

ORASURE TECHNOLOGIES INC  
Form 10-K  
February 28, 2019

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, 2018

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:

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$0.000001 par value per share	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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, 2018):  
\$1,004,924,956

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 21, 2019: 61,663,044 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

---

Table of Contents

PART I

	Page
ITEM 1. <u>Business</u>	2
ITEM 1A. <u>Risk Factors</u>	23
ITEM 1B. <u>Unresolved Staff Comments</u>	48
ITEM 2. <u>Properties</u>	48
ITEM 3. <u>Legal Proceedings</u>	48
ITEM 4. <u>Mine Safety Disclosures</u>	48

PART II

ITEM 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	49
ITEM 6. <u>Selected Consolidated Financial Data</u>	51
ITEM 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	52
ITEM 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	64
ITEM 8. <u>Financial Statements and Supplementary Data</u>	65
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	65
ITEM 9A. <u>Controls and Procedures</u>	65
ITEM 9B. <u>Other Information</u>	66

PART III

ITEM 10. <u>Directors, Executive Officers and Corporate Governance</u>	67
ITEM 11. <u>Executive Compensation</u>	67
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	67
ITEM 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	67

ITEM 14. <u>Principal Accountant Fees and Services</u>	67
--	----

PART IV

ITEM 15. <u>Exhibits and Consolidated Financial Statement Schedules</u>	68
---	----

ITEM 16. <u>Form 10-K Summary</u>	70
-----------------------------------	----

---

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; 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; impact of increased reliance on U.S. government contracts impact of negative economic conditions; 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; 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 meet financial covenants in credit agreements; 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. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products are sold in both professional and over-the-counter (“OTC”) markets in North America, Europe, Central and South America, and Australia.

The second segment is our “DNAG” or molecular collection systems business and is operated primarily through our subsidiary, DNA Genotek Inc. (“DNAG”), a company based in Ottawa, Canada. In the DNAG business we manufacture and sell 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 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 products into the microbiome and tuberculosis markets and 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. We serve 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](http://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.

### Recent Developments

In early January 2019, we acquired two privately-held, early-stage companies, CoreBiome, Inc. (“CoreBiome”) and Novosanis N.V. (“Novosanis”), in order to add differentiated products and services to our molecular collection systems 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. These services provide optimal analytical algorithms to deliver



speed and scalability in the lab with highly precise analytics. 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 was a Belgian company founded as a spin-off from the University of Antwerp, Belgium in 2013. 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.

The acquisitions of both CoreBiome and Novosanis were structured with modest up-front payments and potential additional payments based on future performance of each company. These acquisitions are the first steps in the execution against our long-term strategy of becoming a growth company focused on innovation, both internally and through acquisitions of companies and technologies outside of our existing core businesses.

## Products

The following is a summary of our principal products and services and their regulatory and commercial status, excluding those of CoreBiome and Novosanis:

Product/Service	Description	Regulatory Status	Commercial Status
OraQuick	A rapid, point-of-care qualitative test for antibodies to the Human Immunodeficiency Virus Type 1 (“HIV-1”) and Type 2 (“HIV-2”) and together with HIV-1, “HIV-1/2”) that can be visually read in approximately 20 minutes.	Premarket approval (“PMA”) by the FDA for use with oral fluid, finger-stick and venous whole blood, and plasma.	Marketed
ADVANCE® HIV-1/2	A rapid, point-of-care qualitative test for antibodies to the Human Immunodeficiency Virus Type 1 (“HIV-1”) and Type 2 (“HIV-2”) and together with HIV-1, “HIV-1/2”) that can be visually read in approximately 20 minutes.	CLIA (Clinical Laboratory Improvement Amendments of 1988) waived for use with oral fluid, finger-stick and venous whole blood.	Marketed
		CE mark (European Union) approved for use with oral fluid, finger-stick and venous whole blood and plasma.	Marketed
		Registered in various other countries.	Marketed
OraQuick® HIV – 1/2 (Export Only)	A rapid, point-of-care qualitative test for antibodies to the Human Immunodeficiency Virus Type 1 (“HIV-1”) and Type 2 (“HIV-2”) and together with HIV-1, “HIV1/2”) that can be visually read in approximately 20 minutes.	World Health Organization (“WHO”) pre-qualification.	Marketed
		Registered in various foreign countries.	Marketed
OraQuick® In-Home HIV Test	A rapid, point-of-care qualitative oral fluid HIV-1/2 test for OTC use that can be visually read in approximately 20 minutes.	PMA approved for OTC use.	Marketed
			Not Marketed

CE Mark (European Union)  
approved for OTC use.

OraQuick® HIV Self-Test	Rapid point-of-care qualitative and oral fluid HIV-1/2 Self-Test that can be visually read in approximately 20 minutes.	Registered in various countries.	Marketed
OraQuick® HCV	A rapid, point-of-care qualitative test for antibodies to the hepatitis C virus (“HCV”) that can be visually read in approximately 20 minutes.	WHO pre-qualification. PMA approved and CLIA waived for use with venous whole blood and finger-stick whole blood specimens.	Marketed
		CE mark (European Union) approved for use with oral fluid, finger-stick and venous whole blood, serum and plasma.	Marketed
		Registered in various other countries.	Marketed
		WHO pre-qualification.	Marketed
OraQuick® Ebola	A rapid point-of-care qualitative test for Ebola antigen that can be visually read in approximately 30 minutes.	Emergency Use Authorization (“EUA”) for use with finger stick and venous whole blood specimens from live patients.	Marketed
		EUA for use with oral fluid specimens from cadavers.	Marketed
		Emergency Use Assessment and Listing by WHO for whole blood samples and oral fluid samples from cadavers.	Marketed

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

Product/Service	Description	Regulatory Status	Commercial Status
OraSure QuickFlu® Rapid Flu	A rapid, point-of-care qualitative test for antibodies to influenza (flu) Types A and B, including H1N1 infections, with results available in 10 minutes.	FDA 510(k) cleared for use with nasal swab, nasopharyngeal swab and nasal aspirate/wash.	Marketed
A&B Test		CLIA waived for use with nasal and nasopharyngeal swabs.	Marketed
OraSure®	Oral fluid collection device for detection of HIV-1 antibodies, cocaine and cotinine in a laboratory setting.	PMA approved for detection of HIV-1 antibodies with approved laboratory enzyme immunoassay test and registered as a Class I Medical device in the U.S. for detection of cocaine and cotinine.	Marketed
Oragene® • DX	Non-invasive all-in-one system for the collection, stabilization, transportation and storage of human DNA from saliva.	FDA 510(k) cleared for use with FDA-cleared or exempt molecular tests, including consumer use.	Marketed
Oragene® • DNA	Non-invasive all-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	CE marked and registered as Class 1 Medical Device in Canada.	Marketed
Oragene® • RNA	Non-invasive all-in-one system for the collection, stabilization and transportation of RNA from human saliva.	Registered in various other countries. Research use only product.	Marketed
ORAc collect® • DX	All-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	FDA 510(k) cleared.	Marketed
ORAc collect® • DNA	All-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	CE marked and registered as Class 1 Medical Device.	Marketed
		Registered in various foreign countries.	Marketed

OMNIgene® • ORAL	Non-invasive all-in-one system for the collection, stabilization, transportation, and storage of microbial DNA from saliva.	Research use only product.	Marketed
Performagene™	All-in-one non-invasive swab kit for the collection, stabilization and transportation of animal DNA samples.	Animal research use only.	Marketed
PerformaBiome™ GUT	•All-in-one system for easy collection and stabilization of DNA for animal microbiome profile analysis.	Animal research use only.	Marketing
OMNIgene® • GUT	All-in-one system for the collection, stabilization, transportation and storage of microbial DNA in stool samples.	Research use only product.	Marketed
		CE marked and registered in certain countries.	Marketed
OMNIgene® • SPUTUM	Reagent for liquefying, decontaminating, transporting and preserving tuberculosis bacteria in sputum samples.	Research use only product.  CE marked and registered in certain countries.	Marketed
OMNIgene® • VAGINAL	Device for self-collection and stabilization of DNA and RNA from the vagina.	Research use only.	Marketed
OMNIgene® • ORAL	Device for self-collection and stabilization of DNA and RNA from the mouth.	Research use only.	Marketed

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

Product/Service	Description	Regulatory Status	Commercial Status
Hemagene®	Reagent to stabilize high molecular weight DNA in buffy coat samples at ambient temperature	Research use only.	Marketed
PrepIT®	Reagents for extraction and preparation of DNA from saliva.	CE marked and registered in the U.S., Canada and various other countries.	Marketed
GenoFIND™	End-to-end services for genomics and microbiome analysis	Provided by CLIA and College of American Pathologists (“CAP”) certified lab.	Marketed
Intercept®	Oral fluid collection device for oral fluid drugs-of-abuse (“DOA”) testing in a laboratory setting.	FDA 510(k) cleared for use with nine MICRO-PLATE DOA assays.	Marketed
		CE marked and registered in certain countries.	Marketed
MICRO-PLATE DOA Assays	Used to detect the following drugs in an oral fluid sample collected with Intercept® device: tetrahydrocannabinol (“THC” or marijuana), cocaine, opiates, amphetamines, methamphetamines, phencyclidine (“PCP”), benzodiazepines, barbiturates and methadone.	Nine drug assays – FDA 510(k) cleared.	Marketed
		Assays CE marked and registered in certain countries.	Marketed
Intercept i2®	Oral fluid collection device for oral fluid DOA testing in a laboratory setting using fully-automated, high-throughput oral fluid DOA assays.	Forensic use only product.	Marketed
		Generic device CE marked and registered as Class I Medical Device in the U.S.	Marketed
Homogeneous DOA Assays	Fully-automated high-throughput oral fluid DOA assays jointly developed with Thermo Fisher for use on oral fluid samples collected with an Intercept i2® device to detect PCP, opiates, cocaine, methamphetamines amphetamines, and THC.	Forensic use only.	Marketed

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

Cryosurgical Systems – Professional	Cryosurgical (freezing) system for the removal of warts and other benign skin lesions, marketed under the Histofreezer® tradename primarily to the physicians’ office market.	FDA 510(k) cleared for nine types of skin lesions.	Marketed
		CE marked and registered in certain countries.	Marketed
Cryosurgical Systems – OTC	Cryosurgical system for the removal of common and plantar warts and skin tags, sold in various OTC markets under certain brand names and on a private label basis.	FDA 510(k) cleared for common and plantar warts.	Marketed
		Registered in Canada for warts and skin tags.	Marketed
		CE marked and registered for warts in certain countries under Scholl Freeze Spray® and POINTTS® names and for skin tags under CryoTag name.	Marketed
		CE marked for skin tags.	Marketed

In addition to the above products, we sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications.

### 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 PMA approval 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 Improvements Amendment of 1988, or 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 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 WHO pre-qualification for our export-only version of this product.

### OraQuick® In-Home HIV Test

The OraQuick® In-Home HIV test is an over-the-counter 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.

### 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 into certain foreign countries at a lower cost to meet the needs of those markets. For the past several years, we have 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 the African marketplace. 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. 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 2018, a majority of the sales of our OraQuick® HIV Self-Test occurred outside of 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, or HCV, in a variety of sample types. The OraQuick® HCV test operates in substantially the same manner as the OraQuick® 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 product is also registered and sold in other foreign countries and has received WHO pre-qualification.

#### OraQuick® Ebola Rapid Antigen Test

In 2015, we completed development of our new rapid Ebola test. This product utilizes the OraQuick® technology platform for the detection of Ebola antigen. This test has received EUAs 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) on finger-stick and

venous whole blood samples collected from live patients, as well as oral fluid specimens collected from cadavers. The WHO has also issued an Emergency Use Assessment and Listing for this product with respect to the same specimen types.

#### 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 Princeton BioMeditech Corporation (“PBM”) and is currently sold in certain U.S. markets. PBM has also obtained a CLIA waiver for this test for use 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. 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. Optimized samples are compatible with all routine TB tests, enable cost-effective sample transport and simplify laboratory workflows while eliminating the need for lab reagents that require daily mixing and quality control. We believe OMNIGENE® • SPUTUM can improve laboratory and operational workflows compared to current approaches, and improve overall test results. This product is being offered to TB laboratories for evaluation.

The OMNIgene® • SPUTUM product is CE marked and is gaining greater interest for tuberculosis testing. Healthcare providers from more than 60 countries have expressed interest in evaluating this product and business entities, ranging from Ministries of Health, non-government organizations, donor agencies and diagnostic test developers, have begun their product evaluations. Our tuberculosis products are well positioned to support the U.S. government’s National Action Plan for combatting multi-drug resistant tuberculosis, by providing much needed solutions to developing countries that are at the highest risk for multi-drug resistant tuberculosis.

## Molecular Collection Systems

**Genomics 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 product is sold under the Oragene® brand and is 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.

**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 DNA or RNA collected from the vagina and oral cavity.

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.

**Molecular Services.** Our molecular business also offers customers our GenoFIND™ services, a suite of genomic and microbiome 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. With the acquisition of CoreBiome, we believe we can offer enhanced laboratory service offerings for our customers in the microbiome market.

**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. 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.

#### 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<sup>®</sup> he”. This device offers several important advantages over our original Intercept<sup>®</sup> 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<sup>®</sup>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”).

### Cryosurgical Systems (Skin Lesion Removal Products)

The Histofreezer<sup>®</sup> cryosurgical removal system is a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. The Histofreezer<sup>®</sup> product mixes three cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to a maximum of  $-50^{\circ}\text{C}$  to  $-55^{\circ}\text{C}$ . The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area by freezing. We have received 510(k) clearance for use of the Histofreezer<sup>®</sup> product to remove common warts and eight other types of benign skin lesions, and this product has been CE-marked and registered for distribution in Canada, throughout Europe and in certain other foreign countries. We also supply this product on a private label basis for resale by one of our physician office distributors.

Internationally, we sell an OTC cryosurgical product through our distributor Genomma Labs (“Genomma”), under the POINTTS tradename, in Mexico and a number of South and Central American countries. We sell a CE-marked cryosurgical wart removal product into the OTC foot care market in Europe, Australia and New Zealand through our distributor, Reckitt Benckiser (“Reckitt”), under the Scholl and Dr. Scholl trademarks. Reckitt is the owner of the Scholl and Dr. Scholl trademarks in countries outside North and South America. We also sell OTC cryosurgical products to retailers on a private label basis for the treatment of warts in the U.S., for the treatment of both warts and skin tags in Canada and for the treatment of skin tags in the U.K.

### Immunoassay Tests and Reagents

We develop and sell immunoassay tests in formats, known as MICRO-PLATE and AUTO-LYTE<sup>®</sup>, 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<sup>®</sup> product line to detect drugs-of-abuse in oral fluid specimens.

AUTO-LYTE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> device. Under this agreement, we are currently selling a NIDA-5 panel of assays supplied by Thermo Fisher in the U.S. forensic market. The parties are discussing certain changes to this agreement and assessing their ability to complete development of several additional assays and pursue FDA 510(k) clearance, CE marking and other regulatory approvals of the Intercept i2<sup>®</sup> device for use with a 12-assay panel. Subject to these further discussions with Thermo Fisher, we believe the offering of an Intercept i2<sup>®</sup> device with a full menu of fully-automated high-throughput oral fluid assays 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.<sup>®</sup> Saliva Alcohol Test

Our Q.E.D.<sup>®</sup> 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.<sup>®</sup> 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.<sup>®</sup> 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.

## Products Under Development

### Infectious Disease

One recent area of focus for product development has been our OraQuick® Ebola rapid antigen test. In July 2015, we received an Emergency Use Authorization or EUA for our Ebola test from the FDA. This authorization allows the use of the product for the duration of the U.S. Secretary of the Department of Health and Human Services (“HHS”) August 5, 2014 declaration regarding the emergency use of in vitro diagnostic tests for the detection of the Ebola virus. Under this authorization, the test can be used on finger-stick and venous whole blood samples collected from live patients.

In June 2015, we entered into a contract with the Biomedical Advanced Research Development Authority (“BARDA”) within the HHS for up to \$10.4 million of funding for our OraQuick® Ebola test. The three-year, multi-phased contract included an initial commitment of \$1.8 million and options for up to an additional \$8.6 million to fund certain clinical and regulatory activities. In September 2015 and July 2017, BARDA exercised an option to provide \$7.2 million and \$1.3 million, respectively, in additional funding for our OraQuick® Ebola test.

In March 2016, we received an EUA for use of the Ebola test on oral fluid samples collected from cadavers. The WHO has issued an Emergency Use Assessment and Listing, or EUAL, for use of the product with whole blood samples collected from live patients and with oral fluid samples collected from cadavers. These approvals will allow expanded use of the product, particularly in Africa. We also intend to seek 510(k) clearance of our Ebola test from the FDA in the future.

Our recent product development efforts also focused on addressing global concerns regarding the Zika virus. As a result, we began developing a rapid Zika antibody test on our OraQuick® platform. In August 2016, we entered into a contract with BARDA for up to \$16.6 million of funding for our OraQuick® Zika test. The six-year, multi-phased contract included an initial commitment of \$7.0 million and options for up to an additional \$9.6 million to fund the evaluation of additional product enhancements, and certain clinical and regulatory activities. In May 2017, BARDA exercised an option to provide \$2.6 million in additional funding for our rapid Zika test.

During 2018, because of difficulties in completing development and optimizing our Zika test and because of significant uncertainty regarding the future commercial demand for this product, the scope of this contract was reduced. As a result, our contract with BARDA will be essentially completed in the first quarter of 2019.

### Molecular Collections

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 and RNA from multiple sample types including gut, skin, 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.

### Research and Development

Research and development expenses were \$16.3 million in 2018, \$13.4 million in 2017, and \$9.8 million in 2016. 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.

10

---

We market our products in the United States and internationally. Consolidated net revenues attributable to customers in the United States were \$136.8 million, \$121.5 million and \$99.8 million in 2018, 2017 and 2016, respectively. Consolidated net revenues attributable to international customers amounted to \$44.9 million, \$45.6 million and \$28.4 million, or 25%, 27% and 22% of our total revenues, in 2018, 2017 and 2016, respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Notes 2 and 11 to our consolidated financial statements included elsewhere in this Annual Report.

#### Infectious Disease Testing - Professional

We market the OraQuick ADVANCE<sup>®</sup> HIV-1/2 antibody test directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, family planning clinics, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market, such as AIDS service organizations and various community-based organizations that are set up primarily for the purpose of encouraging and enabling HIV testing. We also sell our OraQuick ADVANCE<sup>®</sup> test directly to hospitals in the U.S. and through distributors into the U.S. physician office market and to retail clinics operated by pharmacies. In addition, we distribute our OraQuick<sup>®</sup> HIV test in certain other foreign countries.

Our OraQuick<sup>®</sup> HCV test is sold primarily to the same markets where our OraQuick<sup>®</sup> ADVANCE HIV test is sold, including public health organizations, hospitals, physicians and retail clinics. We also sell this test in other countries through distributors. A focus for our HCV business has been, and will continue to be, to market our test to foreign countries that intend to implement broad scale testing programs.

We currently sell our OraQuick<sup>®</sup> 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 no Ebola sales in 2018. 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, the availability of government or other funding and whether we are able to obtain FDA 510(k) clearance and pre-qualification with the WHO for our product.

We market the OraSure<sup>®</sup> 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<sup>®</sup> test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure<sup>®</sup> device in the international public health market.

We 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<sup>®</sup> 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.

We have also been working to commercialize the OMNIgene<sup>®</sup> • SPUTUM product. TB is a major global health issue, with long established relationships among public health agencies, NGOs, and suppliers. We have a focused sales and market development team working with these key players to have our product evaluated and adopted where possible.

#### Infectious Disease Testing - OTC

We sell our OraQuick<sup>®</sup> In-Home test in the U.S. retail or consumer market. Retailers carrying the product include CVS, Walgreens, Rite Aid and Wal-Mart. The product is also available for purchase on-line through certain retailers and our website, [www.oraquick.com](http://www.oraquick.com). The primary target population for our HIV-OTC test is comprised of 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, 750,000 OraQuick® HIV Self-Tests were sold to PSI for use in three African countries, Malawi, Zambia and Zimbabwe. More recently, we were selected to participate in Phase II of the project under which approximately 4 million HIV Self-Tests are expected to be deployed over a two-year period.

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.

### Molecular Collection Systems

DNAG sells its products directly to its customers, primarily through its own internal sales force. In some countries distributors are used. Over half of DNAG’s employees work in the areas of sales, marketing, business development or product management. The significant majority of employees who deal directly with customers have molecular science backgrounds, which we believe is useful in selling and marketing molecular collection products, and more importantly, in identifying and evaluating new market and business opportunities.

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. In addition, DNAG is offering laboratory and analytics services in order to more fully meet the needs of its customers.

### 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<sup>®</sup> 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. Subject to our further discussions with Thermo Fisher, we plan to obtain FDA 510(k) clearance of our Intercept i2<sup>®</sup> 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. We expect that the 510(k) cleared Intercept i2<sup>®</sup> device and related fully-automated high-throughput assays will eventually replace our original Intercept<sup>®</sup> collector and MICRO-PLATE assays in the drug testing market.

We distribute our Q.E.D.<sup>®</sup> 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.

#### Cryosurgical Systems

Most of our Histofreezer<sup>®</sup> sales occur in the United States to distributors that, in turn, resell the product to primary care physicians and podiatrists in the United States. Our major U.S. distributors include Cardinal Healthcare, McKesson Medical-Surgical, AmerisourceBergen Corporation, and Henry Schein. We have engaged a manufacturers' representative organization to help our U.S. distributors promote and sell Histofreezer<sup>®</sup>. We also provide a private label version of our professional Histofreezer<sup>®</sup> product to one of our U.S. distributors. Internationally, we sell the Histofreezer<sup>®</sup> product through a network of distributors in more than 20 countries worldwide.

We distribute cryosurgical wart removal products in the OTC foot care market in Europe, Australia and New Zealand through our distributor, Reckitt Benckiser, under its Scholl and Dr. Scholl tradenames, and in the OTC markets in Mexico and several Central and South American countries under the POINTTS tradename through our distributor, Genomma. We sell our product in the U.K. through another distributor, Appia, under the CryoTag tradename, for the removal of skin tags. We also sell OTC private label cryosurgical products for the removal of warts and skin tags in Canada and for the removal of warts in the U.S.

#### Insurance Risk Assessment

We currently market the OraSure<sup>®</sup> 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<sup>®</sup> 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. We sell our OraSure<sup>®</sup> Western blot confirmatory test directly to insurance testing laboratories for use in confirming oral fluid specimens collected with our OraSure<sup>®</sup> device that initially test positive for HIV-1.

There exists a wide range of policy limits where our OraSure<sup>®</sup> product is being used. In general, many (but not all) of our insurance company customers use the OraSure<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> assays and reagents in the insurance testing market directly to certain laboratories.

#### 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,		
	2018	2017	2016
Oragene®	\$75,850	\$69,184	\$29,454
OraQuick® HIV	41,457	35,148	33,067
OraQuick® HCV	12,394	25,409	14,066
Cryosurgical systems	10,767	12,279	13,234

One of our customers accounted for approximately 24% and 25% of our net consolidated revenues in 2018 and 2017, respectively. Another customer accounted for approximately 15% of our net consolidated revenues in 2016.

13

---

## Supply and Manufacturing

Our OraQuick ADVANCE<sup>®</sup> HIV test, OraQuick<sup>®</sup> In-Home HIV test, OraQuick<sup>®</sup> HCV test, OraQuick<sup>®</sup> Ebola test, OraSure<sup>®</sup>, Intercept<sup>®</sup> and Intercept i2<sup>®</sup> collection devices, AUTOLYTE and MICRO-PLATE assays and QED<sup>®</sup> 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<sup>®</sup> HIV device and the OraQuick<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> test is manufactured and supplied by a third party, Princeton BioMeditech. There is no other supply source for this product.

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

The Histofreezer<sup>®</sup> product and our OTC cryosurgical products are assembled by a U.S. vendor with certain components sourced from international suppliers. We believe that additional suppliers for our cryosurgical products are available on terms no less favorable than the terms of our existing supply agreements in the event that our current suppliers would be unable or unwilling to continue supplying components and manufacturing finished products.

DNAG has two long-term contract manufacturing relationships to supply virtually all of its products, including the Oragene<sup>®</sup> 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.

## Employees

As of December 31, 2018, we had 398 full-time employees (including 146 employees at our subsidiary, DNAG). Of this total, there were 128 in sales, marketing and client services; 50 in research and development; 149 in operations, manufacturing, quality control, information systems, purchasing and shipping; 37 in quality assurance and regulatory



affairs; and 35 in administration and finance. This compares to 377 employees as of December 31, 2017. Our employees are not currently represented by a collective bargaining agreement.

### Competition

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. One of our competitors has received FDA approval and a CLIA waiver for a rapid oral fluid HIV test and another sells a rapid HIV antigen/antibody test that is 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 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. The OraQuick® HIV Self-Test that we sell in certain international markets is expected to face 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 regulatory authorization for use on both whole blood samples from living patients and oral fluid samples from cadavers.

15

---

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.

Our Oragene® collection system competes 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® products. Although we believe the Oragene® device offers 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® product is 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.

The OMNIgene® • SPUTUM product is unique and has no direct competition in terms of a comparable product. The primary competition for this product is the incumbent methodologies that are widely adopted for collecting sputum samples and have been used in labs globally for many years.

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<sup>®</sup> assays, and we may eventually stop selling this product line.

Q.E.D.<sup>®</sup> 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.<sup>®</sup> test.

Our professional cryosurgical product is sold primarily to physicians, including family practitioners, pediatricians and podiatrists. This product primarily competes against other portable cryosurgical systems used for the removal of benign skin lesions in both the U.S. and Europe. In addition, certain of our distributors sell private label cryosurgical products that compete with our Histofreezer<sup>®</sup> product. Our OTC cryosurgical products compete against other cryosurgical products offered in the U.S. OTC market and certain international OTC markets.

#### 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 five United States patents for our OraQuick® platform, as well as corresponding related international patents. We also have patent applications pending internationally. Four of the U.S. patents expire from March to July 2019 and the fifth in July 2028.

We hold, through our subsidiary, DNAG, eighteen 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 July 2019 through March 2034.

We have three United States patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products, and we have pending patent applications related to these products in the United States and in certain foreign countries. These patents expire from September 2025 to February 2032.

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®, Histofreezer®, OraSure QuickFlu®, Q.E.D.®, Oragene®, ORAcollect®, OMNIgene® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. With respect to our international OTC cryosurgical products, the Scholl and Dr. Scholl tradenames are owned by Reckitt Benckiser in Europe, Australia, New Zealand and other countries outside North and South America, and the POINTTS tradename is owned by Genomma.

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, or the FDA, along with other federal, state and local agencies and comparable regulatory bodies in other countries. This regulated environment governs almost all aspects of development, production and marketing, including product design and testing, authorizations to market, labeling, advertising and promotion, manufacturing, distribution, post-market surveillance and reporting, and recordkeeping. We believe that our products and procedures are in material compliance with all applicable regulations, but the regulations regarding the manufacture and sale of our products may be unclear and are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

Many of our FDA-regulated products require some form of review and action by the FDA before they can be marketed in the United States. After approval or clearance by the FDA, we must continue to comply with other FDA requirements applicable to marketed products and are subject to periodic inspections by the FDA and other regulatory bodies. Both before and after approval or clearance,

failure to comply with the FDA's requirements can lead to significant penalties or could disrupt our ability to manufacture and sell these products. In addition, the FDA could refuse permission to obtain certificates needed to export our products if the agency determines that we are not in compliance.

#### Domestic Regulation

Most of our products are regulated in the United States as in vitro diagnostic and medical devices.

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 15 months 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 cleared or 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 OSR regulations and other postmarket requirements, but the regulations are subject to change or may be unclear, and we cannot be sure that FDA investigators will agree with our compliance with the FDA's postmarket requirements.

The Clinical Laboratory Improvement Amendments of 1988, 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.

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<sup>®</sup> HIV-1/2 test, the OraQuick<sup>®</sup> HCV test, our Histofreezer<sup>®</sup> product line, our OTC cryosurgical removal product and certain of the Oragene<sup>®</sup> collection kits and OMNIgene<sup>®</sup> products sold by DNAG.

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.

We have obtained WHO pre-qualification for our OraQuick<sup>®</sup> HIV Self-Test and OraQuick<sup>®</sup> 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.

We have experienced strong revenue growth during the past several years, primarily due to increasing sales of our OraQuick® rapid HCV test and our Oragene® saliva DNA collection kit. The higher sales of these products have been driven by increased demand by an increasing number of large customers.

Our molecular collections 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. 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. Since the inception of the contract and through December 31, 2018, we have recognized approximately \$52.8 million of revenue under this contract.

In our infectious disease business, sales of our HCV test fell from \$25.4 million in 2017 to \$12.4 million in 2018. This decline in sales was primarily attributable to sales under a previously announced \$18.0 million contract with a foreign government in support of a country-wide HCV elimination program. This agreement was largely completed in 2017 and this customer unexpectedly decided not to renew the agreement for an additional 12 months.

We expect that sales to the large consumer genetics customer will continue to be a significant growth driver for our molecular business. It is also possible that other countries implementing broad based HCV testing or elimination programs could have a significant impact on our business. As a result, certain parts of our business will likely continue to have a high customer concentration and depend disproportionately on a few large customers. In addition, demand from a large consumer genomics customer increased significantly in 2016 and 2017 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 customers for our products, our revenues and results of operations could be adversely affected.

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

We believe successful new product introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product 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, OMNIgene® • GUT and OMNIgene® • SPUTUM product offerings, and other new products or technologies that may be developed or acquired. To achieve market acceptance, we and/or our distributors 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. In addition, governmental funding for the purchase of our products 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 that may be developed and our marketing efforts for new products may not be successful. 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 will obtain significant market acceptance and fill the market need that is perceived to exist on a timely basis, or at all.

23

---

**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<sup>®</sup> HIV-1/2, OraQuick<sup>®</sup> HCV, OraQuick<sup>®</sup> In-Home HIV test and OraQuick<sup>®</sup> 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 Intense Competition From Other Providers of Diagnostic Tests and Sample Collection Products.**

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<sup>®</sup> HIV-1/2 test. In addition, the Oragene<sup>®</sup> product line sold by our subsidiary, DNAG, competes against other molecular collection products, such as blood collection kits and buccal swabs. There are a number of competitors making investments in competing technologies and products, and a number of our competitors may have a competitive advantage because of their greater financial, technical, research and other resources. Some competitors offer broader product lines, aggressively discount prices for their products 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' products take market share from our products through more effective marketing or competitive pricing, 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 internally develop or acquire their own sample collection devices and use those devices in place of our products 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. 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 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<sup>®</sup> HIV-1/2 test has been purchased through bulk procurement or other funding provided by governmental agencies. Our OraQuick<sup>®</sup> 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. More recently, we 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. 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 cryosurgical products in the consumer or OTC market in the United States and certain countries and we may expand OTC sales of these products into other countries. We also sell 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 in the OTC market 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 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 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

25

---

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. While we believe international sales of our HIV Self-Test 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 continue or increase or if we are otherwise unable to expand international sales of our other 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 \$44.9 million or 25% of consolidated net revenues in 2018, \$45.6 million or 27% of consolidated net revenues in 2017 and \$28.4 million or 22% of consolidated net revenues in 2016. In addition, our molecular collection systems business, which accounted for \$86.5 million or 48% of consolidated net revenues in 2018, 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;
- 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 for reimbursement approvals;
- 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 obtain or maintain regulatory approvals or registrations for our products;
- 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;

26

---



- 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;
- 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<sup>®</sup> HIV-1/2 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.

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

We are currently receiving funding from the U.S. government related to our OraQuick<sup>®</sup> Ebola rapid antigen test 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 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 Are Subject to Future Funding and the Government's Choice to Exercise Options, and May be Terminated for the Government's Convenience.

Our contracts with the U.S. government are subject to future funding and are subject to the right of the government to terminate the contracts in whole or in part for its convenience. There is pressure for the U.S. government to reduce spending. The non-appropriation of funds or the termination for the government's convenience of our contracts could negatively affect our financial results.

For U.S. government contracts that include options, such as our BARDA contracts, the U.S. government generally has the unilateral right not to exercise such options and may not exercise an option if the agency is not satisfied with our performance under the contract or does not receive funding to continue the program, among other reasons. If levels of U.S. government expenditures and authorizations for emerging diseases decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under its contracts with us, our business, revenue and operating results would suffer.

Our U.S. Government Contracts Are Subject To Numerous Requirements in Order to be Reimbursed by the Federal Government.

Our current contracts with BARDA are cost plus fixed fee contracts and potential future contracts with the U.S. government may also be structured this way. Under our cost plus fixed fee contracts, we are allowed to recover our approved costs plus a fixed fee. The total price on a cost plus fixed fee contract is based primarily on allowable costs incurred, but generally is subject to contract funding limitations. U.S. government regulations require us to notify our customer of any cost overruns or underruns on a cost plus contract. If we incur costs in excess of the funding limitation specified in the contract we may not be able to recover those cost overruns.

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.

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 reach the market. Many of our

principal competitors have considerably greater financial, technical and marketing resources than we do. As new products enter the market, our products may become obsolete or a competitor's products may be more effective 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 that would render our technologies and products obsolete or otherwise commercially unattractive, or introduce or commercialize such products, before we can do so. If we fail to convince our customers of the advantages and economic value of our products or otherwise maintain and enhance our competitive position, our customers may decide to use products 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 Products.

In order to remain competitive, we must regularly commit substantial resources to research and development and the commercialization of new or enhanced products. The research and development process generally takes a significant amount of time from product 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 in which we have invested substantial time and money.

Successful products 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. As noted above, regulatory authorities may not approve these products for commercial sale or may substantially delay or condition approval. Even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product and entry into or development of new markets for our products 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. Other factors that could affect the success of our efforts include our ability to manufacture products in a cost-effective manner, whether we can obtain necessary intellectual property rights and protection and our ability to obtain reimbursement authorizations in the markets where the product will be sold.

Accordingly, if we fail to develop and gain commercial acceptance for our products, or if competitors develop more effective products or a greater number of successful new products, customers may decide not to purchase our products or may purchase and use products 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 Successfully Commercialize a Rapid Point-of-Care Ebola Test Could Adversely Affect Our Results of Operations and Business Prospects.

We have completed development of a rapid Ebola antigen test using our OraQuick® technology platform. In 2015 and 2016, under an EUA received from the FDA, we sold \$2.5 million of product to the CDC for field testing. There were minimal sales of this product during 2017 and no sales in 2018. It is uncertain whether, and to what extent, we will be successful in obtaining additional or sustainable purchase commitments for our Ebola test. Significant efforts are

under way to develop a vaccine for the Ebola virus. If a vaccine is developed and widely deployed in the countries at risk for Ebola, the need for testing could be reduced as could the demand for our product.

There is also no assurance that our Ebola test will perform at a level necessary to receive all of the regulatory approvals required for its use. In addition, it is possible that the FDA may revoke our EUA if it is determined that Ebola is no longer an emergency warranting that authorization. Failure to successfully obtain the required regulatory approvals or receive sustainable and significant purchase commitments for our Ebola test could adversely affect our revenues and results of operations.

**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 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, clinical and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new or enhanced products 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 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 manufacture, sell and market our products, 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.**

We may 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 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 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

30

---



•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 and Novosanis

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

The success of the CoreBiome and Novosanis acquisitions will depend, in part, on our ability to successfully combine and integrate our legacy business with the businesses of CoreBiome and Novosanis. The integration of CoreBiome and Novosanis' businesses with our existing business is a complex, costly and time-consuming process. 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 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.

#### 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 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 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 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.

#### 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.

The Affordable Care Act imposes a 2.3% excise tax on certain transactions, including U.S. sales of many medical devices, which includes domestic sales of certain of our products. This new tax became effective in January 2013. However, the Consolidated Appropriations Act of 2016, which was enacted late 2015, suspended the tax beginning January 1, 2016, and this suspension was recently extended through December 31, 2019. Absent further legislative action, this tax will be reinstated in 2020, which could 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 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 our products 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.

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 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.

Certain Changes by the Current Administration Could Affect our Business.

Recent changes by the United States federal government have caused uncertainty about the future of trade partnerships and treaties, such as the North American Free Trade Agreement (“NAFTA”). The current administration has initiated negotiations with Canada and Mexico aimed at re-negotiating NAFTA. The U.S., Mexico and Canada have reached a preliminary U.S.-Mexico-Canada Agreement (“USMCA”) which would replace NAFTA. The USMCA maintains duty-free access for most products and leaves most key provisions of the NAFTA agreement largely intact. The USMCA still requires approval by the U.S. Congress, by Mexico’s National Assembly, and by Canada’s Parliament before it enters into force. In addition, the USMCA is still undergoing a legal review and, if past U.S. free trade agreements are any indication, this could result in follow-up negotiations which could lead to modifications of certain provisions. It is uncertain what the outcome of the Congressional approval process, legal review and any follow-up negotiations will be, but it is possible that revisions to NAFTA or failure to secure Congressional approval could adversely affect the Company’s operations. 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 our revenues and results of operations. Similarly a substantial part of DNAG's revenues represent sales of product from Canada into the United States. The imposition of tariffs or other changes in the trade relationship between Canada and the United States could negatively impact DNAG's performance. Economic and regulatory changes could also affect foreign currency exchange rates which, in turn, could affect our reported financial results and our competitiveness on a worldwide basis.

#### 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. In addition, there may be changes to existing trade agreements, like NAFTA and its anticipated successor agreement, the USMCA, which are still subject to approval by the United States, Mexico and Canada, greater restrictions on free trade generally, and significant increases in tariffs on goods imported into the United States, particularly tariffs on products manufactured in Mexico, among other possible changes. It remains unclear what the U.S. administration or foreign governments will or will not do with respect to tariffs, NAFTA, USMCA or other international trade agreements and policies. Any changes to NAFTA (or subsequent trade agreements) 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.

#### Developments Related To The U.K.'s Referendum On Membership in 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. The U.K. is currently negotiating the terms of its exit from the EU ("Brexit"), which is currently scheduled for March 29, 2019. In November 2018, the U.K. and the EU agreed upon a draft Withdrawal Agreement that sets out the terms of the U.K.'s departure, including commitments on citizen rights after Brexit, a financial settlement from the U.K. and a transition period from March 29, 2019 through December 31, 2020 to allow time for a future trade deal to be agreed. On January 15, 2019, the draft Withdrawal Agreement was rejected by the U.K. Parliament creating significant uncertainty about the terms and timing under which the U.K. will leave the EU.

If the U.K. leaves the EU with no agreement, 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.

Until the precise terms and timing of the U.K.'s exit from the EU are determined, it will be difficult to predict the impact of the Brexit referendum. 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 the Brexit referendum. The U.K.'s decision to exit the EU could 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. The Brexit referendum 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 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, 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 machinery or new manufacturing 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 equipment or facilities may require FDA approval before they can be used to manufacture our products. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products could be adversely affected.

If we or our suppliers are unable to develop necessary manufacturing capabilities in a timely manner, our sales could be adversely affected. If we fail to increase production volumes in a cost effective manner or if we experience lower than anticipated yields or production problems as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, we could experience shipment delays or interruptions and increased manufacturing 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 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, 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, respond to customer inquiries, and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet.

The failure of any of the foregoing systems to operate effectively, problems with transitioning to upgraded or replacement systems, or disruptions in the operation of the internet, could cause delays in product sales and reduced efficiency of 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. Sphere 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 Sole Supply Sources or Third-Party Suppliers 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<sup>®</sup> test and the fully automated high-throughput drug assays sold with our Intercept i2<sup>®</sup> 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<sup>®</sup> HIV device and the OraQuick<sup>®</sup> 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<sup>®</sup> 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;

35

---

- 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. 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;
- 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. However, there have been changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may impact our ability to protect our technology and enforce our intellectual property rights. For example, in 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act (the “AIA”), including changes that would transition the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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, 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. Furthermore, 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. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology. Our competitors may also develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies.

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.

We may collaborate with universities and governmental research organizations which, as a result, may acquire part of the rights to any inventions or technical information derived from our collaboration with them.

37

---

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 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 areas, and additional patents may be issued to third parties relating to our product 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. 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 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. Accordingly, we may be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products 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;
- 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 other products we may develop or acquire;
- We may be required to alter our product, 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; and
- A court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products.

We may indemnify some customers and strategic partners under our agreements with such parties if our products or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Further, our products may contain technology provided to us by other parties, such as contractors, suppliers or customers, 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 the AIA, 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 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. 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 or premarket authorizations can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. These approvals, clearances and other premarket authorizations 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 will be received. A regulatory authority may impose requirements as a condition to granting an approval, clearance, or other premarket authorization 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 or other premarket authorization 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. In addition, the FDA may revoke an Emergency Use Authorization under which our products are sold, where it is determined that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our affected products unless and until a further regulatory approval or authorization is obtained. 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 New European 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.

#### 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.

**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 2018, approximately \$44.9 million of our consolidated net revenues were generated from sales in a variety of foreign countries. These international activities subject us to the FCPA, the U.K. Bribery Act and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by business entities for the purpose of obtaining or retaining business. We have operations, enter into agreements with third parties and make sales in countries known to experience corruption. Further international expansion 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.

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, 2018, the Company had an accumulated deficit of \$99.2 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 our molecular collection systems business;
- Changes in customer buying patterns or a buildup of significant quantities in our distributors' inventories or distribution channels; and
- Our ability to mitigate declining sales of our OraQuick ADVANCE<sup>®</sup> HIV 1/2 test in the United States and expand sales of our OraQuick<sup>®</sup> HIV Self-Test internationally;
- 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 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 certain of its international sales are denominated in local currencies, including the Euro, British Pound and Australian Dollar. 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 DNAG business 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 DNAG's revenues and expenses and the translation of DNAG's 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 makes broad and complex changes to the U.S. tax code, including but not limited to reducing the corporate tax rate from 35% to 21%, requiring a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries and accelerating first year expensing of certain capital expenditures. The Tax Act also introduces new tax laws that may impact our taxable income, which will 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. The ultimate impacts of the Tax Act may differ from the Company's estimates due to changes in the interpretations and assumptions made. The Tax Act could also impact changes to our valuation of deferred tax assets

and liabilities. Any such change in valuation could have a material impact on our income tax expense and deferred tax balances. 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.

Our Revolving Credit Facility Contains Certain Financial Covenants Which, if Not Satisfied, Could Limit Our Ability to Borrow in the Future or Result in the Acceleration of the Amounts Borrowed Under This Facility.

Our revolving credit facility with a commercial bank contains various financial and other covenants with which we must comply on an ongoing or periodic basis. If we enter into new or additional credit facilities or loan agreements, we would expect those arrangements would contain similar types of covenants. Although we do not expect to violate these covenants and obligations, if such a violation were to occur, our ability to borrow funds in the future may be adversely affected. To the extent we borrow funds and a subsequent violation occurs, the outstanding debt under our credit facility or other arrangement could become immediately due and payable and our lender(s) could proceed against any collateral securing such indebtedness.

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;
- The extent to which we gain or expand market acceptance for existing, new or enhanced products;
- The costs and timing of the expansion of our manufacturing 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 or Natural Disasters May Adversely Affect Our Business.

Terrorist attacks or natural disasters, 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 and acts of terrorism, 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, 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;
- Future announcements concerning us and our products, 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 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 one or more of our customers;
- The gain or loss of significant contracts and availability of funding for the purchase of our products;
- Delays in the development, regulatory approval or commercialization of new or enhanced products;
- 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.

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.

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.

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 19, 2019, there were 360 holders of record and approximately 13,015 holders in street name of our Common Stock, and the closing price of our Common Stock was \$11.53 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 <sup>(1, 2)</sup>
October 1, 2018 - October 31, 2018	27,738	<sup>(3)</sup> \$ 14.81	—	11,984,720
November 1, 2018 - November 30, 2018	—	—	—	11,984,720
December 1, 2018 - December 31, 2018	—	—	—	11,984,720
	27,738		—	

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.

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

## Performance Graph

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

The following graph compares the cumulative total returns to investors in the Company’s Common Stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the period from December 31, 2013 through December 31, 2018. The graph assumes that \$100 was invested on December 31, 2013 in the Company’s Common Stock and in each of the above-mentioned indices, and that all dividends, if any, were reinvested.

The NASDAQ Composite Index was chosen because it is a broad index of companies whose equity securities are traded on NASDAQ. The NASDAQ Biotechnology Index was chosen because it includes a number of our competitors. Stockholders are cautioned that the graph shows the returns to investors only as of the dates noted and may not be representative of the returns for any other past or future period.

\*\$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.

	Fiscal year ending December 31,					
	2013	2014	2015	2016	2017	2018
OraSure Technologies, Inc.	100.00	161.21	102.38	139.59	299.84	185.69
NASDAQ Composite	100.00	114.62	122.81	133.19	172.11	165.84
NASDAQ Biotechnology	100.00	131.71	140.56	112.25	133.67	121.24

#### 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,				
	2018	2017	2016	2015	2014
<b>Operating Results:</b>					
Net revenues	\$181,743	\$167,064	\$128,198	(3)\$119,719	\$106,464
Costs and expenses	153,314 (1)	126,826 (2)	107,933	111,661	111,266 (4)
Operating income (loss)	28,429	40,238	20,265	8,058	(4,802 )
Other income, net	3,287	794	58	774	531
Income tax expense	11,320	10,084	603	665	343
Net income (loss)	20,396	30,948	19,720	8,167	(4,614 )
<b>Earnings (loss) per share</b>					
Basic	\$0.33	\$0.52	\$0.35	\$0.14	\$(0.08 )
Diluted	\$0.33	\$0.51	\$0.35	\$0.14	\$(0.08 )
<b>Shares used in computing earnings (loss) per share</b>					
Basic	61,112	59,050	55,615	56,397	55,949
Diluted	62,532	61,024	56,513	56,846	55,949
<b>Cash Flow:</b>					
Cash flows provided by operating activities	\$39,090	\$28,156 (2)	\$24,598	\$15,773	\$7,526 (4)

	December 31,				
	2018	2017	2016	2015	2014
<b>Financial Position:</b>					
Cash, cash equivalents, and investments	\$201,324	\$176,587	\$120,950	\$101,319	\$97,867
Working capital	191,332	189,668	139,106	111,480	104,752
Total assets	315,571	296,201	207,935	189,321	189,633
Accumulated deficit	(99,189 )	(119,510)	(150,458)	(170,178)	(178,345)
Stockholders' equity	283,378	258,081	185,850	159,436	158,701

(1) 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.

(2) 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.

(3) 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.

<sup>(4)</sup> Includes a \$5.5 million gain from the termination of the Company's oral fluid assay agreement with Roche Diagnostics, which was recorded as a reduction of operating expenses in the indicated period.

#### 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 is comprised 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 OSUR diagnostic products include tests 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. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products are sold in both professional and over-the-counter (“OTC”) markets in North America, Europe, Central and South America, and Australia.

Our DNAG or molecular collection systems business is operated by our subsidiary, DNA Genotek Inc. (“DNAG”), a company based in Ottawa, Canada. DNAG's 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 sample collection products into the microbiome and tuberculosis markets and 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. We serve customers worldwide, including many leading research universities and hospitals.

#### Recent Developments

#### Management Succession Plan

In January 2018, we announced the planned retirement of Douglas A. Michels, our then President and Chief Executive Officer (“CEO”), and Ronald H. Spair, our then Chief Financial Officer (“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 April 1, 2018. Dr. Tang replaced Mr. 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 Mr. Spair, who retired as CFO and Chief Operating Officer, and as a member of our Board of Directors, on the same date. Included in our 2018 financial results are \$9.6 million in transition costs associated with these changes in management. These costs largely consist of non-cash stock compensation charges.

#### Business Acquisitions

On January 4, 2019, the Company, through a wholly-owned subsidiary, acquired all of the outstanding stock of CoreBiome, Inc. ("CoreBiome"), pursuant to the terms of a Merger Agreement, dated January 3, 2019. CoreBiome is a Minnesota-based early-stage microbiome laboratory services provider that accelerates research and discovery for customers in the pharmaceutical, agricultural, and research communities. These services provide optimal analytical algorithms to deliver speed and scalability in the lab with precise analytics.

Also on January 4, 2019, the Company, through a wholly-owned subsidiary, acquired all of the outstanding stock of Novosanis NV ("Novosanis"), pursuant to a Share Purchase Agreement, dated January 3, 2019. Novosanis is a Belgian company founded as a spinoff company from the University of Antwerp, Belgium, in 2013. Novosanis is an early commercial-stage producer and distributor of urine

sample collection devices targeted primarily at 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. The initial commercial application of this product is for liquid biopsy in the prostate and bladder cancer markets. Product validation and clinical trials are also under way with various sexually transmitted infection test manufacturers.

Through December 31, 2018, we have incurred a total of \$1.2 million of acquisition related costs, including 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 for the year ended December 31, 2018.

#### BARDA Contract

In August 2016, we entered into a contract with the Biomedical Advanced Research Development Authority ("BARDA") for up to \$16.6 million of funding for our OraQuick<sup>®</sup>Zika test. The six-year, multi-phased contract included an initial commitment of \$7.0 million and options for up to an additional \$9.6 million to fund the evaluation of additional product enhancements, and certain clinical and regulatory activities. In May 2017, BARDA exercised an option to provide \$2.6 million in additional funding for our rapid Zika test. During 2018, because of difficulties in completing development and optimizing our Zika test and because of significant uncertainty regarding the future commercial demand for this product, the scope of work covered by this contract was reduced. As a result, our contract with BARDA will be essentially completed in the first quarter of 2019.

#### Current Consolidated Financial Results

During the year ended December 31, 2018, our consolidated net revenues of \$181.7 million rose 9%, compared to \$167.1 million for the year ended December 31, 2017. Net product revenues during the year ended December 31, 2018 increased 2% when compared to 2017, primarily due to higher sales of our molecular collection systems products and higher international sales of our OraQuick<sup>®</sup> HIV Self-Test, partially offset by lower sales of our OraQuick<sup>®</sup> HCV products, lower domestic sales of our professional OraQuick<sup>®</sup> HIV product and lower sales of our cryosurgical products. Royalty income was \$9.7 million for the year ended December 31, 2018. Other revenues for 2018 were \$6.7 million compared to \$5.1 million in 2017. Other revenues in 2018 included \$5.0 million of funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") related to our Ebola and Zika products and \$1.7 million of cost reimbursement under our Charitable Support Agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"). Other revenues in 2017 included \$4.4 million of BARDA funding and \$689,000 of cost reimbursement.

Our consolidated net income for the year ended December 31, 2018 was \$20.4 million, or \$0.33 per share on a fully-diluted basis, compared to consolidated net income of \$30.9 million, or \$0.51 per share on a fully-diluted basis for the year ended December 31, 2017. Results for the current year include \$1.2 million of pre-tax transaction costs associated with the recent acquisitions discussed above, and \$9.6 million of pre-tax transition costs associated with the executive management changes also noted above. Net income for 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.

Cash provided by operating activities for the year ended December 31, 2018 was \$39.1 million. Cash provided by operating activities during the year ended December 31, 2017 was \$28.2 million and included the \$12.5 million litigation settlement noted above. As of December 31, 2018, we had \$201.3 million in cash (including restricted cash), cash equivalents, and available-for-sale securities, compared to \$176.6 million at December 31, 2017.

## Results of Operations

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,			Percentage of	
	Dollars		%	Total Net	
	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
Royalty income	9,653	-	N/A	5	-
Other	6,662	5,076	31	4	3
Net revenues	\$181,743	\$167,064	9 %	100 %	100 %

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. We recorded \$9.7 million in royalty income under a litigation settlement agreement with Ancestry.com DNAG LLC and its contract manufacturer. 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 the Gates Foundation Charitable Support Agreement. 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.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

Market	Years Ended December 31,			Percentage of	
	Dollars			Total Net	
	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	\$85,635	\$91,965	(7 )%	100 %	100 %

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	41,457	35,148	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	\$53,851	\$60,557	(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 to 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 who 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 have 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 efforts 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) 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	\$96,108	\$75,099	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 ORAcCollect® 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 continues to grow with both new and existing customers.

Early in 2019, we learned that our largest commercial genomics customer intends to change its purchasing patterns and promotional strategies, which would reduce purchases of our products. While this change in purchasing patterns may significantly impact results in the first quarter of 2019, we expect that the effect of these changes will be moderated over the course of the full year 2019 by growth in other genomic accounts.

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 recent 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 Cuts and Jobs Act (the "Tax Act") that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results is 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.

#### YEAR ENDED DECEMBER 31, 2017 COMPARED TO DECEMBER 31, 2016

#### CONSOLIDATED NET REVENUES

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

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-K

	Years Ended December 31,			Percentage of	
	Dollars			Total Net	
	2017	2016	% Change	2017	2016
OSUR	\$86,889	\$74,710	16 %	52 %	58 %
DNAG	75,099	32,214	133	45	25
Net product revenues	161,988	106,924	51	97	83
Other	5,076	21,274	(76 )	3	17
Net revenues	\$167,064	\$128,198	30 %	100 %	100 %

Consolidated net product revenues increased 51% to \$162.0 million in 2017 from \$106.9 million in 2016. Higher sales of our molecular and OraQuick® HCV products and higher international sales of our OraQuick® HIV Self-Test were partially offset by lower domestic sales of our professional OraQuick® HIV product and lower domestic and OTC sales of our cryosurgical products. In 2017, we recognized \$4.4 million as other revenues in connection with funding from BARDA related to our Ebola and Zika products and \$689,000 of cost reimbursement under the Gates Foundation agreement. Other revenues in 2016 included \$18.9 million in exclusivity payments received under our AbbVie HCV co-promotion agreement and \$2.3 million in BARDA funding. Our co-promotion

agreement with AbbVie was terminated on December 31, 2016 and no further revenues were recognized under this agreement after that date.

Consolidated net revenues from products sold to customers outside of the United States were \$45.6 million and \$28.4 million, or 27% and 22% of total net revenues, during the years ended December 31, 2017 and 2016, 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,			Percentage of Total Net Revenues		
	Dollars		%			
	2017	2016	Change	2017	2016	
Infectious disease testing	\$61,951	\$48,408	28	% 67	% 50	%
Risk assessment testing	12,659	13,068	(3 )	14	14	
Cryosurgical systems	12,279	13,234	(7 )	13	14	
Net product revenues	86,889	74,710	16	94	78	
Other	5,076	21,274	(76 )	6	22	
Net revenues	\$91,965	\$95,984	(4 )%	100 %	100 %	%

##### Infectious Disease Testing Market

Sales to the infectious disease testing market increased 28% to \$61.9 million in 2017 from \$48.4 million in 2016. This increase resulted from higher sales of our OraQuick® HCV product and higher international sales of our OraQuick® HIV Self-Test, partially offset by a decline in domestic sales of our professional OraQuick® HIV product.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during 2017 and 2016.

Market	Years Ended December 31,		
	2017	2016	% Change

Domestic HIV	\$23,847	\$27,819	(14 )%
International HIV	11,301	5,248	115
Net HIV revenues	35,148	33,067	6
Domestic HCV	8,448	7,436	14
International HCV	16,961	6,630	156
Net HCV revenues	25,409	14,066	81
Net OraQuick® revenues	\$60,557	\$47,133	28 %

Domestic OraQuick® HIV sales decreased 14% to \$23.8 million for the year ended December 31, 2017 from \$27.8 million for the year ended December 31, 2016. This reduction was primarily the result of competitive losses tied to pricing, the loss of sales to point-of-care HIV tests perceived to be more sensitive, and the testing guidelines issued by the Centers for Disease Control and Prevention (“CDC”) recommending the use of competing fourth generation automated HIV immunoassays performed in a laboratory. An increase in sales of our OraQuick® In-Home HIV test partially offset the decrease in sales of our professional HIV product.

International sales of our OraQuick® HIV products during 2017 rose 115% to \$11.3 million from \$5.2 million in 2016. 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 Africa, Asia, and Latin America, partially offset by a decline in sales in the Middle East and Europe. Funding under the Charitable Support Agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in 2017 included approximately \$1.0 million of support payments under that agreement.

Domestic OraQuick® HCV sales increased 14% to \$8.4 million in 2017 from \$7.4 million in 2016 primarily due to higher sales to our U.S. public health customers in support of HCV testing program expansion, higher sales to non-acute healthcare offices, and increased

sales to hospitals. International OraQuick® HCV sales increased 156% to \$17.0 million in 2017 from \$6.6 million in 2016, largely due to continued product shipments to a foreign government to support a nationwide HCV testing and treatment program and increased sales in Asia and Africa, partially offset by the loss of a multi-national humanitarian organization customer who switched to a competitive product due to pricing. Our supply contract with the foreign government was not renewed. During 2017, we recorded \$11.8 million in revenue from this contract.

#### Risk Assessment Market

Sales to the risk assessment market decreased 3% to \$12.6 million for the year ended December 31, 2017 from \$13.1 million for the year ended December 31, 2016, primarily as a result of a reduction of inventory maintained by one of our largest customers and lab closings due to consolidations occurring in the laboratory service industry, partially offset by higher sales resulting from increased drug testing in the pain management and drug treatment markets.

#### Cryosurgical Systems Market

Sales of our cryosurgical systems products decreased 7% to \$12.3 million in 2017 from \$13.2 million in 2016 due to a decrease in sales of our Histofreezer® product to physicians' offices in the United States primarily due to timing of orders placed by our distributors and loss of sales due to competing private label products. These declines in sales were partially offset by increased sales into new markets and additional business generated by our new mid-tier distributors. In addition, sales of our international OTC cryosurgical products during 2017 decreased largely due to lower sales into Europe as a result of competitive pressures and lower sales in Latin America due to the economic instability of certain countries in that region.

#### Other revenues

Other revenues in 2017 decreased 76% to \$5.1 million from \$21.3 million in 2016. Other revenues in 2016 included AbbVie exclusivity revenues of \$18.9 million. There were no similar revenues in 2017 due to the termination of our AbbVie HCV co-promotion agreement on December 31, 2016. Revenues related to funding from BARDA increased to \$4.4 million in 2017 compared to \$2.3 million in 2016. Revenues in 2017 also include \$689,000 in reimbursement of certain costs under our Charitable Support Agreement with the Gates Foundation. No such cost reimbursement occurred in 2016.

#### DNAG Segment

##### Molecular Collection Systems

Sales of our molecular collection systems products increased 133% to \$75.1 million in 2017 from \$32.2 million in 2016.

The table below shows a breakdown of our total net molecular collection systems revenues (dollars in thousands) generated during 2017 and 2016.

Market	Years Ended December 31,		
	2017	2016	% Change

Genomics	\$71,611	\$31,079	130	%
Microbiome	3,488	1,135	207	
Net molecular collection systems product revenues	75,099	32,214	133	%

Genomics sales were up 130% to \$71.6 million in 2017 compared to \$31.1 million in 2016, largely as a result of higher customer demand primarily from a large customer in the consumer genetics market. Microbiome sales increased 207% to \$3.5 million in 2017 compared to \$1.1 million in 2016 as interest in our microbiome product offering continued to grow with both new and existing customers.

#### CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 59% for the year ended December 31, 2017 compared to 69% for the comparable period of 2016. Gross profit percentage for 2017 decreased primarily due to the absence of AbbVie exclusivity revenues, an increase in lower gross profit percentage international product sales, and higher scrap and spoilage costs.

Consolidated operating income in 2017 was \$40.2 million, a \$19.9 million improvement from \$20.3 million of operating income reported in 2016. Operating income in 2017 benefited from increased product revenues, the Ancestry litigation settlement gain, and

lower sales and marketing costs, partially offset by the loss of AbbVie exclusivity revenues recorded in the prior year and higher research and development and general and administrative expenses.

#### OPERATING INCOME (LOSS) BY SEGMENT

##### OSUR Segment

OSUR's gross profit percentage was 58% in 2017 compared to 69% in 2016. OSUR's gross profit percentage was negatively impacted in 2017 primarily by the absence of exclusivity revenues under our AbbVie agreement (\$18.9 million was recorded in 2016 versus none in 2017), an increase in lower gross profit percentage international product sales, and an increase in scrap and spoilage costs.

Research and development expenses increased 50% to \$10.5 million in 2017 from \$7.0 million in 2016, largely as a result of the inclusion in 2016 of a \$1.4 million payment received to settle a claim against one of our raw material suppliers. This settlement was recorded as a reduction in research and development expense in 2016. During 2017, research and development expenses also increased due to higher supply costs associated with the development of our Ebola and Zika products and increased staffing expenses.

Sales and marketing expenses decreased 11% to \$18.9 million in 2017 from \$21.3 million in 2016, primarily as a result of the termination of our AbbVie HCV co-promotion agreement on December 31, 2016. During 2016, we incurred \$1.1 million of detailing and co-promotion expenses associated with the AbbVie agreement. No such costs were incurred for 2017. For the year ended December 31, 2017, we also experienced lower staffing costs, partially offset by higher external commissions payable to certain international distributors.

General and administrative expenses increased 16% to \$26.1 million in 2017 from \$22.6 million in 2016 due to higher staffing costs and an increase in accrued employee bonuses as a result of the Company's strong performance.

All of the above contributed to OSUR's operating loss of \$2.7 million for 2017, which included non-cash charges of \$3.2 million for depreciation and amortization and \$6.4 million for stock-based compensation.

##### DNAG Segment

DNAG's gross profit percentage was 61% in 2017 compared to 67% in 2016. The decline in gross profit percentage was primarily due to an increase in lower gross profit percentage sales in 2017 as compared to 2016.



Research and development expenses increased 4% to \$2.8 million in 2017 from \$2.7 million in 2016 due to higher staffing costs.

Sales and marketing expenses increased 15% to \$9.6 million in 2017 compared to \$8.3 million in 2016 due to higher staffing and commission expenses.

General and administrative expenses decreased 45% to \$3.2 million in 2017 compared to \$5.7 million in 2016, largely due to lower legal costs as our lawsuit with Ancestry and its contract manufacturer was settled in the first quarter of 2017.

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 \$43.0 million for 2017, which included non-cash charges of \$3.2 million for depreciation and amortization and \$543,000 for stock-based compensation.

#### CONSOLIDATED INCOME TAXES

For the year ended December 31, 2017, we recorded state income tax expense of \$0 compared to \$250,000 in the year ended December 31, 2016. Canadian income tax expense of \$10.1 million and \$353,000 was recorded in 2017 and 2016, respectively. Canadian taxes in 2017 included the additional taxes due as a result of the \$12.5 million Ancestry litigation settlement gain and DNAG's increased pre-tax income.

Liquidity and Capital Resources

December 31,  
2018            2017  
(In thousands)