revenues increased 12% to $166.4 million for the year ended December 31, 2020 from $148.1 million for 2019 due to the inclusion of product revenues associated with COVID-19 testing from our Molecular Solutions segment coupled with increased international sales of our OraQuick® HIV Self-Test and higher laboratory services revenues. These increases were partially offset by lower sales of our genomics, HCV, risk assessment, domestic HIV, and microbiome products and the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019. Other revenues for the year ended December 31, 2020 were $5.3 million compared to $6.5 million in 2019. This decline was largely due to lower royalty income partially offset by increased revenues from funded research and development associated with the development of our adherence tests and COVID-19 products.

Consolidated net revenues derived from products sold to customers outside of the United States were $40.9 million and $47.3 million, or 24% and 31% of total net revenues, during the years ended December 31, 2020 and 2019, 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.

	Years Ended December 31,						
	Dollars			Percentage of Total Net Revenues			
Market	2020	2019	% Change	2020		2019	
Infectious disease testing	$54,227	$58,016	(7)%	83	%	74	%
Risk assessment testing	9,374	12,189	(23)	14		16	
Cryosurgical systems	—	7,054	(100)	0		9	
Net product revenues	63,601	77,259	(18)	97		99	
Other	1,638	966	70	3		1	
Net revenues	$65,239	$78,225	(17)%	100	%	100	%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 7% to $54.2 million in 2020 from $58.0 million in 2019. This decrease resulted from lower world-wide sales of our OraQuick® HCV products and lower domestic sales of our OraQuick® HIV products partially offset by higher 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 2020 and 2019.

	Years Ended December 31,		
Market	2020	2019	% Change
Domestic HIV	$15,184	$17,984	(16)%
International HIV	29,040	25,108	16
Net HIV revenues	44,224	43,092	3
Domestic HCV	4,793	8,108	(41)
International HCV	3,655	4,864	(25)
Net HCV revenues	8,448	12,972	(35)
Net OraQuick® revenues	$52,672	$56,064	(6)%

Domestic OraQuick® HIV sales decreased 16% to $15.2 million for the year ended December 31, 2020 from $18.0 million for the year ended December 31, 2019. This decrease was primarily the result of the decline in domestic HIV testing in public health clinics, hospitals and doctors' offices resulting from the COVID-19 pandemic partially offset by increased sales for our at-home test as a result of the COVID-19 pandemic.

International sales of our OraQuick® HIV products during 2020 increased 16% to $29.0 million from $25.1 million in 2019. This increase was largely due to higher sales of our OraQuick® HIV Self-Test in Africa.

Domestic OraQuick® HCV sales decreased 41% to $4.8 million in 2020 from $8.1 million in 2019. International OraQuick® HCV sales decreased 25% to $3.7 million in 2020 from $4.9 million in 2019. The declines in HCV sales in both the domestic and international markets were due to the closure of testing programs due to the COVID-19 pandemic.

Risk Assessment Market

Sales to the risk assessment market decreased 23% to $9.4 million for the year ended December 31, 2020 from $12.2 million for the year ended December 31, 2019 due to unemployment and reductions in workplace and insurance testing programs resulting from the COVID-19 pandemic.

Cryosurgical Systems Market

In August 2019, we sold our cryosurgical systems line of business and as such have stopped recording revenues associated with that business since the third quarter of 2019.

Other revenues

Other revenues for the year ended December 31, 2020 increased 70% to $1.6 million from $966,000 for the year ended December 31, 2019. Revenue associated with funding of our research and development efforts increased to $1.6 million for the year ended December 31, 2020 from $705,000 for the year ended December 31, 2019 as new grants for COVID-19 funded projects and adherence test research and development funding were partially offset by the wind-down of efforts to develop our rapid Ebola test. Other revenues for the year ended December 31, 2020 also included $68,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation compared to $261,000 for the year ended December 31, 2019.

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, 2020 and 2019.

	Years Ended December 31,			
Market	**2020**	**2019**	**% Change**	
Genomics	$37,141	$56,200	(34	)%
Microbiome	6,156	7,172	(14	)
COVID-19	49,802	—	N/A	
Laboratory services	9,564	6,767	41	
Other product revenues	117	675	(83	)
Net molecular product and services revenues	102,780	70,814	45	
Other	3,701	5,566	(34	)
Net revenues	$106,481	$76,380	39	%

Sales of our genomics products decreased 34% to $37.1 million in 2020 compared to $56.2 million in 2019, largely due to the timing of orders placed by one of our largest genomics customer and the reduction in genomics testing due to the COVID-19 pandemic.

Microbiome revenues decreased 14% to $6.2 million in 2020 compared to $7.2 million in 2019 largely due to reduced product demand caused by the COVID-19 pandemic.

During 2020, we sold $49.8 million of sample collection devices for use in the collection and transport of samples for COVID-19 molecular testing. There were no similar sales in 2019.

Laboratory services revenues increased 41% to $9.6 million in 2020 compared to $6.8 million in 2019, due to the inclusion of revenues generated by Diversigen which was acquired in the fourth quarter of 2019, partially offset by a decline in laboratory testing due to the inability of our customers to collect samples as a result of the COVID-19 pandemic.

Other revenues in 2020 decreased 34% to $3.7 million from $5.6 million in 2019 largely as a result of lower royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 59% for the year ended December 31, 2020 compared to 61% for 2019. The decrease in gross profit percentage was primarily due to lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases, increased scrap and spoilage expense and the decline in other revenues which contribute 100% to our gross profit percentage. These declines in gross profit percentage were partially offset by a more favorable product mix.

Consolidated operating loss in 2020 was $5.2 million, a $23.8 million decline from the $18.6 million of operating income reported in 2019. Results in 2020 were negatively impacted by increased operating expenses related to COVID-19 product development, higher staffing costs and the inclusion of expenses attributable to Diversigen and UrSure. The operating loss in 2020 included $1.1 million of non-cash income related to the fair value change of acquisition-related contingent consideration compared to $664,000 of non-cash income in the comparable period of the prior year. Results in 2019 also included the pre-tax gain of $10.2 million from the sale of our cryosurgical systems business.

OPERATING INCOME BY SEGMENT

Diagnostic Segment

The gross profit percentage of the Diagnostics business was 42% in 2020 compared to 55% in 2019. This decrease is largely due to a less favorable product mix, lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases and increased scrap and spoilage expense.

Research and development expenses increased 75% to $21.3 million in 2020 from $12.2 million in 2019, largely due to spending associated with COVID-19 product development, higher staffing costs, and the inclusion of UrSure expenses not present in 2019.

Sales and marketing expenses increased 24% to $22.4 million in 2020 from $18.1 million in 2019, due to higher staffing costs as a result of increased headcount, increased commissions and the additional costs associated with the retirement of a senior executive who previously led our Diagnostics Business Unit and the on-boarding costs of his successor. Also contributing to the higher sales and marketing expense was an increase in our reserve for uncollectible accounts associated primarily with one of our distributors located in Africa, higher marketing costs and the inclusion of UrSure expenses not present in 2019. These increases were partially offset by lower travel and trade show costs due to the COVID-19 pandemic.

General and administrative expenses increased 25% to $28.1 million in 2020 from $22.5 million in 2019 largely due to higher staffing costs associated with increased employee bonuses as a result of our strong financial performance in 2020 and an increase in headcount, and the inclusion of $393,000 in transaction costs associated with the UrSure acquisition. These increases were partially offset by a decline in professional fees related to business development activities and lower travel expenses due to the COVID-19 pandemic.

Operating income in 2019 also included a $10.2 million pre-tax gain on the sale of our cryosurgical systems business. In August 2019, we sold all assets necessary to operate this line of business to a third party for $12.0 million. The $10.2 million gain includes the $12.0 million proceeds received net of the fair value of the assets sold, which consisted of inventory and fully-depreciated fixed assets, the legal fees associated with the transaction, and a value attributed to the transition services.

All of the above contributed to an operating loss of $43.2 million for 2020, which included non-cash charges of $3.3 million for depreciation and amortization and $6.0 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax gain of $989,000 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 70% in 2020 compared to 68% in 2019. This increase was attributable to a more favorable product mix as a result of higher sales of higher gross profit products and services partially offset by the decline in other revenues which contribute 100% to the gross profit percentage.

Research and development expenses increased 31% to $9.8 million in 2020 from $7.5 million in 2019 due higher staffing costs and the inclusion of research and development expenses incurred by Diversigen for the full year in 2020 compared to two months in 2019.

Sales and marketing expenses decreased 12% to $12.0 million in 2020 compared to $13.7 million in 2019 largely due to a prior period increase in our reserve for uncollectible accounts associated primarily with a receivable from a large Chinese genomics customer and

a decline in travel expenses due to the COVID-19 pandemic. These decreases were partially offset by increased staffing costs and a full year of expenses incurred by Diversigen compared to two months in 2019.

General and administrative expenses increased 14% to $14.6 million in 2020 compared to $12.8 million in 2019, due to the inclusion of expenses incurred by Diversigen for in the full year 2020 compared to two months in 2019.

All of the above contributed to operating income of $38.0 million for 2020, which included non-cash charges of $6.0 million for depreciation and amortization and $1.1 million for stock-based compensation. The Molecular Solutions segment operating income also included a non-cash pre-tax gain of $110,000 associated with the change in the fair value of acquisition-related contingent consideration.

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, 2020, we recorded a federal tax benefit of $637,000 and a state income tax benefit of $156,000 compared to a federal tax benefit of $832,000 and state income tax expense of $892,000 for the year ended December 31, 2019. Foreign income tax expense of $12.2 million and $4.6 million was recorded in 2020 and 2019, respectively. The increase in income tax expense was largely a result of the increase in income before taxes generated by our Canadian subsidiary.

Liquidity and Capital Resources

	December 31, 2020	2019
	(In thousands)	
Cash and cash equivalents	$160,802	$75,715
Available for sale securities	96,317	114,043
Working capital	242,404	191,837

Our cash and cash equivalents and available-for-sale securities increased to $257.1 million at December 31, 2020 from $189.8 million at December 31, 2019. Our working capital increased to $242.4 million at December 31, 2020 from $191.8 million at December 31, 2019.

During 2020, net cash provided by operating activities was $5.8 million. Our net loss of $14.9 million included non-cash charges for depreciation and amortization expense of $9.4 million, stock-based compensation expense of $7.1 million, a provision for doubtful accounts of $941,000, and other net non-cash charges of $165,000. Operating activities also included a $1.1 million non-cash gain associated with the change in the estimated fair value of contingent consideration and a $496,000 contingent consideration payment representing the excess of the total contingent consideration payment made during the first quarter of 2020 over the fair value of the liability estimated at the time of acquisition. Sources of cash generated from our working capital accounts included a $7.4 million increase in accounts payable due to the timing of invoice payments, a $7.3 million increase in accrued expenses associated with the accruals for current year management incentive bonuses and higher sales tax payable, and a $1.1 million increase in deferred revenue associated with customer prepayments. Offsetting these sources of cash were an increase in inventory of $8.6 million to meet anticipated demand to support COVID-19 testing programs and to fulfill international HIV sales. An additional use of cash was a $2.3 million increase in accounts receivable largely resulting from an increase in product orders placed during the fourth quarter of 2020.

Net cash used in investing activities was $14.0 million for the year ended December 31, 2020, which reflects $90.1 million used to purchase investments, $26.7 million used to acquire property and equipment largely associated with increasing capacity in anticipation of increased product demand in 2021, $3.0 million to acquire UrSure, and $2.3 million used to purchase certain patent and product rights from a third party, partially offset by $107.7 million in proceeds from the maturities and redemptions of investments.

Net cash provided by financing activities was $92.5 million for the year ended December 31, 2020, which largely resulted from the $95.0 million in net proceeds from the issuance of common stock in connection with a public offering and proceeds of stock option exercises of $3.2 million, partially offset by $3.0 million used for payment of an acquisition-related contingent consideration obligation and $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.

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 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, $99.4 million or 39% of our $257.1 million in cash, cash equivalents and available-for-sale securities at December 31, 2020 as held by to our Canadian subsidiary, DNAG. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

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 to the retail trade, and (iii) under the terms of a long-term contract with a genomics customer, which was amended in 2020 to remove the return rights provision.

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.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2020 and 2019 included customer prepayments of $3.2 million and $1.9 million, respectively. Deferred revenue as of December 31, 2020 and 2019 also included $1.6 million and $1.8 million, 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 the 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 over the life of the related sales contract.

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.

During 2020, 2019, and 2018, we wrote-off inventory which had a cost of $2.6 million, $1.3 million and $1.3 million, respectively. These write-offs were a result of quality, scrap and product expiration issues. 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, 2020, we had federal Net Operating Loss ("NOL") carryforwards of $136.3 million. The net deferred tax assets, before the valuation allowance, associated with these NOLs and other temporary differences were $35.4 million at December 31, 2020. Net operating losses will begin to expire in 2021. 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, 2020 and 2019 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, 2020, 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 5.0% of our total revenues for the year ended December 31, 2020. 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 $161.5 million in U.S. Dollars, which are included in the Company’s consolidated balance sheet as of December 31, 2020. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have decreased our comprehensive income by approximately $12.9 million in the year ended December 31, 2020.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in our Consolidated Financial Statements included in 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 and Chief Financial 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, 2020. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2020 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 and Chief Financial 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, 2020.

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

The Company acquired UrSure, Inc. during 2020, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, the acquired company representing approximately 1.7% of total assets and 0.5% of total revenues of the Company as of and for the year ended December 31, 2020. Management plans to fully integrate the operations of these businesses into the assessment of the effectiveness of the Company's internal control over financial reporting in 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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, 2020 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes (collectively, the consolidated financial statements), and our report dated March 1, 2021 expressed an unqualified opinion on those consolidated financial statements.

The Company acquired UrSure, Inc. during 2020, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, UrSure, Inc.'s internal control over financial reporting associated with approximately 1.7% of total assets and 0.5% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2020. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of UrSure, Inc.

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, 2021

ITEM 9B. Other Information.

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.

Certain information required by this Item is incorporated by reference to the information under the captions "Proposal No. 1. Election of Directors," "Corporate Governance - Governance Guidelines and Code of Conduct," "Corporate Governance – Committees of the Board," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

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 is incorporated by reference to the information under the captions "Compensation Committee Matters" (including the "Compensation Committee Report"), "Compensation Discussion and Analysis," "Compensation Tables," "Employment Agreements and Potential Payments Upon Termination or Change in Control," and "Director Compensation" in the Proxy Statement.

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

The information required by this Item with respect to the securities ownership of certain beneficial owners and management, and equity compensation plan information, is incorporated by reference to the information under the captions "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement.

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

The information required by this Item is incorporated by reference to the information under the captions "Transactions with Related Persons" and "Corporate Governance - Director Independence" in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the information under the caption "Audit Committee Matters" in the Proxy Statement.

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	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.*
10.3	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.*
10.4	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.*
10.5	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.*
10.6	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.*
10.7	Retirement Agreement, dated as of May 1, 2020, between OraSure technologies, Inc. and Anthony Zezzo II is incorporated by reference to Exhibit 10.1 to the Company's Current Report on For 8-K filed May 5, 2020*
10.8	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.*
10.9	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.*
10.10	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.*
10.11	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.*
10.12	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.*

Exhibit Number	Exhibit
10.13	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.*
10.14	Form of Restricted Share Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015.*
10.15	Form of Restricted Unit Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016. *
10.16	Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.17	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.18	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.19	Description of the OraSure Technologies, Inc. 2020 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 21, 2020.*
10.20	Description of Long-Term Incentive Policy and 2019 Award Performance Measures is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 21, 2020.*
10.21	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.*
10.22	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.*
10.23	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.
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 Roberto Cuca 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 Roberto Cuca 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.

* 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, 2021.

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, 2021, 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/ Roberto Cuca Roberto Cuca	Chief Financial Officer (Principal Financial Officer)
/s/ Michele Miller Michele Miller	Vice President, Finance and Controller (Principal Accounting Officer)
*MARA ASPINALL Mara Aspinall	Director
*MICHAEL CELANO Michael Celano	Director
*JAMES A. DATIN James A. Datin	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

*By: */s/ Jack E. Jerrett*
Jack E. Jerrett
(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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020, 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, 2021 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 9 to the consolidated financial statements, the Company has elected to change its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update No. 2016-02, *Leases*.

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 5 to the consolidated financial statements, the Company has inventories with a carrying value of $31,863 thousand as of December 31, 2020. 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, 2021

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

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 160,802	$ 75,715
Short-term investments	48,599	80,623
Accounts receivable, net of allowance for doubtful accounts of $3,654 and $2,666	38,835	36,948
Inventories	31,863	23,155
Prepaid expenses	3,860	2,433
Other current assets	4,934	5,676
Total current assets	288,893	224,550
Noncurrent Assets:		
Property, plant and equipment, net	51,860	30,339
Operating right-of-use assets, net	4,461	4,996
Finance right-of-use assets, net	1,312	1,951
Intangible assets, net	17,904	14,674
Goodwill	40,351	36,201
Long-term investments	47,718	33,420
Other noncurrent assets	1,973	3,164
Total noncurrent assets	165,579	124,745
TOTAL ASSETS	$ 454,472	$ 349,295
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 17,407	$ 9,567
Deferred revenue	4,811	3,713
Accrued expenses	22,227	14,288
Finance lease liability	517	613
Operating lease liability	1,125	1,032
Acquisition-related contingent consideration obligation	402	3,500
Total current liabilities	46,489	32,713
Noncurrent Liabilities:		
Finance lease liability	895	1,372
Operating lease liability	3,591	4,206
Acquisition-related contingent consideration obligation	2,049	112
Other noncurrent liabilities	1,682	2,848
Deferred income taxes	1,195	899
Total noncurrent liabilities	9,412	9,437
TOTAL LIABILITIES	55,901	42,150
COMMITMENTS AND CONTINGENCIES (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 71,738 and 61,731 shares issued and outstanding	—	—
Additional paid-in capital	505,123	401,814
Accumulated other comprehensive loss	(9,097)	(12,136)
Accumulated deficit	(97,455)	(82,533)
Total stockholders' equity	398,571	307,145
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 454,472	$ 349,295

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,		
	2020	2019	2018
NET REVENUES:			
Products and services	$ 166,381	$ 148,073	$ 165,428
Other	5,340	6,532	16,315
	171,721	154,605	181,743
COST OF PRODUCTS SOLD	69,853	60,022	68,130
Gross profit	101,868	94,583	113,613
OPERATING EXPENSES:			
Research and development	31,032	19,629	16,250
Sales and marketing	34,459	31,869	30,609
General and administrative	42,653	35,287	38,325
Change in the estimated fair value of acquisition-related contingent consideration	(1,099)	(664)	—
Gain on sale of business		(10,149)	—
	107,045	75,972	85,184
Operating income (loss)	(5,177)	18,611	28,429
OTHER INCOME	1,653	2,720	3,287
Income (loss) before income taxes	(3,524)	21,331	31,716
INCOME TAX EXPENSE	11,398	4,675	11,320
NET INCOME (LOSS)	$ (14,922)	$ 16,656	$ 20,396
EARNINGS (LOSS) PER SHARE:			
BASIC	$ (0.22)	$ 0.27	$ 0.33
DILUTED	$ (0.22)	$ 0.27	$ 0.33
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	67,505	61,675	61,112
DILUTED	67,505	62,170	62,532

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,		
	2020	2019	2018
NET INCOME (LOSS)	$ (14,922)	$ 16,656	$ 20,396
OTHER COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments	3,273	5,767	(8,003)
Unrealized gain (loss) on marketable securities	(234)	803	(363)
COMPREHENSIVE INCOME (LOSS)	$ (11,883)	$ 23,226	$ 12,030

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2020, 2019 and 2018
(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
Balance at January 1, 2018	60,662	—	387,931	(10,340)	(119,510)	258,081
Adoption of ASU 2014-9					(75)	(75)
Common stock issued upon exercise of options	227	—	1,697	—	—	1,697
Vesting of restricted stock	578	—	—	—	—	—
Purchase and retirement of common shares	(191)	—	(3,592)	—	—	(3,592)
Stock-based compensation	—	—	15,237	—	—	15,237
Net income	—	—	—	—	20,396	20,396
Currency translation adjustments	—	—	—	(8,003)	—	(8,003)
Unrealized loss on marketable securities	—	—	—	(363)	—	(363)
Balance at December 31, 2018	61,276	—	401,273	(18,706)	(99,189)	283,378
Common stock issued upon exercise of options	27	—	196	—	—	196
Vesting of restricted stock and performance stock units	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

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,		
	2020	2019	2018
OPERATING ACTIVITIES:			
Net income (loss)	$ (14,922)	$ 16,656	$ 20,396
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	7,139	4,057	15,237
Depreciation and amortization	9,387	7,339	6,451
Other non-cash amortization	327	391	771
Provision for doubtful accounts	941	2,248	(53)
Unrealized foreign currency (gain) loss	269	385	(400)
Interest expense on finance leases	72	36	—
Deferred income taxes	(392)	(1,457)	(919)
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 contingent earn-out consideration	(1,099)	(664)	—
Payment of acquisition related contingent consideration	(496)	—	—
Changes in assets and liabilities			
Accounts receivable	(2,324)	(2,210)	6,688
Inventories	(8,607)	(1,324)	(3,857)
Prepaid expenses and other assets	(104)	200	(366)
Accounts payable	7,379	(1,537)	208
Deferred revenue	1,051	(297)	2,240
Accrued expenses and other liabilities	7,297	(4,017)	(7,306)
Net cash provided by operating activities	5,807	9,804	39,090
INVESTING ACTIVITIES:			
Purchases of investments	(90,137)	(92,173)	(163,763)
Proceeds from maturities and redemptions of investments	107,718	93,491	152,680
Purchases of property and equipment	(26,674)	(9,314)	(6,344)
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	351	—	—
Net cash used in investing activities	(14,029)	(19,797)	(17,427)
FINANCING ACTIVITIES:			
Repayments of loans	—	(724)	—
Cash payments for lease liability	(687)	(442)	—
Proceeds from issuance of common stock, net	95,036	—	—
Proceeds from exercise of stock options	3,222	196	1,701
Payment of acquisition related contingent consideration	(3,004)	—	—
Repurchase of common stock	(2,088)	(3,712)	(3,592)
Net cash provided by (used in) financing activities	92,479	(4,682)	(1,891)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	830	1,952	(4,203)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	85,087	(12,723)	15,569
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	75,715	88,438	72,869
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 160,802	$ 75,715	$ 88,438

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, which was previously named "OSUR" and our "Molecular Solutions" segment, which was previously name "DNAG". 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. Our Molecular Solutions business consists of the manufacture and sale of kits that are used to collect, stabilize, transport and store biological samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, infectious disease diagnostics, pharmacogenomics, personalized medicine, microbiome and animal genetics markets. Our collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets and in the sexually transmitted infection screening market. In addition, our Molecular Solutions business provides microbiome laboratory and bioinformatics services.

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 business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. These products include laboratory-based tests that can measure levels of the medication in a patient's urine or blood, as well as point of care products currently in development. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. We sold the assets associated with our cryosurgical systems business to a third party in August 2019. In 2020, we began the development of a rapid antigen self-test for COVID-19 and a COVID-19 antibody ELISA test for use in laboratory settings. We expect to begin selling these products in 2022.

Our Molecular Solutions business is operated by our subsidiaries, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen"), and Novosanis NV ("Novosanis"). In DNAG's business, we manufacture and sell kits that are used to collect, stabilize, transport and store 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. In 2020, two of our collection devices were 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.

Supplemental Cash Flow Information

In 2020, 2019 and 2018, we paid income taxes of $9,263, $10,611 and $17,126, respectively.

In 2020, 2019 and 2018, we recorded through the consolidated statements of operations an increase (decrease) in our allowance for doubtful accounts of $941, $2,248 and $(53), respectively. We had write-offs of $501, $110 and $11 in 2020, 2019, and 2018, respectively.

As of December 31, 2020, 2019 and 2018, we had accruals for purchases of property and equipment of $802, $660, and $964, 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. As of December 31, 2020, we determined that the decline in the market value of our available-for-sale investment was not due to credit-related factors and as such no allowance for credit-loss was necessary.

The following is a summary of our available-for-sale securities as of December 31, 2020 and 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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
December 31, 2019				
Guaranteed investment certificates	$24,632	$—	$—	$24,632
Corporate bonds	89,525	271	(385)	89,411
Total available-for-sale securities	$114,157	$271	$(385)	$114,043
At December 31, 2020, maturities of our available-for-sale securities were as follows:				
Less than one year	$48,835	$114	$(350)	$48,599
Greater than one year	$47,830	$21	$(133)	$47,718

Fair Value of Financial Instruments

As of December 31, 2020 and 2019, 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, 2020 and 2019. Our guaranteed investment certificates are measured as Level 1 instruments as of December 31, 2020 and 2019.

Included in cash and cash equivalents at December 31, 2020 and 2019, was $71,489 and $1,624 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, 2020 and 2019 was $2,565 and $3,519, 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

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 depreciated over twenty to forty years, while computer equipment, 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, 2020 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, return rights on sales of our OraQuick® In-Home HIV test to the retail trade, and under the terms of a long-term contract with a genomics customer, which was amended in 2020 to remove the return rights provision.

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 and 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 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 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, 2020 and 2019 included customer prepayments of $3,216 and $1,904, respectively. Deferred revenue as of December 31, 2020 and 2019 also included $1,595 and $1,809, 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:

	Year Ended December 31,		
	2020	2019	2018
Infectious disease testing	$54,227	$58,016	$56,159
Risk assessment testing	9,374	12,189	12,058
Cryosurgical systems	—	7,054	10,767
Genomics	37,141	56,200	79,754
Microbiome	6,156	7,172	6,690
COVID-19	49,802	—	—
Laboratory services	9,564	6,767	—
Other product revenue	117	675	—
Net product and service revenues	166,381	148,073	165,428
Royalty income	3,432	5,116	9,653
Other non-product revenues	1,908	1,416	6,662
Other revenues	5,340	6,532	16,315
Net revenues	$171,721	$154,605	$181,743

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,		
	2020	2019	2018
United States	$130,835	$107,279	$136,847
Europe	12,068	11,752	11,062
Other regions	28,818	35,574	33,834
	$171,721	$154,605	$181,743

Customer and Vendor Concentrations. One of our customers accounted for 11% of our accounts receivable as of December 31, 2020 and another customer accounted for 19% of our accounts receivable as of December 31, 2019. The same customer accounted for approximately 15% and 24% of our net consolidated revenues for the year ended December 31, 2019 and 2018, respectively. We had no customers that accounted for more than 10% of our consolidated net revenues for the year ended December 31, 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.

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 2020, 2019, and 2018, we incurred $1,126, $468, and $745, 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 gains (losses) resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of operations were $(337), $(1,339), and $831 for the years ended December 31, 2020, 2019, and 2018, 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:

	Year ended December 31,		
	2020	2019	2018
Net income (loss)	$(14,922)	$16,656	$20,396
Weighted average shares of common stock outstanding:			
Basic	67,505	61,675	61,112
Dilutive effect of stock options, restricted stock, and performance stock units	—	495	1,420
Diluted	67,505	62,170	62,532
Earnings (loss) per share:			
Basic	$(0.22)	$0.27	$0.33
Diluted	$(0.22)	$0.27	$0.33

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

For the years ended December 31, 2019, and 2018, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 768 and 291 shares, respectively, 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, 2020 consists of $8,749 of currency translation adjustments and $348 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, 2019 consists of $12,022 of currency translation adjustments and $114 of net unrealized losses on marketable securities.

Recent Accounting Pronouncements

In June 2016, the FASB issued guidance on the measurement of credit losses, which requires measurement and recognition of expected credit losses for financial assets, including trade receivables and capital lease receivables, held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The method to determine a loss requires a credit loss to be recognized when it is probable. We adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements as credit losses are not expected to be significant based on historical collection trends, the financial condition of payment partners, and external market factors. The Company will continue to actively monitor the impact of the coronavirus (COVID-19) pandemic on expected credit losses. In addition, the new guidance requires us to record an allowance for credit loss when a decline in investment market value is due to credit-related factors. As of January 1, 2020, there was no material decline in the market value of available-for-sale investments due to credit-related factors.

In February 2018, the FASB issued guidance allowing a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the U.S. Tax Cuts and Jobs Act. If elected, the reclassification can be applied in either the period of adoption or retrospectively to the period of the enactment of the U.S. Tax Cuts and Jobs Act (i.e., our first quarter of fiscal year 2018). We adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements.

In August 2018, the FASB issued guidance related to fair value measurement disclosures. This guidance removes the requirement to disclose the amount of and reasons for transfers between Levels 1 and 2 of the fair value hierarchy, the policy for determining that a transfer has occurred, and valuation processes for Level 3 fair value measurements. Additionally, this guidance modifies the disclosures related to the measurement uncertainty for recurring Level 3 fair value measurements (by removing the requirement to disclose sensitivity to future changes) and the timing of liquidation of invested assets (by removing the timing requirement in certain instances). The guidance also requires new disclosures for Level 3 financial assets and liabilities, including the amount and location of unrealized gains and losses recognized in other comprehensive income(loss) and additional information related to significant unobservable inputs used in determining Level 3 fair value measurements. We adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements.

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.

Pursuant to our acquisition agreements, we may pay up to an additional $28,000 of contingent consideration over the next four years 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 fair value of the contingent consideration obligation changed from $3,440 as of the acquisition date to $2,451 as of December 31, 2020 largely due to changes in the timing of achieving certain clinical milestones.

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.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.

Revenues from UrSure primarily consist of grant money received to fund the development of certain new technology and approximated $842 since acquisition. Effective as of July 22, 2020, the financial results of UrSure are included in our Diagnostics segment.

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.

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 yrs)**	**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.

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. For the year ended December 31, 2019, consolidated net revenues include revenues associated with the Diversigen business of $1,046 and consolidated results from operations include a net loss of $47 generated since the acquisition date.

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. As of December 31, 2020, and based on current and forecasted revenue results, it is not expected than any further contingent consideration will be paid through the final potential payment date of July 2021.

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 yrs)	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.

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. For the year ended December 31, 2019, consolidated net revenues include combined revenues associated with the CoreBiome and Novosanis business of $5,152. Consolidated results from operations for the year ended December 31, 2019 included a net loss of $2,450 generated from the combined companies since the acquisition date.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the CoreBiome, Diversigen, Novosanis acquisitions as if they had been consummated as of January 1, 2018 and the results of UrSure as if it had been consummated as of January 31, 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 the January 1, 2018 and 2019 dates.

	Year Ended December 31,		
	2020	2019	2018
Revenue	$172,563	$159,632	$190,487
Net income	(14,937)	16,261	19,448
Net income per share, basic	(0.22)	0.26	0.32
Net income per share, diluted	(0.22)	0.26	0.31

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 income 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. INVENTORIES:

	December 31,	
	2020	2019
Raw materials	$ 15,425	$ 14,168
Work in process	2,572	643
Finished goods	13,866	8,344
	$ 31,863	$ 23,155

6. PROPERTY, PLANT AND EQUIPMENT:

	December 31,	
	2020	2019
Land	$ 1,118	$ 1,118
Buildings and improvements	26,480	23,231
Machinery and equipment	36,878	33,568
Computer equipment and software	13,024	11,590
Furniture and fixtures	3,545	2,791
Construction in progress	24,419	4,923
	105,464	77,221
Less accumulated depreciation	(53,604)	(46,882)
	$ 51,860	$ 30,339

Depreciation expense was $5,514, $4,421, and $3,828 for 2020, 2019, and 2018, respectively.

7. GOODWILL AND OTHER INTANGIBLE ASSETS:

The changes in goodwill are as follows:

	December 31,	
	2020	2019
Balance as of January 1	36,201	18,521
Goodwill acquired during the year	3,586	16,811
Purchase price adjustment	(126)	—
Change related to foreign currency translation	690	869
Balance as of December 31	$ 40,351	$ 36,201

Intangible assets consist of the following:

		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

		December 31, 2019		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer relationships	10	$ 14,731	$ (8,054)	$ 6,677
Patents and product rights	10	5,400	(5,158)	242
Developed technology	7-10	12,410	(7,982)	4,428
Tradename	5-15	5,553	(2,226)	3,327
		$ 38,094	$ (23,420)	$ 14,674

Amortization expense for 2020, 2019, and 2018 was $3,246, $2,522, and $2,623, respectively.

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

2021	3,291
2022	2,345
2023	2,345
2024	2,302
2025	2,050
Beyond	5,571
	$ 17,904

8. ACCRUED EXPENSES:

	December 31,	
	2020	2019
Payroll and related benefits	$ 14,769	$ 6,088
Professional fees	978	2,769
Other	6,480	5,431
	$ 22,227	$ 14,288

9. LEASES:

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The standard requires lessees to recognize lease assets and lease liabilities on the balance sheet and requires expanded disclosures about leasing arrangements. We adopted this standard on January 1, 2019 on a modified retrospective basis and did not restate comparative amounts.

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, 2020, 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.

The components of lease expense are as follows:

	Year ended December 31, 2020	Year ended December 31, 2019
Operating Lease Cost	$ 1,291	$ 964
Finance Lease Cost		
Amortization of right-of use assets	627	410
Interest on lease liabilities	72	36
Total Finance Lease Cost	$ 699	$ 446

Lease cost for the year ended December 31, 2018 was $1,461.

Supplemental cash flow information related to leases is as follows:

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

Right of use assets obtained include those assets acquired and entered into during 2020 and 2019.

Supplemental balance sheet information related to leases is as follows:

	December 31, 2020	December 31, 2019
Operating Leases		
Right-of-use assets	$ 4,461	$ 4,996
Current lease liabilities	1,125	1,032
Non-current lease liabilities	3,591	4,206
Total operating lease liabilities	$ 4,716	$ 5,238
Finance Leases		
Right-of-use assets	$ 1,312	$ 1,951
Current lease liabilities	517	613
Non-current lease liabilities	895	1,372
Total finance lease liabilities	$ 1,412	$ 1,985

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

As of December 31, 2020, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2021	566	1,332
2022	566	1,315
2023	337	874
2024	25	894
2025	4	520
Thereafter	-	325
Total Minimum Lease Payments	1,498	5,260
Less: imputed interest	(86)	(544)
Present Value of Lease Liabilities	$ 1,412	$ 4,716

10. INCOME TAXES:

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

	Years Ended December 31,		
	2020	2019	2018
United States	$(47,995)	$3,106	$(11,728)
Foreign	44,471	18,225	43,444
	$(3,524)	$21,331	$31,716

The components of income tax expense are as follows:

	Years Ended December 31,		
	2020	2019	2018
Current			
Federal	$—	$—	$—
State	(106)	1,033	155
Foreign	11,896	5,099	12,084
	11,790	6,132	12,239
Deferred			
Federal	(20,946)	3,568	9,200
State	(1,053)	125	1,011
Foreign	(410)	(697)	(919)
	(22,409)	2,996	9,292
Decrease in valuation allowance	22,017	(4,453)	(10,211)
	(392)	(1,457)	(919)
Total income tax expense	$11,398	$4,675	$11,320

For the years ended December 31, 2020, 2019, and 2018 we recorded foreign income tax expense of $12,185, $4,607, and $11,165, 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 GILTI computation for 2018 was completed and is reflected in the 2018 income tax provision. 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 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, 2020, 2019, and 2018 is as follows:

	2020	2019	2018
Statutory U.S. federal income tax rate	21.0 %	21.0 %	21.0 %
Deemed repatriation tax	—	—	10.9
GILTI tax	—	16.9	22.2
Nondeductible executive compensation	(0.9)	0.4	4.8
Impact of share-based payment awards	(12.4)	(5.3)	0.6
Tax effect of foreign items	(70.7)	4.5	6.8
State income taxes, net of federal benefit	26.0	4.0	2.8
U.S. and foreign tax credits	34.9	(1.1)	(1.0)
Nondeductible transaction costs	(2.8)	1.6	—
Nondeductible expenses and other	(2.6)	0.4	(0.2)
NOL adjustment due to change in GILTI regulations	308.9	—	—
Change in valuation allowance, federal and state	(624.8)	(20.5)	(32.2)
Effective tax rate	(323.4)%	21.9 %	35.7 %

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, 2020 and 2019 are as follows:

	2020	2019
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$31,701	$9,897
Inventories	1,593	2,002
Capitalized research and development costs	746	1,183
Accruals and reserves currently not deductible	3,200	2,272
Acquired intangible assets	(3,870)	(3,525)
Depreciation and amortization	(2,695)	(1,999)
Stock-based compensation	1,354	1,777
Tax credit carryforwards	3,354	2,055
Net deferred tax asset	35,383	13,662
Valuation allowance	(36,578)	(14,561)
Net deferred tax liability	$(1,195)	$(899)

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, 2020 and 2019 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, 2020, 2019, or 2018.

Our Federal NOL carryforwards expire as follows:

Year of Expiration	NOLs	
2021 - 2031	$	26,317
2032 - 2037	$	45,072
Non-Expiring		64,865
	$	136,254

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.

Effective January 1, 2018, there is a transition to a participation exemption system whereby distributions from foreign subsidiaries to U.S. shareholders are generally exempt from taxation. Our intention is 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, 2020, our gross unrecognized tax benefits totaled $1,172, 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 2020, 2019 and 2018. 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, 2020.

A reconciliation of our unrecognized tax benefits is as follows:

	2020	2019	2018
Balance as of January 1	$ 1,308	$ 1,676	$ 1,663
Additions for tax positions of prior periods	1	4	44
Reductions for tax positions of prior periods	(137)	(372)	(31)
Balance as of December 31	$ 1,172	$ 1,308	$ 1,676

11. 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, 2020, 5,595 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	2020	2019	2018
Risk-free interest rate(1)	1.33 %	2.52 %	2.60 %
Expected dividend yield	—	—	—
Expected stock price volatility(2)	42 %	41 %	43 %
Expected life of stock options (in years)(2)	5	5	6

(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, 2020, 2019 and 2018 was $2.79, $5.19 and $9.15, respectively.

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

	Years Ended December 31,		
	2020	2019	2018
Total compensation cost during the year	$ 892	$ 1,161	$ 2,163
Amounts capitalized into inventory during the year	(466)	(343)	(420)
Amounts recognized in cost of products sold for amounts previously capitalized	360	405	396
Amounts charged against income	$ 786	$ 1,223	$ 2,139

The aggregate intrinsic value of options exercised during the years ended December 31, 2020, 2019, and 2018 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $3,117, $92, and $2,314, 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, 2020	1,193	10.68		
Granted	510	7.16		
Exercised	(402)	8.03		
Expired	(5)	8.73		
Forfeited	(64)	10.12		
Outstanding on December 31, 2020	1,232	$ 10.12	6.79	$ 2,688
Vested or expected to vest as of December 31, 2020	1,232	$ 10.12	6.79	$ 2,688
Exercisable on December 31, 2020	636	$ 11.62	4.87	$ 1,034

As of December 31, 2020, there was $1,689 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.6 years.

Net cash proceeds from the exercise of stock options were $3,222, $196 and $1701 for the years ended December 31, 2020, 2019, and 2018, 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, 2020:

	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	665	7.7	$ 6.94	182	$ 6.30
$8.87 - $13.31	368	5.8	10.99	276	10.39
$14.95 - $22.43	199	5.5	19.19	178	18.97
	1,232	6.8	$ 10.12	636	$ 11.62

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 restrictions lapse. Compensation cost of $4,094 $2,979 and $6,357 related to restricted shares was recognized during the years ended December 31, 2020, 2019, and 2018, 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, 2020	464	12.86
Granted	561	8.35
Vested	(342)	11.14
Forfeited	(24)	11.90
Issued and unvested, December 31, 2020	659	$ 9.95
Issued and expected to vest, December 31, 2020	659	$ 9.95

As of December 31, 2020, there was $3,697 of unrecognized compensation expense related to unvested restricted stock awards and unvested restricted stock units that is expected to be recognized over a weighted average period of 1.7 years.

In connection with the vesting of restricted shares during the years ended December 31, 2020, 2019 and 2018, we purchased and immediately retired 127, 76 and 171 shares with aggregate values of $1,219, $949 and $3,291, 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 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. Performance during the one-year period will be based on a one-year earnings per share or income before taxes target. If the one-year target is achieved, the PSUs will then vest three years from grant date. Performance during the three-year period will be based on achievement of a three-year compound annual growth rate for consolidated product revenues. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested. 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 $2,153, $(83) and $6,717 related to the PSUs was recognized during the years ended December 31, 2020, 2019 and 2018, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2020	525	12.52
Granted (1)	368	7.57
Performance adjustment (2)	104	N/A
Vested	(311)	8.87
Forfeited	(35)	13.87
Issued and unvested, December 31, 2020	651	$ 11.30
Issued and expected to vest, December 31, 2020	651	$ 11.30

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.

In connection with the vesting of performance stock units during the year ended December 31, 2020, 2019 and 2018, we purchased and immediately retired 121, 213, and 20 shares with aggregate values of $869, $2,763 and $301, 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 2020, 2019 or 2018.

12. TRANSITION COSTS

In January 2018, we announced the retirement of our President and CEO and our CFO and Chief Operating Officer. Stephen S. Tang, Ph.D., who served as Chairman of the Board of Directors (the "Board"), was appointed as the Company's new President and CEO, effective as of April 1, 2018. Dr. Tang replaced Douglas A. Michels, who retired as President and CEO, and as a member of the Board, on March 31, 2018. In addition, Roberto Cuca was appointed as the Company's new CFO, effective June 8, 2018. Mr. Cuca replaced Ronald H. Spair, our former CFO and Chief Operating Officer, who retired on that same date. Charges associated with these transitions were $9,602 during 2018 and are included in general and administrative expenses in the consolidated statement of income. These charges primarily reflect non-cash charges associated with modifications to existing stock grants held by the retiring executives and expenses associated with the onboarding of the Company's new President and CEO.

13. BUSINESS SEGMENT INFORMATION:

Our business consists of two segments: our "Diagnostics" business, which was previously named "OSUR", primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our Diagnostics segment includes the financial results of UrSure. Our "Molecular Solutions" business, which was previously named "DNAG," consists of the development, manufacture, marketing and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing. Our collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets; and in the sexually transmitted infection screening market. In addition, our Molecular Solutions business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research markets. Financial results of Diversigen, CoreBiome and Novosanis are included in our Molecular Solutions segment. Our cryosurgical systems business was included in our Diagnostics segment and the impact of the sale of that business in August 2019 is reflected in the results presented below.

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.

Operating income (loss) for the year ended December 31, 2018 has been modified to conform to the classification of the intercompany service fee presentation for 2019. Beginning with the first quarter of 2019, we have included the fees for intercompany services in our segment operating income (loss) in order to more accurately reflect the results of each segment.

The following table summarizes operating segment information for the years ended December 31, 2020, 2019, and 2018, and asset information as of December 31, 2020 and 2019:

	Years Ended December 31,		
	2020	2019	2018
Net revenues:			
Diagnostics	$ 65,240	$ 78,225	$ 85,635
Molecular Solutions	106,481	76,380	96,108
Total	$ 171,721	$ 154,605	$ 181,743
Operating income (loss):			
Diagnostics	$ (43,156)	$ 154	$ (15,188)
Molecular Solutions	37,979	18,457	43,617
Total	$ (5,177)	$ 18,611	$ 28,429
Depreciation and amortization:			
Diagnostics	$ 3,345	$ 3,039	$ 3,755
Molecular Solutions	6,042	4,300	3,467
Total	$ 9,387	$ 7,339	$ 7,222
Capital expenditures:			
Diagnostics	$ 17,860	$ 6,073	$ 4,893
Molecular Solutions	8,814	3,241	1,451
Total	$ 26,674	$ 9,314	$ 6,344

	December 31,	
	2020	2019
Total assets:		
Diagnostics	$ 242,613	$ 163,943
Molecular Solutions	211,859	185,352
Total	$ 454,472	$ 349,295

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

	December 31,	
	2020	2019
United States	$ 36,897	$ 23,846
Canada	10,616	5,697
Other regions	4,347	796
	$ 51,860	$ 30,339

14. COMMITMENTS AND CONTINGENCIES:

Purchase Commitments

As of December 31, 2020, we had outstanding non-cancelable purchase commitments related to inventory, supplies, capital expenditures, and other goods or services as follows:

2021	16,542
2022	20
2023	18
	$16,580

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:

2021	2,947
2022	1,213
2023	409
2024	—
	$4,569

Litigation

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.

On February 6, 2017, DNAG entered into a settlement and license agreement (the "Settlement Agreement") in order to settle certain patent infringement and breach of contract litigation against Ancestry.comDNA, LLC ("Ancestry") and its contract manufacturer. This litigation was related to a saliva DNA collection device sold by Ancestry that was similar to products sold by DNAG. Under the terms of the Settlement Agreement, DNAG and Ancestry agreed to certain procedures for considering whether future versions of Ancestry's saliva DNA collection product are covered by the DNAG patents licensed to Ancestry (the "Licensed Patents") and thus subject to ongoing royalties under the Settlement Agreement. A dispute arose among the parties regarding whether certain new Ancestry products are covered by the Licensed Patents. Pursuant to the terms of the Settlement Agreement, a binding arbitration proceeding was commenced to resolve the dispute. In February 2020, an arbitration panel issued a decision finding that the future Ancestry products do not infringe the DNAG patents asserted in the arbitration and would no longer be subject to the royalties under the Settlement Agreement.

Following the completion of the arbitration, a new patent was issued to DNAG that is a continuation of a patent licensed to Ancestry and is thus a Licensed Patent under the Settlement Agreement. DNAG notified Ancestry of this new patent and following discussions between the parties Ancestry initiated a new arbitration proceeding during the third quarter of 2020 pursuant to the Settlement Agreement with respect to the applicability of the new patent to the future Ancestry products and the validity of that patent. Following the initiation of the arbitration by Ancestry, DNAG filed a statement of defense and an objection to the arbitration on the basis that a dispute between the parties has not yet occurred and therefore the alleged dispute is not sufficiently ripe to arbitrate. An arbitration panel has been appointed. The parties have since engaged in settlement discussions and the commencement of the arbitration has been delayed.

15. 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 $994, $754 and $721 to the 401(k) Plan, net of forfeitures, in 2020, 2019, and 2018, 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, 2020 and 2019, the value of the assets associated with this plan was $2,565 and $3,519, 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, 2020 and 2019, our total obligation under this plan was $2,565 and $3,519, 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 $366, $184 and $163 to the RRSP in 2020, 2019, and 2018, respectively.

Exhibit 23

Consent of Independent Registered Public Accounting Firm

The Board of Directors
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-3 (No. 333-228877) and Form S-8 (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) of OraSure Technologies, Inc. of our reports dated March 1, 2021, with respect to the consolidated balance sheets of OraSure Technologies, Inc. as of December 31, 2020 and 2019, and 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, 2020, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2020, which reports appear in the December 31, 2020 annual report on Form 10-K of OraSure Technologies, Inc.

Our report on the consolidated financial statements refers to a change in the accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases*.

Our report dated March 1, 2021, on the effectiveness of internal control over financial reporting as of December 31, 2020, contains an explanatory paragraph that states that the Company acquired UrSure, Inc. during 2020, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, UrSure Inc.'s internal control over financial reporting associated with approximately 1.7% of total assets and 0.5% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2020. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of UrSure, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 1, 2021

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/s/ *Stephen S. Tang*,
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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/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 Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

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

David J. Shulkin, M.D.
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Miller and Jack E. Jerrett,** 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, 2020, 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 March 1, 2021.

/s/ *James A. Datin*
Signature

James A. Datin
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, 2021

/s/ Stephen S. Tang
Stephen S. Tang, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Roberto Cuca, 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, 2021

/s/ Roberto Cuca
Roberto Cuca
Chief Financial Officer
(*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, 2020 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, 2021

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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roberto Cuca, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/Roberto Cuca
Roberto Cuca
Chief Financial Officer
March 1, 2021