ORASURE TECHNOLOGIES INC
Form 10-K
March 14, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

OR

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

For the transition period from to

Commission File No. 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
220 East First Street	
Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip Code)**

(610) 882-1820

(Registrant s Telephone Number, Including Area Code)

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

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 x

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 x

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 x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes x 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. x

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

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, 2015): $298,662,067

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 10, 2016: 55,482,238 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

Table of Contents

Table of Contents

Table of Contents

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 market and sell products, whether through our internal, direct sales force or third parties; 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 FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; the continuation of our HCV co-promotion agreement with AbbVie and our ability to achieve financial and performance objectives under that agreement; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNAG to achieve its financial and strategic objectives; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit 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 testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; 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; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully under Item 1A, entitled Risk Factors, and elsewhere in this Annual Report. Although forward-looking statements help to provide 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. 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

Table of Contents

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.

Table of Contents

PART I

ITEM 1. Business.

Our business principally involves 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. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. Our 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. One of our diagnostic products, the OraQuick® HCV rapid antibody test, is the first and only rapid HCV test approved by the U.S. Food and Drug Administration (FDA) for sale in the United States. In addition, our OraQuick® In-Home HIV test is the first and only rapid HIV test approved by the FDA for sale in the over-the-counter (OTC) or consumer retail market in the United States. More recently, we completed development and recorded initial sales of our new OraQuick® rapid Ebola antigen test. We also sell OTC cryosurgical products to consumers in North America, Europe, Central and South America, and Australia.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers. We have targeted the use of oral fluid in our products as a differentiating factor and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

Through our subsidiary, DNA Genotek Inc. (DNAG), a company based in Ottawa, Canada, 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 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. 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 or furnished to the SEC. Our Internet website and the information contained in or connected to that website are not intended to be incorporated by reference into this Annual Report.

Table of Contents

Products

The following is a summary of our principal products and their regulatory and commercial status:

Product	Description	Regulatory Status	Commercial Status
OraQuick *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.	Premarket approval (PMA) by the FDA for use with oral fluid, finger-stick and venous whole blood, and plasma.	Marketed
OraQuick® HIV 1/2 (Export Only)		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, serum and plasma.	Marketed
		World Health Organization (WHO) pre-qualification.	Pending
		Also registered in various other 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.	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. Also registered in various other 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
		CE Mark (European Union) approved for OTC use.	Not Marketed
		Investigational use only.	Marketed

OraQuick® HIV Self-Test	Rapid point of care qualitative and oral fluid HIV1/2 self-test that can be visually read in approximately 20 minutes.		
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.	Marketed
		EUA for use with oral fluid specimens from cadavers.	Marketed

Table of Contents

Product	Description	Regulatory Status	Commercial Status
OraSure QuickFlu® Rapid Flu A&B Test	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
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 OTC 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. Registered in various other countries.	Marketed
Oragene® RNA	Non-invasive all-in-one system for the collection, stabilization and transportation of RNA from human saliva.	Research use only product.	Marketed
ORAcollect®	All-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	FDA 510(k) clearance pending. CE marked and registered as Class 1 Medical Device in the U.S. and Canada. Registered in various other countries.	Marketed
OMNIgene® DISCOVER	Non-invasive all-in-one system for the collection, stabilization, transportation, and storage of	Research use only product.	Marketed

	microbial DNA from saliva.		
Performagene LIVESTOCK and Oragene® ANIMAL	All-in-one systems for the collection, stabilization, transportation, and storage of livestock DNA from nasal samples.	Animal research use only.	Marketed
OMNIgene® Gut	All-in-one system for the collection, stabilization, transportation and storage of microbial DNA in stool samples	Research use only product. CE marked and registered in certain countries.	Marketed

Table of Contents

Product	Description	Regulatory Status	Commercial Status
OMNIgene® Sputum	Reagent for liquefying, decontaminating, transporting and preserving TB bacteria in sputum samples	Research use only product.	Marketed
		CE marked and registered in certain countries.	
PrepIT® MAX	Reagent for extraction and preparation of DNA from saliva.	CE marked and registered in the U.S., Canada and various other countries.	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

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

Table of Contents

Product	Description	Regulatory Status	Commercial Status
Cryosurgical Systems OTC	Cryosurgical system for the removal of common and plantar warts, 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.	Marketed
		CE marked for skin tags.	Not Marketed

In addition to the above products, we also sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test for confirming positive HIV-1 test results obtained from the use of our OraSure® collection device; and the FDA 510(k) cleared Q.E.D.® rapid point-of-care saliva alcohol test.

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 submitted an application for WHO pre-qualification for our export only version of this product.

We believe that the OraQuick® device, because it is approved for detecting antibodies to both HIV-1 and HIV-2 in finger-stick and venous whole blood, oral fluid and plasma samples, provides a competitive advantage in the market for rapid HIV testing in the United States and elsewhere.

OraQuick® In-Home HIV Test

The OraQuick® In-Home HIV test is an over-the-counter version of our OraQuick *ADVANCE*® HIV 1/2 Antibody Test. We received PMA approval to sell this test in the U.S. OTC market and we have also received CE

Table of Contents

mark authorization for sale of this product 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 a toll free, 24/7, 365-day per year customer call center to provide additional information and referral support for consumers.

OraQuick® HIV Self-Test

We have completed development of a low cost OraQuick® HIV self-test for use in certain foreign countries. This product has the same diagnostic capabilities as our U.S. approved OraQuick® In-Home HIV test. We are working with Population Services International (PSI), a leading global health organization, along with UNITAID, the WHO and health officials from Malawi, Zambia and Zimbabwe to launch the UNITAID-PSI HIV Self-Testing in Africa (STAR) project. As part of STAR, PSI is implementing a two-year pilot program funded by UNITAID. We expect that our new OraQuick® self-test, with labeling and instructions specifically tailored for the African marketplace, will be used in the two-year initial phase of the program. The purpose of the STAR project is 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 for the first phase of the PSI pilot because of its quality, ease-of-use and oral fluid option. Initial shipments of our test to PSI occurred during the first quarter of 2016.

OraQuick® HCV Rapid Antibody Test

Another test available on the OraQuick® platform is the OraQuick® HCV rapid antibody test. Like the OraQuick® HIV 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 for use of the test in detecting HCV antibodies in venous whole blood and finger-stick whole blood specimens, making it the first rapid and only HCV test approved by the FDA for use in the United States. We have also received a CLIA waiver for use of this product in the same specimen types. 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 and other foreign countries.

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 an EUA from the FDA for emergency use by laboratories and facilities adequately equipped, trained and capable of testing for Ebola infection (including treatment centers and public health clinics) on finger-stick and venous whole blood samples. More recently, we received an EUA for use of the product in oral fluid specimens collected from cadavers.

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 ten minutes. This product is manufactured for us under an agreement with Princeton BioMeditech Corporation and is currently sold in certain U.S. markets.

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,

Table of Contents

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 our oral fluid Western blot HIV-1 confirmatory test (described below).

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

We believe that oral fluid testing has several significant advantages over blood-based systems for infectious disease testing, for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a non-invasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and reducing the cost of administration by a trained health care professional.

Molecular Collection Systems

Our wholly-owned subsidiary, DNAG, sells a number of 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. DNAG s lead product is sold under the Oragene® brand and is used to collect DNA from human saliva. DNAG products are currently sold to thousands of academic and research customers in many countries worldwide.

DNAG products are available in several different configurations and contain proprietary chemical solutions that are optimized for the specific application for which each product is designed. Product physical design is focused on ease-of-use and reliability for self or assisted collection of samples. For example, several of the Oragene® products require users to simply hold the product close to their mouth and spit into the collection device. When the container is closed, the reagents stored in the lid of the container are mixed with the captured saliva and immediately protect the nucleic acids in the sample. This non-invasive collection method yields nucleic acid that remains stable at ambient temperature for extended periods. The stabilizing technology results in high quality and high quantity nucleic acids that are required for most genetic testing and analysis methods.

We believe these products provide significant advantages over competing DNA and RNA collection methods such as blood collection or buccal swabs, particularly in human genetic applications. Benefits include the reliable collection of high quality and stable genetic samples, use of simple non-invasive collection methods, the ability to store and

transport collected samples for extended periods at ambient temperatures and compatibility with fully-automated laboratory testing systems.

DNAG products historically have been sold primarily as Class I medical devices for use by research and academic institutions. DNAG has received FDA 510(k) clearance for the Oragene® Dx product which enables the Oragene® Dx product to be used with other FDA-cleared or exempt molecular diagnostic applications. 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 tests. An application for 510(k) clearance of DNAG s ORAcollect® product is currently pending with the FDA.

Table of Contents

DNAG has received CE mark approval for the OMNIgene® GUT microbiome collection kit. This 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 use settings. The 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. Current methodologies for gut microbiome profiling have distinct shortcomings due to the introduction of bias, leading to a lack of reproducibility in the field.

Intercept® Drug Testing System

A collection device that is substantially similar to the OraSure® device is sold by us under the name Intercept®, and is used to collect 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.

During 2014, we completed development of a next generation collection device, which we are marketing under the tradename Intercept i2® *he* . This device offers several important advantages over our original Intercept® device, including a sample adequacy indicator that provides a visual prompt when the appropriate volume of oral fluid has been collected, the ability to collect a larger sample required by current laboratory testing protocols and a more optimized chemistry that results in improved recovery of the targeted drug analytes. The Intercept i2® 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® 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® 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°C to 55°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® 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. In 2014, we began supplying 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. and for the treatment of both warts and skin tags in Canada.

Table of Contents

Immunoassay Tests and Reagents

We develop and sell immunoassay tests in formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of our customers. During 2014, we also began selling fully-automated high-throughput oral fluid drug assays developed under our agreement with Thermo Fisher.

In a MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of reagents by laboratory personnel. Test results are analyzed by any of a variety of commercially available laboratory instruments, which we may also provide to our laboratory customers. MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in urine, serum and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs-of-abuse in oral fluid specimens.

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

We entered into the agreement with Thermo Fisher in 2013 after terminating a similar agreement with Roche Diagnostics. Under our new agreement, Thermo Fisher has agreed to develop and supply up to 12 fully-automated high-throughput oral fluid drug assays for use with our Intercept i2®*he* device. Under the first phase of this agreement, we are selling a NIDA-5 panel of assays supplied by Thermo Fisher. The parties expect to complete development of several additional assays and obtain FDA 510(k) clearance of the Intercept i2®*he* device for use with a 12-assay panel. We also expect to obtain CE mark and other regulatory approvals to enable us to sell our Intercept i2®*he* collector and Thermo Fisher assays into Europe and other foreign countries.

The assays from Thermo Fisher will be optimized as needed to comply with new oral fluid guidelines expected to be issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the federally regulated market and certain other markets that follow Federal drug testing guidelines, none of which is currently served by OraSure. We believe the offering of an Intercept i2® 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.

Western blot HIV-1 Confirmatory Test

We sell an oral fluid Western blot HIV-1 confirmatory test that received premarket approval from the FDA in 1996. This test uses the original specimen collected with the OraSure® oral fluid collection device to confirm positive results of initial oral fluid HIV-1 EIA screening tests.

Q.E.D.® Saliva Alcohol Test

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

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

Table of Contents

Products Under Development

Infectious Disease Testing

Since 2014, we have been pursuing the development and commercialization of a rapid Ebola antigen test using our OraQuick® technology platform. Product development is now largely complete and significant progress has been made in preparing for the commercial manufacturing of the product and obtaining the required regulatory approvals and registrations. In July 2015, we received an EUA for our OraQuick® Ebola rapid antigen 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.

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, BARDA exercised an option to provide $7.2 million of this funding for our OraQuick® Ebola test. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are being performed.

In March 2016, we received an EUA for use of the Ebola test on oral fluid samples collected from cadavers and we have submitted for pre-qualification of the product with the WHO. 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 next year to eighteen months.

In response to global concerns regarding the Zika virus, we are evaluating the technical feasibility of developing a rapid Zika test on our OraQuick® platform. This virus is believed to be spread primarily through infected mosquitoes and has been linked as a possible cause of microcephaly in new born babies whose mothers are infected. There has also been some potential correlation reported with Guillain-Barre syndrome in certain other infected patients. We expect to continue our feasibility work during 2016.

Molecular Collection Systems

The following new product initiatives are continuing at DNAG:

OMNIgene® GUT is a system for the collection, stabilization, transportation and storage of microbial DNA in stool samples. This product is being offered to academic researchers for early-stage testing in gut microbiome studies.

PrepIT® MAX for tuberculosis (TB) is a reagent for extraction of DNA from TB bacteria. This product is being offered for early-stage testing by TB researchers, clinical laboratories, and diagnostic developers who need to extract DNA from TB bacteria for molecular analysis.

OMNIgene® SPUTUM is a reagent for the liquefying, decontaminating, transporting and preserving of TB bacteria in sputum samples. OMNIgene® SPUTUM is expected to improve laboratory and operational workflows, compared to current approaches, and improve overall test results. This product is being offered to TB laboratories for evaluation.

These products represent potential, long-term market opportunities that we are still developing or are in the early stages of commercializing. Much of our activities for these products are currently centered around ensuring that early versions are being provided to key opinion leaders or early adopters in the relevant markets. We expect these products will enable researchers and other customers to improve their results through better and lower cost sample collection, stabilization and preservation.

Table of Contents

Microbiome

During 2015, we received CE mark approval and completed design validation on a high-throughput automated processing system for the OMNIgene® GUT product. Several technical manuscripts with academic and biotech groups are also in process which will report on the ability of this product to snapshot microbiome communities at the point of collection.

Tuberculosis

The OMNIgene® Sputum and PrepIT® MAX products are gaining greater interest for tuberculosis testing. Healthcare providers from more than 60 countries have expressed interest in evaluating these products and more than 20 entities, ranging from Ministries of Health, non-government organizations, donor agencies and diagnostic test developers, have begun their evaluations of our product offerings. Our tuberculosis products are well positioned to support the National Action Plan for combatting multi drug-resistant tuberculosis, recently announced by the Obama Administration, by providing much needed solutions to developing countries that are at the highest risk for multi-drug resistant tuberculosis.

Although we are excited about the potential opportunities in this market, it will likely take some time for these products to generate meaningful financial results.

Research and Development

In 2015, our research and development activities focused primarily on development of our next generation Intercept i2®collection device, our new rapid Ebola antigen test, our molecular collection product offerings for the microbiome and tuberculosis markets, and clinical and technical support for our existing products. From time to time, we have contracted with third parties to conduct research and development activities and we may do so in the future.

Research and development expenses were $11.7 million in 2015, $12.1 million in 2014, and $10.9 million in 2013. These expenses include our costs associated with research and development, regulatory affairs, clinical trials and product support.

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic arrangements and independent distributors. Our marketing strategy is to create or raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs, distributor promotions, telemarketing and the use of digital and social media in order to stimulate sales in each target market.

We market our products in the United States and internationally. Consolidated net revenues attributable to customers in the United States were $96.5 million, $82.3 million and $77.2 million in 2015, 2014 and 2013, respectively. Consolidated net revenues attributable to international customers amounted to $23.2 million, $24.2 million and $21.7 million, or 19%, 23% and 22% of our total revenues, in 2015, 2014 and 2013, respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Note 10 to our consolidated financial statements included elsewhere in this Annual Report.

Infectious Disease Testing Professional

We market the OraQuick *ADVANCE*® rapid 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

Table of Contents

encouraging and enabling HIV testing. We also sell our OraQuick *ADVANCE*® 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. We have engaged two manufacturers representative organizations to assist with sales to U.S. physicians and retail clinics. Internationally, we distribute our OraQuick® HIV test in Europe and certain other foreign countries.

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

Our OraQuick® HCV test is sold primarily to the same markets where our OraQuick® ADVANCE HIV test is sold, including public health organizations, hospitals, physicians and retail clinics. We also sell this test in Europe and other countries through distributors. Under an agreement with AbbVie, we are co-promoting our OraQuick® HCV test in certain U.S. markets, including general practitioners and certain specialty physicians. Under this arrangement, AbbVie has agreed to detail our OraQuick® HCV test in the physician markets and we pay AbbVie a fee for these detailing services. In addition, we have implemented a broad-based program for training physicians on our OraQuick® HCV test and have developed and implemented a patient care database under this agreement.

We currently sell our OraQuick® Ebola test under an EUA and our only customer to date has been the CDC, which has purchased the product for field testing in Africa. Our ability to expand sales of this test to other customers will likely depend on 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 have distribution rights to an FDA 510(k) cleared rapid flu A&B test, which we market under our proprietary OraSure QuickFlu® tradename. Under our agreement with the supplier of this product, we are permitted to sell this product into the U.S. hospital and public health markets.

Infectious Disease Testing OTC

We sell our OraQuick® In-Home test in the U.S. retail or consumer market. Retailers carrying the product include CVS, Walgreens, Rite Aid, Wal-Mart and Kroger. The product is also available for purchase on-line through certain retailers and our website, www.oraquick.com. The primary target population for our HIV-OTC test 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. In 2014, we changed our promotional strategy by implementing a more cost-effective promotional approach focused on retail outlets and moved away from more expensive broad-based consumer advertising. We continued this strategy in 2015.

To support individuals that purchase and use our test, we have established a toll-free customer support center that operates on a 24/7, 365-day per year basis. Through this center, consumers will have access to highly-trained, bi-lingual 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.

Molecular Collection Systems

DNAG sells its products directly to its customers, primarily through its own internal sales force. In some countries distributors are used, particularly in the Asia-Pacific region. 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.

Table of Contents

Historically, most of DNAG s revenues have been derived from product sales into the academic and research markets. However, sales to commercial customers providing consumer genetics and clinical diagnostic services have been increasing and now 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 a number of established global customers in the livestock market, including breed associations and research institutions.

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 initial product offering, OMNIgene® Gut, is focused on the human gut microbiome (microbes living in human stool). In 2015, DNAG sold in excess of $500,000 of this product to a variety of both academic and commercial research organizations. 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 has been working to bring to market the OMNIgene® Sputum and PrepIT® Max products. These products include a lab reagent for liquefying, decontaminating, transporting and preserving TB bacteria in sputum samples. TB is a major global health issue, with long established relationships among public health agencies, NGO s, and suppliers. DNAG has a focused sales and market development team working with these key players to have its products evaluated and adopted where possible.

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 in 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 have also launched our next generation Intercept i2® collection device with a NIDA-5 panel of fully-automated high-throughput oral fluid assays developed with Thermo Fisher for the detection of PCP, THC, opiates, cocaine, methamphetamines and amphetamines. These products are currently sold into the criminal justice and drug treatment markets. We plan to obtain FDA 510(k) clearance of our Intercept i2T® 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® device and related fully-automated high-throughput assays will eventually replace our original Intercept® collector and MICRO-PLATE assays in the drug testing market.

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

Table of Contents

Cryosurgical Systems

Most of our Histofreezer® 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®. We also provide a private label version of our professional Histofreezer® product to one of our U.S. distributors. Internationally, we sell the Histofreezer® 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 also sell OTC cryosurgical products for the removal of warts and skin tags under private label arrangements with retailers in Canada and private label OTC wart remover products to several U.S. retailers.

Insurance Risk Assessment

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

We also promote use of the OraSure® device directly to insurance companies for life insurance risk assessment. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. We sell our OraSure® Western blot confirmatory test directly to insurance testing laboratories for use in confirming oral fluid specimens collected with our OraSure® device that initially test positive for HIV-1.

There exists a wide range of policy limits where our OraSure® product is being used. In general, many (but not all) of our insurance company customers use the OraSure® device in connection with life insurance policies having face amounts of up to $250,000, with some customers using the device for policies of up to $500,000 in amount. Some insurance companies have chosen to extend their testing to lower policy limits where they did not test at all before, while others have used OraSure® to replace some of their blood and urine-based testing. In recent years, some insurance customers have adopted a Simplified Issues policy, where lab testing is no longer required and instead the applicant completes a questionnaire about personal behaviors.

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

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 OraQuick® rapid HIV testing products, the cryosurgical systems products, and our Oragene® product line accounted for total revenues of $34.3 million, $11.9 million and $29.4 million, respectively, in 2015, $38.9 million, $15.5 million and $23.8 million, respectively, in 2014, and $44.8 million, $14.5 million and $20.4 million, respectively, in 2013.

One of our customers accounted for approximately 12% of our net consolidated revenues in 2015. We had no individual customers who accounted for more than 10% of our total revenues in 2014 or 2013.

16

Table of Contents

Financial Information by Segment

We operate our business within two reportable segments. The first is our OSUR business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices, and medical devices. The second is our DNAG or molecular collection systems business, which consists primarily of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, and store samples of genetic material for molecular testing.

OSUR revenues consist primarily of product sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. OSUR also derives revenues from the sale of OTC products to retail pharmacies and mass merchandisers, and to consumers over the internet and from licensing and product development activities. DNAG revenues consist of product sold into the academic research, consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome and animal genetics markets. For more information about our revenues from external customers, income and total assets, please see the sections entitled Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 10 to the consolidated financial statements, included elsewhere in this Annual Report on Form 10-K.

Supply and Manufacturing

Our OraQuick *ADVANCE*® HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraQuick® Ebola test, OraSure®, Intercept® and Intercept i2® collection devices, Western blot HIV-1 confirmatory test, AUTOLYTE and MICRO-PLATE assays and QED® saliva alcohol test are all manufactured in our Bethlehem, Pennsylvania facilities. We expect to continue to manufacture these products at this location for the foreseeable future.

We have contracted with a third party in Thailand for the assembly of the OraQuick® HIV device 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 manufacture the OraQuick® test on terms no less favorable than those set forth in the agreement if the Thailand contractor would be unable or unwilling to continue manufacturing this product. This supplier will also assemble our OraQuick® HIV self-test.

We can purchase the HIV antigens, the nitrocellulose and certain other critical components used in the OraQuick® HIV product lines, the HCV antigens used in the OraQuick® HCV test and the antigen used in the Western blot HIV-1 confirmatory test only from a limited number of sources. If for any reason these suppliers are unwilling or no longer able to supply our antigen or nitrocellulose needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in any of the antigens, the nitrocellulose or other critical components used in our products would require FDA approval and some additional development work. This in turn could require significant time to complete, increase our costs and disrupt our ability to manufacture and sell the affected products.

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

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

Table of Contents

The Histofreezer® product sold in the U.S. is assembled by U.S. vendors and the Histofreezer® product sold internationally was previously assembled in the Netherlands by Koninklijke, Utermöhlen, N.V. (Utermöhlen), the company from which we acquired the product line in 1998. The supply agreement with Utermöhlen has expired and we have successfully transferred our supply arrangement for international versions of this product to a vendor located in Germany. The cryosurgical wart removal products distributed in OTC markets are assembled by vendors located in the United States. We believe that additional suppliers of all of 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 manufacturing these products.

DNAG has two long-term contract manufacturing relationships to supply virtually all of its products, including the Oragene® product line. Many of the raw materials and components used in these products are also purchased from third parties, including one critical component that is purchased from a sole source supplier. We believe there are other suppliers that can manufacture and supply the raw materials and components for the DNAG products.

Employees

As of December 31, 2015, we had 326 full-time employees (including 103 employees at our subsidiary, DNAG). Of this total, there were 119 in sales, marketing and client services; 36 in research and development; 123 in operations, manufacturing, quality control, information systems, purchasing and shipping; 18 in quality assurance and regulatory affairs; and 30 in administration and finance. This compares to 320 employees as of December 31, 2014. 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.

Important 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 requirements (i.e., good manufacturing practices);

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.

Table of Contents

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.

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 FDA Emergency Use Authorization (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.

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.

Table of Contents

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.

OMNIgene® Gut is being sold in the emerging microbiome market where the primary competition currently is 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 and PrepIT® MAX products are unique and have no direct competition in terms of a comparable product. The primary competition for these products 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 during the past several years, primarily due to competition from home-brew assays developed internally by our laboratory customers, which can be produced at a cost lower than the price typically paid for our products. Many of our customers no longer purchase our AUTO-LYTE® assays, and we may eventually stop selling this product line.

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

Table of Contents

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® 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 six 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 patents expire from September 2016 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 have obtained licenses to certain lateral flow patents and to certain HIV-1 and HIV-2 patents held by other parties. We also have obtained a license to certain HCV patents which we use to manufacture and sell a rapid HCV test on the OraQuick® technology platform. We obtained these licenses through the payment of certain upfront fees and an agreement to pay ongoing royalties. We believe these fees and royalties are comparable to those generally paid by other companies under similar arrangements.

We hold, through our subsidiary, DNAG, seventeen 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 2031.

We have two United States patent 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 August 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®, PrepIT® and AUTO-LYTE® trademarks. We also own many of these marks and

Table of Contents

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 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 testing, authorizations to market, labeling, promotion, manufacturing and recordkeeping. We believe that our products and procedures are in material compliance with all applicable FDA regulations, but the regulations regarding the manufacture and sale of our products 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.

All of our FDA-regulated products require some form of 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. 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 medical devices.

There are several mechanisms by which regulated medical 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 provide a premarket notification that it intends to begin marketing the product, and show that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may only commence when the FDA issues a clearance letter finding substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. 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 medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA s regulations to have an approved PMA), the

FDA must approve a PMA before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, supported by valid scientific evidence, including the results of preclinical and clinical studies. Preparing a PMA is a detailed 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 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. In addition, if the FDA discovers that an applicant has submitted false or misleading information, the FDA may 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 premarket notification or PMA 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 indications for use, manufacturing process, manufacturing facility, critical components, labeling and design.

A clinical trial may be required in support of a 510(k) submission and generally is required for a 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 a non-significant risk study, which is eligible for an exemption from the IDE requirements. The IDE application must be supported by appropriate data, such as laboratory testing results. 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 trials support the safety and effectiveness 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. 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 non-medical 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 Emergency Use Authorization, or 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.

Every company that manufactures medical 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

manufacturing process, 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 and quality to ensure full technical compliance.

Table of Contents

We believe that our facilities and procedures are in material compliance with the FDA s QSR regulations, but the regulations are subject to change, and we cannot be sure that FDA investigators will agree with our compliance with the QSR requirements. 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. Medical 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.

On December 23, 2013, our molecular collection systems subsidiary, DNAG, received a warning letter from the FDA. The warning letter primarily focused on DNAG s response to two Form 483 observations issued by the FDA as a result of an inspection of DNAG s Ottawa, Canada facilities in September 2013.

Specifically, the warning letter indicated the need for additional documentation regarding design and development activities for DNAG s products and focused in particular on the design planning and design history file for DNAG s 510(k)-cleared Oragene® Dx collection device. In addition, the warning letter requested additional documentation related to finished product acceptance testing activities for DNAG s ORAcollect® collection device. The letter further noted that DNAG does not currently have in place an approved PMA or 510(k) clearance for its ORAcollect® device.

DNAG has submitted a formal response and is actively engaged and working with the FDA to address the issues referenced in the warning letter. In addition, DNAG has submitted to the FDA an application for 510(k) clearance of its ORAcollect® device. While the warning letter still remains pending, DNAG intends to continue to sell and market all of its products. We expect no material impact to product sales or our consolidated financial performance for the forseeable future as a result of the issues raised by the warning letter.

The Clinical Laboratory Improvement Amendments of 1988, or CLIA, prohibit any facility that does 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. 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. 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.

24

Table of Contents

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, the Office of Inspector General of the Department of Health and Human Services, and various state attorney generals. 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. 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 or European regulating bodies, 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. 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.

International

We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval 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) 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 affix the CE mark to our products, without which they may not be placed on the market in the EU.

Table of Contents

We have received authorization to use the CE mark for the OraQuick *ADVANCE*® HIV-1/2 test, the OraQuick® HCV test, our Histofreezer® product line, our OTC cryosurgical removal product and certain of the Oragene® collection kits and OMNIgene® 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.

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 gifts or other payments to 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

Table of Contents

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.

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.

27

Table of Contents

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.

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.

The process of obtaining required approvals or registrations can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. These approvals and registrations 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 approval or registration. The submission of an application to the FDA or other regulatory authority does not guarantee that an approval or registration to market or import the product will be received. A regulatory authority may impose requirements as a condition to granting an approval or registration, may include significant restrictions or limitations as part of any approval or clearance it grants and may delay or refuse to grant approval or registration, 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 clearances or approvals 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 approval or registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries. Any change in our arrangement with such a 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 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, storage, advertising, promotion and record keeping. We and our suppliers and distributors are subject to routine inspection by the FDA and other agencies to determine compliance with QSR

28

Table of Contents

and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO regulations. We believe that our facilities and procedures are in material compliance with the QSR requirements, but the regulations are subject to change and we cannot be sure that the FDA investigators will agree with our compliance with the QSR requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved products or place conditions on any product approvals that could restrict the 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, including withdrawal of the product from the market.

Failure to comply with the applicable requirements 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 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.

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 Ability 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, including the QSR, but the regulations regarding the manufacture and sale of our products and the QSR requirements 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 product approvals. 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. 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 by our vendors, 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.

Table of Contents

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 and labor or employment practices. 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.

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

Many laws and regulations impose obligations on public companies, which 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

Table of Contents

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 claimed regulatory authority over laboratory-developed tests, or LDTs, but has exercised enforcement discretion in not regulating LDTs performed by high complexity CLIA-certified laboratories. LDTs are tests developed in-house by a laboratory where the laboratory makes a determination about its ability to perform the test and whether the test yields clinically relevant information. A significant portion of the total volume of genetic or molecular testing is performed with LDTs.

In mid-2014, the FDA announced that it would begin regulating LDTs, including laboratory developed molecular tests, and has issued proposed guidance on the regulation of LDTs for public comment. 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 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 other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices and laws requiring the reporting of certain transactions between us 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 are new and 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.

In 2015, approximately $23.2 million of our consolidated net revenues were generated from sales in a variety of foreign countries. These international activities subject us to the U.S. Foreign Corrupt Practices Act (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, agreements with third parties and make sales in countries known to experience

Table of Contents

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 Our Industry, Business and Strategy

If We Fail to Achieve Performance Objectives Under Our HCV Agreement With AbbVie or this Agreement is Terminated, Our Financial Results and Business Prospects Could Be Adversely Affected.

We have entered into an agreement with AbbVie for the co-promotion of our OraQuick® HCV test into certain markets in the U.S. Under the agreement, we have granted exclusive co-promotion rights to AbbVie for the OraQuick® HCV test in these markets and we provide certain services in support of HCV testing. In exchange for these exclusive rights and the services provided to AbbVie, we are eligible to receive up to $75.0 million in aggregate payments over the term of the agreement, which runs through December 31, 2019. If certain performance milestones are achieved, we will also be eligible to receive additional annual incentive fees. The agreement contains certain termination, indemnification and other provisions typical of agreements of its type.

We have not yet earned an incentive fee under the AbbVie agreement and it is difficult to predict when, or if, we will be able to achieve one or more of the performance milestones required to receive such a fee. In addition, under certain circumstances, either party may terminate the agreement before its expiration and such a termination could occur as early as December 31, 2016. In 2015 and 2014, $13.5 million and $7.6 million of our revenues, respectively, were from the recognition of exclusivity revenues under the AbbVie agreement. If we fail to achieve performance milestones under the AbbVie agreement or AbbVie terminates the agreement before its expiration, the amount of exclusivity payments and incentive fees we receive under the agreement could be reduced or eliminated and our financial results and business prospects could be materially and adversely affected.

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 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.

Table of Contents

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. 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.

During 2015, 2014 and 2013, we incurred $11.7 million, $12.1 million and $10.9 million, respectively, in research and development expenses. We expect to continue to incur significant costs related to our research and development activities.

Successful products require significant development and investment, including testing to demonstrate their performance capabilities, cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained before most products may be sold. 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. In addition, even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product. Moreover, we may spend a significant amount of money on advertising 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, point-of-care Ebola antigen test using our OraQuick® technology platform. In 2015, under an EUA (Emergency Use Authorization) received from the FDA for this product, we sold $2.3 million of this product to the CDC for field testing. Despite this initial progress, there is no assurance that our 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. Such action would negatively affect our ability to sell the product.

It is also uncertain whether, and to what degree, we will be successful in obtaining sustainable purchase commitments for our Ebola test. 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.

Table of Contents

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, achieve the performance milestones under our HCV agreement with AbbVie, or continue growing our molecular collection systems 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. 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;

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;

Table of Contents

We may not be able to accurately forecast the performance or ultimate impact of an acquired business;

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

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.

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.

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 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 and may continue to reduce funding in an effort to lower overall federal healthcare spending. The ultimate content and timing of any healthcare reform legislation and its 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.

Table of Contents

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, with the suspension ending December 31, 2017. It is unclear whether and to what extent this tax will impact our business if and when the suspension is lifted.

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 (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 decreased 17% from 2014 to 2015, in part due to customer migration to automated fourth generation HIV immunoassays performed in a laboratory, as recommended under new 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.

Our subsidiary, DNAG, sells many of its products to researchers at academic institutions, pharmaceutical and biotechnology companies, government laboratories and private foundations. Many of DNAG s 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. 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.

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.

Table of Contents

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, interactions with our third-party logistics provider, 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. In addition, we rely on information technology systems for the development and implementation of a patient care database that we are providing as part of our services under the HCV co-promotion agreement with AbbVie. This database contains patient specific healthcare information and must be maintained and operated in accordance with stringent privacy and security requirements.

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 date.

Computer hackers may attempt to penetrate our computer systems or our third party IT service provider s systems and, if successful, misappropriate personal or confidential information. In addition, a contractor or other

Table of Contents

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 proceedings, liability under laws to protect, privacy of personal information, and regulatory penalties, disrupt our operations, require significant management attention and resources to remedy any damages that result, damage our reputation and customers willingness to transact business with us, any of which could adversely affect our business.

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, nitrocellulose and certain other components required to make our OraQuick HIV, HCV and Ebola products are currently purchased from sole source suppliers. Our OraSure QuickFlu® test and the fully automated high-throughput drug assays sold with our Intercept i2® device are manufactured and supplied by sole source suppliers and the conjugates used in our MICROPLATE oral fluid drugs-of-abuse assays are obtained from third party suppliers.

In addition, our subsidiary, DNAG, uses two third-party manufacturers to supply virtually all of its products, including its Oragene® line of collection kits. Many of the raw materials and components used in its products are also purchased from third parties, a critical one of which is obtained from a sole source supplier.

If our third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work and it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. We may also need to obtain FDA or other regulatory approvals for the use of an alternative component or for changes to our products or manufacturing process. Completing that development and obtaining such approvals could require significant time and expense and such approvals may not occur at all. The availability of critical components and products from sole supply sources or other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business.

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

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

Table of Contents

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

Although we will try to maintain and expand our business with distributors and customers and require that they fulfill their contractual obligations, there can be no assurance that such companies will do so or that new distribution channels will be available on satisfactory terms. As a result, our revenues and business could be adversely affected.

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

Although we may elect to pursue some product opportunities independently, opportunities that require a technology controlled by a third party, a significant level of investment for development and commercialization or a distribution network beyond our existing sales force may necessitate involving one or more strategic partners. Our strategy for development and commercialization of products may entail entering into arrangements with distributors or other corporate partners, universities, research laboratories, 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 partners, 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;

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.

An important strategic arrangement is our HCV co-promotion agreement with AbbVie. Our ability to increase HCV sales and receive additional compensation under this agreement will depend on whether the

Table of Contents

agreement continues through at least the end of its initial term and whether AbbVie fulfills its contractual obligations, including its obligation to detail our OraQuick® HCV test into the physician and specialty physician office markets and the success of those detailing efforts.

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.

Actions of Third-Party Inventory Management and Logistics Providers Could Adversely Affect Our Ability to Supply Products to Our Customers.

We use third-party logistics providers to store and manage our finished goods inventory and ship finished product to our customers. We have selected highly reputable providers with extensive experience in the logistics field for these services. However, in the event any of our providers lose or damage our products, experience a casualty or catastrophic event at a warehouse or otherwise fail to provide safe storage and timely handling and delivery of our products, we could incur additional costs, experience difficulty in supplying our products to our customers or suffer damage to our reputation in the industry. These events could, in turn, reduce our revenues and adversely affect our results of operations.

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 revenue 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.

Table of Contents

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.

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.

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.

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 or our customers 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.

41

Table of Contents

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;
- 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;
- 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.

The Sales Potential for Our OraQuick® Products Could be Affected by Our Ability to Obtain Certain Licenses and by Future Litigation.

Our OraQuick® test platform is a lateral flow assay that tests for specific antibodies or other substances. The term lateral flow generally refers to a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices. There are also patents that cover the type of analyte or antibody (i.e., HIV-1, HIV-2, HCV, Ebola, etc.) which our OraQuick® test is designed to detect. Some of these patents may broadly cover aspects of our OraQuick® test and are in force in the United States and other countries. We may not be able to make or sell the OraQuick® test in the United States or other countries where these patents are in force.

Table of Contents

We have obtained licenses under several lateral flow patents, and patents covering assays directed at specific analytes, which we believe are sufficient to permit the manufacturing and sale of our OraQuick® products as currently contemplated. However, licenses under additional patents may be required and it is possible that a third party could seek to enforce one or more patents against us.

If we are unable to successfully defend against or resolve patent infringement litigation or it is determined that a license is required and it is not possible to negotiate or otherwise obtain a license agreement on reasonable terms under a necessary patent, our ability to manufacture and sell OraQuick® products and develop and commercialize new applications using the same technology could be limited and we may incur increased costs or damages. In such case, we may be able to modify an OraQuick® product to avoid the claim of infringement or the need for a license. However, this alternative could preclude or limit our ability to sell the OraQuick® product in the United States and other markets, which would adversely affect our results of operations, cash flow and business.

Risks Relating to Products, Marketing and Sales

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

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as our OraQuick® HCV test, OraQuick® In-Home HIV 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® HCV and Ebola tests 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.

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

We have made significant progress in gaining acceptance of oral fluid testing products, particularly for (i) HIV testing in the public health, hospital, insurance and other markets, and (ii) drugs-of-abuse testing in the workplace and criminal justice markets. Our subsidiary, DNAG, has also made significant progress in gaining acceptance of oral fluid collection products that are used with molecular testing applications. However, the degree of acceptance for these products is uncertain, and one or more markets may resist the adoption of oral fluid products as a replacement for other testing or collection methods in use today. As a result, there can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

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

Sales of our rapid point-of-care diagnostic products, such as our OraQuick *ADVANCE*® HIV-1/2, OraQuick® HCV and OraQuick® In-Home HIV tests, 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

Table of Contents

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*® HIV-1/2 test. In addition, the Oragene® 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. 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.

Sales of Our OraSure QuickFlu® Test May be Affected by Factors Beyond Our Control.

We sell a rapid flu test under the tradename OraSure QuickFlu®, primarily in the U.S. hospital and public health markets. A number of factors that are beyond our control could affect sales of this product, including:

- Variability in the timing of the onset, length and severity of the flu season, which typically occurs from November of one year to May of the following year;
- Competition from other rapid flu tests in the markets we serve;
- Deficiencies in the manufacture, design or performance of the product or failure by the manufacturer to meet applicable quality and regulatory standards;
- The inability of our supplier to provide sufficient quantities of the product;
- Changes in the types or strains of influenza during a particular flu season; and

Lower than expected market penetration of the OraSure QuickFlu® test.

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. Specifically, we will continue to expand the impact of our direct field sales force, use third-party distributors and manufacturers sales representatives, and implement other sales and marketing programs. 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.

Table of Contents

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*® HIV-1/2 test has been purchased through bulk procurement or other funding provided by governmental agencies. Our OraQuick® HCV test has been purchased by customers who receive government funding, and we believe increased funding from the CDC and other agencies will be required to substantially increase the volume of HCV testing, especially in the public health market. There can be no assurance that purchases or funding from these agencies will occur or continue, especially if current negative economic conditions continue or intensify. 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 intend to 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

Table of Contents

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 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 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 $23.2 million or 19% of consolidated net revenues in 2015, $24.2 million or 23% of consolidated net revenues in 2014, and $21.7 million or 22% of consolidated net revenues in 2013. In addition, our molecular collection systems business, which accounted for $29.9 million or 25% of consolidated net revenues in 2015, is operated in Canada.

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, 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;

Table of Contents

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;

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;

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® 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 Government Contracts and Related Administrative Processes Are Subject To Audits and Cost Adjustments by the Federal Government

We sell some of our products to the federal government and we are receiving federal funding related to our OraQuick® Ebola rapid antigen test. As a result, we must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. 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. These fines and penalties could be imposed for failing to file 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 if allegations of impropriety related to such contracts are made against us.

In addition, 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

Table of Contents

convenience of our contracts could negatively affect our financial results. For U.S. government contracts that include options, such as our Ebola funding contract with BARDA, 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.

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. 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 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. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase 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 a History of Losses and May Not Be Able to Achieve Sustained Profitability.

We experienced annual net losses during the five years prior to 2015. In addition, as of December 31, 2015, the Company had an accumulated deficit of $170.2 million. Even though we achieved profitability in 2015 there can be no assurance that we will be able to achieve or sustain 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 increase use of our OraQuick® HCV test and continue to receive compensation under our HCV co-promotion agreement with AbbVie;

The potential for AbbVie to unilaterally terminate our HCV co-promotion agreement on or after December 31, 2016;

Creating market acceptance for and selling increasing volumes of our OraQuick *ADVANCE*® HIV-1/2 test, OraQuick® HCV test and other products in the United States and internationally;

Our ability to continue growing our molecular collection systems business;

Table of Contents

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 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 targets for growth in revenues;

Changes in distributor buying patterns or a buildup of significant quantities in our distributors inventories or distribution channels; and

The costs and results of patent infringement, product liability and other litigation or claims asserted 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 customer demand or other factors, including continued volatility and disruption in economic conditions, increasing competition, 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 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.

Our Estimates or Judgments Relating to Critical Accounting Policies Are Based on Assumptions That Can Change or Prove to be Incorrect.

Our discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The

Table of Contents

preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate significant estimates used in preparing our financial statements, including those related to:

Revenue recognition;

Potential impairment of long-lived and intangible assets including goodwill;

Customer sales returns and allowances;

Allowance for uncollectible accounts receivable;

Reserve for inventory write-downs;

Stock-based compensation;

Income taxes; and

Contingencies.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in our discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if our assumptions change or if actual circumstances differ from those in our assumptions. If our operating results fall below the expectations of securities analysts and investors, the price of our Common Stock may decline.

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. For example, in 2015, DNAG generated total revenues of U.S. $29.9 million and incurred total operating expenses of $17.0 million. As a result of a favorable change in the U.S./Canadian dollar exchange rate, DNAG s cost of goods sold and operating expenses were reduced by approximately $800,000 and $2.0 million, respectively, in 2015. 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.

Table of Contents

Changes in Tax Laws or Their Application Could Adversely Affect Our Results of Operations.

Changes in tax laws or their application could increase our costs and adversely affect our results of operations. Such changes could affect applicable tax rates, utilization of tax loss carryforwards, and treatment of inter-company debt and interest payments.

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.

Table of Contents

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;
- The continuation of our HCV co-promotion agreement with AbbVie and the successful execution of other strategic arrangements;
- Future announcements concerning us and our products, including with respect to significant acquisitions, strategic collaborations and joint ventures;
- 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;
- 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;

The relatively low trading volume for our Common Stock;

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.

Table of Contents

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 a 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.

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

Table of Contents

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. In addition, our subsidiary, DNAG, changed the location of its offices near the end of 2015 and now leases a 35,883 square foot facility in Ottawa, Canada, which is used as its primary corporate office and houses sales and marketing, 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.

In May 2015, our subsidiary DNAG filed a complaint in the United States District Court for the District of Delaware against Ancestry.com DNA LLC (Ancestry) relating to the manufacture and sale by Ancestry of its oral fluid DNA collection device (the Ancestry Device). Ancestry previously purchased DNAG s patented oral fluid DNA collection

devices. The complaint alleges that the manufacture and sale by Ancestry of the Ancestry Device infringes U.S. Patent No. 8,221,381 B2, which is owned by DNAG. In addition, the complaint alleges that Ancestry has breached the terms of agreements under which Ancestry previously purchased DNAG products. The complaint also contains claims for conversion and trespass to chattel and includes an action to quiet title to the Ancestry Device and related patent applications. DNAG is requesting the court to grant injunctive relief and damages.

Table of Contents

On October 20, 2015, Ancestry filed with the United States Patent and Trademark Office (USPTO) a Petition for *Inter Partes* Review of some, but not all, claims of U.S. Patent No. 8,221,381 B2. We expect the PTO to decide whether to initiate review of the DNAG patent in April 2016.

In July 2015, DNAG filed a complaint in the United States District Court for the District of Delaware against Spectrum DNA, Spectrum Solutions L.L.C. and Spectrum Packaging L.L.C. (collectively Spectrum) relating to the manufacture and sale by Spectrum of an oral fluid DNA collection device (the Spectrum Device). We believe the Spectrum Device is the same as the Ancestry device mentioned above and that Spectrum is the manufacturer of the Ancestry Device for Ancestry. The complaint alleges that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. patent number 8,221,381 B-2, which is owned by DNAG. DNAG is requesting the court to grant injunctive relief and damages.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

Table of Contents

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. High and low sales prices reported by NASDAQ during the periods indicated are shown below.

	Year ended December 31			
	2015		2014	
	High	Low	High	Low
First Quarter	$ 10.62	$ 6.10	$ 8.60	$ 5.34
Second Quarter	$ 7.64	$ 4.42	$ 9.00	$ 5.78
Third Quarter	$ 5.95	$ 4.39	$ 8.94	$ 7.21
Fourth Quarter	$ 6.99	$ 4.40	$ 10.93	$ 6.93

On March 7, 2016, there were 415 holders of record and approximately 14,500 holders in street name of our Common Stock, and the closing price of our Common Stock was $7.17 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 [2, 3]
October 1, 2015 - October 31, 2015	255[1]	$ 4.94		$ 19,570,287
November 1, 2015 - November 30, 2015				19,570,287

December 1, 2015 - December 31, 2015	777,061	6.34	777,061	14,644,661
	777,316			

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

(2) 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.

(3) 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.

Table of Contents

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, 2010 through December 31, 2015. The graph assumes that $100 was invested on December 31, 2010 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.

	12/10	12/11	12/12	12/13	12/14	12/15
OraSure Technologies, Inc.	**100.00**	**158.43**	**124.87**	**109.39**	**176.35**	**112.00**
NASDAQ Composite	**100.00**	**100.62**	**116.97**	**166.27**	**188.90**	**200.15**
NASDAQ Biotechnology	**100.00**	**113.92**	**153.97**	**263.29**	**348.49**	**369.05**

Table of Contents

Securities Authorized for Issuance Under Equity Compensation Plans

For certain information concerning securities authorized for issuance under our equity compensation plan, see Item 12, Securities 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,				
	2015	**2014**	**2013**	**2012**	**2011** [5]
Operating Results:					
Net revenues	$ 119,719	$ 106,464	$ 98,940[2]	$ 87,820	$ 81,881
Costs and expenses	111,661	111,266[1]	111,102[3]	104,090	91,278
Operating income (loss)	8,058	(4,802)	(12,162)	(16,270)	(9,397)
Other income (expense), net	774	531	200	(242)	(313)
Income tax expense (benefit)	665	343	(772)	(1,397)	(869)
Net income (loss)	8,167	(4,614)	(11,190)	(15,115)	(8,841)
Earnings (loss) per share					
Basic and Diluted	$ 0.14	$ (0.08)	$ (0.20)	$ (0.29)	$ (0.19)
Shares used in computing earnings (loss) per share					
Basic	56,397	55,949	55,555	51,457	46,908
Diluted	56,846	55,949	55,555	51,457	46,908
Cash Flow:					
Cash flows provided by (used in) operating activities	$ 15,773	$ 7,526[1]	$ 8,385[3]	$ (5,373)	$ (2,994)

	December 31,				
	2015	**2014**	**2013**	**2012** [4]	**2011** [5]
Financial Position:					
Cash and short-term investments	$ 101,319	$ 97,867	$ 93,191	$ 87,888	$ 23,878
Working capital	111,480	104,752	100,590	103,483	30,860
Total assets	189,321	189,633	184,245	191,439	127,861
Accumulated deficit	(170,178)	(178,345)	(173,731)	(162,541)	(147,426)
Stockholders equity	159,436	158,701	161,146	170,315	100,250

(1)

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.

(2) Includes a non-recurring net favorable $2.5 million adjustment to account for a change in the Company s revenue recognition policy related to its OraQuick® In-Home HIV test.

(3) Includes an $8.3 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.

(4) We received net proceeds of $70.2 million from a stock offering of 6,100,000 common shares completed on July 11, 2012.

(5) Includes the results of DNA Genotek, Inc. from the acquisition date of August 17, 2011, as well as $2.6 million of transaction costs associated with the acquisition.

Table of Contents

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

We develop, manufacture, market and sell 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 that are performed on a rapid basis at the point-of-care, tests that are processed in a laboratory, and a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (OTC) market. We also manufacture and sell oral fluid collection devices used to collect, stabilize 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. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet.

Current Consolidated Financial Results

During the year ended December 31, 2015, our consolidated net revenues were $119.7 million, compared to $106.5 million for the year ended December 31, 2014. Net product revenues during the year ended December 31, 2015 increased 6% to $104.5 million when compared to 2014, primarily as a result of higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products. These increases were partially offset by lower sales of our OraQuick® professional HIV and cryosurgical systems products. Consolidated other revenues for 2015 were $15.3 million, of which $13.5 million represents the ratable recognition of payments for exclusive co-promotion rights and certain services provided under our HCV co-promotion agreement with AbbVie, and $1.8 million represents revenue recognized in connection with Ebola-related funding 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). Other revenues in 2014 of $7.6 million represent the recognition of exclusivity payments under the AbbVie co-promotion agreement.

Our consolidated net income for the year ended December 31, 2015 was $8.2 million, or $0.14 per share on a fully diluted basis, compared to a net loss of $4.6 million, or ($0.08) per share, for the year ended December 31, 2014. Our consolidated net income for the current period reflects the increase in product and other revenues, lower advertising and promotional expenses associated with our OraQuick® In-Home HIV test, and the impact of a favorable change in the Canadian to U.S. dollar exchange rate of approximately $2.8 million. These improvements to the bottom line were partially offset by the absence of a $5.5 million Roche termination payment received in 2014 and which was reflected as a reduction in operating expenses. Additionally, we experienced higher legal costs and increased expenses under

our HCV co-promotion agreement with AbbVie in 2015 than in the prior year.

Table of Contents

Cash provided by operating activities for the year ended December 31, 2015 was $15.8 million, compared to $7.5 million for the year ended December 31, 2014. As of December 31, 2015, we had $101.3 million in cash and short term investments, compared to $97.9 million at December 31, 2014.

2015 Developments

Rapid Ebola Test

Early in 2015, we completed the design of a rapid Ebola antigen test using our OraQuick® platform. In June 2015, we entered into a contract for up to $10.4 million in total funding from BARDA related to 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, BARDA exercised an option under the contract to provide $7.2 million in additional funding for our OraQuick® Ebola test. This funding will be used primarily for clinical and regulatory activities required to request FDA 510(k) clearance for this product. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are being performed.

In July 2015, we received a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the OraQuick® Ebola test. This authorization allows the use of the test 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. In March 2016, we received an EUA for use of the Ebola test on oral fluid samples collected from cadavers. We have also submitted for pre-qualification of this product with the World Health Organization.

During 2015, we recognized $2.3 million in revenue from sales of this product to the Centers for Disease Control and Prevention (CDC) for investigational use and field testing in Africa. Data generated in these clinical and non-clinical studies was used in the application to obtain the EUA from the FDA. We are also continuing to focus our efforts on securing sustainable product purchase commitments from both government and non-government sources for the OraQuick® Ebola rapid antigen test.

Microbiome Product Offering

During 2015, an area of focus for our molecular collection business has been the microbiome market, through the offering of our OMNIgene® Gut product for which we received CE mark approval and completed design validation on a high-throughput automated processing system. Several technical manuscripts with academic and biotech groups are in process that will report on the ability of this product to snapshot microbiome communities at the point of collection. We sold our collection kit to over 100 customers and generated approximately $539,000 of revenue in 2015.

Business Segments

We operate our business within two reportable segments: our OSUR business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices, and medical devices, and our DNAG or molecular collection systems business, which consists primarily of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, transport, and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians offices, commercial and industrial entities, retail pharmacies, mass merchandisers

and consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome and animal genetic testing, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

Table of Contents

Results of Operations

YEAR ENDED DECEMBER 31, 2015 COMPARED TO DECEMBER 31, 2014

CONSOLIDATED NET REVENUES

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

	Year Ended December 31,				
	Dollars		%	Percentage of Total Net Revenues	
	2015	2014	Change	2015	2014
OSUR	$ 74,534	$ 75,116	(1)%	62%	71%
DNAG	29,924	23,778	26	25	22
Net product revenues	104,458	98,894	6	87	93
Other	15,261	7,570	102	13	7
Net revenues	$ 119,719	$ 106,464	12%	100%	100%

Consolidated net product revenues increased 6% to $104.5 million in 2015 from $98.9 million in 2014, primarily as a result of higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products. These increases were partially offset by lower sales of our OraQuick® professional HIV and cryosurgical systems products. Other revenues were $15.3 million in 2015, of which $13.5 million represents exclusivity payments received under our HCV co-promotion agreement with AbbVie and $1.8 million represents Ebola-related funding from BARDA. Other revenues were $7.6 million in 2014, all which represent exclusivity payments from AbbVie.

Consolidated net revenues derived from products sold to customers outside the U.S. were $23.2 million and $24.2 million, or 19% and 23% of consolidated net revenues during the years ended December 31, 2015 and 2014, 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 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.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2015	2014	Change	2015	2014
Infectious disease testing	$ 49,129	$ 47,515	3%	55%	58%

Substance abuse testing	10,271	8,437	22	11	10
Cryosurgical systems	11,920	15,505	(23)	13	19
Insurance risk assessment	3,214	3,659	(12)	4	4
Net product revenues	74,534	75,116	(1)	83	91
Other	15,261	7,570	102	17	9
Net revenues	$ 89,795	$ 82,686	9%	100%	100%

Table of Contents

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 3% to $49.1 million in 2015 from $47.5 million in 2014, primarily due to higher sales of our OraQuick® HCV product and OraQuick® In-Home HIV test, partially offset by lower sales of our OraQuick® HIV professional product. In addition, 2015 net infectious disease testing revenues included $2.3 million in initial sales of our OraQuick® Ebola rapid antigen test to the CDC for field testing in Africa.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during 2015 and 2014.

	Year Ended December 31,		
Market	**2015**	**2014**	**% Change**
Domestic HIV	$ 24,956	$ 29,933	(17)%
International HIV	2,410	2,483	(3)
Domestic OTC HIV	6,992	6,493	8
Net HIV revenues	34,358	38,909	(12)
Domestic HCV	7,502	4,220	78
International HCV	3,884	3,048	27
Net HCV revenues	11,386	7,268	57
Net OraQuick® revenues	$ 45,744	$ 46,177	(1)%

Domestic OraQuick® HIV sales decreased 17% to $24.9 million in 2015 from $29.9 million in 2014. This decrease was primarily the result of the migration of some customers to fourth generation automated HIV immunoassays performed in a laboratory or at the point-of-care, as recommended under testing guidelines issued by the CDC, or to competitive point-of-care HIV tests perceived to be more sensitive. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC s testing guidelines, changes in government funding, and continued price and product competition. International sales of our OraQuick® HIV test decreased 3% during 2015 to $2.4 million from $2.5 million in 2014 primarily due to lower sales in Africa and Europe partially offset by an increase in sales in Asia.

Sales of our OraQuick® In-Home HIV test increased 8% to $7.0 million in 2015 from $6.5 million in 2014 largely due to a price increase implemented in August 2015 and an increase in sales volume in the fourth quarter of 2015 immediately following a celebrity s announcement that he had tested positive for the HIV virus. These increases in the latter half of 2015 were partially offset by a decline in sales in the first quarter of the year which was primarily the result of our decision to transition away from broad-based consumer advertising and focus our marketing and promotional efforts at the retail outlet level in the second half of 2014.

Domestic OraQuick® HCV sales increased 78% to $7.5 million in 2015 from $4.2 million in 2014, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 27% to $3.9 million in 2015 from $3.0 million in 2014, primarily due to the expansion of our business into Asia.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the recent FDA approval of several new drug therapies for treating HCV. However, demand for our HCV product, particularly in the public health marketplace, may be somewhat tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing. Sales to physicians can also be adversely affected by the level of reimbursement available from insurance providers and competition from laboratory-based HCV tests. The intensely competitive market for new HCV therapies and the decisions by insurance providers and payors to grant preferred or exclusive formulary status to one HCV therapy over another have adversely affected our initiatives under the HCV co-promotion agreement with AbbVie. These and other factors could limit the future growth of our HCV business.

Table of Contents

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Net substance abuse testing revenues increased 22% to $10.3 million in 2015 from $8.4 million in 2014, primarily as a result of higher sales of our Intercept® drug testing system. Domestic Intercept® sales in 2015 increased to $7.8 million compared to $6.1 million in 2014 largely due to the recovery of customers previously lost to competition, improved domestic employment conditions, and the addition of customers who we believe recognize the advantages of oral fluid testing in identifying recent drug use.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) decreased 23% to $11.9 million in 2015 from $15.5 million in 2014.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during 2015 and 2014.

	Year Ended December 31,		
Market	**2015**	**2014**	**% Change**
Domestic professional	$ 4,311	$ 6,750	(36)%
International professional	916	693	32
Domestic OTC	390	108	261
International OTC	6,303	7,954	(21)
Net cryosurgical systems revenues	$ 11,920	$ 15,505	(23)%

Sales of our Histofreezer® product in the domestic professional market decreased 36% to $4.3 million in 2015, compared to $6.8 million in 2014 largely as a result of distributor consolidation and competition from new private-label brands. During 2015, international sales of Histofreezer® increased to $916,000, compared to $693,000 in the prior year primarily due to higher sales in Asia.

In the fourth quarter of 2014, we re-launched our OTC wart removal product in the U.S. retail market through private labeling with a large pharmacy chain. Sales related to this product were $390,000 for the full year of 2015 compared to $108,000 in 2014. We expect this area of cryosurgical sales to increase due to broader retail adoption of our product.

Sales of our international OTC cryosurgical products during 2015 decreased 21% to $6.3 million, compared to $8.0 million in 2014, largely due to lower sales to our Latin American distributor. Sales decreased to $1.3 million, compared to $3.0 million in 2014, due to challenges in the local markets, including declining economic conditions in Argentina, a restructuring of our distributor s business operations in Mexico, and overall customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 12% to $3.2 million in 2015 from $3.7 million in 2014, as a result of reduced demand in the domestic life insurance market, as well as the continued adoption by some underwriters of a Simplified Issue policy. Where such a policy is issued, applicants are required to respond to a questionnaire about their behaviors rather than undergoing lab-based tests. We expect this trend to continue.

Table of Contents

Other revenues

Other revenues were $15.3 million in 2015, of which $13.5 million represent the recognition of exclusivity revenues under our HCV co-promotion agreement with AbbVie, and $1.8 million represents Ebola-related funding from BARDA. Other revenues in 2014 were $7.6 million and represent the recognition of exclusivity revenues from AbbVie.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 26% to $29.9 million in 2015 from $23.8 million in 2014. Sales of Oragene® in the commercial market increased approximately 41% in 2015, primarily due to increased orders from DNAG s largest existing U.S. customer and incremental revenues from new customers, partially offset by lower sales to other existing U.S. customers who experienced regulatory and reimbursement challenges during 2015. Sales in the academic market were flat at $9.8 million in both 2015 and 2014.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 67% in 2015 compared to 63% in 2014. This increase was largely due to the $7.7 million increase in other revenues, a reduction in royalty expense and a favorable change in the exchange rate between the Canadian and U.S. dollar.

Consolidated operating income increased by $12.9 million to $8.1 million in 2015, compared to an operating loss of $4.8 million in 2014. The higher operating income reflects the increase in product and other revenues, the impact of a favorable change in the Canadian to U.S. dollar exchange rate, and lower advertising and promotional expenses associated with our OraQuick® In-Home HIV test. These improvements were partially offset by the absence of a $5.5 million Roche termination payment received in 2014 (which was reflected as a reduction in operating expenses), as well as higher legal costs and increased expenses under our HCV co-promotion agreement with AbbVie in 2015.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR s gross margin was 66% in 2015 compared to 60% in 2014. OSUR s 2015 margin was positively impacted by the increase in other revenues and a reduction in royalty expense during the current year.

Research and development expenses decreased 5% to $8.9 million in 2015 from $9.4 million in 2014, largely due to lower lab supply costs, partially offset by higher study and program costs related to the fully-automated high-throughput drugs-of-abuse assays we are jointly developing with Thermo Fisher.

Sales and marketing expenses decreased 20% to $26.6 million in 2015 from $33.1 million in 2014, primarily as a result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $1.8 million in 2015, as compared to $8.5 million in 2014, partially offset by higher sales and marketing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie.

General and administrative expenses decreased 2% to $20.1 million in 2015 from $20.6 million in 2014 due to lower staffing expenses.

In 2014, we received a $5.5 million Roche termination payment which was treated as a reduction in operating expenses. This payment did not recur in 2015.

Table of Contents

All of the above contributed to OSUR s operating income of $3.6 million for 2015, which included non-cash charges of $3.0 million for depreciation and amortization and $5.5 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 70% in 2015 compared to 73% in 2014. This decrease was attributable to an increased volume of lower margin sales experienced in 2015 when compared to 2014, partially offset by a favorable change in the U.S./Canadian dollar exchange rate of approximately $849,000 as compared to approximately $430,000 in 2014.

Research and development expenses increased 4% to $2.7 million in 2015 compared to $2.6 million in 2014 due to increased spending on the microbiome product and the new product initiatives, partially offset by a favorable change in the U.S./Canadian dollar exchange rate of approximately $357,000 in 2015 as compared to approximately $179,000 in 2014.

Sales and marketing expenses increased 6% to $8.4 million in 2015 from $8.0 million in 2014 due to higher commission and staffing costs, partially offset by a favorable change in the U.S./Canadian dollar exchange rate of $1.1 million in 2015 as compared to approximately $508,000 in 2014.

General and administrative expenses increased 68% to $5.3 million in 2015 compared to $3.1 million in 2014, largely due to higher litigation costs partially offset by a favorable change in the U.S./Canadian dollar exchange rate of $464,000 as compared to approximately $218,000 in 2014.

All of the above contributed to DNAG s operating income of $4.5 million for 2015, which included non-cash charges of $2.7 million for depreciation and amortization and $566,000 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. As a result, no U.S. income tax expense was recorded for OSUR s pre-tax income in 2015 and no income tax benefit was recorded for OSUR s pre-tax loss in 2014. For the year ended December 31, 2015 and 2014, we recorded Canadian income tax expense of $665,000 and $343,000, respectively.

YEAR ENDED DECEMBER 31, 2014 COMPARED TO DECEMBER 31, 2013

CONSOLIDATED NET REVENUES

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

	Year Ended December 31,				
	Dollars		%	Percentage of Total Net Revenues	
	2014	2013	Change	2014	2013
OSUR	$ 75,116	$ 77,936	(4)%	71%	78%
DNAG	23,778	20,381	17	22	21

Net product revenues	98,894	98,317	1	93	99
Other	7,570	623	NM*	7	1
Net revenues	$ 106,464	$ 98,940	8%	100%	100%

* Calculation is not considered meaningful.

Table of Contents

Consolidated net product revenues increased 1% to $98.9 million in 2014 from $98.3 million in 2013, primarily as a result of higher sales of our molecular collection systems, OraQuick® HCV and cryosurgical systems products. These increases were partially offset by lower sales of our OraQuick® In-Home HIV test and our professional OraQuick® HIV, substance abuse, and insurance risk assessment products. Other revenues were $7.6 million in 2014 and represent the recognition of revenues from AbbVie for exclusive co-promotion rights and certain services provided under our HCV agreement. Other revenues were $623,000 in 2013 and represent royalties received on sales of Merck s OTC cryosurgical wart removal product pursuant to a license and settlement agreement that expired in August 2013.

Consolidated net revenues derived from products sold to customers outside the U.S. were $24.2 million and $21.7 million, or 23% and 22% of consolidated net revenues during the years ended December 31, 2014 and 2013, 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 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.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Net Revenues	
Market	**2014**	**2013**	**Change**	**2014**	**2013**
Infectious disease testing	$ 47,515	$ 50,961	(7)%	58%	65%
Substance abuse testing	8,437	8,571	(2)	10	11
Cryosurgical systems	15,505	14,468	7	19	18
Insurance risk assessment	3,659	3,936	(7)	4	5
Net product revenues	75,116	77,936	(4)%	91	99%
Other	7,570	623	NM*	9	1
Net revenues	$ 82,686	$ 78,559	5%	100%	100%

* Calculation is not considered meaningful.

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 7% to $47.5 million in 2014 from $51.0 million in 2013, primarily due to lower sales of our OraQuick® HIV professional product and OraQuick® In-Home HIV test, partially offset by higher sales of our OraQuick® HCV product.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during 2014 and 2013.

	Year Ended December 31,		
Market	**2014**	**2013**	**% Change**
Domestic HIV	$ 29,933	$ 32,301	(7)%
International HIV	2,483	3,365	(26)
Domestic HIV OTC	6,493	9,106	(29)
Net HIV revenues	38,909	44,772	(13)
Domestic HCV	4,220	2,847	48
International HCV	3,048	2,268	34
Net HCV revenues	7,268	5,115	42
Net OraQuick® revenues	$ 46,177	$ 49,887	(7)%

Table of Contents

Domestic OraQuick® HIV sales decreased 7% to $29.9 million in 2014 from $32.3 million in 2013. This decrease was primarily the result of customer migration to automated fourth generation HIV immunoassays performed in a laboratory, as recommended under new testing guidelines issued by the CDC, and some price competition. International sales of our OraQuick® HIV test during 2014 decreased 26% to $2.5 million from $3.4 million in 2013 largely due to lower order volume related to testing initiatives in Africa and the inconsistent purchasing patterns of certain Latin American distributors.

During 2014, we recorded $6.5 million in net revenues from sales of our OraQuick® In-Home HIV test. In 2013, we recorded $9.1 million in net revenues from sales of our OraQuick® In-Home HIV test, including $2.5 million of previously deferred gross revenue recognized in December 2013 when we changed our revenue recognition policy. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of the product to retailers or distributors. Based on available retail point-of-sale data, consumer purchases increased 5% in 2014 as compared to 2013.

Sales of our OraQuick® In-Home HIV test in 2014 and 2013 included approximately $392,000 and $701,000, respectively, of direct sales to public health customers.

Domestic OraQuick® HCV sales increased 48% to $4.2 million in 2014 from $2.8 million in 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 34% to $3.0 million in 2014 from $2.3 million in 2013, primarily as a result of the inclusion in 2014 of a full year of purchases by a multi-national humanitarian organization, which first purchased the product in the latter half of 2013. Also contributing to the increase in international sales was higher sales into certain Asian markets.

Substance Abuse Testing Market

Net substance abuse testing revenues decreased 2% to $8.4 million in 2014 from $8.6 million in 2013, primarily as a result of slightly higher sales of our Intercept® drug testing system offset by lower sales of our Q.E.D.® rapid point-of-care saliva alcohol test. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during 2014 and 2013.

	Year Ended December 31,		
Market	**2014**	**2013**	**% Change**
Domestic	$ 6,101	$ 5,693	7%
International	149	500	(70)
Net Intercept® revenues	$ 6,250	$ 6,193	1%

Domestic Intercept® sales in 2014 increased to $6.1 million compared to $5.7 million in 2013, primarily due to market growth resulting from increased interest in oral fluid testing by customers who previously used alternative specimen types for drug testing and improved domestic employment conditions. International Intercept® sales decreased 70% to $149,000 in 2014 from $500,000 in 2013 largely due to the absence of purchases by a UK distributor who began selling its own competing oral specimen collection device in 2012. Sales to this distributor were $316,000 in 2013.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) increased 7% to $15.5 million in 2014 from $14.5 million in 2013.

Table of Contents

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during 2014 and 2013.

	Year Ended December 31,		
Market	2014	2013	% Change
Domestic professional	$ 6,750	$ 6,020	12%
International professional	693	1,441	(52)
Domestic OTC	108		100
International OTC	7,954	7,007	14
Net cryosurgical systems revenues	$ 15,505	$ 14,468	7%

Sales of our Histofreezer® product in the domestic professional market increased 12% to $6.8 million in 2014, compared to $6.0 million in 2013. This increase is largely due to higher sales by one of our distributors to teaching hospitals, physician offices, and the military. This increase also reflects below normal sales in early 2013, resulting from higher distributor purchases in the fourth quarter of 2012 in advance of a price increase implemented in January 2013. The current year increase in net revenues was negatively impacted by the merger of our two largest distributors, who began selling a private label cryosurgical product in direct competition with our Histofreezer® product in 2014.

During 2014, international sales of Histofreezer® decreased to $693,000, compared to $1.4 million in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with a contract manufacturer terminated in late 2013, and that former supplier has since begun promoting a competing product similar to Histofreezer®. In order to remain competitive with this new product, we have decreased the per unit sales price of our Histofreezer® product in certain international markets. In addition, we experienced delivery problems and inventory shortages as we transitioned to a new manufacturer of our international Histofreezer® product line.

In the fourth quarter of 2014, we launched our wart removal product in the U.S. retail market through private labeling with a large pharmacy chain. Sales related to this product were $108,000.

Sales of our international OTC cryosurgical products during 2014 increased 14% to $8.0 million compared to $7.0 million in 2013, largely due to higher sales to our European distributor, partially offset by lower sales to our Latin American distributor.

Sales to our European distributor increased to $4.8 million, compared to $3.6 million during 2013, primarily due to the launch of our product into new geographic territories and new market segments in Europe. Sales to our Latin American distributor decreased to $3.0 million, compared to $3.3 million in 2013, reflecting lower sales into Brazil, partially offset by an increase in sales into Mexico.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 7% to $3.7 million in 2014 from $3.9 million in 2013, as a result of reduced demand in the domestic life insurance market, resulting from the adoption by some underwriters of a Simplified Issue policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

Other revenues

Other revenues were $7.6 million in 2014 and represent the recognition of exclusivity revenues under our HCV co-promotion agreement with AbbVie. Other revenues in 2013 were $623,000 and represent royalties paid on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to a license and settlement agreement which expired in August 2013.

Table of Contents

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 17% to $23.8 million in 2014 from $20.4 million in 2013. Sales of Oragene® in the commercial market increased approximately 9% in 2014, primarily as a result of overall market growth and increased use of our Oragene® product in pharmacogenomics testing. Sales of Oragene® in the academic market increased 35% largely due to orders placed by two new international customers as well as higher sales to one of the Company s larger existing academic customers. Sales to DNAG s largest commercial customer decreased approximately $3.4 million in 2014. Sales to DNAG s other customers grew 48% in the current year and substantially offset the lower sales to this large customer.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 63% in 2014 compared to 59% in 2013. This increase was largely due to the $7.6 million of other revenues associated with our AbbVie agreement, as well as a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating loss decreased by $7.4 million to $4.8 million in 2014, compared $12.2 million in 2013. The lower operating loss was primarily due to the higher licensing and product development revenues and lower HIV OTC sales and marketing expenses in 2014, partially offset by a $2.8 million reduction in contract termination payments received from Roche during 2014.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR s gross margin was 60% in 2014 compared to 57% in 2013. OSUR s 2014 margin was positively impacted by an increase in other revenues recorded during 2014.

Research and development expenses increased 13% to $9.4 million in 2014 from $8.4 million in 2013 largely due to increased lab supply costs partially offset by lower clinical trial and staffing expenses.

Sales and marketing expenses decreased 16% to $33.1 million in 2014 from $39.5 million in 2013, primarily as a result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $8.5 million in 2014, as compared to $18.8 million in 2013. This reduction in spending was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising in June 2014. Partially offsetting this decrease were higher sales and marketing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie.

General and administrative expenses increased 13% to $20.6 million in 2014 from $18.2 million in 2013 due to higher legal, staffing and consulting expenses.

All of the above, along with the $5.5 million contract termination payment from Roche, contributed to OSUR s operating loss of $8.3 million for 2014, which included non-cash charges of $3.3 million for depreciation and amortization and $5.3 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 73% in 2014 compared to 67% in 2013. This improvement was primarily attributable to an increased volume of higher margin sales experienced in 2014 when compared to 2013.

Table of Contents

DNAG operating expenses rose to $13.7 million in 2014 from $13.0 million in 2013. Research and development expenses remained relatively flat at $2.6 million in 2014 and 2013. Sales and marketing expenses increased 14% to $8.0 million in 2014 from $7.0 million in 2013 largely due to higher staffing and consulting costs. General and administrative expenses decreased 9% to $3.1 million in 2014 from $3.4 million in 2013 largely due to lower legal fees.

All of the above contributed to DNAG s operating income of $3.5 million for 2014, which included non-cash charges of $3.1 million for depreciation and amortization and $432,000 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. As a result, no U.S. income tax benefit was recorded for OSUR s pre-tax loss in 2014 or 2013. For the year ended December 31, 2014, we recorded Canadian income tax expense of $343,000. For the year ended December 31, 2013, we recorded a Canadian income tax benefit of $772,000 which was associated with certain Canadian research and development and investment tax credits. The Canadian income tax benefit was considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Liquidity and Capital Resources

	December 31,	
	2015	2014
	(In thousands)	
Cash	$ 94,094	$ 92,867
Short-term investments	7,225	5,000
Working capital	111,480	104,752

Our cash and short-term investment balances increased to $101.3 million at December 31, 2015 from $97.9 million at December 31, 2014. Our working capital increased to $111.5 million at December 31, 2015 from $104.8 million at December 31, 2014.

During 2015, we generated $15.8 million in cash from our operating activities. Our net income of $8.2 million was increased by non-cash stock-based compensation expense of $6.0 million, depreciation and amortization expense of $5.7 million, and other non-cash charges of $605,000. A $2.3 million decrease in inventory balances largely associated with our OraQuick® HCV product also contributed to cash generated in 2015. Also contributing to cash provided by operations in 2015 was a net increase in deferred revenue of $1.7 million, which represents the receipt of cash payments from AbbVie reduced by the amounts ratably recognized in revenue during the period. Uses of cash in operating activities during 2015 included a $3.7 million increase in accounts receivable resulting from a higher level of product orders placed near the end of the year; a $2.6 million decrease in accounts payable largely associated with a decrease in expenses related to the AbbVie agreement; a $1.4 million increase in prepaid expenses and other assets largely associated with the new Canadian office lease and the buy-out of our royalty obligation under one of our license agreements; and a $992,000 decrease in accrued expenses and other liabilities largely associated with a decrease in our royalty obligations.

We used a net amount of $6.7 million in investing activities during 2015 to purchase $26.9 million in short-term investments and $3.7 million to acquire property and equipment. These payments were offset by proceeds received

from the maturities of short-term investments of $23.9 million. During the year ending December 31, 2016, we expect to invest approximately $5.3 million in capital expenditures, primarily to purchase additional manufacturing equipment, upgrade certain older equipment and make improvements to our facilities.

Table of Contents

Net cash used in financing activities was $5.7 million in 2015, which resulted from the use of $4.9 million to repurchase shares under our stock repurchase plan and $1.2 million for the repurchase of common stock for withholding taxes related to the vesting of restricted shares. These uses of cash were partially offset by $404,000 in proceeds received from the exercise of stock options.

Our current cash balance is expected to be sufficient to fund our current operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock repurchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations as of December 31, 2015 (in thousands) for future payments under contracts and other contingent commitments, for the year 2016 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2016**	**2017**	**2018**	**2019**	**2020**	**Thereafter**
Operating leases[1]	$ 2,488	$ 362	$ 355	$ 351	$ 334	$ 362	$ 724
Employment contracts[2]	1,957	1,957					
Purchase obligations[3]	4,488	4,488					
Minimum commitments under contracts[4]	1,292	500	500	292			
Total contractual obligations	$ 10,225	$ 7,307	$ 855	$ 643	$ 334	$ 362	$ 724

1 Represents payments required under our operating leases. See Note 11 of the Notes to the consolidated financial statements included herein.

2 Represents salary payments payable under the terms of employment agreements executed by us with certain executives. See Note 11 of the Notes to the consolidated financial statements included herein.

3 Represents payments required by non-cancellable purchase orders related to inventory, capital expenditures and other goods or services. See Note 11 of the Notes to the consolidated financial statements included herein.

4 Represents payments required pursuant to certain licensing agreements executed by the Company. These agreements are cancellable within a specified number of days after communication by the Company of its intent to terminate. See Note 11 of the Notes to the consolidated financial statements included herein.

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

Critical Accounting Policies and Estimates

This Management s Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition,

Table of Contents

contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 of the Notes to the consolidated financial statements included in Item 15 of this Annual Report. We consider the following accounting policies, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition and cash flows.

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. Other than for our OraQuick® In-Home HIV test, we do not grant price protection or product return rights to our customers except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We began selling our OraQuick® In-Home HIV test in the third quarter of 2012. From launch through November 2013, our revenue practices with respect to the OraQuick® In-Home HIV test were different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV test was a new product for which we did not have a historical record of returns, we did not believe we could reasonably determine a return rate. As a result we initially did not recognize revenue when we shipped to the retail trade. For these product shipments, we invoiced the retailer or distributor, recorded deferred revenue at the gross invoice sales price, and classified the cost basis of the product held by the retailer or distributor as a component of inventory. We then recognized revenue upon the consummation of a sale to the retail customer either in a store or over the internet. With the passage of time, however, we concluded that we had sufficient data and visibility into our distribution channel to develop a reasonable estimate of the level of expected returns. As such, commencing in December 2013, we recognized previously deferred revenue and its related cost of goods sold, and began to recognize revenue for this product upon shipment to the retailers or distributors.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising, discounts, rebates, and chargebacks. Some of these allowances are estimates established by management, based upon currently available information, and are adjusted to reflect known changes in the factors that impact those estimates. These allowances are recorded as a reduction of gross revenue when recognized in our statement of operations.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee. It is recorded as other revenue in our statements of operations.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

On June 10, 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie, to co-promote our OraQuick® HCV test in the United States. The product is used to test individuals at-risk for HCV. We are responsible for manufacturing and selling the product into all markets covered by this agreement.

Pursuant to the Co-Promotion Agreement, we have granted exclusive co-promotion rights for the OraQuick® HCV test in certain markets to AbbVie and we have agreed to develop, implement, administer and maintain a

Table of Contents

patient care database for the exclusive use of AbbVie. This patient care database is being used to compile patient information regarding new individuals who have tested positive for HCV using our OraQuick® HCV test. We have also jointly agreed with AbbVie to co-promote our OraQuick® HCV test in certain market segments.

Under the terms of this agreement, which runs through December 31, 2019, we are eligible to receive up to $75.0 million in aggregate payments. We are recognizing these payments ratably on a monthly basis over the term of the agreement. In addition, if certain performance-based milestones are achieved, we may be eligible to receive additional milestone payments. These payments would be based upon the aggregate number of new patients enrolled in the patient care database, in a given calendar year, after exceeding a baseline threshold, and could range from $3.5 million to $55.5 million annually over the term of the agreement. The first performance-based milestone period ended on December 31, 2015 and we did not achieve this milestone during this period. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Under certain circumstances, either party may terminate the agreement before its expiration and such a termination could occur as early as December 31, 2016. Amounts related to this agreement are recorded as other revenue in our statements of operations.

On June 12, 2015, we entered into a contract for up to $10.4 million in total funding from BARDA related to the development of our OraQuick® Ebola Rapid Antigen test. The three-year, multi-phased contract includes 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, BARDA exercised an option to provide $7.2 million in additional funding for our OraQuick® Ebola Rapid Antigen test. Amounts related to this contract are recorded as other revenue in our statement of operations as the activities are being performed and the related costs are incurred. During 2015, $1.8 million was recognized in connection with this contract.

Customer Sales Returns and Allowances. We do not grant product return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statement of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of December 31, 2015 and 2014, the reserve for sales returns and allowances was $310,000 and $437,000, respectively. While product returns have been within our expectations and the allowance provided, if actual product returns differ materially from our reserve amount, or if a determination is made that this product s distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, we perform credit evaluations of our customers and adjust credit limits based upon the customer s payment history and creditworthiness, as determined by a review of their current credit information. We also continuously monitor collections and payments from our customers.

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $798,000 as of December 31, 2015. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period. Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. The current economic environment could adversely affect the operations, cash flows and financial condition of our customers. These circumstances may adversely impact the liquidity or financial position of our customers and could have a material impact on the collectability of our accounts receivable and future operating results.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2015 and 2014 includes customer prepayments of $784,000 and

$613,000, respectively. Deferred revenue as of December 31, 2015 and 2014 also includes $8.9 million and $7.4 million, respectively, from AbbVie, which represents the excess of the payments received from AbbVie over the amounts earned and recognized ratably in our consolidated statement of operations.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories based primarily on the estimated forecast of product sales. When, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. During 2015, we wrote-off inventory which had a cost of $2.6 million. In 2014 and 2013, we wrote-off inventory which had a cost of $1.8 million and $1.3 million, respectively. These write-offs were a result of quality, scrap and product expiration issues. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Stock-Based Compensation. We recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards is estimated using a Black-Scholes option valuation model. This valuation model s computations incorporate highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award. The fair value of the options, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the option. The fair value of our restricted shares is based on the market value of the shares at the date of grant and is recognized on a straight-line basis over the related vesting period of the award.

Long-Lived and Intangible Assets. Our long-lived assets are comprised of property and equipment, intangible assets and goodwill. Together, these assets had a net book value of $50.9 million, or 27% of our total assets, as of December 31, 2015. Property and equipment and intangible assets are depreciated or amortized on a straight-line basis over their estimated useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of our assets may not be recoverable. Events which could trigger asset impairment include significant underperformance relative to historical or projected future operating results, significant changes in the manner of our use of an asset or in our overall business strategy, significant negative industry or economic trends, and shortening of product life-cycles or changes in technology. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference.

We currently believe the future cash flows to be received from all remaining long-lived and intangible assets as of December 31, 2015 will exceed their book value. We did not recognize any impairment losses for the years ended December 31, 2015, 2014, or 2013. Any unanticipated significant impairment in the future, however, could have a material adverse impact to our balance sheet and future operating results.

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG in August 2011. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the fair value of a

reporting unit is greater than its carrying amount, then we would not be required to perform the two-step quantitative impairment test. Otherwise, performing the two-step impairment test is necessary. The first step of the two-step quantitative impairment test involves comparing the fair value of the

Table of Contents

applicable reporting unit with its aggregate carrying value, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit s fair value, we perform the second step of the test to determine the amount of the impairment loss, if any. The second step involves measuring any impairment by comparing the implied fair values of the affected reporting unit s goodwill and intangible assets with their respective carrying values.

We performed our annual impairment assessment as of July 31, 2015 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying value. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management s estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs.

Deferred Tax Assets and Liabilities. At December 31, 2015, we had federal Net Operating Loss (NOL) carryforwards of $63.0 million. The net deferred tax assets, before the valuation allowance, associated with these NOLs and other temporary differences were $39.4 million at December 31, 2015. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment.

We currently have a full valuation allowance recorded against our total U.S. deferred tax asset as we had determined in 2008 that it was more likely than not that we would not realize the benefits associated with our deferred tax asset in the immediate future. Each year, we continue to reevaluate our valuation allowance position and believe that it is more likely than not that our U.S. deferred income tax asset will not be realized in the immediate future. As such, we maintain a full valuation allowance as of December 31, 2015 and 2014 against our deferred tax assets associated with the operations subject to income tax in the U.S.

Our ability to use our federal NOL carryforwards to offset future federal income tax obligations could be limited by changes in the ownership of our stock. Internal Revenue Code (IRC) Section 382 contains provisions that limit the amount of federal NOL carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. During 2005, the Company completed an analysis, with the assistance of independent tax specialists, to determine if any IRC Section 382 ownership changes had occurred that would limit the amount of NOLs that could be utilized to offset future taxable income. As a result of this analysis, the Company concluded that prior period ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. The Company does not believe, however, that this limitation will impair our future ability to utilize NOLs to offset our future taxable income. The Company continues to review ownership changes on an annual basis and we do not believe we have had a subsequent ownership change that would impact the NOLs.

In connection with the DNAG acquisition in August 2011, a deferred tax liability was recorded to reflect the tax effects of basis differences of intangible assets and inventories for financial reporting and Canadian income tax purposes. For the year ended December 31, 2015 and 2014, we recorded Canadian income tax expense of $665,000 and $343,000, respectively. For the years ended December 31, 2013, we recorded a Canadian income tax benefit of $772,000 associated with certain Canadian research and development and investment tax credits and DNAG s loss before income taxes in that year. The income tax benefit associated with DNAG was considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Contingencies. In the ordinary course of business, we have entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees,

Table of Contents

suppliers, vendors and other parties. As such, we could be subject to litigation, claims or assessments arising from any or all of these relationships. We record a loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

As of December 31, 2015, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.4% of our total revenues for the year ended December 31, 2015. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of their revenues are recorded in U.S. dollars, almost all of their operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets of $58.0 million CDN ($41.9 million USD), which are included in the Company s consolidated balance sheet as of December 31, 2015. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would reduce our comprehensive income by $4.2 million, resulting in a comprehensive loss of $3.8 million.

ITEM 8. Consolidated Financial Statements and Supplementary Data.

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

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

ITEM 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2015. Based on that evaluation, the Company s management, including such officers, concluded that as of December 31, 2015 the Company s disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is

accumulated and communicated to the Company s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Management s Report on Internal Control Over Financial Reporting.

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company s management, including our principal

Table of Contents

executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

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

(c) Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(d) Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

OraSure Technologies, Inc.:

We have audited OraSure Technologies, Inc. s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). OraSure Technologies, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that

transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Table of Contents

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

In our opinion, OraSure Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity and cash flows for each of the years in the three-year period ended December 31, 2015, and our report dated March 14, 2016 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2016

ITEM 9B. Other Information.
Not applicable.

Table of Contents

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders (the Proxy Statement), which will be filed within 120 days after the end of our fiscal year pursuant to Regulation 14A.

ITEM 10. Directors, Executive Officers and Corporate Governance.

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

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and principal accounting officer, as well as to the members of our Board of Directors and our other officers and employees. This Code of Business Conduct and Ethics is available on our website at www.orasure.com. We intend to satisfy the amendment and waiver disclosure requirements under applicable securities regulations by posting any amendments of, or waivers to, the Code of Business Conduct and Ethics on our website.

ITEM 11. Executive Compensation.

The information required by this Item is incorporated by reference to the information under the captions Compensation Committee Matters, Compensation Discussion and Analysis, Compensation Tables, Employme Agreements and Potential Payments Upon Termination or Change in Control, and Director Compensation in the Proxy Statement.

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

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

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

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

ITEM 14. Principal Accountant Fees and Services.

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

Table of Contents

PART IV

ITEM 15. Exhibits and Consolidated Financial Statement Schedules.

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

(a)(3). Exhibits. See Index to Exhibits following the consolidated financial statements in this Annual Report.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 14, 2016.

ORASURE TECHNOLOGIES, INC.

By: */s/ Douglas A. Michels*

Douglas A. Michels
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 14, 2016, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ Douglas A. Michels Douglas A. Michels	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Ronald H. Spair Ronald H. Spair	Chief Operating Officer, Chief Financial Officer and Director (Principal Financial Officer)
/s/ Mark L. Kuna Mark L. Kuna	Senior Vice President, Finance and Controller (Principal Accounting Officer)
*MICHAEL CELANO Michael Celano	Director
*RONNY B. LANCASTER Ronny B. Lancaster	Director
*CHARLES W. PATRICK Charles W. Patrick	Director
*ROGER L. PRINGLE Roger L. Pringle	Director
*STEPHEN S. TANG Stephen S. Tang	Director
*DOUGLAS G. WATSON Douglas G. Watson	Director

*By: */s/ Jack E. Jerrett*

Jack E. Jerrett
(Attorney-in-Fact)

Table of Contents

Index to Consolidated Financial Statements

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

OraSure Technologies, Inc.:

We have audited the accompanying consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), OraSure Technologies, Inc. s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2016 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 14, 2016

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31, 2015	2014
ASSETS		
CURRENT ASSETS:		
Cash	$ 94,094	$ 92,867
Short-term investments	7,225	5,000
Accounts receivable, net of allowance for doubtful accounts of $798 and $533	19,265	16,138
Inventories	13,242	15,763
Prepaid expenses	1,533	1,140
Other current assets	1,355	306
Total current assets	136,714	131,214
PROPERTY AND EQUIPMENT, net	20,083	17,934
INTANGIBLE ASSETS, net	12,591	17,505
GOODWILL	18,250	21,734
OTHER ASSETS	1,683	1,246
	$ 189,321	$ 189,633
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,087	$ 7,148
Deferred revenue	9,735	8,043
Deferred income taxes		139
Accrued expenses	10,412	11,132
Total current liabilities	25,234	26,462
OTHER LIABILITIES	1,768	1,234
DEFERRED INCOME TAXES	2,883	3,236
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued		
Common stock, par value $.000001, 120,000 shares authorized, 55,705 and 56,187 shares issued and outstanding		
Additional paid-in capital	345,253	344,894
Accumulated other comprehensive loss	(15,639)	(7,848)
Accumulated deficit	(170,178)	(178,345)

Total stockholders equity	159,436	158,701
	$ 189,321	$ 189,633

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	For the years ended December 31,		
	2015	**2014**	**2013**
NET REVENUES:			
Product	$ 104,458	$ 98,894	$ 98,317
Other	15,261	7,570	623
	119,719	106,464	98,940
COST OF PRODUCTS SOLD	39,426	39,840	40,351
Gross profit	80,293	66,624	58,589
OPERATING EXPENSES:			
Research and development	11,654	12,058	10,932
Sales and marketing	35,088	41,118	46,465
General and administrative	25,493	23,750	21,654
Gain on contract termination settlement		(5,500)	(8,300)
	72,235	71,426	70,751
Operating income (loss)	8,058	(4,802)	(12,162)
OTHER INCOME	774	531	200
Income (loss) before income taxes	8,832	(4,271)	(11,962)
INCOME TAX EXPENSE (BENEFIT)	665	343	(772)
NET INCOME (LOSS)	$ 8,167	$ (4,614)	$ (11,190)
EARNINGS (LOSS) PER SHARE:			
BASIC	$ 0.14	$ (0.08)	$ (0.20)
DILUTED	$ 0.14	$ (0.08)	$ (0.20)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	56,397	55,949	55,555
DILUTED	56,846	55,949	55,555

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	For the years ended December 31,		
	2015	**2014**	**2013**
NET INCOME (LOSS)	$ 8,167	$ (4,614)	$ (11,190)
OTHER COMPEHENSIVE LOSS			
Currency translation adjustments	(7,791)	(4,051)	(3,131)
COMPREHENSIVE INCOME (LOSS)	$ 376	$ (8,665)	$ (14,321)

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

For the years ended December 31, 2015, 2014 and 2013

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2013	55,281	$	$ 333,522	$ (666)	$ (162,541)	$ 170,315
Common stock issued upon exercise of options	80		409			409
Vesting of restricted stock	395					
Purchase and retirement of common shares	(124)		(829)			(829)
Compensation cost for restricted stock			2,878			2,878
Compensation cost for stock option grants			2,694			2,694
Net loss					(11,190)	(11,190)
Currency translation adjustments				(3,131)		(3,131)
Balance at December 31, 2013	55,632		338,674	(3,797)	(173,731)	161,146
Common stock issued upon exercise of options	249		1,115			1,115
Vesting of restricted stock	428					
Purchase and retirement of common shares	(122)		(639)			(639)
Compensation cost for restricted stock			2,663			2,663
Compensation cost for stock option grants			3,081			3,081
Net loss					(4,614)	(4,614)