ORASURE TECHNOLOGIES INC
Form 10-K
March 12, 2015
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, 2014

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, 2014): $473,975,954

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 9, 2015: 56,415,992 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2015 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 could cause actual performance or results to be materially different from those expressed or implied in these statements. These factors 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 the 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; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; the impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; 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, including the OraQuick® In-Home HIV test; 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.

Table of Contents

Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

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

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. 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 genetics, clinical genetic testing, academic research, pharmacogenomics, personalized medicine, 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		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. 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
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
OraSure QuickFlu® Rapid Flu	A rapid, point-of-care qualitative test for antibodies to influenza (flu) Types A and B, including	FDA 510(k) cleared for use with nasal swab, nasopharyngeal swab and nasal aspirate/wash.	Marketed

A&B Test	H1N1 infections, with results available in 10 minutes.

Table of Contents

Product	Description	Regulatory Status	Commercial Status
OraSure®	Oral fluid collection device for detection of HIV-1 antibodies, cocaine and continine 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 microbial DNA from saliva.	Research use only product.	Marketed
Performagene LIVESTOCK and	All-in-one systems for the collection, stabilization, transportation, and storage of	Animal research use only.	Marketed

Oragene®	ANIMAL	livestock DNA from nasal samples.		
HEMAgene	BUFFY COAT	Reagent for stabilizing DNA from Buffy Coat (blood) for ambient temperate transport and/or storage.	Research use only product.	Marketed

Table of Contents

Product	Description	Regulatory Status	Commercial Status
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
OMNIgene Gut	All-in-one system for the collection, stabilization, transportation and storage of microbial DNA in stool samples	Research use only product.	Marketed
OMNIgene Sputum	Reagent for liquefying, decontaminating, transporting and preserving TB bacteria in sputum samples	Research use only product.	Not 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
			Marketed
		CE marked and registered in certain countries.	
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
			Marketed
		Assays CE marked and registered in certain countries.	
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,	Forensic use only.	Marketed

cocaine, methamphetamines
amphetamines, and THC.

Table of Contents

Product	Description	Regulatory Status	Commercial Status
Cryosurgical Systems Professional	Cryosurgical (freezing) system for the removal of warts and other benign skin lesions, marketed under the Histofreezer® tradename primarily to the physicians office market.	FDA 510(k) cleared for nine types of skin lesions.	Marketed
		CE marked and registered in certain countries.	Marketed
Cryosurgical Systems OTC	Cryosurgical system for the removal of common and plantar warts, sold in various OTC markets.	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.	Not Marketed
		CE marked for skin tags.	

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.

Table of Contents

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 significant 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 applied for CE mark authorization for this product. 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® 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.

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 and other analytes. This device consists of a small, treated cotton-fiber pad on a handle that is placed in a person s mouth for two to five minutes. The device collects oral mucosal transudate (OMT), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

The OraSure® collection device is FDA approved for use in the detection of HIV-1 antibodies and 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).

Table of Contents

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® name 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 ORAcollectproduct is currently pending with the FDA.

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-

Table of Contents

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. 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.

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.

Table of Contents

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 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 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 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.

Products Under Development

Infectious Disease Testing

In 2014, we began efforts to develop and commercialize a rapid, point-of-care antigen test for the Ebola virus, using our OraQuick® technology platform. We have achieved significant development and clinical milestones for this product and we are close to finalizing the design of a prototype device. Subject to receipt of external funding as described below, we expect to place this test into more extensive field testing in Africa in the near future.

Despite the good progress we have made on the development front, whether this product will ultimately contribute to our business depends on several factors. First, we are seeking funding for our development efforts from a variety of Federal agencies. The costs to complete development and obtain the applicable regulatory approvals for this product are significant. Second, as we complete our clinical development and prepare for field testing, we are also in discussions with various government agencies regarding product procurement. Our goal is to obtain substantial and sustainable product purchase commitments, along with the external development funding. Third, assuming the field testing of this product is successful we plan to seek an Emergency Use Authorization from the FDA and other

longer-term regulatory approvals from the FDA and other regulatory bodies as required to commercialize this product.

Table of Contents

Although we have made progress in our development efforts and we have received some positive feedback on funding from several agencies, it is difficult to predict whether we will be successful in completing our product development, obtaining the required regulatory approvals or achieving our funding goals. If we are unable to reach one or more of these objectives, we will likely discontinue our work on this project.

Molecular Collection Systems

The following new product initiatives are underway at DNAG:

HEMAgene BUFFY COAT is a reagent for stabilizing buffy coat, a derivative of whole blood, for ambient temperature transport and storage. An initial version of this product is being marketed to academic researchers that use buffy coat for DNA or RNA analysis.

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.

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.

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.

Research and Development

In 2014, our research and development activities focused primarily on development of our next generation Intercept i2 collection device, assessing initial feasibility of a new rapid point-of-care Ebola test using our OraQuick® platform, 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 $12.1 million in 2014, $10.9 million in 2013 and $12.4 million in 2012. 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 $82.3 million, $77.2 million and $67.5 million in 2014, 2013 and 2012, respectively. Consolidated net revenues attributable to international customers amounted to $24.2 million, $21.7 million and $20.3 million, or 23%, 22% and 23% of our total revenues, in 2014, 2013 and 2012, 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.

Table of Contents

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 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, the professional trucking industry and retail pharmacies and clinics. 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 we have developed and implemented a patient care database and limited co-payment reimbursement program under this agreement.

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.

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 primarily 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. A molecular collection product focused on the infectious disease research market is also sold by DNAG.

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 i2 device for use with the NIDA-5 assay panel, along with an additional six fully-automated high-throughput assays in order to expand sales of this product line into the workplace testing market and other markets that require 510(k) cleared drug tests. 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.

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 also engaged a manufacturers representative organization to help our U.S. distributors promote and sell Histofreezer®. In 2014, we began selling a private label version of our professional Histofreezer® product for resale by one of our U.S.

distributors. Internationally, we sell the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

Table of Contents

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. For several years, we have sold OTC cryosurgical products for the removal of both warts and skin tags under private label arrangements with retailers in Canada. In 2014, we began selling a private label version of our OTC product to a large U.S. retailer.

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