

**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, 2019

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)

(610) 882-1820

(Registrant's Telephone Number, Including Area Code):

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock, \$0.000001 par value per share

Name of Each Exchange on Which Registered
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 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, 2019): \$569,761,924

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 21, 2020: 62,002,705 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2020 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; 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 “OSUR” business, which 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 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.

The second segment is our “DNAG” or molecular products and services business and is operated primarily through our subsidiaries, DNA Genotek Inc. (“DNAG”), a company based in Ottawa, Canada, CoreBiome, Inc. (“CoreBiome”), Diversigen, Inc. (“Diversigen”) and Novosanis NV (“Novosanis”). In the DNAG 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. Our Oragene® DNA sample collection kit provides an all-in-one system for the collection, stabilization, transportation and storage of DNA from human saliva. 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 CoreBiome and Diversigen. 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 DNAG business serves customers in many countries worldwide, including many leading research universities and hospitals.

OraSure was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. (“STC Technologies”) and Epitope, Inc. (“Epitope”), and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into OraSure on September 29, 2000. Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

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.

2019 Developments

In early January 2019, we acquired two privately-held, early-stage companies, CoreBiome and Novosanis, in order to add differentiated products and services to the molecular collection systems segment of our business.

CoreBiome, a spin-off from the University of Minnesota, is based in St. Paul, Minnesota and provides microbiome laboratory and analytical services that can accelerate research and discovery for customers in the pharmaceutical, agricultural and academic research communities. CoreBiome was co-founded in 2016 by Dr. Dan Knights, a globally-recognized expert in microbiome informatics who has developed leading methods for analyzing microbiome data, along with Dr. Daryl Gohl and Dr. Kenny Beckman, domain experts in microbiome sample processing and analysis.

Novosanis is a Belgian company that was founded in 2013 as a spin-off from the University of Antwerp, Belgium. Novosanis is an early commercial stage producer and distributor of urine sample collection devices targeting the liquid biopsy and sexually transmitted infection screening markets. Novosanis’ primary product is Colli-Pee, an easy to use device designed for the standardized collection of first-void urine which can be used in the privacy of the user’s home or in a clinic. Product validation and clinical trials are also under way with various sexually transmitted infection test manufacturers.

In August 2019, we sold our cryosurgical systems line of business to a third party. This line of business consisted of medical devices used for the removal of benign skin lesions by cryosurgery or freezing.

In November 2019, we acquired another microbiome laboratory services provider, Diversigen. Based in Houston, Texas, Diversigen provides science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome. The company was founded in 2013 by Dr. Joseph Petrosino, director of the Alkek Center for Metagenomics and Microbiome Research at the Baylor College of Medicine (“BCM”), where Diversigen was a BCM portfolio company. Diversigen was the first company to establish microbiome protocols in accordance with College of American Pathologists (“CAP”) accreditation and Clinical Laboratory Improvements Amendments of 1988 (“CLIA”) guidelines.

OSUR Segment Products

The following is a summary of our principal products for the infectious disease and risk management markets, which comprise the OSUR 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 generally 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 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 Improvement 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 uses the same diagnostic technology as our U.S. approved OraQuick *ADVANCE*® HIV test but is sold for use by individuals in certain foreign countries at a lower cost to meet the needs of those markets. For the past several years, we worked with Population Services International (“PSI”), a leading global health organization, along with UNITAID, the WHO and health officials from several African countries to deploy our Self-Test through the UNITAID-PSI HIV Self-Testing in Africa (“STAR”) project. The OraQuick® Self-Test has labeling and instructions specifically tailored for each market in which it is sold. The purpose of the STAR project was to generate crucial information about how best to deliver HIV self-testing, how to generate demand for HIV testing in this manner and what the potential public health impact of self-testing will be. Our OraQuick® Self-Test was chosen by PSI because of its quality, ease-of-use and oral fluid option. The STAR project has largely been completed. 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. During 2019, a majority of the sales of our OraQuick® HIV Self-Test occurred in countries outside of the African countries covered by the STAR project.

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

In 2019, we received 510(k) clearance from the FDA for our new 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. Under this 510(k) clearance, which came through the FDA’s Breakthrough Devices Program that allows for expedited clearance for treatment or diagnosis of life-threatening or increasingly debilitating diseases, our test 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. This test had previously received emergency use authorization (“EUA”) from the FDA for emergency use by laboratories and facilities adequately equipped, trained and capable of testing for Ebola infection (including treatment centers and public health clinics). The WHO also previously issued an Emergency Use Assessment and Listing for this product.

OraSure QuickFlu® Rapid Flu A&B Test

The OraSure QuickFlu® Rapid Flu A&B test is an FDA 510(k) cleared rapid qualitative test for the detection of influenza (flu) Types A and B, including H1N1 viral infections. The test utilizes specimen collected with a nasal swab, nasopharyngeal swab or nasal aspirate/wash. A reagent is first inserted into a test cartridge, the specimen is added and the test is allowed to flow. Results are available in as little as 10 minutes. This product is manufactured for us under an agreement with a third party and is currently sold in certain U.S. markets. The manufacturer of this product has also obtained a CLIA waiver for use of the test with nasal and nasopharyngeal swabs.

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 either a western blot confirmatory test or 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.

Tuberculosis (“TB”) Products

OMNIgene® • SPUTUM is a non-toxic and highly stable reagent that liquefies and decontaminates sputum samples at the point-of-collection or in the lab while preserving the viability of TB bacteria for at least eight (8) days at ambient temperatures.

Although the OMNIgene® • SPUTUM product is CE marked and was being evaluated by a number of TB laboratories, demand for this product has not met expectations. Accordingly, we decided to stop selling this product in the second half of 2019.

Intercept® Drug Testing System

A collection device that is substantially similar to the OraSure® 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 an amendment to the Thermo Fisher agreement, we have agreed to modify the configuration of our Intercept i2®*he* device and Thermo Fisher will further optimize its assays and related calibrators in order to meet recently issued oral fluid drug testing guidelines issued by the Substance Abuse and Mental Health Services Administration (“SAMHSA”). We also intend to obtain FDA 510(k) clearance of our device for use with a 12-assay panel of the Thermo Fisher assays.

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.

In a MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of reagents by laboratory personnel. Test results are analyzed by any of a variety of commercially available laboratory instruments, which we may also provide to our laboratory customers. 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.

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. These reagents are run on commercially available laboratory-based automated analytical instruments, which are manufactured by a variety of third parties. AUTO-LYTE® is typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput. Our AUTO-LYTE® tests continue to face strong competition from cheaper “home-brew” tests developed internally by our laboratory customers. As a result, we may eventually stop selling our AUTO-LYTE® tests.

We previously entered into an agreement with Thermo Fisher under which Thermo Fisher would develop and supply up to 12 fully-automated high-throughput oral fluid drug assays for use with our Intercept i2® device. Under this agreement, we are currently selling a NIDA-5 panel of assays supplied by Thermo Fisher in the U.S. forensic market. As noted above, the parties amended this agreement and have agreed to modify our Intercept i2® collector and optimize the assays and related calibrators to meet recently issued SAMHSA drug testing guidelines and to pursue FDA 510(k) clearance of the Intercept i2® device for use with a 12-assay panel. We believe the offering of an Intercept i2® device with a full menu of fully-automated high-throughput oral fluid assays that meet the SAMHSA guidelines will better meet the needs of our laboratory drug testing customers and allow us to compete more effectively against fully automated urine drug assays that dominate the drug testing market.

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 Products and Services 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 DNA 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.

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 vaginal and oral samples.

Molecular Services.

Our molecular business also offers customers our GenoFIND[™] services, a suite of genomic services that range from package customization and study design optimization to extraction, analysis and reporting services. Our GenoFIND[™] offering has become an increasingly valuable tool for meeting the needs of our molecular customers.

Through our subsidiaries, CoreBiome and Diversigen, we also offer our customers microbiome laboratory testing and analytical services. CoreBiome provides its services with a focus on accelerating microbiome discovery for customers in the pharmaceutical, agriculture, and research communities, to unleash the translational potential of the microbiome. Through its proprietary BenchMark[™], BoosterShot[™], and Core Analysis[™] platforms, CoreBiome provides fast and information-rich characterizations of microbial diversity and function paired with expert analytics.

Diversigen’s offering provides 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 was the first company to establish microbiome protocols that comply with CAP accreditation and CLIA guidelines. We are 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 collection 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. Both CoreBiome and Diversigen provide molecular services in CLIA-certified laboratories and as noted above, Diversigen's laboratory protocols comply with CAP guidelines.

Products Under Development

Infectious Disease

Our research and development efforts include programs targeted at expanding and enhancing our infectious disease business. These programs primarily focus on products related to drug monitoring, rapid tests for diseases other than HIV and HCV and drug testing. A significant amount of effort in 2020 will be devoted to modifying our Intercept® i2he collection device and optimizing the Thermo Fisher fully-automated oral fluid drug assays to meet the recently issued SAMSHA drug testing guidelines. Another development area is focused on increasing the number of country registrations for our HIV Self-Test and expanding our self-testing franchise to include other diseases such as HCV. Finally, we are looking at both internal and external opportunities to develop rapid point-of-care assays for drug adherence testing in the same markets where we currently sell our infectious disease diagnostic products.

Molecular Product and Services

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.

Research and Development

Research and development expenses were \$19.6 million in 2019, \$16.3 million in 2018 and \$13.4 million in 2017. These expenses include our costs associated with research and development, regulatory affairs, clinical trials and product support.

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 \$107.3 million, \$136.8 million and \$121.5 million in 2019, 2018 and 2017, respectively. Consolidated net revenues attributable to international customers amounted to \$47.3 million, \$44.9 million and \$45.6 million, or 31%, 25% and 27% of our total revenues, in 2019, 2018 and 2017, respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Notes 2 and 14 to our consolidated financial statements included elsewhere in this Annual Report.

Infectious Disease Testing - 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. In the past, we sold our OraQuick *ADVANCE*[®] test directly to hospitals in the U.S. through our internal sales force. We are now changing this approach to sell to hospitals 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.

We initially sold our OraQuick[®] Ebola test under an EUA and our only customer to date has been the CDC, which has purchased the product for field testing in Africa. There were approximately \$200,000 of Ebola sales in 2019. Our ability to expand sales of this test to other customers will likely depend on the timing and extent of future outbreaks of the disease and the availability of government or other funding. We recently obtained FDA 510(k) clearance for this product and plan to request pre-qualification with the WHO.

We market the OraSure[®] oral fluid collection device for HIV-1 testing, on its own and as a kit in combination with laboratory testing services. To better serve our public health customers, we have contracted a commercial laboratory to provide prepackaged OraSure[®] test kits, with prepaid laboratory testing and specimen shipping costs included.

We also have distribution rights to an FDA 510(k) cleared and CLIA waived rapid flu A&B test, which we market under our proprietary OraSure QuickFlu[®] tradename. Under our agreement with the supplier of this product, we are permitted to sell this product into the U.S. hospital and public health markets.

Infectious Disease Testing - 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 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.

To support individuals that purchase and use our test, we offer toll-free customer support on a 24/7, 365-day per year basis. This service provides consumers with access to trained representatives who can answer questions about HIV/AIDS and the use of our test, and refer consumers to appropriate resources for follow-up confirmatory testing, counseling and medical treatment.

In 2016, we began selling our OraQuick[®] HIV Self-Test to PSI (Population Services International) for use in a self-testing pilot program called the HIV Self-Testing in Africa, or STAR, project. Under Phase I of the project, our test was sold in three African countries, Malawi, Zambia and Zimbabwe. We were also selected to participate in Phase II of the project under which additional HIV Self-Tests were deployed. Although our participation in the STAR project has largely been completed, we registered our HIV Self-Test and continue to sell this product in other countries in Africa and elsewhere.

In June 2017, we entered into a Charitable Support Agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) that has enabled us 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 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 funding from the Gates Foundation will be in an aggregate amount not to exceed \$20.0 million over the four-year term or \$6.0 million each year of the agreement.

In July 2017, our OraQuick® HIV Self-Test was prequalified by the WHO. WHO prequalification aims to 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 an amendment to our Thermo Fisher agreement, we plan 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 recently issued 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 expect that the 510(k) cleared Intercept i2® device and related fully-automated high-throughput assays will eventually replace our original Intercept® collector and MICRO-PLATE assays in the drug testing market.

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.

Insurance Risk Assessment

We currently market the OraSure® oral fluid collection device for use in screening life insurance applicants in the United States and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine and cotinine (a metabolite of nicotine). Devices are sold to insurance testing laboratories, which in turn sell the devices to insurance companies, usually in combination with testing services.

We also promote use of the OraSure® device directly to insurance companies for life insurance risk assessment. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services.

There exists a wide range of policy limits where our OraSure® product is being used. In general, many (but not all) of our insurance company customers use the OraSure® device in connection with life insurance policies having face amounts of up to \$250,000, with some customers using the device for policies of up to \$500,000 in amount. Some insurance companies have chosen to extend their

testing to lower policy limits where they did not test at all before, while others have used OraSure® to replace some of their blood and urine-based testing. In recent years, some insurance customers have adopted a “Simplified Issues” policy, where lab testing is no longer required and instead the applicant completes a questionnaire about personal behaviors.

We also sell our AUTO-LYTE® assays and reagents in the insurance testing market directly to certain laboratories.

Molecular Products and Services

DNAG sells its products directly to its customers, primarily through its own internal sales force. In many international markets, distributors are used.

Most of DNAG’s revenues are derived from product sales to commercial customers and 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 of DNAG’s revenues. A significant portion of DNAG’s sales are derived from repeat customers, in both markets. DNAG also has customers in the livestock and companion animal markets.

DNAG has expanded its market focus by developing new collection devices for the emerging microbiome market, which is focused on the study of microbes and their effect on human health. DNAG’s primary product offering in the microbiome market, OMNIgene® • GUT, is focused on the human gut microbiome (microbes living in human stool). DNAG is leveraging its 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.

During 2019, we began selling the Colli-Pee® device for the volumetric collection of first void urine, as a result of our acquisition of Novosanis. 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.

DNAG is also 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. We expect to integrate the laboratory operations of CoreBiome and Diversigen so that we can provide a single-integrated offering to our customers.

Significant Products and Customers

Several different products 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 revenues (dollars in thousands).

	For the years ended December 31,		
	2019	2018	2017
OraGene®	\$ 46,701	\$ 69,798	\$ 67,232
OraQuick® HIV	43,092	41,457	35,148
OraQuick® HCV	12,972	12,394	25,409

One of our customers accounted for approximately 15%, 24% and 25% of our net consolidated revenues in 2019, 2018 and 2017, respectively.

Supply and Manufacturing

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 are all manufactured 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. This supply agreement had an initial term of one year, and automatically renews for additional annual periods unless either party provides a timely notice of termination prior to the end of an annual period. 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.

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.

Our OraSure QuickFlu® test is manufactured and supplied under a private label agreement with a third party. There is no other supply source for this product.

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 two 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.

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 subsidiaries, CoreBiome and Diversigen.

Employees

As of December 31, 2019, we had 472 full-time employees. Of this total, there were 139 in sales, marketing and client services; 58 in research and development; 187 in operations, manufacturing, quality control, information systems, purchasing and shipping; 44 in quality assurance and regulatory affairs; and 44 in administration and finance. This compares to 398 employees as of December 31, 2018. Our employees are not currently represented by a collective bargaining agreement.

Competition

OSUR 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.

Competition for our OraQuick® Ebola test includes government and commercially-developed laboratory and point-of-care molecular tests, along with a small number of rapid antigen tests sold under an FDA EUA. Our Ebola test is the only product with FDA 510(k) clearance for use on both whole blood samples from living patients and oral fluid samples from cadavers.

The OraSure QuickFlu® test competes primarily against other rapid flu tests sold by various third parties in the U.S. hospital and public health markets.

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. In the past, these laboratories have typically had to rely on radioimmunoassay test methods to provide an adequate level of sensitivity. Radioimmunoassays require radioactive materials, which have a short shelf-life and disposal problems. Our MICRO-PLATE tests meet the laboratories’ sensitivity needs, run on automated equipment, are not radioimmunoassays, and are offered to the laboratory as a complete system solution of reagents, instrumentation and software to meet the specific needs of each customer. We compete with both homogeneous and heterogeneous tests manufactured by many companies.

Sales of our AUTO-LYTE® urine assays have declined substantially over a number of years, primarily due to competition from “home-brew” assays developed internally by our laboratory customers, which can be produced at a cost lower than the price typically paid for our products. Many of our customers no longer purchase our AUTO-LYTE® assays, and we may eventually stop selling this product line.

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 Products and Services

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.

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, DNAG is 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 November 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 hold, through our subsidiary, DNAG, twenty 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, two United States patents and numerous foreign patents covering a medical device for capturing a predetermined volume of first void urine and an intradermal injection device for accurate injection of small volumes of drugs in the skin. These patents expire from April 2034 through April 2035.

Our subsidiary, CoreBiome, 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.

Our subsidiary, Diversigen, has 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[®], ORAcollect[®], OMNIgene[®], Diversigen[®], Colli-Pee[®], VAX-ID[®], 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 U.S. Food and Drug Administration ("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.

There are several mechanisms by which regulated devices can be placed on the market in the United States. Some products 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 FDA has previously 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) application at least 90 days before commercial distribution of the affected 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 high risk device, the FDA must approve either a request for *de novo* classification or a premarket approval application, or 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. Clearance of a *de novo* request generally takes 150 days from the time of submission of the *de novo* request, although it can take longer. PMAs are generally required for devices that are determined to be high risk 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 (AIP). 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.

If there are any modifications made to our marketed devices, a new premarket notification or PMA supplement may be required to be submitted to, and approved 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 Investigational Device Exemption, or IDE, application approved in advance by the FDA for a specified number of patients, unless the proposed study is deemed to be exempt from the IDE requirements. In addition, if a study meets the requirements for a non-significant risk study, it may be eligible for compliance with "abbreviated" IDE requirements, which include a subset of the requirements applicable to significant risk medical device studies. If a full IDE is required, 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, or IRBs, 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.

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.

Another option for marketing a product in the U.S. is through an EUA that is granted by the FDA as a result of the Secretary of Health and Human Services declaring an emergency justifying the authorization of emergency use of certain in vitro diagnostic devices to aid in addressing the emergency. Typically, analytical and clinical studies are completed as required by the FDA. Products are exempt from design controls and other quality requirements in order to expedite development of diagnostic tools to aid in the diagnosis of viral pathogens that have the potential to affect public health.

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 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 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 QSR 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, or 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 applicable to the category of examination or procedure performed. Tests may be waived from this regulatory oversight if they 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. A CLIA waiver allows certain customers to use the waived products that may not have been able to use them without complying with applicable quality control and other requirements.

The laboratory services provided by our subsidiaries, CoreBiome and Diversigen, operate under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and consist of microbiome and metagenomics sequencing, bioinformatics and analysis. CoreBiome has recently received a CLIA certificate of registration in Minnesota and Diversigen operates under the Baylor College of Medicine CLIA certificate of compliance and CAP accreditation. 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. CAP accredits 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 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 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 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 device Regulation (the “EU MDR”) and the In Vitro Diagnostic Regulation (the “EU IVDR”), each of which 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 2020 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 have completed the applicable conformity assessment procedures and obtained the right to use the CE mark for the OraQuick *ADVANCE*[®] HIV-1/2 test, OraQuick In-Home HIV Test, the OraQuick[®] HCV test and certain of the Oragene[®] collection kits and OMNIgene[®] products sold by DNAG and the Colli-Pee[®] first-void urine collection devices manufactured and sold by Novosanis.

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 OSUR segment 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 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. 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 false claims laws, marketing conduct laws and laws constraining 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 professionals and providers. For example, under the Sunshine Act provisions of the Affordable Care Act, device manufacturers are subject to new federal reporting and disclosure requirements with regard to payments or other transfers of value made to physicians and teaching hospitals. Reports submitted under the Sunshine Act are placed in a public database. Device manufacturers are required to submit annual reports by March 31 which cover the prior calendar year. To be in compliance with such disclosure laws, 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”) prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to use any means of interstate commerce corruptly in the furtherance of any offer, payment, promise to pay or authorization of payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. 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. Those laws 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 Restriction of the Use of Hazardous Substances Directive, or RoHS. RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU’s Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products.

Future environmental laws may require us to alter our manufacturing processes, thereby increasing our manufacturing costs. 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

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

Customer Concentration and Purchase Seasonality Creates Risk for Our Business.

Our revenues have been heavily impacted by purchases from a few large customers. For example, our molecular collections product sales grew from \$75.1 million in 2017 to \$86.5 million in 2018, largely as a result of increased orders of our Oragene® collection systems by our largest customer serving the consumer genomics market. However, sales of molecular products declined in 2019 to \$70.8 million. In November 2017, we announced the execution of a multi-year purchase agreement for the sale of \$144 million of our Oragene® product to a large consumer genomics customer. The reduction in molecular product sales in 2019 was largely due to the large consumer genetics customer, which changed its promotional and purchasing plans at the end of 2018 and lowered purchases in 2019. We recently amended our agreement with this customer to extend its term for an additional two years and lower the customer's annual purchase volumes to better reflect market conditions, although the aggregate purchase commitment under this agreement did not change.

We expect that sales to the large consumer genetics customer will continue to be a significant contributor to our molecular business. As a result, certain parts of our business may continue to have a high customer concentration and depend disproportionately on a few large customers. In addition, demand from the large consumer genomics customer increased significantly in prior periods due to special retail promotions and holiday shopping towards the end of these years. To the extent that such a large customer fails to meet its purchase commitments, does not continue such promotional programs, changes its ordering patterns or business strategy, or otherwise reduces its purchases or stops purchasing our products, or if we experience difficulty in meeting the high demand by these larger customers for our products, our revenues and results of operations could be adversely affected.

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. As noted above, 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 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 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 service offerings, such as the microbiome laboratory testing and analytical services we provide through CoreBioime and Diversigen. To achieve market acceptance, we will likely be required to undertake substantial marketing efforts and spend significant funds to inform potential customers and the public of the existence and perceived benefits of these products and services. In addition, governmental funding for the purchase of our products and services may be needed to help create market acceptance and expand the use of our products.

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 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 OraQuick® Ebola test or the new sample collection and stabilization products being commercialized by DNAG. 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.

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. 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.

Our Customers May Resist Adoption of Rapid Point-of-Care Diagnostic Testing.

Sales of our rapid point-of-care diagnostic products, such as our OraQuick *ADVANCE*® HIV-1/2, OraQuick® HCV, OraQuick® In-Home HIV test and OraQuick® HIV Self-Test products, are an important part of our business. Rapid point-of-care tests are beneficial because, among other things, they can be administered by healthcare providers in their own facilities or used by consumers at home without sending samples to central laboratories and can help ensure that test results are delivered to the individuals being tested.

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. 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.

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.

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 Inability to Carry Out Certain of Our Marketing and Sales Plans May Make it Difficult for Us to Grow or Maintain Our Business.

We have implemented in the past, and we intend to implement in the future, an aggressive sales and marketing plan to expand sales of our products and services. If we are unable to successfully implement these programs or modify these programs in response to evolving market and economic conditions, we may be unable to grow and our business could suffer.

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.

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.

The Insurance We Purchase to Cover Our Potential Business Risks May be Inadequate.

Although we believe that our present product liability and other insurance coverage is sufficient to cover our current estimated exposures, we cannot be sure that we will not incur liabilities in excess of our policy limits. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

We Could Suffer Monetary Damages, Incur Substantial Costs or be Prevented From Using Technologies Important to Our Products and Services as a Result of Legal Proceedings.

We have been, and in the future may become, involved in various legal proceedings arising out of our businesses. These may include commercial disputes, negligence claims or various other lawsuits arising in the ordinary course of our business, including employment matters. Such lawsuits can seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, result in the termination or modification of a material contract or otherwise have a material adverse effect on our sales, operations or financial performance.

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 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. While we believe international sales these and other products represent attractive long-term opportunities with significant growth potential, there is no guarantee that these opportunities will 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 \$47.3 million or 31% of consolidated net revenues in 2019, \$44.9 million or 25% of consolidated net revenues in 2018 and \$45.6 million or 27% of consolidated net revenues in 2017. In addition, our subsidiary DNAG, which accounted for \$70.2 million or 45% of consolidated net revenues in 2019, is operated in Canada. 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 outbreak emanating from China 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

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.

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.

Accordingly, 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.

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.

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;
- 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.

Risks Relating To Our Acquisitions of CoreBiome, Diversigen and Novosanis.

The integration of the CoreBiome, Diversigen and Novosanis businesses may be more difficult, costly or time consuming than expected, and the anticipated benefits and cost savings of these acquisitions may not be realized in full or at all.

The success of the CoreBiome, Diversigen and Novosanis acquisitions will depend, in part, on our ability to successfully combine and integrate our legacy business with the businesses of CoreBiome, Diversigen and Novosanis. The integration of CoreBiome, Diversigen and Novosanis' businesses with our existing business and the integration of the CoreBiome and Diversigen laboratory operations are each 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 CoreBiome, Diversigen and Novosanis 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 the Combined Companies May Be Adversely Impacted if We Do Not Effectively Manage Our Expanded Operations.

Following the completion of the CoreBiome, Diversigen and Novosanis 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 CoreBiome, Diversigen and Novosanis 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 testing products. For example, domestic professional OraQuick® HIV sales have decreased in recent years 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.

New Tariffs and Other Trade Measures Could Adversely Affect Our Financial Position, Results of Operations and Cash Flows.

The current U.S. Administration has expressed strong concerns about imports from countries that it perceives as engaging in unfair trade practices, and it is possible the administration could impose import duties or other restrictions on products, components or raw materials sourced from those countries, which may include countries from which we import components or raw materials. Any such import duties or restrictions could have a material adverse effect on our business, results of operations or financial condition. Moreover, these new tariffs, or other changes in U.S. trade policy, could trigger retaliatory actions by affected countries. Certain foreign governments have instituted or are considering imposing trade sanctions on certain U.S. goods.

Other foreign governments are considering the imposition of sanctions that will deny U.S. companies access to critical raw materials. A “trade war” of this nature or other governmental actions related to tariffs or international trade agreements or policies has the potential to adversely impact demand for our products, our costs, customers, suppliers and/or the economic environments in which we operate and, thus may adversely impact our businesses. Recent international events have introduced greater uncertainty with respect to trade wars and tariffs, which may affect trade between the United States and other countries, particularly with China. On January 15, 2020, the United State and China signed a “Phase One” deal in the ongoing trade war, resulting in suspension of a second tranche of certain duties.

In addition, the U.S., Mexico and Canada have negotiated and reached an agreement on the U.S. Mexico Canada Agreement (the “USMCA”), the successor agreement to the North American Free Trade Agreement (“NAFTA”). The USMCA maintains duty-free access for most products and leaves most key provisions of NAFTA largely intact. As of the date of this report, the USMCA still needs to be ratified by Canada before going into force. It remains unclear whether Canada will ratify the USMCA. Any changes to USMCA could impact our operations in countries where we manufacture or sell products or source components, or materials, which could adversely affect our operating results and our business. For example, changes in the level of reimbursement or the availability of funding for health care could create uncertainty for our business and negatively impact or revenues and results of operations. Similarly, a substantial part of DNAG’s revenues represent sales of product from Canada to the U.S. The imposition of tariffs or other changes in the trade relationship between Canada and the United States could negatively impact DNAG’s performance.

The United Kingdom’s Decision to Leave the EU Could Adversely Affect Us.

In June 2016, a majority of voters in the United Kingdom (“U.K.”) elected to withdraw from the EU in a national referendum (“Brexit”). Although the U.K. officially left the EU on January 31, 2020, the withdrawal agreement setting forth the terms of the U.K.’s departure allows for a transition period during which the U.K.’s trading relationship with the EU will remain largely unchanged. The transition period is due to end on December 31, 2020. During this transition period, the U.K. and the EU will continue to negotiate the details of their future relationship, including trade, tariff, financial services and security cooperation.

If no agreement is reached between the U.K. and the EU by the end of the transition period, it will likely have an adverse impact on labor and trade in addition to creating further short-term uncertainty and currency volatility. In the absence of a future trade deal, the U.K.’s trade with the EU and the rest of the world would be subject to tariffs and duties set by the World Trade Organization. Additionally, the movement of goods between the U.K. and the remaining member states of the EU will be subject to additional inspections and documentation checks, leading to possible delays at ports of entry and departure. These changes to the trading relationship between the U.K. and EU would likely result in increased costs of goods imported into and exported from the U.K.

At this time, the impact of Brexit remains uncertain and will depend, in part, on the final outcome of the negotiations between the U.K. and the EU. Our business in the U.K., the EU and world-wide could be affected during this period of uncertainty, and perhaps longer, by the impact of Brexit. Brexit has led to, and could further cause, volatility in global financial markets, including in global currency exchange rates, resulting in a slow-down in economic activity in the U.K., Europe or globally, negatively impact new trade agreements between the U.K and other countries, including the United States, and result in significant regulatory changes and uncertainty. One or more of these events could make it more difficult or costly to sell our products, particularly in the U.K. and Europe, and negatively affect our revenues and results of operations. Brexit may also influence other countries and result in additional countries deciding to leave the EU. This in turn could result in additional changes and uncertainty, any or all of which could negatively impact our business.

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 data.

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.

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 two third-party manufacturers to supply virtually all of its products, including its Oragene[®] line 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.

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 currently aware could adversely impact our relationship;
- Our collaborators may be acquired by another company, 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 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 gross 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.

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.

The Company believes it is neither a covered entity nor a business associate of a covered entity and is not responsible for complying with the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”). However, the Company has in place certain administrative, technical and physical safeguards to protect the privacy and security of consumers’ personal information and endeavors to comply with all applicable state and federal laws with respect to the protection of consumers’ personal information. The Company is required to comply with varying state privacy, security and breach reporting laws. If 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. 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 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 evaluating these new requirements and implementing a plan to ensure compliance. 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.

Compliance With Regulations Governing Public Company Corporate Governance and Reporting is Complex and Expensive.

Many laws and regulations impose obligations on public companies, and these obligations have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Examples include the Sarbanes-Oxley Act of 2002, the requirements of The NASDAQ Global Market, The Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC’s requirements for public companies to provide financial statements in interactive data format using the eXtensible Business Reporting Language (“XBRL”), and the International Financial Reporting Standards conversion requirements. Our implementation of certain aspects of these laws and regulations has required and will continue to require substantial management time and oversight and may require us to incur significant additional accounting and legal costs. We continually evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the ultimate amount of additional costs we may incur or the timing of such costs. These laws and regulations are also subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Although we are committed to maintaining high standards of corporate governance and public disclosure, if we fail to comply with any of these requirements, legal proceedings may be initiated against us, which may adversely affect our business.

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 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.

Evolving Legislative, Judicial and Ethical Standards on the Use of Technology and Biotechnology Could Affect Our Molecular Collection Systems Business.

The adoption of genetic testing is occurring within the broader context of a myriad of decisions related to genetic patenting and genotyping. Issues associated with regulatory requirements, health insurance, data access and privacy, intellectual property protection, national and international legislative initiatives and other variables impact the widespread adoption of genetic testing or specific segments or tests within the genetic testing market. These developments could impact sales of our molecular collection systems products.

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.

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 2019, approximately \$47.3 million of our consolidated net revenues were generated from sales in a variety of foreign countries. These international activities subject us to the FCPA, the U.K. Bribery Act and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by business entities for the purpose of obtaining or retaining business. We have operations, enter into agreements with third parties and make sales in countries known to experience corruption. Further international expansion, including the acquisition of foreign entities, may create increased exposure to such practices. Our activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents or distributors that could be in violation of various laws, including the FCPA, even though these parties are not always subject to our control. It is our policy to implement safeguards to discourage these practices by our employees and distributors, including employee training, contracts requiring compliance with the FCPA and similar rules, and standard reviews of our distributors. However, our existing safeguards and any future improvements may not prove to be effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA and other laws may result in criminal or civil sanctions, which could be severe and we may be subject to other liabilities, which could negatively affect our reputation, business, results of operations and financial condition.

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

Economic Volatility and Disruption Could Adversely Affect Our Results of Operations, Cash Flow and Financial Condition or Those of Our Customers and Suppliers.

Volatile economic conditions may occur again or continue in the future. 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. 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, 2019, our consolidated balance sheet reflected approximately \$36.2 million of goodwill and approximately \$14.7 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. In addition, as of December 31, 2019, the Company had an accumulated deficit of \$82.5 million. Even though we achieved profitability since 2015, 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 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.

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.

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.

Tax Matters, Including the Changes in Corporate Tax Rates, Disagreements with Taxing Authorities and Imposition of New Taxes Could Impact our Results of Operations and Financial Condition.

We are subject to income and other taxes in the U.S. and our operations, plans and results are affected by tax and other initiatives. On December 22, 2017, the U.S. Government enacted comprehensive tax legislation known as the Tax Cuts and Jobs Act (the "Tax Act"). This legislation made broad and complex changes to the U.S. tax code, including but not limited to a reduction in the corporate tax rate from 35% to 21%, a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries and a first year acceleration of expensing of certain capital expenditures. The Tax Act also introduced new tax laws that may impact our taxable income, which include, but not be limited to, a new provision designed to tax global intangible low taxed income ("GILTI"), limitations on the deductibility of certain executive compensation, creating a base erosion anti-abuse tax ("BEAT") and modifying or repealing many deductions and credits. Changes in the political makeup of the U.S. Congress could also result in the reversal of some or all of the effects of the Tax Act.

We are also subject to regular reviews, examinations, and audits by the Internal Revenue Service and other taxing authorities with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position.

We also need to comply with new, evolving or revised tax laws and regulations. The enactment of new or revised foreign or domestic tax regulations or increases in tariffs or changes in the application or interpretation of the Tax Act, could have an adverse effect on our business or on our results of operations.

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 or Other Catastrophic Events May Adversely Affect Our Business.

Terrorist attacks, natural disasters or other catastrophic events, 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. These events could disrupt 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.

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. Various types of disasters, including earthquakes, fires, floods, acts of terrorism and pandemics, may affect our manufacturing facilities and computer systems. 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.

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 collection systems 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;
- 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.

Investor Confidence and Share Value May be Adversely Impacted if We and/or Our Independent Registered Public Accounting Firm Conclude That Our Internal Control Over Financial Reporting is Not Effective.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us, as a public company, to include a report in our Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal control over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the overall quality of our internal controls may be affected by the internal control over financial reporting implemented by any business we acquire and our ability to assess and successfully integrate the internal controls of any such business.

If, during any year, our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, operated, tested or assessed, or if the independent registered public accounting firm interprets the requirements, rules or regulations differently than we do, then it may issue a report that is qualified. We also could conclude that our internal control over financial reporting is not effective. These events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our Common Stock.

Our Business Could Be Negatively Impacted as a Result of Stockholder Activism or an Unsolicited Takeover Proposal or a Proxy Contest.

In recent years, proxy contests and other forms of stockholder activism have been directed against numerous public companies. If a proxy contest or an unsolicited takeover proposal is made with respect to us, we could incur significant costs in defending our Company, which would have an adverse effect on our financial results. Stockholder activists may also seek to involve themselves in the governance, strategic direction and operations of our Company. Such proposals may disrupt our business and divert the attention of our management and employees, and any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers, and make it more difficult to attract and retain qualified personnel and business partners, all of which could adversely affect our business. In addition, actions of activist stockholders may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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.

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, CoreBiome, 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. We have been in a dispute with Ancestry regarding whether yet-to-be launched Ancestry products are covered by the Licensed Patents. In March 2019, Ancestry filed a Dispute Notice and Request for Arbitration (the "Notice") with an alternative dispute resolution services provider in order to initiate a binding arbitration proceeding pursuant to the Settlement Agreement. DNAG denied the allegations contained in the Notice and asserted that the potential new Ancestry products are covered by the Licensed Patents and would be subject to ongoing royalties if such products are commercialized by Ancestry. A panel of arbitrators was appointed (the "Panel") and this arbitration proceeding was completed in January 2020. In February 2020, the Panel issued a decision that found that the potential new Ancestry products do not infringe the DNAG patents asserted in the arbitration. As a result, these new Ancestry products will not be subject to the royalties under the Settlement Agreement. Under the terms of the Settlement Agreement, the Panel's decision is final and binding on the parties.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

Our Common Stock is listed for trading on the Global Select Market tier of The Nasdaq Stock Market LLC (“NASDAQ”) under the symbol “OSUR”. On February 21, 2020, there were 357 holders of record and approximately 15,402 holders in street name of our Common Stock, and the closing price of our Common Stock was \$6.09 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, 2019- October 31, 2019	—	—	—	\$ 11,984,720
November 1, 2019 - November 30, 2019	—	—	—	\$ 11,984,720
December 1, 2019 - December 31, 2019	—	—	—	\$ 11,984,720
	<u>—</u>		<u>—</u>	

⁽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

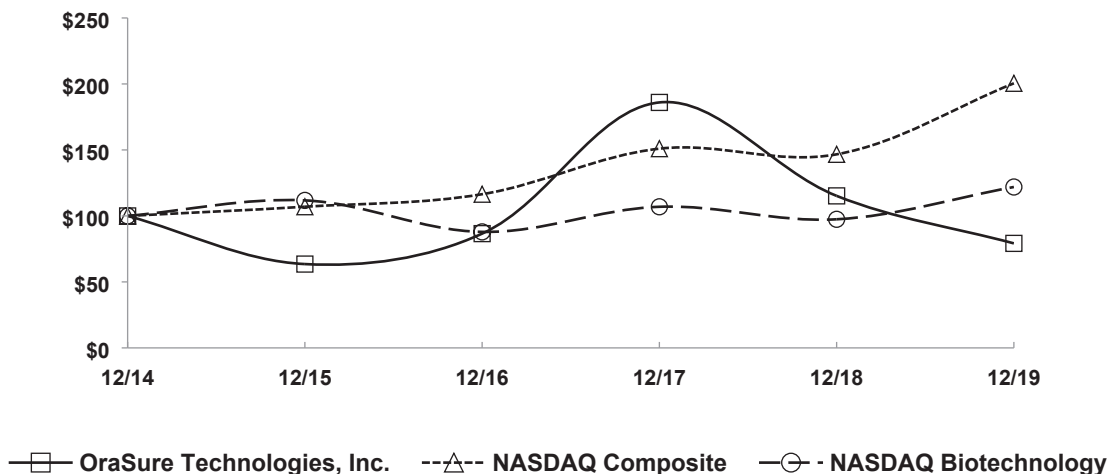
The performance graph set forth below shall not be deemed “soliciting material” or “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that Section. This graph will not be deemed “incorporated by reference” 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, 2014 through December 31, 2019. The graph assumes that \$100 was invested on December 31, 2014 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.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among OraSure Technologies, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index



*\$100 invested on 12/31/14 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

* \$100 invested on 12/31/14 in stock or index, including reinvestment of dividends.

	Fiscal year ending December 31,					
	2014	2015	2016	2017	2018	2019
OraSure Technologies, Inc.....	100.00	63.51	86.59	186.00	115.19	79.19
NASDAQ Composite	100.00	106.96	116.45	150.96	146.67	200.49
NASDAQ Biotechnology	100.00	111.77	87.91	106.92	97.45	121.92

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 6. Selected Consolidated Financial Data.

The following table sets forth selected consolidated financial data of the Company. This information should be read in conjunction with the consolidated financial statements and notes thereto included in Item 15 and the information set forth in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Selected Consolidated Financial Data
(In thousands, except per share data)

	Years ended December 31,				
	2019	2018	2017	2016	2015
Operating Results:					
Net revenues.....	\$ 154,605	\$ 181,743	\$ 167,064	\$ 128,198 ⁽⁴⁾	\$ 119,719
Costs and expenses.....	135,994 ⁽¹⁾	153,314 ⁽²⁾	126,826 ⁽³⁾	107,933	111,661
Operating income.....	18,611	28,429	40,238	20,265	8,058
Other income, net.....	2,720	3,287	794	58	774
Income tax expense.....	4,675	11,320	10,084	603	665
Net income.....	16,656	20,396	30,948	19,720	8,167
Earnings per share					
Basic.....	\$ 0.27	\$ 0.33	\$ 0.52	\$ 0.35	\$ 0.14
Diluted.....	\$ 0.27	\$ 0.33	\$ 0.51	\$ 0.35	\$ 0.14
Shares used in computing earnings per share					
Basic.....	61,675	61,112	59,050	55,615	56,397
Diluted.....	62,170	62,532	61,024	56,513	56,846
Cash Flow:					
Cash flows provided by operating activities.....	\$ 9,804 ⁽¹⁾	\$ 39,090	\$ 28,156 ⁽³⁾	\$ 24,598	\$ 15,773
December 31,					
	2019	2018	2017	2016	2015
Financial Position:					
Cash, cash equivalents, and investments.....	\$ 189,758	\$ 201,324	\$ 176,587	\$ 120,950	\$ 101,319
Working capital.....	191,837	191,332	189,668	139,106	111,480
Total assets.....	349,295	315,571	296,201	207,935	189,321
Accumulated deficit.....	(82,533)	(99,189)	(119,510)	(150,458)	(170,178)
Stockholders' equity.....	307,145	283,378	258,081	185,850	159,436

⁽¹⁾ Includes a pre-tax gain on sale of our cryosurgical business of \$10.1 million and \$664,000 of non-cash pre-tax income associated with the change in the fair value of acquisition-related contingent consideration, both of which was recorded as a reduction of operating expenses in the indicated period and \$1.8 million of transaction costs associated with our acquisitions of CoreBiome, Novosanis and Diversigen.

⁽²⁾ Includes \$9.6 million of transition costs associated with our change in management and \$1.2 million of transaction costs associated with our acquisitions of CoreBiome and Novosanis.

⁽³⁾ Includes a \$12.5 million gain associated with the settlement of our litigation with Ancestry.com DNA LLC and its contract manufacturer, which was recorded as a reduction of operating expenses in the indicated period.

⁽⁴⁾ Includes an additional \$5.4 million of exclusivity payments recognized in other revenues as a result of the early termination of our HCV co-promotion agreement with AbbVie, bringing total exclusivity payments recognized in 2016 to \$18.9 million.

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.

Overview and Business Segments

Our business consists of two segments: our “OSUR” business 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 molecular products and services or “DNAG” 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. 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 DNAG business provides microbiome laboratory and bioinformatics services. The DNAG segment also includes genomic and microbiome laboratory testing and analytical services.

Our OSUR 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, 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 OTC and public health markets in the U.S. and as a self-test to individuals in a number of other countries. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products were sold in both professional and OTC markets in North America, Europe, Central and South America, and Australia. We sold the assets associated with our cryosurgical systems business to a third party in August 2019.

Our DNAG or molecular products and services systems business is operated by our subsidiaries, DNAG, CoreBiome, Novosanis and Diversigen. DNAG’s specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other biological sample types for genetic and microbiome applications. 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 in DNA or RNA for the diagnosis of acute disease. CoreBiome and Diversigen provide the laboratory testing and bioinformatics services. Novosanis’ Colli-Pee collection device is designed for the volumetric collection of first-void urine for use in research, screening and diagnostics for the liquid biopsy and sexually transmitted infection markets. We also sell research use only sample collection products into the microbiome market and we offer our customers a suite of genomics and microbiome services, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide in the research, healthcare, pharmaceutical and agricultural communities.

Recent Developments

Business Acquisitions

In early January 2019, we acquired two privately-held, early-stage companies, CoreBiome and Novosanis, in order to add differentiated products and services to the molecular collection systems segment of our business.

CoreBiome, a spin-off from the University of Minnesota, is based in St. Paul, Minnesota and provides microbiome laboratory and analytical services that can accelerate research and discovery for customers in the pharmaceutical, agricultural and academic research communities. CoreBiome was co-founded in 2016 by Dr. Dan Knights, a globally-recognized expert in microbiome informatics who has developed leading methods for analyzing microbiome data, along with Dr. Daryl Gohl and Dr. Kenny Beckman, domain experts in genomics methods and clinical lab operations.

Novosanis is a Belgian company that was founded in 2013 as a spin-off from the University of Antwerp, Belgium. Novosanis is an early commercial stage producer and distributor of urine sample collection devices targeting the liquid biopsy and sexually transmitted infection screening markets. Novosanis' primary product is Colli-Pee, an easy to use device designed for the standardized collection of first-void urine which can be used in the privacy of the user's home or in a clinic. Product validation and clinical trials are also under way with various sexually transmitted infection test manufacturers.

In November 2019, we acquired another microbiome laboratory services provider, Diversigen. Based in Houston, Texas, Diversigen provides science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome. The company was founded in 2013 by Dr. Joseph Petrosino, director of the Alkek Center for Metagenomics and Microbiome Research at the Baylor College of Medicine ("BCM"), where Diversigen was a BCM portfolio company. Diversigen was the first company to establish microbiome protocols in accordance with CAP accreditation and CLIA guidelines.

We used cash of \$23.8 million in the aggregate to pay for the acquisition of these three companies. Through December 31, 2019, we have incurred a total of \$1.8 million of acquisition related costs, including investment banking fees and accounting, legal and other professional fees, related to the acquisitions, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of income for the year ended December 31, 2019.

Sale of Business Line

In August 2019, we sold all rights and title to the assets necessary to operate our cryosurgical systems line of business to a third party for \$12.0 million. We also entered into a transition services agreement with this party in which both parties agreed to provide certain transition services beginning after the closing. This line of business consisted of medical devices used for the removal of benign skin lesions by cryosurgery or freezing. A \$10.2 million pre-tax gain on the sale of the business is reflected in our statement of income for the year ended December 31, 2019 and 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.

Current Consolidated Financial Results

During the year ended December 31, 2019, our consolidated net revenues decreased 15% to \$154.6 million, compared to \$181.7 million for the year ended December 31, 2018. Net product and service revenues during the year ended December 31, 2019 decreased 10% when compared to 2018, primarily due to lower sales of our genomics products and lower cryosurgical sales as a result of the divestiture of our cryosurgical systems business in mid-August. Partially offsetting these decreases were higher sales of our microbiome and OraQuick® HIV and HCV products. Other revenues in 2019 were \$6.5 million compared to \$16.3 million in 2018. Other revenues in 2019 consisted of royalty income of \$5.1 million and other revenues of \$1.4 million associated with funded research and development, reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"), and grant revenue. Other revenues in 2018 consisted of royalty income of \$9.7 million and \$6.6 million of other revenue associated with funded research and development and cost reimbursement from the Gates Foundation.

Our consolidated net income for the year ended December 31, 2019 was \$16.7 million, or \$0.27 per share on a fully-diluted basis, compared to consolidated net income of \$20.4 million, or \$0.33 per share on a fully-diluted basis, for the year ended December 31, 2018. Results for the current year 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 pre-tax acquisition-related transaction costs associated with the three acquisitions that occurred in 2019. The combined net impact of these items increased earnings per share by approximately \$0.14. Results for the year ended December 31, 2018 included \$9.6 million of management transition costs associated with the 2018 retirements of our former President and Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") and Chief Operating Officer, and the appointment of their successors. The results for the year ended December 31, 2018 also included \$1.2 million of pre-tax acquisition-related transaction costs associated with the acquisitions that were completed in January 2019. The combined impact of these charges decreased earnings per share by approximately \$0.18.

Cash provided by operating activities for the year ended December 31, 2019 was \$9.8 million. Cash provided by operating activities during the year ended December 31, 2018 was \$39.1 million. As of December 31, 2019, we had \$189.8 million in cash, cash equivalents, and available-for-sale securities, compared to \$201.3 million at December 31, 2018.

Results of Operations

YEAR ENDED DECEMBER 31, 2019 COMPARED TO DECEMBER 31, 2018

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		
	2019	2018	% Change	2019	2018	
OSUR.....	\$ 77,259	\$ 78,973	(2) %	50 %	43 %	
DNAG.....	70,814	86,455	(18)	46	48	
Net product and service revenues.....	148,073	165,428	(10)	96	91	
Other	6,532	16,315	(60)	4	9	
Net revenues.....	<u>\$ 154,605</u>	<u>\$ 181,743</u>	(15) %	<u>100 %</u>	<u>100 %</u>	

Consolidated net product and service revenues decreased 10% to \$148.1 million in 2019 from \$165.4 million in 2018. Lower sales of our genomics and cryosurgical systems products were partially offset by higher microbiome product and service revenues and by higher OraQuick® HIV and HCV product revenues. Other revenues in 2019 consisted of \$5.1 million in royalty income and \$1.4 million associated with funded research and development, grants, and reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Other revenues in 2018 consisted of royalty income of \$9.7 million and \$6.6 million of other revenue associated with funded research and development and cost reimbursement from the Gates Foundation.

Consolidated net revenues from products sold to customers outside of the United States were \$47.3 million and \$44.9 million, or 31% and 25% of total net revenues, during the years ended December 31, 2019 and 2018, 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

OSUR Segment

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

Market	Years Ended December 31,					
	Dollars			Percentage of Total Net Revenues		
	2019	2018	% Change	2019	2018	
Infectious disease testing.....	\$ 58,016	\$ 56,148	3 %	74 %	65 %	
Risk assessment testing.....	12,189	12,058	1	16	14	
Cryosurgical systems	7,054	10,767	(34)	9	13	
Net product revenues.....	77,259	78,973	(2)	99	92	
Other	966	6,662	(85)	1	8	
Net revenues.....	<u>\$ 78,225</u>	<u>\$ 85,635</u>	(9) %	<u>100 %</u>	<u>100 %</u>	

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 3% to \$58.0 million in 2019 from \$56.1 million in 2018. This increase resulted from higher international sales of our OraQuick® HIV Self-Test and higher domestic sales of our OraQuick® HCV product, partially offset by lower domestic sales of our OraQuick® HIV professional product and our OraQuick® In-Home test.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during 2019 and 2018.

Market	Years Ended December 31,		
	2019	2018	% Change
Domestic HIV	\$ 17,984	\$ 19,663	(9)%
International HIV	25,108	21,794	15
Net HIV revenues	43,092	41,457	4
Domestic HCV	8,108	7,490	8
International HCV	4,864	4,904	(1)
Net HCV revenues	12,972	12,394	5
Net OraQuick® revenues	<u>\$ 56,064</u>	<u>\$ 53,851</u>	4 %

Domestic OraQuick® HIV sales decreased 9% to \$18.0 million for the year ended December 31, 2019 from \$19.7 million for the year ended December 31, 2018. This decrease was primarily the result of reduced sales of our professional product due to price competition and competition from fourth generation automated HIV immunoassays performed in a laboratory and lower sales of our OTC product.

International sales of our OraQuick® HIV products during 2019 increased 15% to \$25.1 million from \$21.8 million in 2018. This increase was largely due higher sales of our OraQuick® Self-Test in Africa as well as increased sales of our professional product in Asia. Product revenues in 2019 and 2018 included approximately \$3.3 million and \$4.4 million, respectively, of support payments under the charitable support agreement with the Gates Foundation.

Domestic OraQuick® HCV sales increased 8% to \$8.1 million in 2019 from \$7.5 million in 2018 primarily due to increased demand driven by the domestic opioid crisis. International OraQuick® HCV sales remained consistent at \$4.9 million in 2019 and 2018.

Risk Assessment Market

Sales to the risk assessment market increased 1% to \$12.2 million for the year ended December 31, 2019 from \$12.1 million for the year ended December 31, 2018.

Cryosurgical Systems Market

Sales of our cryosurgical systems products decreased 34% to \$7.1 million in 2019 from \$10.8 million in 2018 due to the sale of this business in August 2019.

Other revenues

Other revenues in 2019 decreased 85% to \$966,000 from \$6.7 million in 2018. Revenue associated with funding of our research and development efforts decreased to \$706,000 in 2019 compared to \$5.0 million in 2018 as a result of the completion of our contract with Biomedical Advanced Research Development Authority (“BARDA”) associated with our Zika product and lower spending on our Ebola product as the project reaches completion. During 2018, because of difficulties in completing development and optimizing our Zika test and because of significant uncertainty regarding the commercial demand for this product, the scope of the work covered by our Zika contract with BARDA was reduced and this project was substantially completed in the first quarter of 2019. Other revenues in 2019 and 2018 also included \$261,000 and \$1.7 million, respectively, in cost reimbursement under our charitable support agreement with the Gates Foundation, which is separate from the above-referenced support payments from the Gates Foundation that are included in product revenues.

DNAG Segment

Molecular Products and Services

Our products and services revenues decreased 21% to \$76.4 million in 2019 from \$96.1 million in 2018.

The table below shows a breakdown of our total net molecular product and services revenues (dollars in thousands) during 2019 and 2018.

Market	Years Ended December 31,		
	2019	2018	% Change
Genomics	\$ 57,365	\$ 79,765	(28) %
Microbiome.....	12,786	6,690	91
Other	663	—	100
Net molecular product and services revenues.....	70,814	86,455	(18)
Other	5,566	9,653	(42)
Net molecular product and services revenues.....	<u>\$ 76,380</u>	<u>\$ 96,108</u>	(21) %

Sales of our genomics products decreased 28% to \$57.4 million in 2019 compared to \$79.8 million in 2018, largely due to lower customer demand, primarily from a large consumer genomics customer that changed its promotional tactics and resulting purchasing patterns.

Microbiome revenues increased 91% to \$12.8 million in 2019 compared to \$6.7 million in 2018 due to the inclusion of laboratory service revenues generated by CoreBiome and Diversigen and increased product sales.

Other product revenues represent sales of our Colli-Pee product sold by Novosanis.

Other revenues in 2019 decreased 42% to \$5.6 million from \$9.7 million largely as a result of lower royalty income partially offset by funded research and development and grant revenues recognized by Novosanis and CoreBiome. Royalty income decreased to \$5.1 million in 2019 compared to \$9.7 million in 2018.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 61% for the year ended December 31, 2019 compared to 63% for 2018. Gross profit percentage in 2019 was negatively affected by the decline in other revenues which contribute 100% to our gross profit percentage and a less favorable product mix as a result of higher sales of lower gross profit products and services partially offset by lower royalty expense.

Consolidated operating income in 2019 was \$18.6 million, a \$9.8 million decline from the \$28.4 million of operating income reported in 2018. Operating income in 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, \$1.8 million of pre-tax acquisition-related transaction costs, and operating expenses of the Company's newly acquired subsidiaries. Operating income in 2018 included \$9.6 million of transition costs associated with executive management changes and \$1.2 million of pre-tax acquisition-related transaction costs.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 55% in 2019 compared to 56% in 2018. OSUR's gross profit percentage in 2019 was negatively impacted by an increase in lower profit percentage revenues as a result of the sale of the cryosurgical systems business partially offset by a decrease in royalty expense.

Research and development expenses decreased 4% to \$12.2 million in 2019 from \$12.7 million in 2018, due to the elimination of spending on our Zika project which was completed in early 2019 and lower spending related to our Ebola product, partially offset by higher costs associated with the development of automated drug testing assays.

Sales and marketing expenses decreased 9% to \$18.1 million in 2019 from \$19.9 million in 2018, largely due to lower staffing costs.

General and administrative expenses decreased 26% to \$22.5 million in 2019 from \$30.3 million in 2018 largely due to \$9.6 million of transition costs associated with executive management changes in 2018 that did not reoccur in 2019, partially offset by higher professional fees associated with our business development activities.

OSUR's operating income for 2019 also included a \$10.2 million pre-tax gain on the sale of our cryosurgical systems business. In August 2019, we sold all rights and title to the assets necessary to operate this line of business to CryoConcepts 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 which are being provided by OSUR employees to CryoConcepts for a limited time after closing as agreed to under a transition services agreement.

All of the above contributed to OSUR's operating income of \$154,000 for 2019, which included non-cash charges of \$3.0 million for depreciation and amortization and \$3.3 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 68% in 2019 compared to 69% in 2018. This decrease was attributable to the decline in other revenues which contribute 100% to the gross profit percentage and a less favorable product mix as a result of higher sales of lower gross profit products and services.

Research and development expenses increased 114% to \$7.5 million in 2019 from \$3.5 million in 2018 due to the inclusion of research and development expense incurred by the newly acquired subsidiaries, higher staffing costs, and higher lab supply and consulting costs in support of bioinformatics and new product initiatives.

Sales and marketing expenses increased 28% to \$13.7 million in 2019 compared to \$10.7 million in 2018 largely due to an increase in our reserve for uncollectible accounts largely associated with a receivable from a large Chinese genomics customer, and the inclusion of expenses generated by the newly acquired subsidiaries, partially offset by lower staffing costs.

General and administrative expenses increased 60% to \$12.8 million in 2019 compared to \$8.0 million in 2018, due the inclusion of expenses generated by the Company's newly acquired subsidiaries and increased staffing, legal and consulting costs.

All of the above contributed to DNAG's operating income of \$18.5 million for 2019, which included non-cash charges of \$4.3 million for depreciation and amortization and \$777,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's 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, 2019, we recorded a federal tax benefit of \$832,000 and state income tax expense of \$892,000 compared to \$155,000 of state tax expense recorded in the year ended December 31, 2018. Foreign income tax expense of \$4.6 million and \$11.2 million was recorded in 2019 and 2018, respectively. The decrease in income tax expense was largely a result of the decrease in income before taxes generated by DNAG and the results generated by Novosanis.

YEAR ENDED DECEMBER 31, 2018 COMPARED TO DECEMBER 31, 2017

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		% Change	Percentage of Total Net Revenues	
	2018	2017		2018	2017
OSUR	\$ 78,973	\$ 86,889	(9)%	43 %	52 %
DNAG	86,455	75,099	15	48	45
Net product revenues	165,428	161,988	2	91	97
Other	16,315	5,076	221	9	3
Net revenues	<u>\$181,743</u>	<u>\$167,064</u>	9 %	<u>100 %</u>	<u>100 %</u>

Consolidated net product revenues increased 2% to \$165.4 million in 2018 from \$162.0 million in 2017. Higher sales of our molecular collection systems products and higher international sales of our OraQuick® HIV Self-Test were partially offset by lower sales of our

OraQuick® HCV products, lower domestic sales of our OraQuick® HIV products and lower sales of our cryosurgical products. In 2018 we recorded \$9.7 million in royalty income under a litigation settlement agreement. We also recognized \$5.0 million as other revenues in connection with funding from BARDA related to our Ebola and Zika products and \$1.7 million of cost reimbursement under our charitable support agreement with the Gates Foundation. Other revenues in 2017 included \$4.4 million of BARDA funding and \$689,000 of cost reimbursement.

Consolidated net revenues from products sold to customers outside of the United States were \$44.9 million and \$45.6 million, or 25% and 27% of total net revenues, during the years ended December 31, 2018 and 2017, 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

OSUR Segment

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

Market	Years Ended December 31,					
	Dollars			Percentage of Total Net Revenues		
	2018	2017	% Change	2018	2017	
Infectious disease testing	\$ 56,148	\$ 61,951	(9)%	65 %	67 %	
Risk assessment testing.....	12,058	12,659	(5)	14	14	
Cryosurgical systems	10,767	12,279	(12)	13	13	
Net product revenues.....	78,973	86,889	(9)	92	94	
Other	6,662	5,076	31	8	6	
Net revenues.....	<u>\$ 85,635</u>	<u>\$ 91,965</u>	(7)%	<u>100 %</u>	<u>100 %</u>	

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 9% to \$56.1 million in 2018 from \$62.0 million in 2017. This decrease resulted from lower domestic and international sales of our OraQuick® HCV product and lower domestic sales of our OraQuick® HIV product, partially offset by higher international sales of our OraQuick® HIV Self-Test.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during 2018 and 2017.

Market	Years Ended December 31,		
	2018	2017	% Change
Domestic HIV	\$ 19,663	\$ 23,847	(18)%
International HIV	21,794	11,301	93
Net HIV revenues	<u>41,457</u>	<u>35,148</u>	18
Domestic HCV	7,490	8,448	(11)
International HCV	4,904	16,961	(71)
Net HCV revenues.....	12,394	25,409	(51)
Net OraQuick® revenues.....	<u>\$ 53,851</u>	<u>\$ 60,557</u>	(11)%

Domestic OraQuick® HIV sales decreased 18% to \$19.7 million for the year ended December 31, 2018 from \$23.8 million for the year ended December 31, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product and competition from fourth generation automated HIV immunoassays performed in a laboratory.

International sales of our OraQuick® HIV products during 2018 rose 93% to \$21.8 million from \$11.3 million in 2017. This increase was largely due to the continued shipment of product in support of an HIV self-testing program in Africa, and higher sales of our professional product into certain areas of Europe, Africa, Asia, and Latin America, partially offset by a decline in sales in the Middle East. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product

revenues in 2018 and 2017 included approximately \$4.4 million and \$1.0 million of support payments under that agreement, respectively.

Domestic OraQuick® HCV sales decreased 11% to \$7.5 million in 2018 from \$8.4 million in 2017 primarily due to customer ordering patterns and the non-renewal of, or reductions in, grant funding of HCV testing programs. International OraQuick® HCV sales decreased 71% to \$4.9 million in 2018 from \$17.0 million in 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program and the loss of a multi-national humanitarian organization customer that switched to a competitive product due to pricing.

Risk Assessment Market

Sales to the risk assessment market decreased 5% to \$12.1 million for the year ended December 31, 2018 from \$12.6 million for the year ended December 31, 2017, primarily as a result of a large customer that stopped performing pre-employment drug testing.

Cryosurgical Systems Market

Sales of our cryosurgical systems products decreased 12% to \$10.8 million in 2018 from \$12.3 million in 2017 due to lower sales of our domestic Histofreezer® product to physicians' offices due to competitive losses from lower-priced products that entered the market as result of the expiration of the patents associated with our cryosurgical technology and lower sales of our international OTC cryosurgical products.

Other revenues

Other revenues in 2018 increased 31% to \$6.7 million from \$5.1 million in 2017. Revenue from BARDA funding increased to \$5.0 million in 2018 compared to \$4.4 million in 2017 as a result of increased work related to our Ebola and Zika products. Other revenues in 2018 also included \$1.7 million in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Reimbursement of these costs began in the third quarter of 2017 and other revenue in 2017 included \$689,000 of such cost reimbursement.

DNAG Segment

Molecular Collection Systems

Sales of our molecular collection systems products increased 28% to \$96.1 million in 2018 from \$75.1 million in 2017.

The table below shows a breakdown of our total net molecular collection systems revenues (dollars in thousands) generated during 2018 and 2017.

Market	Years Ended December 31,		
	2018	2017	% Change
Genomics	\$ 79,765	\$ 71,611	11 %
Microbiome	6,690	3,488	92
Net molecular collection systems product revenues.....	86,455	75,099	15 %
Royalty income	9,653	—	N/A
Net molecular collection systems revenues.....	<u>\$ 96,108</u>	<u>\$ 75,099</u>	28 %

Sales of our genomics products rose 11% to \$79.8 million in 2018 compared to \$71.6 million in 2017, largely as a result of higher customer demand primarily from a large consumer genetics customer, higher sales to academic customers, increased demand of our genomics business in Asia, and higher sales of our ORAcollect® product. Microbiome sales increased 92% to \$6.7 million in 2018 compared to \$3.5 million in 2017 as interest in our microbiome product offering continued to grow with both new and existing customers.

We recorded \$9.7 million of royalty income in 2018 earned under a litigation settlement agreement. This royalty agreement was entered into in 2017 and required royalty payments beginning in the first quarter of 2018. There were no revenues of this nature in 2017.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 63% for the year ended December 31, 2018 compared to 59% for 2017. Gross profit percentage in 2018 benefited from improved product mix associated with an increase in higher gross profit percentage sales, lower manufacturing costs associated with our Oragene® product, increased royalty income and other revenues which have a gross profit percentage of 100%, lower scrap and spoilage costs and lower royalty expense.

Consolidated operating income in 2018 was \$28.4 million, an \$11.8 million decline from \$40.2 million of operating income reported in 2017. Operating income in 2017 included a pre-tax gain of \$12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer. In addition, our results for 2018 were negatively impacted by the inclusion of \$9.6 million of transition costs associated with executive management changes, \$1.2 million of transaction costs associated with our January 4, 2019 acquisitions, and increased spending on research and development and sales and marketing.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 56% in 2018 compared to 58% in 2017. OSUR's gross profit percentage in 2018 was negatively impacted by an increase in lower profit percentage revenues as a result of higher international sales, partially offset by the increase in BARDA funding and cost reimbursement from the Gates Foundation, and lower scrap and spoilage costs and royalty expense.

Research and development expenses increased 21% to \$12.7 million in 2018 from \$10.5 million in 2017, due to increased spending on our Ebola and Zika products, higher staffing costs, and increased product registration fees related to our expansion in more international markets.

Sales and marketing expenses increased 5% to \$19.9 million in 2018 from \$18.9 million in 2017, primarily as a result of increased consulting costs associated with our international sales contractors and increased staffing costs associated with higher headcount.

General and administrative expenses increased 35% to \$35.3 million in 2018 from \$26.1 million in 2017 as a result of the inclusion of \$9.6 million of transition costs associated with executive management changes, \$1.2 million of transaction costs associated with our recent acquisitions, and higher consulting costs partially offset by a decrease in other staffing related costs.

All of the above contributed to OSUR's operating loss of \$20.1 million for 2018, which included non-cash charges of \$3.8 million for depreciation and amortization and \$14.7 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 69% in 2018 compared to 61% in 2017. This increase was attributable to the royalty income recorded in 2018 and improved product mix associated with an increase in higher gross profit percentage sales and lower manufacturing costs associated with our Oragene® product. No royalty income was recorded in 2017.

Research and development expenses increased 25% to \$3.5 million in 2018 from \$2.8 million in 2017 due to higher staffing costs associated with the development of new product and service offerings.

Sales and marketing expenses increased 12% to \$10.7 million in 2018 compared to \$9.6 million in 2017 due to higher staffing and commission expenses.

General and administrative expenses decreased 4% to \$3.1 million in 2018 compared to \$3.2 million in 2017, due to lower legal costs.

Operating expenses in 2017 were offset by the \$12.5 million pre-tax gain associated with the settlement of the Ancestry litigation.

All of the above contributed to DNAG's operating income of \$48.6 million for 2018, which included non-cash charges of \$3.4 million for depreciation and amortization and \$540,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR’s 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, 2018, we recorded state income tax expense of \$155,000 compared to \$0 in the year ended December 31, 2017. Canadian income tax expense of \$11.2 million and \$10.1 million was recorded in 2018 and 2017, respectively. The increase in income tax expense was largely a result of the increase in income before taxes generated by DNAG partially offset by the additional taxes recorded during 2017 related to the \$12.5 million litigation settlement which did not re-occur in 2018. On December 22, 2017, the U.S. enacted the Tax Act that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results was not material given OSUR has a full valuation allowance against its total U.S. deferred tax assets and due to the net operating losses (“NOLs”) and tax credits that are being generated by the U.S. entity.

Liquidity and Capital Resources

	December 31,	
	2019	2018
	(In thousands)	
Cash and cash equivalents	\$ 75,715	\$ 88,438
Available for sale securities	114,043	112,886
Working capital	191,837	191,332

Our cash, cash equivalents, and available-for-sale securities decreased to \$189.8 million at December 31, 2019 from \$201.3 million at December 31, 2018. Our working capital increased to \$191.8 million at December 31, 2019 from \$191.3 million at December 31, 2018.

During 2019, we generated \$9.8 million in cash from operating activities. Our net income of \$16.7 million included the pre-tax gain on the sale of our cryosurgical systems business of \$10.2 million, non-cash charges for stock-based compensation expense of \$4.1 million, depreciation and amortization expense of \$7.3 million, and a provision for doubtful accounts of \$2.2 million offset by a non-cash benefit for the change in the estimated fair value of acquisition-related contingent consideration of \$664,000 and other non-cash benefits of \$498,000. Offsetting the adjusted net income was a \$2.2 million increase in accounts receivable largely resulting from an increase in product orders placed during the fourth quarter of 2019, a decrease in accrued expenses and other liabilities of \$4.0 million largely due to the submission of tax payments to the Canadian taxing authorities and payment of our 2018 management incentive bonuses, a decrease in accounts payable associated with the timing of invoices paid during the year, and an increase in inventory of \$1.3 million in order to meet contractual obligations associated with our HCV raw materials.

Net cash used in investing activities was \$19.8 million for the year ended December 31, 2019, which reflects \$92.2 million used to purchase investments, \$23.8 million to acquire CoreBiome, Novosanis, and Diversigen, and \$9.3 million to acquire property and equipment partially offset by \$93.5 million in proceeds from the maturities and redemptions of investments and \$12.0 million from the sale of the cryosurgical systems business.

Net cash used in financing activities was \$4.7 million in 2019, which resulted from \$3.7 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted and performance award shares partially offset by \$724,000 to payoff loans which were assumed in the acquisition of Novosanis.

On March 29, 2019, we terminated our credit agreement with a commercial bank, which was initially entered into on September 30, 2016 (as amended in December 2017) and had a maturity date of September 30, 2019. The credit agreement was terminated because of our strong cash position and the availability of alternative financing sources, which, if needed would be more suited to our business needs. There were no borrowings outstanding at December 31, 2018 or at the time of termination of the credit agreement.

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, 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, \$90.7 million or 48% of our

\$189.8 million in cash, cash equivalents, and available-for-sale securities belongs to our Canadian subsidiary. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations as of December 31, 2019 (in thousands) for future payments under contracts and other contingent commitments, for the year 2020 and beyond:

Contractual Obligations	Total	Payments due by December 31,				
		2020	2021	2022	2023	2024
Employment contracts ¹	5,561	3,110	1,682	460	309	—
Purchase obligations ²	10,337	10,279	20	20	18	—
Total contractual obligations	<u>\$ 15,898</u>	<u>\$ 13,389</u>	<u>\$ 1,702</u>	<u>\$ 480</u>	<u>\$ 327</u>	<u>\$ —</u>

¹ Represents salary payments payable under the terms of employment agreements executed by us with certain executives. See Note 15 of the Notes to the consolidated financial statements included herein

² Represents payments required by non-cancellable purchase orders or supply agreements related to inventory, supplies, capital expenditures and other goods or services. The supply agreements are cancellable within a specified number of days of written notice to the supplier. See Note 15 of the Notes to the consolidated financial statements included herein.

Off-Balance Sheet Arrangements. We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

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. In January 2018, we adopted Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers*, using the modified retrospective method applied to contracts existing as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previous guidance.

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.

Our net revenues recorded for sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising and discounts. The allowance for expected returns is an estimate established by management, based upon currently available information, and is adjusted to reflect known changes in the factors that impact this estimate. Other customer allowances are at contractual rates and are recorded as a reduction of gross revenue when recognized in our consolidated statements of operations.

Other than for 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, we generally do not grant product return rights to our customers except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

As a result of the return rights granted to our customers for our OraQuick® In-Home HIV test, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected. The amounts of returns agreed to under the long-term customer contract are based on a pre-determined percentage of revenues and as such, our estimate of expected returns is calculated in accordance with the terms of the contract. As of December 31, 2019 and December 31, 2018, the reserve for sales returns and allowances was \$472 and \$191, respectively.

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

Service revenues represent microbiome laboratory testing and analytical services. We recognize revenues and satisfy our performance obligation for services rendered when the testing is complete and the associated results are reported.

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 reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an observable cost plus margin approach if selling price on a stand-alone basis is not available. 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 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.

We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2019 and 2018 includes customer prepayments of \$1,904 and \$2,057, respectively. Deferred revenue as of December 31, 2019 and 2018 also included \$1,809 and \$1,464, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of contract was determined and revenue is recognized at that rate when the product is delivered to the customer.

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.

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.

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. 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. In addition to reserving for these items identified through specific identification procedures, we also reserve for unidentified scrap or spoilage based on historical write-off rates.

During 2019, 2018, and 2017 we wrote-off inventory which had a cost of \$1.3 million, \$1.3 million and \$3.3 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. In 2017, we re-measured our federal net deferred tax asset based on the federal rate at which they were expected to reverse in the future which is 21% pursuant to the Tax Act. We also re-measured our state net deferred asset since the future federal benefit was reduced to 21%.

At December 31, 2019, we had federal Net Operating Loss (“NOL”) carryforwards of \$36.4 million. The net deferred tax assets, before the valuation allowance, associated with these NOLs and other temporary differences were \$13.7 million at December 31, 2019. Net operating losses will begin to expire in 2030. 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 asset in the immediate future. 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 in the immediate future. As such, we maintain a full valuation allowance as of December 31, 2019 and 2018 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 the CoreBiome, Novosanis, and Diversigen 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.

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, 2019, 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 4.0% of our total revenues for the year ended December 31, 2019. 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 \$140.8 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of December 31, 2019. 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 \$11.9 million in the year ended December 31, 2019.

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, 2019. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2019 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, 2019.

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 CoreBiome, Inc., Novosanis NV, and Diversigen, Inc. collectively, the "acquired companies," during 2019, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, the acquired companies' representing approximately 11.7% of total assets and 4.0% of total revenues of the Company as of and for the year ended December 31, 2019. 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 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019 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, 2019, 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, 2019, 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, 2019 and 2018, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and related notes (collectively, the consolidated financial statements), and our report dated March 2, 2020 expressed an unqualified opinion on those consolidated financial statements.

The Company acquired CoreBiome, Inc., Novosanis NV and Diversigen, Inc. (collectively, the "Acquired Companies") during 2019, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, the Acquired Companies' internal control over financial reporting associated with 11.7% of total assets and 4.0% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2019. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of the Acquired Companies.

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 2, 2020

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 2019 Annual 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
2.1	Asset Purchase Agreement, dated August 15, 2019, between OraSure Technologies, Inc. and CryoConcepts LP is incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed August 19, 2019.
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.
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	Employment Agreement, dated as of January 3, 2011, between the Company and Anthony Zizzo II is incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
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	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 May 11, 2018. *
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 May 23, 2019.*
10.11	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.*

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| 10.12 | 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.* |
| 10.13 | OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.* |
| 10.14 | Amended and Restated OraSure Technologies, Inc. Stock Award Plan, effective February 21, 2017, is incorporated by reference to Exhibit A to the Company's Proxy Statement, filed April 5, 2017, for the 2017 Annual Meeting of Stockholders.* |
| 10.15 | 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.* |
| 10.16 | 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.* |
| 10.17 | Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.* |
| 10.18 | Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.* |
| 10.19 | Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.* |
| 10.20 | Description of the OraSure Technologies, Inc. 2019 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 8, 2019.* |
| 10.21 | 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.* |
| 10.22 | Description of Amendment to Long-Term Incentive Policy is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed August 17, 2018.* |
| 10.23 | Description of Long-Term Incentive Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 14, 2019.* |
| 10.24 | 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.* |
| 10.25 | 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.* |
| 10.26 | 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.* |
| 10.27 | 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. |

Exhibit Number	Exhibit
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, 2019, 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 2, 2020.

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 2, 2020, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
<u>/s/ Stephen S. Tang</u> Stephen S. Tang, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Roberto Cuca</u> Roberto Cuca	Chief Financial Officer (Principal Financial Officer)
<u>/s/ Michele Miller</u> 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
*CHARLES W. PATRICK Charles W. Patrick	Director
*ARADHANA SARIN Aradhana Sarin	Director
*By: <u>/s/ Jack E. Jerrett</u> Jack E. Jerrett (Attorney-in-Fact)	

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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, 2019 and 2018, the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, 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 February 28, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 10 to the consolidated financial statements, the Company has changed 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Assessment of the acquisition-date fair value of developed technology

As discussed in Note 3 to the consolidated financial statements, the Company acquired a business in January 2019. As a result of this transaction, the Company acquired a developed technology intangible asset. The acquisition date fair value of the developed technology was \$5.0 million. The purchase price of the business combination was allocated to the assets acquired and liabilities assumed, in each case based on estimates of their respective fair values at the acquisition date. Fair values of intangible assets are estimated using valuation models prepared by the Company with the assistance of third-party specialists.

We identified the assessment of the acquisition-date fair value of the developed technology for the business acquisition as a critical audit matter. Assessing the estimated fair value of the developed technology resulted in the application of a high degree of auditor judgment. The revenue growth rates and the discount rate used to determine the fair value of the developed technology were challenging to evaluate as there was limited observable market information and minor changes to those assumptions could have a significant effect on the acquisition-date fair value of the intangible asset.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's business combinations process, including controls related to the determination of the fair value of the acquired intangible assets and the related revenue growth rates and the discount rate. We evaluated the Company's projected revenue growth rates for the developed technology by comparing the growth assumptions to historical growth rates of comparable products. We compared the acquired business' forecasted revenue growth rates to their actual historical results. In addition, we involved a valuation professional with specialized skill and knowledge, who assisted in:

- evaluating the Company's discount rate, by comparing it against a discount rate range that was independently developed using publicly available market data; and
- developing an estimate of the developed technology fair value using the Company's cash flow forecast for the developed technology and an independently developed discount rate, and compared the results of our estimate to the Company's fair value estimate.

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 \$23.2 million as of December 31, 2019. 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 forecasts of product sales.

We identified the evaluation of net realizable value adjustments to inventories for excess or obsolescence as a critical audit matter. The Company's estimates regarding forecasted sales and the resulting inventory consumption and considerations related to the ability to extend inventory expiration dates result in the application of a high degree of auditor judgment.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's process for determining net realizable value adjustments for inventory excess or obsolescence. We evaluated historic write-off activity as compared to total inventories. 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 using historic inventory consumption, the expiration date of certain on-hand inventory items and the ability to extend expiration dates.

/s/ KPMG LLP

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

Philadelphia, Pennsylvania

March 2, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 75,715	\$ 88,438
Short-term investments	80,623	68,134
Accounts receivable, net of allowance for doubtful accounts of \$2,666 and \$418 ...	36,948	34,842
Inventories	23,155	22,888
Prepaid expenses.....	2,433	1,925
Other current assets	5,676	3,085
Total current assets.....	224,550	219,312
Noncurrent Assets:		
Property, plant and equipment, net	30,339	24,299
Operating right-of-use assets, net	4,996	—
Finance right-of-use assets, net	1,951	—
Intangible assets, net.....	14,674	5,137
Goodwill	36,201	18,521
Long-term investments	33,420	44,752
Other noncurrent assets	3,164	3,550
Total noncurrent assets.....	124,745	96,259
TOTAL ASSETS	\$ 349,295	\$ 315,571
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable.....	\$ 9,567	\$ 10,598
Deferred revenue	3,713	3,521
Accrued expenses	14,288	13,861
Finance lease liability	613	—
Operating lease liability.....	1,032	—
Acquisition-related contingent consideration obligation.....	3,500	—
Total current liabilities	32,713	27,980
Noncurrent Liabilities:		
Finance lease liability	1,372	—
Operating lease liability	4,206	—
Acquisition-related contingent consideration obligation.....	112	—
Other noncurrent liabilities	2,848	3,312
Deferred income taxes	899	901
Total noncurrent liabilities	9,437	4,213
TOTAL LIABILITIES	42,150	32,193
COMMITMENTS AND CONTINGENCIES (Note 15)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 61,731 and 61,276 shares issued and outstanding	—	—
Additional paid-in capital	401,814	401,273
Accumulated other comprehensive loss	(12,136)	(18,706)
Accumulated deficit.....	(82,533)	(99,189)
Total stockholders' equity	307,145	283,378
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 349,295	\$ 315,571

See accompanying notes to the consolidated financial statements.

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

	For the years ended December 31,		
	2019	2018	2017
NET REVENUES:			
Products and services	\$ 148,073	\$ 165,428	\$ 161,988
Other	6,532	16,315	5,076
	<u>154,605</u>	<u>181,743</u>	<u>167,064</u>
COST OF PRODUCTS SOLD	60,022	68,130	68,108
Gross profit	<u>94,583</u>	<u>113,613</u>	<u>98,956</u>
OPERATING EXPENSES:			
Research and development	19,629	16,250	13,365
Sales and marketing	31,869	30,609	28,532
General and administrative	35,287	38,325	29,321
Gain on litigation settlement	—	—	(12,500)
Change in the estimated fair value of acquisition-related contingent consideration	(664)	—	—
Gain on sale of business	<u>(10,149)</u>	<u>—</u>	<u>—</u>
	<u>75,972</u>	<u>85,184</u>	<u>58,718</u>
Operating income	18,611	28,429	40,238
OTHER INCOME	2,720	3,287	794
Income before income taxes	21,331	31,716	41,032
INCOME TAX EXPENSE	4,675	11,320	10,084
NET INCOME	<u>\$ 16,656</u>	<u>\$ 20,396</u>	<u>\$ 30,948</u>
EARNINGS PER SHARE:			
BASIC	<u>\$ 0.27</u>	<u>\$ 0.33</u>	<u>\$ 0.52</u>
DILUTED	<u>\$ 0.27</u>	<u>\$ 0.33</u>	<u>\$ 0.51</u>
SHARES USED IN COMPUTING EARNINGS PER SHARE:			
BASIC	<u>61,675</u>	<u>61,112</u>	<u>59,050</u>
DILUTED	<u>62,170</u>	<u>62,532</u>	<u>61,024</u>

See accompanying notes to the consolidated financial statements.

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

	For the years ended December 31,		
	2019	2018	2017
NET INCOME	\$ 16,656	\$ 20,396	\$ 30,948
OTHER COMPEHENSIVE INCOME (LOSS)			
Currency translation adjustments	5,767	(8,003)	4,433
Unrealized gain (loss) on marketable securities	803	(363)	(553)
COMPREHENSIVE INCOME	\$ 23,226	\$ 12,030	\$ 34,828

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2019, 2018 and 2017
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2017	56,001	\$ —	\$ 350,528	\$ (14,220)	\$ (150,458)	\$ 185,850
Common stock issued upon exercise						
of options	4,413	—	31,670	—	—	31,670
Vesting of restricted stock	378	—	—	—	—	—
Purchase and retirement of common						
shares	(130)	—	(1,240)	—	—	(1,240)
Compensation cost for restricted stock.....	—	—	2,705	—	—	2,705
Compensation cost for stock option						
grants.....	—	—	2,045	—	—	2,045
Compensation cost for performance						
stock units	—	—	2,223	—	—	2,223
Net income.....	—	—	—	—	30,948	30,948
Currency translation adjustments	—	—	—	4,433	—	4,433
Unrealized loss on marketable securities..	—	—	—	(553)	—	(553)
Balance at December 31, 2017	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)
Compensation cost for restricted stock.....	—	—	6,357	—	—	6,357
Compensation cost for stock option						
grants.....	—	—	2,163	—	—	2,163
Compensation cost for performance						
stock units	—	—	6,717	—	—	6,717
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)
Compensation cost for restricted stock.....	—	—	2,979	—	—	2,979
Compensation cost for stock option						
grants.....	—	—	1,161	—	—	1,161
Compensation cost for performance						
stock units	—	—	(83)	—	—	(83)
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

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,		
	2019	2018	2017
OPERATING ACTIVITIES:			
Net income	\$ 16,656	\$ 20,396	\$ 30,948
Adjustments to reconcile net income to net cash provided by operating activities:			
Stock-based compensation	4,057	15,237	6,973
Depreciation and amortization	7,339	6,451	6,075
Other non-cash amortization	391	771	327
Provision for doubtful accounts	2,248	(53)	(13)
Unrealized foreign currency (gain) loss	385	(400)	156
Interest expense on finance leases	36	—	—
Deferred income taxes	(1,457)	(919)	(649)
Loss (gain) on sale of fixed assets	147	—	(25)
Gain on sale of business	(10,149)	—	—
Change in the estimated fair value of contingent earn-out consideration	(664)	—	—
Changes in assets and liabilities			
Accounts receivable	(2,210)	6,688	(22,103)
Inventories	(1,324)	(3,857)	(7,391)
Prepaid expenses and other assets	200	(366)	(384)
Accounts payable	(1,537)	208	5,157
Deferred revenue	(297)	2,240	(93)
Accrued expenses and other liabilities	(4,017)	(7,306)	9,178
Net cash provided by operating activities	<u>9,804</u>	<u>39,090</u>	<u>28,156</u>
INVESTING ACTIVITIES:			
Purchases of investments	(92,173)	(163,763)	(161,269)
Proceeds from maturities and redemptions of investments	93,491	152,680	69,253
Purchases of property and equipment	(9,314)	(6,344)	(4,337)
Acquisition of businesses, net of cash acquired	(23,801)	—	—
Proceeds from sale of business	12,000	—	—
Net cash used in investing activities	<u>(19,797)</u>	<u>(17,427)</u>	<u>(96,353)</u>
FINANCING ACTIVITIES:			
Repayments of loans	(724)	—	—
Cash payments for lease liability	(442)	—	—
Proceeds from exercise of stock options	196	1,701	31,675
Repurchase of common stock	(3,712)	(3,592)	(1,240)
Net cash provided by (used in) financing activities	<u>(4,682)</u>	<u>(1,891)</u>	<u>30,435</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	1,952	(4,203)	841
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(12,723)	15,569	(36,921)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD	<u>88,438</u>	<u>72,869</u>	<u>109,790</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD	<u>\$ 75,715</u>	<u>\$ 88,438</u>	<u>\$ 72,869</u>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts, unless otherwise indicated)

1. THE COMPANY:

Our business consists of two segments: our “OSUR” business 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 molecular collections systems or “DNAG” business consists of the manufacture and sale of kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, 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 DNAG business provides microbiome laboratory and bioinformatics services.

Our OSUR 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, 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. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products were sold in both professional and OTC markets in North America, Europe, Central and South America, and Australia. We sold the assets associated with our cryosurgical systems business to a third party in August 2019. See further discussion at Note 4.

Our DNAG or molecular collection systems business is operated by our subsidiaries, DNA Genotek Inc. (“DNAG”), CoreBiome Inc. (“CoreBiome”), Novosanis NV (“Novosanis”), and Diversigen, Inc. (“Diversigen”). DNAG’s specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other sample types for genetic and microbiome applications. CoreBiome and Diversigen provide laboratory and bioinformatics services. Novosanis’ Colli-Pee collection device is designed for the volumetric collection of first-void urine for use in research, screening and diagnostics for the liquid biopsy and sexually transmitted infection markets. We also sell research use only sample collection products into the microbiome market and we offer our customers a suite of genomics and microbiome services, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide in the research, healthcare, pharmaceutical and agricultural communities.

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, CoreBiome, Novosanis and Diversigen. 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 2019, 2018 and 2017, we paid income taxes of \$10,611, \$17,126 and \$4,309, respectively.

In 2019, 2018 and 2017, we recorded through the consolidated statements of income an increase (decrease) in our allowance for doubtful accounts of \$2,231, \$(27) and \$172, respectively. We had \$110, \$11 and \$200 in write-offs against the allowance for doubtful accounts in 2019, 2018, and 2017, respectively.

As of December 31, 2019, 2018 and 2017, we had accruals for purchases of property and equipment of \$660, \$964 and \$449, 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.

The following is a summary of our available-for-sale securities as of December 31, 2019 and 2018:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2019				
Guaranteed investment certificates	\$ 24,632	\$ —	\$ —	\$ 24,632
Corporate bonds	89,525	271	(385)	89,411
Total available-for-sale securities.....	<u>\$ 114,157</u>	<u>\$ 271</u>	<u>\$ (385)</u>	<u>\$ 114,043</u>
December 31, 2018				
Guaranteed investment certificates	\$ 23,096	\$ —	\$ —	\$ 23,096
Corporate bonds	90,707	—	(917)	89,790
Total available-for-sale securities.....	<u>\$ 113,803</u>	<u>\$ —</u>	<u>\$ (917)</u>	<u>\$ 112,886</u>
At December 31, 2019, maturities of our available-for-sale securities were as follows:				
Less than one year	<u>\$ 80,754</u>	<u>\$ 163</u>	<u>\$ (294)</u>	<u>\$ 80,623</u>
Greater than one year	<u>\$ 33,403</u>	<u>\$ 108</u>	<u>\$ (91)</u>	<u>\$ 33,420</u>

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. 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. In addition to reserving for these items identified through specific identification procedures, we also reserve for unidentified scrap or spoilage based on historical write-off rates.

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 income.

Intangible Assets

Intangible assets consist of customer relationships, patents and product rights, developed 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

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible 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 we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG, CoreBiome, Novosanis and Diversigen. All acquired goodwill has been allocated to our DNAG segment. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. 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, 2019 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying value. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. 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. As of December 31, 2019, we believe no indicators of impairment exist.

Revenue

In January 2018, we adopted Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*, using the modified retrospective method applied to contracts existing as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previous guidance.

Upon adoption, we recorded a reduction of \$75 to the opening balance of accumulated deficit as of January 1, 2018. This adjustment is related to the change in revenue recognition associated with our drug testing kit sales. Sales of our drug testing kits include two performance obligations: sales of the device and laboratory services. Under this new accounting standard, we adjusted the allocation of the transaction price to the performance obligations and the estimate of unexercised rights ("breakage") associated with the contracts. Prior to the adoption of the new guidance, we used the residual value method to allocate the transaction prices. With the adoption of ASU 2014-09, we allocated transaction prices based upon the stand-alone selling price, or fair value method. This change in methodology also impacted our estimated breakage amount.

The following table summarizes the impact of the new revenue standard adjustment on our opening balance sheet:

	<u>Balance at December 31, 2017</u>	<u>New Revenue Standard Adjustment</u>	<u>Balance at January 1, 2018</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Deferred revenue	1,314	75	1,389
STOCKHOLDERS' EQUITY			
Accumulated deficit	(119,510)	(75)	(119,585)

The adoption of this new standard had an immaterial impact on our 2018 reported total revenues and operating income, as compared to what would have been reported under the prior standard. We expect the impact of adoption in future periods to continue to be immaterial. Our accounting policies under the new standard were applied prospectively and are described below.

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.

Our net revenues recorded for sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising and discounts. The allowance for expected returns is an estimate established by management, based upon currently available information, and is adjusted to reflect known changes in the factors that impact this estimate. Other customer allowances are at contractual rates and are recorded as a reduction of gross revenue when recognized in our consolidated statements of operations.

Other than for 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, we generally do not grant product return rights to our customers except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

As a result of the return rights granted to our customers for our OraQuick® In-Home HIV test, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected. The amounts of returns agreed to under the long-term customer contract are based on a pre-determined percentage of revenues and as such, our estimate of expected returns is calculated in accordance with the terms of the contract. As of December 31, 2019 and December 31, 2018, the reserve for sales returns and allowances was \$472 and \$191, respectively.

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 when the testing is complete and the associated results are reported

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 reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an observable cost plus margin approach if selling price on a stand-alone basis is not available. 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, 2019 and 2018 includes customer prepayments of \$1,904 and \$2,057, respectively. Deferred revenue as of December 31, 2019 and 2018 also included \$1,809 and \$1,464, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of contract was determined 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,		
	2019	2018	2017
OraQuick®	\$ 56,064	\$ 53,851	\$ 60,558
Oragene®	46,701	69,798	67,232
ORAcollect®	10,651	6,052	1,952
Intercept®	8,105	7,709	8,125
Microbiome laboratory services	6,104	1,563	1,223
Histofreezer® (through August 16, 2019)	5,702	8,983	10,312
OMNIgene® • GUT	5,226	4,193	2,072
Other products	9,520	13,279	10,514
Net product and service revenues	<u>148,073</u>	<u>165,428</u>	<u>161,988</u>
Royalty income	5,116	9,653	—
Research and development funding	851	4,951	4,387
Charitable support reimbursement	261	1,711	689
Grant funding	304	—	—
Other revenues	<u>6,532</u>	<u>16,315</u>	<u>5,076</u>
Net revenues	<u>\$ 154,605</u>	<u>\$ 181,743</u>	<u>\$ 167,064</u>

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

	December 31,		
	2019	2018	2017
United States.....	\$ 107,279	\$ 136,847	\$ 121,458
Europe.....	11,752	11,062	11,827
Other regions	35,574	33,834	33,779
	<u>\$ 154,605</u>	<u>\$ 181,743</u>	<u>\$ 167,064</u>

Customer and Vendor Concentrations

One of our customers accounted for 19% and 7% of our accounts receivable as of December 31, 2019 and 2018, respectively. The same customer accounted for approximately 15%, 24% and 25% of our net consolidated revenues for the year ended December 31, 2019, 2018, and 2017 respectively.

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. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its 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.

Leases

In February 2016, the Financial Accounting Standards Board (“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 have not restated comparative amounts. Also, we elected the practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification, our assessment on whether a contract is or contains a lease, and our initial direct costs for any leases that exist prior to adoption of the new standard. Leases with an initial term of 12 months or less are not recognized on the balance sheet and the associated lease payments are included in the consolidated statements of operations on a straight-line basis over the lease term. As a result, on January 1, 2019, we recorded right-of-use assets of \$4,027 and lease liabilities of \$4,263 on our consolidated balance sheet.

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 CoreBiome, Novosanis, and Diversigen 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.

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 2019, 2018, and 2017, we incurred \$524, \$763, and \$717, 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 income 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 income were \$(1,339), \$831, and \$(1,442) for the years ended December 31, 2019, 2018, and 2017, respectively.

Earnings Per Share

Basic earnings per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in a manner similar to basic earnings 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.

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

	Year ended December 31,		
	2019	2018	2017
Net income	<u>\$ 16,656</u>	<u>\$ 20,396</u>	<u>\$ 30,948</u>
Weighted average shares of common stock outstanding:			
Basic	61,675	61,112	59,050
Dilutive effect of stock options, restricted stock, and performance stock units	<u>495</u>	<u>1,420</u>	<u>1,974</u>
Diluted	<u>62,170</u>	<u>62,532</u>	<u>61,024</u>
Earnings per share:			
Basic	<u>\$ 0.27</u>	<u>\$ 0.33</u>	<u>\$ 0.52</u>
Diluted	<u>\$ 0.27</u>	<u>\$ 0.33</u>	<u>\$ 0.51</u>

For the years ended December 31, 2019, 2018, and 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 768, 291, and 180 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, 2019 consists of \$12,022 of currency translation adjustments and \$114 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, 2018 consists of \$17,789 of currency translation adjustments and \$917 of net unrealized losses on marketable securities.

Fair Value of Financial Instruments

As of December 31, 2019 and 2018, the carrying values of cash and cash equivalents, accounts receivable, and accounts payable 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, 2019 and 2018.

Included in cash and cash equivalents at December 31, 2019 and 2018, was \$1,624 and \$21,631 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 and Company stock. The fair value of the plan assets as of December 31, 2019 and 2018 was \$3,519 and \$3,884, 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.

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 is different from the existing guidance, which requires a credit loss to be recognized when it is probable. The guidance is effective beginning in fiscal year 2020, with early adoption permitted beginning in fiscal year 2019. We have determined that this new guidance will not have a material impact on our consolidated financial statements.

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. The guidance is effective in fiscal year 2020, with early adoption permitted, including adoption in an interim period. 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 have determined that this new guidance will not have a material impact on our 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 investee 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. This guidance is effective beginning in fiscal year 2020. We have determined that this new guidance will not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance related to accounting for implementation costs incurred in hosted cloud computing service arrangements. Under the new guidance, implementation costs incurred in a hosting arrangement that is a service contract should be expensed or capitalized based on the nature of the costs and the project stage during which such costs are incurred. If the implementation costs qualify for capitalization, they must be amortized over the term of the hosting arrangement and assessed for impairment. Companies must disclose the nature of any hosted cloud computing service arrangements. This guidance also provides guidance for balance sheet and income statement presentation of capitalized implementation costs and statement of cash flows presentation for the related payments. This guidance will be effective beginning in the first quarter of our fiscal year 2020. This guidance may be adopted either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We will prospectively adopt this guidance and have determined that it will not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued guidance that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in Accounting Standards Codification (“ASC”) 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The standard also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. This guidance is effective beginning in fiscal year 2020, with early adoption permitted beginning in fiscal year 2019. We have early-adopted this guidance and determined that this new guidance does not have a material impact on our consolidated financial statements.

3. BUSINESS COMBINATIONS

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. 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 income.

Pursuant to our acquisition agreements, we were to pay up to an additional \$32,400 of contingent consideration over the next 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 calculates 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 is 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. As of December 31, 2019, we may pay up to an additional \$27,400 of contingent consideration over the next two years.

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.....	<u>20,370</u>
Liabilities Assumed	
Current liabilities	1,180
Notes payable, short-term	730
Deferred tax liability	819
Other long-term liabilities	74
Total liabilities assumed.....	<u>2,803</u>
Net Assets Acquired	17,567
Estimated fair value of contingent consideration	(4,350)
Net Cash Paid (net of cash acquired of \$103)	<u><u>\$ 13,217</u></u>

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:

<u>Description</u>	<u>Estimated Useful Life (in yrs)</u>	<u>Amount</u>
Developed Technology	10	\$ 5,000
Customer relationships.....	10	2,200
Tradenames	8.34	1,200
Total acquired intangibles.....		<u>\$ 8,400</u>

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 DNAG 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 DNAG 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.

Diversigen

On November 8, 2019, the Company acquired all of the outstanding stock of Diversigen, Inc. (“Diversigen”), pursuant to the terms of a merger agreement. We began operating this entity as of the November 8, 2019 closing date.

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 income for the year ended December 31, 2019.

Pursuant to our acquisition agreements, 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. The estimated acquisition-date fair value of the acquisition-related contingent consideration was \$0. The fair value of the contingent consideration obligation of \$0 is a result of not achieving the defined revenue metrics.

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		6,443
Total assets acquired.....		<u>13,198</u>
Liabilities Assumed		
Current liabilities		1,123
Deferred tax liability		598
Other long-term liabilities		893
Total liabilities assumed		<u>2,614</u>
Net Assets Acquired		10,584
Estimated fair value of contingent consideration		-
Net Cash Paid (net of cash acquired of \$479)	\$	<u><u>10,584</u></u>

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:

<u>Description</u>	<u>Estimated Useful Life (in yrs)</u>	<u>Amount</u>
Customer relationships.....	10	2,900
Tradenames	9	660
Total acquired intangibles.....		<u>\$ 3,560</u>

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 DNAG segment.

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

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the CoreBiome, Diversigen, and Novosanis acquisitions as if they had been consummated as of January 1, 2017. The unaudited pro forma results include the amortization associated with acquired intangible assets and the estimated tax effect of adjustments to income before income taxes but do not include changes in the fair value of our contingent consideration obligations. Material nonrecurring charges, directly attributable to the transactions, including direct acquisition costs, are also excluded. In addition, the unaudited pro forma results do not include any expected benefits of the acquisitions. Accordingly, the unaudited pro forma results are not necessarily indicative of either future results of operations or results that might have been achieved had the acquisitions been consummated as of January 1, 2017.

	Year Ended December 31,		
	2019	2018	2017
Revenue.....	\$ 158,576	\$ 190,487	\$ 173,554
Net income	16,806	19,448	27,436
Net income per share, basic	0.27	0.32	0.46
Net income per share, diluted	0.27	0.31	0.45

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,	
	2019	2018
Raw materials	\$ 14,168	\$ 14,092
Work in process	643	544
Finished goods	8,344	8,252
	<u>\$ 23,155</u>	<u>\$ 22,888</u>

6. PROPERTY, PLANT AND EQUIPMENT:

	December 31,	
	2019	2018
Land	\$ 1,118	\$ 1,118
Buildings and improvements	23,231	22,480
Machinery and equipment	33,568	29,017
Computer equipment and software	11,590	9,632
Furniture and fixtures	2,791	2,681
Construction in progress	4,923	2,168
	<u>77,221</u>	<u>67,096</u>
Less accumulated depreciation	<u>(46,882)</u>	<u>(42,797)</u>
	<u>\$ 30,339</u>	<u>\$ 24,299</u>

Depreciation expense was \$4,421, \$3,828, and \$3,434 for 2019, 2018, and 2017, respectively.

7. GOODWILL AND OTHER INTANGIBLE ASSETS:

The changes in goodwill are as follows:

	December 31,	
	2019	2018
Balance as of January 1	18,521	20,083
Goodwill acquired during the year	16,811	—
Change related to foreign currency translation.....	869	(1,562)
Balance as of December 31	<u>\$ 36,201</u>	<u>\$ 18,521</u>

Intangible assets consist of the following:

	Amortization Period (Years)	December 31, 2019		
		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
		<u>\$ 38,094</u>	<u>\$ (23,420)</u>	<u>\$ 14,674</u>

	Amortization Period (Years)	December 31, 2018		
		Gross	Accumulated Amortization	Net
Customer relationships	10	\$ 9,186	\$ (6,532)	\$ 2,654
Patents and product rights	10	5,400	(4,708)	692
Developed technology	7	7,135	(7,135)	-
Tradename	15	3,521	(1,730)	1,791
		<u>\$ 25,242</u>	<u>\$ (20,105)</u>	<u>\$ 5,137</u>

Amortization expense for 2019, 2018, and 2017 was \$2,522, \$2,623, and \$2,641, respectively.

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

2020	2,619
2021	2,375
2022	1,470
2023	1,470
2024	1,430
Beyond.....	5,310
	<u>\$ 14,674</u>

8. ACCRUED EXPENSES:

	December 31,	
	2019	2018
Payroll and related benefits	\$ 6,088	\$ 8,926
Professional fees.....	2,769	1,541
Income taxes payable	—	1,447
Other.....	5,431	1,947
	<u>\$ 14,288</u>	<u>\$ 13,861</u>

9. CREDIT FACILITY:

On March 29, 2019, we terminated our credit agreement with a commercial bank which was entered into on September 30, 2016 and had a maturity date of September 30, 2019. There were no borrowings under the credit agreement during 2019, 2018, or 2017.

10. 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 will 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, 2019, 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, 2019
Operating Lease Cost.....	\$ 964
Finance Lease Cost	
Amortization of right-of use assets	410
Interest on lease liabilities.....	36
Total Finance Lease Cost.....	<u>\$ 446</u>

Lease cost for the years ended December 31, 2018 and 2017 was \$1,461 and \$852, respectively.

Supplemental cash flow information related to leases is as follows:

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

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

Supplemental balance sheet information related to leases is as follows:

	<u>December 31, 2019</u>
Operating Leases	
Right-of-use assets	\$ 4,996
Current lease liabilities	1,032
Non-current lease liabilities.....	4,206
Total operating lease liabilities	<u>\$ 5,238</u>
Finance Leases	
Right-of-use assets	\$ 1,951
Current lease liabilities	613
Non-current lease liabilities.....	1,372
Total finance lease liabilities	<u>\$ 1,985</u>

Weighted Average Remaining Lease Term

Weighted-average remaining lease term—operating leases.....	5.21
Weighted-average remaining lease term—finance leases	3.45

Weighted Average Discount Rate

Weighted-average discount rate—operating leases.....	4.31%
Weighted-average discount rate—finance leases	4.40%

As of December 31, 2019, minimum lease payments by period are expected to be as follows:

	<u>Finance</u>	<u>Operating</u>
2020	685	1,273
2021	556	1,214
2022	555	1,194
2023	325	759
2024	17	777
Thereafter	4	760
Total Minimum Lease Payments.....	2,142	5,977
Less: imputed interest.....	(157)	(739)
Present Value of Lease Liabilities.....	<u>\$ 1,985</u>	<u>\$ 5,238</u>

As of December 31, 2018, minimum lease payments under non-cancelable operating leases by period were expected to be as follows:

2019.....	\$ 903
2020.....	902
2021.....	877
2022.....	850
2023.....	506
Thereafter	737
	<u>\$ 4,775</u>

11. INCOME TAXES:

Income before income tax expense consists of the following:

	Years Ended December 31,		
	2019	2018	2017
United States	\$ 3,106	\$ (11,728)	\$ 2,270
Foreign	18,225	43,444	38,762
	<u>\$ 21,331</u>	<u>\$ 31,716</u>	<u>\$ 41,032</u>

The components of income tax expense are as follows:

	Years Ended December 31,		
	2019	2018	2017
Current			
Federal	\$ —	\$ —	\$ —
State	1,033	155	—
Foreign.....	5,099	12,084	10,733
	<u>6,132</u>	<u>12,239</u>	<u>10,733</u>
Deferred			
Federal	3,568	9,200	10,297
State	125	1,011	(827)
Foreign.....	(697)	(919)	(649)
	<u>2,996</u>	<u>9,292</u>	<u>8,821</u>
Decrease in valuation allowance.....	<u>(4,453)</u>	<u>(10,211)</u>	<u>(9,470)</u>
	<u>(1,457)</u>	<u>(919)</u>	<u>(649)</u>
Total income tax expense.....	<u>\$ 4,675</u>	<u>\$ 11,320</u>	<u>\$ 10,084</u>

For the years ended December 31, 2019, 2018, and 2017 we recorded foreign income tax expense of \$4,607, \$11,165, and \$10,084, respectively.

The Tax Cuts and Jobs Act

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the “Tax Act”) that instituted fundamental changes to the taxation on multinational corporations. Although the Tax Act is generally effective January 1, 2018, U.S. generally accepted accounting principles requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. Among the numerous provisions, the Tax Act includes three provisions in particular which require consideration for financial reporting: a permanent reduction in the corporate tax rate to 21%, a one-time tax on undistributed foreign earnings, and a new U.S. tax on global intangible low taxed income (“GILTI”) which is a tax on certain earnings of foreign affiliates.

The reduction in the U.S. corporate tax rate to 21% became effective in 2018. This change resulted in a re-measurement of our net deferred tax balance at the end of 2017 with no net financial statement impact due to a comparable decrease in our deferred tax valuation allowance.

The one-time tax on undistributed and previously untaxed post-1986 foreign earnings and profits (E&P) of foreign affiliates owned by U.S. shareholders as of December 31, 2017 was analyzed for our Canadian subsidiary. For the 2017 federal tax return filed during 2018 our U.S. federal taxable loss exceeded and offset the provisional mandatory repatriation net inclusion and as such, no additional taxes were due as a result of the deemed repatriation of these foreign earnings.

In addition, the Tax Act also included changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion and promote U.S. production. The Tax Act also included repeal of the corporate alternative minimum tax, expensing of capital investment, changes to the Federal net operating loss (“NOL”) utilization and carryforward rules, and limitations of the deduction for interest expense and certain employee compensation.

As a result of the complex impact of the Tax Act, the SEC provided guidance under Staff Accounting Bulletin No. 118 (“SAB 118”) that allowed the Company to record provisional amounts as of December 31, 2017 for the impact of the Tax Act, provided that the provisional amounts could be reasonably determined and with the requirement that the final accounting be completed in a period not to exceed one year from the date of enactment. As of December 31, 2018, the Company has completed the accounting for the tax effects of the Tax Act, and therefore, has recorded final amounts which include:

- (a) The impact of the one-time transition tax on existing net operating loss and foreign tax credit carryforwards generated, as well as the related offsetting valuation allowances. The final one-time transitioned income reported on the 2017 federal tax return filed in 2018 was \$17,724. This amount decreased both the net operating loss carryforward as well as the corresponding valuation allowance. Based on updated guidance, in 2018 the Company elected to deduct foreign taxes and therefore did not generate foreign tax credits. As such the deferred tax asset recorded as of December 31, 2017 associated with foreign tax credits was reversed in 2018.
- (b) The valuation allowance for the Company’s deferred tax assets as of December 31, 2017, was primarily dependent on forecasted future taxable income in the U.S. and Canada and was impacted by the provisions of the Tax Act. The primary impact of the Tax Act was the lowering of the statutory rate to 21%. This lowered the deferred tax assets and corresponding valuation allowance by \$11,273.

The Tax 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.

A reconciliation of the statutory United States federal income tax rate to our effective tax rate for each of the years ended December 31, 2019, 2018, and 2017 is as follows:

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Statutory U.S. federal income tax rate.....	21.0 %	21.0 %	34.0 %
Deemed repatriation tax.....	—	10.9	7.8
GILTI tax.....	16.9	22.2	—
Statutory rate change, deferred tax impact.....	—	—	29.4
Nondeductible executive compensation.....	0.4	4.8	—
Impact of share-based payment awards.....	(5.3)	0.6	(16.0)
Tax effect of foreign items.....	4.5	6.8	(8.3)
State income taxes, net of federal benefit.....	4.0	2.8	(1.1)
Nondeductible transaction costs.....	1.6	—	—
Nondeductible expenses and other.....	(0.7)	(1.2)	1.9
Change in valuation allowance, federal and state.....	<u>(20.5)</u>	<u>(32.2)</u>	<u>(23.1)</u>
Effective tax rate.....	<u>21.9 %</u>	<u>35.7 %</u>	<u>24.6 %</u>

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, 2019 and 2018 are as follows:

	<u>2019</u>	<u>2018</u>
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 9,897	\$ 10,812
Inventories	2,002	1,005
Capitalized research and development costs	1,183	1,697
Accruals and reserves currently not deductible.....	2,272	3,767
Acquired intangible assets.....	(3,525)	(1,153)
Depreciation and amortization	(1,999)	(1,082)
Stock-based compensation	1,777	1,248
Tax credit carryforwards	<u>2,055</u>	<u>1,819</u>
Net deferred tax asset	13,662	18,113
Valuation allowance.....	<u>(14,561)</u>	<u>(19,014)</u>
Net deferred tax liability	<u>\$ (899)</u>	<u>\$ (901)</u>

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, 2019 and 2018 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, 2019, 2018, or 2017.

Our Federal NOL carryforwards expire as follows:

<u>Year of Expiration</u>	<u>NOLs</u>
2030 – 2034	\$ 22,653
2035 – 2037	\$ 12,055
Non-Expiring	<u>1,709</u>
	<u>\$ 36,417</u>

The accounting guidance under ASU 2016-09 allows for the recognition of excess tax benefits associated with stock-based compensation awards regardless of whether the deduction reduces taxes payable. On January 1, 2017, we recorded a cumulative adjustment to retained earnings of \$3,391 to recognize the increase in our net operating loss carryforwards from the cumulative excess tax benefits not recognized in periods prior to January 1, 2017. A corresponding \$3,391 increase to our valuation allowance associated with this tax benefit was also recorded to retained earnings thereby resulting in no impact to retained earnings.

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, 2019, our gross unrecognized tax benefits totaled \$1,308, 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 2019, 2018 and 2017. 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, 2019.

A reconciliation of our unrecognized tax benefits is as follows:

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Balance as of January 1	\$ 1,676	\$ 1,663	\$ 2,084
Additions for tax positions of prior periods	4	44	-
Reductions for tax positions of prior periods	(372)	(31)	(421)
Balance as of December 31	<u>\$ 1,308</u>	<u>\$ 1,676</u>	<u>\$ 1,663</u>

12. STOCKHOLDERS' EQUITY:

Stock-Based Awards

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

As of December 31, 2019, 2,534 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:

Black-Scholes Option Valuation Assumptions	<u>Years Ended December 31,</u>		
	<u>2019</u>	<u>2018</u>	<u>2017</u>
Risk-free interest rate ⁽¹⁾	2.52 %	2.60 %	2.22 %
Expected dividend yield	—	—	—
Expected stock price volatility ⁽²⁾	41 %	43 %	43 %
Expected life of stock options (in years) ⁽²⁾	5	6	7

⁽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, 2019, 2018 and 2017 was \$5.19, \$9.15 and \$4.71, respectively.

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

	<u>Years Ended December 31,</u>		
	<u>2019</u>	<u>2018</u>	<u>2017</u>
Total compensation cost during the year	\$ 1,161	\$ 2,163	\$ 2,045
Amounts capitalized into inventory during the year	(343)	(420)	(371)
Amounts recognized in cost of products sold for amounts previously capitalized	405	396	276
Amounts charged against income	<u>\$ 1,223</u>	<u>\$ 2,139</u>	<u>\$ 1,950</u>

The aggregate intrinsic value of options exercised during the years ended December 31, 2019, 2018, and 2017 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was \$92, \$2,314, and \$35,631, 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, 2019	1,083	10.19		
Granted	215	12.71		
Exercised	(27)	7.17		
Expired	(41)	8.68		
Forfeited	(37)	13.05		
Outstanding on December 31, 2019	<u>1,193</u>	\$ 10.68	<u>5.89</u>	<u>\$ 651</u>
Vested or expected to vest as of December 31, 2019	<u>1,193</u>	<u>\$ 10.68</u>	<u>5.89</u>	<u>\$ 651</u>
Exercisable on December 31, 2019	<u>896</u>	<u>\$ 9.79</u>	<u>4.99</u>	<u>\$ 630</u>

As of December 31, 2019, there was \$1,423 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.5 years.

Net cash proceeds from the exercise of stock options were \$196, \$1,701 and \$31,675 for the years ended December 31, 2019, 2018, and 2017, 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, 2019:

Range of exercise prices	Options outstanding			Options exercisable	
	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	371	4.6	\$ 6.16	352	\$ 6.13
\$8.87 - \$14.95	657	6.1	10.82	432	10.08
\$16.80 - \$21.89	165	8.1	20.30	112	20.15
	<u>1,193</u>	5.9	\$ 10.68	<u>896</u>	\$ 9.79

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 \$2,979, \$6,357 and \$2,705 related to restricted shares was recognized during the years ended December 31, 2019, 2018, and 2017, 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, 2019.....	357	12.14
Granted	329	11.58
Vested.....	(212)	10.30
Forfeited	(10)	13.69
Issued and unvested, December 31, 2019.....	<u>464</u>	<u>\$ 12.86</u>
Issued and expected to vest, December 31, 2019	<u>464</u>	<u>\$ 12.86</u>

As of December 31, 2019, there was \$3,200 of unrecognized compensation expense related to unvested restricted stock awards and unvested restricted stock units that is expected to be recognized over a weighted average period of 1.9 years.

In connection with the vesting of restricted shares during the years ended December 31, 2019, 2018 and 2017, we purchased and immediately retired 76, 171 and 130 shares with aggregate values of \$949, \$3,291 and \$1,240, 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 \$(83), \$6,717 and \$2,223 related to the PSUs was recognized during the years ended December 31, 2019, 2018 and 2017, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted- Average Grant Date Fair Value
Issued and unvested, January 1, 2019.....	661	9.26
Granted ⁽¹⁾	201	12.98
Performance adjustment ⁽²⁾	168	12.98
Vested.....	(505)	5.47
Issued and unvested, December 31, 2019.....	<u>525</u>	<u>\$ 12.52</u>
Issued and expected to vest, December 31, 2019	<u>525</u>	<u>\$ 12.52</u>

^{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, 2019 and 2018, we purchased and immediately retired 213 and 20 shares with aggregate values of \$2,763 and \$301, respectively. No performance stock units vested in 2017.

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 2019, 2018 or 2017.

13. 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.

14. BUSINESS SEGMENT INFORMATION:

Our business consists of two segments: our “OSUR” business 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 molecular collections systems or “DNAG” business 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 DNAG business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research markets. Financial results of CoreBiome, Novosanis and Diversigen are included in our DNAG segment. Our cryosurgical system business was included in our OSUR 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 and 2017 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, 2019, 2018, and 2017, and asset information as of December 31, 2019 and 2018:

	Years Ended December 31,		
	2019	2018	2017
Net revenues:			
OSUR.....	\$ 78,225	\$ 85,635	\$ 91,965
DNAG.....	76,380	96,108	75,099
Total	<u>\$ 154,605</u>	<u>\$ 181,743</u>	<u>\$ 167,064</u>
Operating income (loss):			
OSUR.....	\$ 154	\$ (15,188)	\$ (1,685)
DNAG.....	18,457	43,617	41,923
Total	<u>\$ 18,611</u>	<u>\$ 28,429</u>	<u>\$ 40,238</u>
Depreciation and amortization:			
OSUR.....	\$ 3,039	\$ 3,755	\$ 3,170
DNAG.....	4,300	3,467	3,232
Total	<u>\$ 7,339</u>	<u>\$ 7,222</u>	<u>\$ 6,402</u>
Capital expenditures:			
OSUR.....	\$ 6,073	\$ 4,893	\$ 2,752
DNAG.....	3,241	1,451	1,585
Total	<u>\$ 9,314</u>	<u>\$ 6,344</u>	<u>\$ 4,337</u>

	December 31,	
	2019	2018
Total assets:		
OSUR	\$ 163,943	\$ 190,178
DNAG	185,352	125,393
Total	<u>\$ 349,295</u>	<u>\$ 315,571</u>

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

	December 31,	
	2019	2018
United States.....	\$ 23,846	\$ 18,776
Canada	5,697	5,192
Other regions	796	331
	<u>\$ 30,339</u>	<u>\$ 24,299</u>

15. COMMITMENTS AND CONTINGENCIES:

Purchase Commitments

As of December 31, 2019, we had outstanding non-cancelable purchase commitments related to inventory, supplies, capital expenditures, and other goods or services as follows:

2020	10,279
2021	20
2022	20
2023	18
2024	-
	<u>\$ 10,337</u>

Employment Agreements

Under terms of employment agreements with certain employees, which extend through 2023, we are required to pay each individual a base salary for continuing employment with us as follows:

2020	3,110
2021	1,682
2022	460
2023	309
	<u>\$ 5,561</u>

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.

16. RETIREMENT PLANS:

Substantially all of our U.S. employees are eligible to participate in the OraSure Technologies, Inc. 401(k) Plan (the "401(k) Plan"). The 401(k) Plan permits voluntary employee contributions to be excluded from an employee's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The 401(k) Plan also provides for us to match employee contributions up to \$4 per year. We contributed \$754, \$721 and \$617 to the 401(k) Plan, net of forfeitures, in 2019, 2018, and 2017, 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, 2019 and 2018, the value of the assets associated with this plan was \$3,519 and \$3,884, 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, 2019 and 2018, our total obligation under this plan was \$3,519 and \$3,884, 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 \$2 per year. We contributed \$184, \$163 and \$145 to the RRSP in 2019, 2018, and 2017, respectively.

17. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2019 and 2018. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein.

	2019 Results			
	Three months ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Net revenues.....	\$ 30,122	\$ 38,826	\$ 35,989	\$ 49,668
Costs and expenses	33,933	33,541	22,937	(1) 45,583
Operating income (loss)	(3,811)	5,285	13,052	(1) 4,085
Other income, net.....	524	524	1,195	477
Income (loss) before income taxes	(3,287)	5,809	14,247	4,562
Income tax expense.....	(29)	1,411	1,169	2,124
Net income (loss).....	<u>\$ (3,258)</u>	<u>\$ 4,398</u>	<u>\$ 13,078</u>	<u>\$ 2,438</u>
Earnings (loss) per share				
Basic	<u>\$ (0.05)</u>	<u>\$ 0.07</u>	<u>\$ 0.21</u>	<u>\$ 0.04</u>
Diluted.....	<u>\$ (0.05)</u>	<u>\$ 0.07</u>	<u>\$ 0.21</u>	<u>\$ 0.04</u>

	2018 Results			
	Three months ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Net revenues.....	\$ 41,987	\$ 43,625	\$ 45,885	\$ 50,246
Costs and expenses	42,485	38,067	35,028	37,734
Operating income	(498)	5,558	10,857	12,512
Other income, net.....	412	736	510	1,629
Income before income taxes.....	(86)	6,294	11,367	14,141
Income tax expense.....	2,033	2,173	3,271	3,843
Net income	<u>\$ (2,119)</u>	<u>\$ 4,121</u>	<u>\$ 8,096</u>	<u>\$ 10,298</u>
Earnings per share				
Basic	<u>\$ (0.03)</u>	<u>\$ 0.07</u>	<u>\$ 0.13</u>	<u>\$ 0.17</u>
Diluted.....	<u>\$ (0.03)</u>	<u>\$ 0.07</u>	<u>\$ 0.13</u>	<u>\$ 0.16</u>

(1) Includes a \$10,149 gain associated with the sale of the cryosurgical business, which was recorded as a reduction of operating expenses in the indicated period.

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BOARD OF DIRECTORS

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Alexion Pharmaceuticals

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2. Audit
3. Nominating and Corporate Governance