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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

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 ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☒
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 ☒

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, 2013): $212,516,664

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 7, 2014: 55,831,886 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

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This Report contains certain "forward-looking statements," within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, 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. 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.

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

PART I

ITEM 1. Business.

Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid 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® In-Home HIV Test, is the first and only rapid HIV test approved by the U.S. Food and Drug Administration ("FDA") for sale in the over-the-counter ("OTC") or consumer retail market in the United States. We also sell 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, 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 and transportation 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.

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
		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

Product	Description	Regulatory Status	Commercial Status
		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&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 the detection of antibodies to HIV-1 and for detection of cocaine and cotinine in an oral fluid sample in a laboratory setting.	PMA approved by FDA for use in detecting antibodies to HIV-1.	Marketed
		FDA 510(k) cleared for use in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid.	Marketed
		CE marked and registered in various countries.	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 in vitro diagnostic use with FDA-cleared molecular tests.	Marketed
Oragene®·DNA	Non-invasive all-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	CE marked and registered as Class 1 Medical Device in Canada.	Marketed
		Registered in various other countries.	
Oragene®·DISCOVER	Non-invasive all-in-one system for the collection, stabilization, transportation, and storage of human DNA from saliva.	Research use only product.	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

Product	Description	Regulatory Status	Commercial Status
ORAcollect™	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 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 Oragene®·ANIMAL	All-in-one systems for the collection, stabilization, transportation, and storage of livestock DNA from nasal samples.	Animal research use only.	Marketed
HEMAgene™· BUFFY COAT	Reagent for stabilizing DNA from Buffy Coat (blood) for ambient temperate transport and/or storage.	Research use only product.	Marketed
PrepIT™ L2P	Reagent for extraction and preparations 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. CE marked and registered in certain countries.	Marketed 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. Assays CE marked and registered in certain countries.	Marketed Marketed
Homogeneous DOA Assays	Homogeneous fully- automated oral fluid DOA assays jointly developed with Roche Diagnostics for use on oral fluid samples collected with Intercept® device.	FDA 510(k) cleared for use with PCP, opiates, cocaine, methamphetamines and amphetamines assays with Intercept® collection device.	Marketed

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.	Not 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 believe that the OraQuick *ADVANCE*® 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 in mid-2012. 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 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. Our clinical program for approval of an oral fluid claim for this product is on hold pending further discussions with the FDA. 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 510(k) cleared 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 or urine-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 providing easy-to-use and reliable products 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 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 received FDA 510(k) clearance for the Oragene®—Dx product in the first quarter of 2012. This clearance will enable the Oragene®—Dx product to be used with other FDA-cleared molecular diagnostic applications.

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.

In an effort to expand our Intercept® product line and meet the needs of our laboratory customers, we jointly developed with Roche Diagnostics a series of homogeneous fully-automated oral fluid drugs-of-abuse assays. These assays use Roche's KIMs (kinetic interaction of micro-particles in solution) technology and are designed to run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved by our laboratory customers with urine-based drug tests.

We had experienced significant delays in completing the development of these assays with Roche, which led to an agreement to terminate the collaboration in late 2013. As part of this termination, Roche paid us $8.3 million and agreed to continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We have the right to stop the supply of assays prior to the end of this five-year period and could receive an additional payment from Roche of up to $5.5 million depending on how early in that five-year period the supply obligation is ended.

Concurrently with the Roche termination, we entered into a new agreement with Thermo Fisher Scientific ("Thermo Fisher") for the development and supply of up to 12 homogeneous fully-automated oral fluid drugs-of-abuse assays. These assays are intended to replace the Roche assays and will be used with a new version of our Intercept® collection device. Under this new agreement, a NIDA-5 panel of assays is initially expected to be sold with our new Intercept® device in the domestic criminal justice and forensics markets beginning in the second half of 2014. Eventually, the parties expect to complete development of several more assays and obtain FDA 510(k) clearance and approvals in certain foreign countries. The assays 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.

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.

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 also sell a CE marked cryosurgical wart removal product into the OTC footcare 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 for the treatment of both warts and skin tags to retailers in Canada on a private label basis.

Immunoassay Tests and Reagents

We develop and sell immunoassay tests in two formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of our customers.

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.

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.

Research and Development

In 2013, our research and development activities focused primarily on development of a next generation Intercept® collection device and assessing initial feasibility of certain other 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 $10.9 million in 2013, $12.4 million in 2012 and $18.4 million in 2011. 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 collaborations 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. Revenues attributable to customers in the United States were $77.2 million, $67.5 million and $67.6 million in 2013, 2012 and 2011, respectively. Revenues attributable to international customers amounted to $21.7 million, $20.3 million and $14.2 million, or 22%, 23% and 17% of our total revenues, in 2013, 2012 and 2011, respectively. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Note 11 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 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.

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 order to increase awareness and consumer sales of this product, we engage in significant public relations and advertising activities related to this product.

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 through its own global 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.

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 is 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 has also been launched 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 Intercept® collection devices 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 continue to sell 510(k)-cleared fully-automated high-throughput oral fluid assays developed with Roche Diagnostics for the detection of PCP, opiates, cocaine, methamphetamines and amphetamines with oral fluid samples collected with our Intercept® device. These assays are being made available on a transitional basis until we can replace them with similar assays developed under our new collaboration with Thermo Fisher for use with a new version of our Intercept® collection device.

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 two manufacturers' representative organizations to help our U.S. distributors promote and sell Histofreezer®. 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 footcare 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.

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. More recently, 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 $44.8 million, $14.5 million and $20.4 million in 2013 and $37.9 million, $14.9 million and $14.3 million in 2012, respectively. The OraQuick® rapid HIV testing products, the cryosurgical systems products, and the OraSure® and Intercept® oral fluid collection devices accounted for total revenues of $41.7 million, $12.0 million and $10.7 million in 2011.

We had no individual customers who accounted for more than 10% of our total revenues in 2013, 2012 or 2011.

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 oral fluid diagnostic products and specimen collection devices and medical devices used for the removal of benign skin lesions by cryosurgery. The second is our “DNAG” or molecular collection systems business, which consists 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, hospital, clinics, community-based organizations, public health organizations, distributors,

government agencies, physicians' offices, and commercial and industrial entities. OSUR also derives revenues from licensing and product development activities. DNAG revenues consist of product sold into the academic research, consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine 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 11 to the consolidated financial statements, included elsewhere in this Annual Report.

Supply and Manufacturing

Our OraQuick *ADVANCE*® HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraSure® and Intercept® 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.

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 and could 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 Histofreezer® product sold in the U.S. is assembled by U.S. vendors and the Histofreezer® product sold internationally is assembled in the Netherlands by Koninklijke, Utermöhlen, N.V. ("Utermöhlen"), the company from which we acquired the product in 1998. The cryosurgical wart removal products distributed in OTC markets are also 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. Our supply agreement with Utermöhlen has expired, and we are in the process of transferring our supply arrangement to one or more other vendors.

DNAG has engaged two contract manufacturers 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, 2013, we had 293 full-time employees (including 75 employees at our subsidiary, DNAG). Of this total, there were 98 in sales, marketing and client services; 34 in research and development; 113 in operations, manufacturing, quality control, information systems, purchasing and shipping; 16 in quality assurance and regulatory affairs; and 32 in administration and finance. This compares to 313 employees as of December 31, 2012. 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.

Important competitive factors for our products include product quality, performance, price, ease of use, customer service and reputation. Industry competition is based on the following:

- 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.

The future market for diagnostic products is expected to be characterized by consolidation, greater cost consciousness, the development of new technologies, and tighter reimbursement policies. 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® and Intercept® 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 that may be developed. One of our competitors has received FDA approval for a rapid oral fluid HIV test, although this product has not yet received a CLIA waiver. 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 include medical diagnostic companies and specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions. Competing tests are often sold at a lower price than we charge for our products. This competition can result in lost sales and degradation of the price (and therefore the applicable profit margins) we can charge for our HIV and HCV tests.

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

Our OraQuick® In-Home HIV oral fluid test is the only rapid HIV test approved by the FDA for sale in the U.S. OTC market. We compete against one other non-rapid HIV blood test available in the OTC market, which requires consumers to self-collect a blood sample and then send it to a laboratory for testing.

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

Our Oragene® collection system competes against other types of collection devices used for molecular testing, such as blood collection devices and buccal swabs, which often are sold for prices lower than the prices charged for the Oragene® products. Although we believe the Oragene® device offers a number of advantages over these other products, the availability of lower price competitive devices can result in lost sales and degradation in pricing and profit margin.

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.

Our MICRO-PLATE oral fluid drug assays, which are sold for use with the Intercept® and OraSure® collection devices, 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.

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. Our OTC cryosurgical products compete against other cryosurgical products in 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 eight 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 November 2015 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 in the United States and 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 may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain other intellectual property patents in order to manufacture and sell the OraQuick *ADVANCE*® HIV test or other tests that use the same or similar technology platform. See Section 1A, entitled "Risk Factors," for a further discussion of these issues.

We hold, through our subsidiary, DNAG, ten United States patents and numerous foreign patents issued for compositions, methods and apparatus 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 June 2023 through June 2028.

We have one 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 June 2029. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products.

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, the agreements provide that all inventions conceived by the individual during his or her tenure with 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®, OraQuick®, OraQuick *ADVANCE*®, Histofreezer®, OraSure QuickFlu®, Q.E.D.®, Oragene®, ORAcollect™, OMNIgene™, Performagene™, PrepIT™, HEMAgene™, and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. With respect to our international OTC cryosurgical products, the Scholl and Dr. Scholl tradenames are owned by Reckitt Benckiser in Europe, Australia, New Zealand and other countries outside North and South America, and the POINTTS tradename is owned by Genomma.

Although important, the issuance of a patent or existence of trademark or trade secret protection does not in itself ensure the success of our business. Competitors may be able to produce products competing with our patented products without infringing our patent rights. Issuance of a patent in one country generally does not prevent manufacture or sale of the patented product in other countries. The issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent. The validity or enforceability of a patent can be challenged by litigation after its issuance. 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 two 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, 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 and many of our drugs-of-abuse products sold to state crime laboratories are for forensic use. The FDA does not currently regulate products used for these purposes, although other state and federal regulatory requirements may apply.

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.

We believe that our facilities and procedures are in material compliance with 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 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 OrageneDx collection device. In addition, the warning letter requested additional documentation related to finished product acceptance testing activities for DNAG's ORAcollect OC-100 collection device. The letter further noted that DNAG does not currently have in place an approved PMA or 510(k) clearance for its ORAcollect OC-100 device. This product accounted for less than 3% of DNAG's sales and less than 0.5% of our consolidated revenues during 2013.

DNAG has submitted a formal response and is actively engaged and working with the FDA to address the issues referenced in the warning letter. While this warning letter 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.

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. Recently, promotional activities for FDA-regulated products of other companies have 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.

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 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 will be placed in a public database. Device manufacturers were required to begin collecting data in August 2013 and will be required to submit reports March 31, 2014 (and annually thereafter). To be in compliance with such disclosure laws, we have implemented necessary systems for accurately tracking 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

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.

Environmental Regulation

Because of the nature of our current and proposed research, development, and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge and handling and disposal of solid wastes, hazardous materials and hazardous wastes. Products that we sell in Europe are subject to regulation in European Union, or EU, markets under the Restriction of the Use of Hazardous Substances Directive, or RoHS. RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU’s Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products.

Future environmental laws may require us to alter our manufacturing processes, thereby increasing our manufacturing costs. We believe that our products and manufacturing processes at our facilities comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be completely eliminated.

The foregoing discussion of our business should be read in conjunction with the consolidated financial statements and accompanying notes included in Item 15 of this Annual Report.

ITEM 1A. Risk Factors

You should carefully consider the risks and uncertainties described below, together with all of the other information included in this Annual Report and our other SEC filings, in considering our business and prospects. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not disclosed or not presently known to us or that we currently deem immaterial also may impair our business operations. The occurrence of any of the following risks could harm our business, financial condition or results of operations.

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. 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.

The process of obtaining required approvals or registrations from governmental or public health agencies 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.

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.

Our Ability to Respond to Changes in Regulatory Requirements Could Adversely Affect Our Business.

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. In addition, the FDA and other regulatory authorities 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.

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. For example, our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections. 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. We are also subject to routine inspection by the FDA and other agencies for compliance with Quality System Requirement and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO regulations.

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 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.

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.

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 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.

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, 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, and 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. 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.

Risks Relating to Our Industry, Business and Strategy

Our Ability to Sell Products Could be Adversely Affected by Competition From New and Existing Diagnostic Products.

The diagnostics industry is focused on the testing of biological specimens in a laboratory or at the point of care and is highly competitive and rapidly changing. Many of our principal competitors have considerably greater financial, technical and marketing resources. 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. 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.

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.

Our Research, Development and Commercialization Efforts May Not Succeed and Our Competitors May Develop and Commercialize More Effective or Successful Diagnostic 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 2013, 2012 and 2011, we incurred $10.9 million, $12.4 million and $18.4 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. 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 to 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 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 newest products, the OraQuick® In-Home HIV test and the OraQuick® HCV test, 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. 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 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 enter into 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 may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, general economic conditions and increased competition;

- We may be unable to successfully integrate an acquired company's personnel, assets, management systems, products and/or technology into our business;
- Worse than expected performance of an acquired business may result in the impairment of intangible assets;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- We may not be able to accurately forecast the performance or ultimate impact of an acquired business;
- 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, 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, healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product and procedure. The overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis. In addition, consolidation among healthcare providers or other participants in the healthcare industry is occurring and has resulted, and may continue to result, in fewer, more powerful healthcare groups with increased purchasing power and the ability to drive down the prices paid for our products.

Changes in Healthcare Regulation Could Affect Our Revenues, Costs and Financial Condition.

In recent years, there have been numerous initiatives at the federal and state level for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care Act, the Federal healthcare reform law enacted in 2010 ("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.

The new 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. It is unclear whether and to what extent other unanticipated developments resulting from the Affordable Care Act, such as an increase in the number of people with health insurance, will provide us with additional revenue to help offset this tax. If such additional revenue does not materialize or our efforts to offset the excise tax through spending cuts, price increases or other actions are unsuccessful, the increased tax burden will adversely affect our financial performance.

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. 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 test and our OraQuick® HCV test 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, including to hospitals owned or operated by agencies of the U.S. government. 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 the current economic downturn, future 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 could cause our customers to delay, reduce or forego purchases of our products.

In August 2011, President Obama signed into law the Budget Control Act of 2011, which was designed to reduce federal spending over the next 10 years by $2.5 trillion. Under that law, a select committee of Congress was tasked with identifying and recommending $1.2 trillion in spending cuts by late November 2011. Because the committee did not agree on spending cuts within that time frame, certain automatic cuts to discretionary, national defense and Medicare spending became effective on March 1, 2013. We cannot predict whether Congress will attempt to suspend or restructure the automatic budget cuts or what other deficit reduction initiatives may be proposed by Congress. Although their full impact is uncertain, the spending cuts implemented under this law have adversely affected and are expected to continue to adversely affect our customers' ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new 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.

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 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 and various other processes and transactions. Our ability to effectively manage our business, coordinate the production, distribution and sale of our products and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet.

The failure of these systems to operate effectively, problems with transitioning to upgraded or replacement systems, a breach in security of these systems through a cyber attack or otherwise, or disruptions in the operation of the internet, could cause delays in product sales and reduced efficiency of our operations. Significant capital investments could be required to remediate any such problem. Security breaches of employee information or other confidential or proprietary data could also adversely impact our reputation, and could result in litigation against us or the imposition of penalties.

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 *ADVANCE*® HIV-1/2 test, OraQuick® In-Home HIV test and OraQuick® HCV test are currently purchased from sole source suppliers. Our OraSure QuickFlu™ test is manufactured and supplied by a sole source supplier 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. We may also need to obtain FDA or other regulatory approvals for the use of an alternative component or for changes to our products or manufacturing process. Completing that development and obtaining such approvals could require significant time and expense and such approvals may not occur at all. The availability of critical components and products from sole supply sources or other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business.

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

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

Relying on distributors or others to market and sell our products could harm our business for various reasons, including:

- 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 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.

The Unavailability of an FDA-Approved HIV-1 EIA Screening Test Distributed by a Third Party Could Adversely Affect Sales of Our OraSure® Oral Fluid Collection Device.

In testing an oral fluid sample collected with an OraSure® device for HIV-1 in the United States, our customers must use an HIV-1 EIA screening test approved by the FDA for use with our OraSure® collection device. There is currently only one company, Avioq, Inc., that manufactures and sells such an FDA-approved screening test. If at some point in the future our customers cannot purchase the Avioq HIV-1 EIA or otherwise obtain an HIV-1 EIA screening test that has been approved by the FDA for use with our OraSure® collection device, sales of our OraSure® device could be negatively affected.

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

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 and the amount and timing of resources to be devoted to these activities will be controlled by others. Consequently, there can be no assurance that any revenues or profits will be 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.

The diagnostics 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 apparatus relating to the use or manufacture of those products. However, there have been recent 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 September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

We also rely on trade secrets, know-how and continuing technological advancements to protect our proprietary technology. We have entered, and will continue to enter, into confidentiality agreements with our employees, consultants, advisors and collaborators. Our employees and third-party consultants also sign agreements

requiring that they assign to us interests in inventions and original expressions and any patents or copyrights arising from their work. However, these parties may not honor these agreements.

We cannot guarantee that the process of filing patents, the laws governing trade secrets and proprietary information, or any agreements we enter into with employees, consultants, advisors or collaborators will provide adequate protection of our intellectual property rights. For example, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the United States. Furthermore, for a variety of reasons, we may decide not to file for patent, copyright or trademark protection outside of the U.S. Our trade secrets could become known through other unforeseen means. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology. Our competitors may also develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies.

Moreover, issued patents remain in effect for a fixed period and after expiration will not provide protection of the inventions they cover. Once our patents expire, we may be faced with increased competition, which could reduce our revenues. We may also not be able to successfully protect our rights to unpatented trade secrets and know-how.

Some of our employees, including scientific and management personnel, were previously employed by competing companies. Although we encourage and expect all of our employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against us.

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.

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. An adverse decision in any proceeding regarding intellectual property rights could result in the loss or limitation of our rights to a patent, an invention or trademark.

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, etc.) which our OraQuick® test is designed to detect. Some of these patents may broadly cover the 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.

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 the OraQuick® device 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® devices 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 the OraQuick® test 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® test 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, our OraQuick® In-Home HIV test, 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 test. 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 and OraQuick® HCV tests, are an important part of our business. Rapid point-of-care tests are beneficial to healthcare providers because, among other things, they can be administered by providers in their own facilities without sending samples to central laboratories and can help ensure that test results are delivered to the individuals being tested.

However, clinical reference laboratories and hospital-based laboratories currently provide the majority of diagnostic tests used by physicians and other healthcare providers in the U.S. In certain international markets such as Europe, diagnostic testing is performed primarily by centralized laboratories. Our future sales will depend, in part, on our ability to expand market acceptance of rapid point-of-care testing by physicians and other healthcare providers 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 and other healthcare providers may resist changing to rapid point-of-care tests and instead may choose to use competing 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.

Our Future Growth Depends, In Part, on Our Ability to Commercialize the OraQuick® In-Home HIV Test.

Our future growth will depend, in part, on our ability to commercialize and market the OraQuick® In-Home HIV test in the OTC market. Successful commercialization of the OraQuick® In-Home HIV test will depend on a number of factors, including achieving widespread awareness and adoption of the product among the targeted consumer base, initiating and maintaining relationships with suppliers and retailers, reducing the use of security devices and other barriers to purchase in retail stores, protecting against and effectively responding to any claims by holders of patents and other intellectual property rights that our OTC product infringes their rights, obtaining and maintaining sufficient inventory of the product, the performance of our toll-free customer support center and our comprehensive consumer website relating to the product, and our ability to successfully market the product at the projected selling price. There can be no assurance that we will be successful in these endeavors. Because of the need to build broad awareness for this new product, our advertising and marketing expenditures have been substantial. If we continue advertising and marketing expenditures consistent with historic levels, our operating results will be negatively impacted unless we are successful in substantially increasing sales of this product. Conversely, if we decide to reduce these expenditures, our costs will be lower but sales of our OraQuick® In-Home test could be adversely impacted. In addition, retailers generally have broad product return rights which may be exercised if sufficiently high sales to consumers are not achieved. Successful commercialization of this product will also depend on whether any unanticipated adverse effects result from use of the product, or unfavorable publicity develops in respect of the product, as well as the emergence of new or existing products as competition, which are proven to be more clinically or cost-effective.

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;
- Lower than expected market penetration of the OraSure QuickFlu™ test; and
- Our inexperience in selling a rapid flu 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.

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;
- 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 certain countries and we may expand OTC sales of these products into other countries. We also launched the OraQuick® In-Home HIV test in the United States OTC market, and we are considering the expansion of this product internationally. We believe the sale of products in the OTC market increases our potential exposure to product liability and other claims.

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

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

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

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

Performance of Our Products May Affect Our Revenues, Stock Price and Reputation.

Our products are generally sold with labeling that contains performance claims approved or cleared by the FDA or other regulators. However, our products may not perform as expected. For example, a defect in one of our diagnostic products or a failure by a customer to follow proper testing procedures, may cause the product to report inaccurate information such as a false positive result or a false negative result. A false positive or negative result can also occur even when there is no apparent product defect and the customer has apparently used our product properly. Identifying the root cause of a product performance or quality issue can be difficult and time consuming.

If our products fail to perform in accordance with the applicable label claims or otherwise in accordance with the expectations or needs of our customers, customers may switch to a competing product or otherwise stop using our products, and our revenues could be adversely affected. Under such circumstances, we may be required to implement shipment holds or product recalls and incur warranty obligations, which would increase our costs. In addition, poor performance by one or more of our products and publicity surrounding 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 $21.7 million or 22% of consolidated net revenues in 2013, $20.3 million or 23% of consolidated net revenues in 2012 and $14.2 million or 17% of consolidated net revenues in 2011. In addition, our molecular collection systems business, which accounted for $20.4 million or 21% of consolidated net revenues in 2013, 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;
- The inability to obtain or maintain ISO certification for our or our suppliers' manufacturing facilities;
- Our inability to obtain or maintain regulatory approvals or registrations for our products;
- Our inability to identify international distributors and negotiate acceptable terms for distribution agreements;
- Diversion to the U.S. of our products 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;
- 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;
- Our exposure to liability under the Foreign Corrupt Practices Act and various other laws, rules and/or regulations applicable to us as a result of our international sales;
- 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. In addition, the Histofreezer® cryosurgical product sold in international markets is currently manufactured by a third party in The Netherlands. 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.

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

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

Current volatile economic conditions may continue for the foreseeable future and intensify. These conditions have adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could 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 the economic recovery.

We Have a History of Losses and May Not Be Able to Achieve Sustained Profitability.

We have experienced annual net losses since 2008. In addition, as of December 31, 2013, the Company had an accumulated deficit of $173.7 million. Even though we achieved profitability a number of years ago, there can be no assurance that we will be able to achieve or sustain profitability in the future.

Our ability to achieve and sustain profitability in the future will be dependent upon a number of factors including, without limitation, the following:

- Creating market acceptance for and selling increasing volumes of our OraQuick *ADVANCE*® HIV-1/2 test and our OraQuick® HCV test in the United States and internationally;
- Our ability to successfully commercialize our OraQuick® In-Home HIV test and the magnitude of promotional costs related to this product;
- The success and revenue growth of our molecular collection systems business;
- 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 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;

- Changes in the level of competition, such as would occur if larger and financially stronger competitors introduced new or lower priced products 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. 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 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, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

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 operating results 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. In 2013, DNAG reported total revenues of U.S. $20.4 million. 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. Unfavorable currency exchange rate fluctuations could negatively affect our consolidated financial statements including our balance sheet, revenues and results of operations. 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.

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 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;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

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.

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:

- Future announcements concerning us and our products, including with respect to significant acquisitions, strategic collaborations and joint ventures;
- The performance of our business, including our efforts to commercialize the OraQuick® In-Home HIV test and increase sales of our HCV testing and molecular collection systems products;
- 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.

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 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, leases a 23,500 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.

Employment Termination Claim

In August 2012, DNA Genotek Inc. ("DNAG") received a Statement of Claim filed by a former employee with the Ontario Superior Court of Justice alleging, among other things, that DNAG had wrongfully terminated this individual and had breached the terms of his employment. In so doing, DNAG is also alleged to have violated this individual's rights under the Ontario Human Rights Code. The Statement of Claim is seeking to recover in excess of $500,000 CDN in damages from DNAG. A Statement of Defence denying the allegations was filed by DNAG in October 2012. DNAG has also served discovery requests on the complainant but has not yet received any response. We believe the claims asserted by the complainant are without merit and DNAG intends to vigorously defend this matter.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

Our Common Stock is listed for trading on the Global Select Market tier of The Nasdaq Stock Market LLC ("NASDAQ") under the symbol OSUR. High and low sales prices reported by NASDAQ during the periods indicated are shown below.

	Year ended December 31,			
	2013		2012	
	High	Low	High	Low
First Quarter	$7.52	$5.25	$11.78	$9.17
Second Quarter	5.45	3.75	12.28	8.90
Third Quarter	6.46	3.86	14.01	9.39
Fourth Quarter	7.25	5.64	11.34	6.56

On March 6, 2014, there were 436 holders of record and approximately 13,000 holders in street name of our Common Stock, and the closing price of our Common Stock was $8.13 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

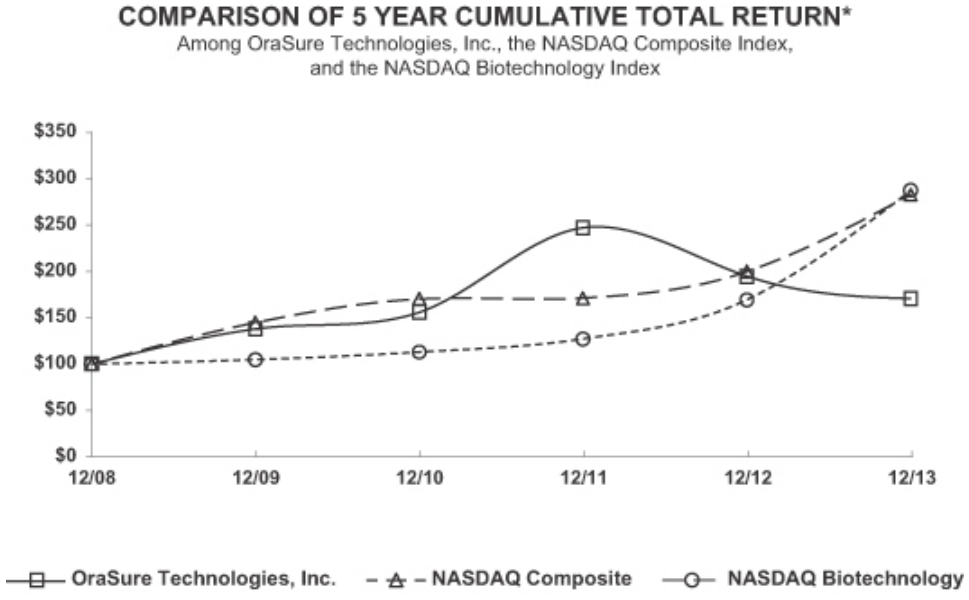
Pursuant to our Stock Award Plan and in connection with the vesting of restricted shares, we retired 124 shares to satisfy minimum tax withholding obligations during the three months ended December 31, 2013. No shares were repurchased under our $25.0 million share repurchase program during the same period.

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, 2008 through December 31, 2013. The graph assumes that $100 was invested on December 31, 2008 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.



	12/08	12/09	12/10	12/11	12/12	12/13
OraSure Technologies, Inc.	**100.00**	**138.04**	**156.25**	**247.55**	**195.11**	**170.92**
NASDAQ Composite	**100.00**	**144.84**	**170.58**	**171.34**	**200.03**	**283.43**
NASDAQ Biotechnology	**100.00**	**104.67**	**112.89**	**127.04**	**169.50**	**288.38**

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,				
	2013	2012	2011 (4)	2010	2009
Operating Results:					
Net revenues	$ 98,940 (1)	$ 87,820	$ 81,881	$ 75,015	$ 77,026
Costs and expenses	111,102 (2)	104,090	91,278	78,369	85,819
Operating loss	(12,162)	(16,270)	(9,397)	(3,354)	(8,793)
Other income (expense), net	200	(242)	(313)	(143)	357
Income tax benefit	(772)	(1,397)	(869)	—	(622)
Net loss	(11,190)	(15,115)	(8,841)	(3,497)	(7,813)
Basic and diluted loss per share	$ (0.20)	$ (0.29)	$ (0.19)	$ (0.08)	$ (0.17)
Shares used in computing basic and diluted loss per share	55,555	51,457	46,908	46,187	45,878
Cash Flow:					
Cash flows provided by (used in) operating activities	$ 8,385 (2)	$ (5,373)	$ (2,994)	$ 3,887	$ (293)

	December 31,				
	2013	2012 (3)	2011 (4)	2010	2009
Financial Position:					
Cash, cash equivalents, and short-term investments	$ 93,191	$ 87,888	$ 23,878	$ 75,738	$ 79,670
Working capital	100,590	103,483	30,860	77,808	89,435
Total assets	184,245	191,439	127,861	122,520	126,991
Long-term debt, excluding current portion	—	—	—	—	7,792
Accumulated deficit	(173,731)	(162,541)	(147,426)	(138,585)	(135,088)
Stockholders' equity	161,146	170,315	100,250	102,843	103,807

(1) 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 tests.

(2) Includes an $8.3 million gain from the termination of the Company's oral fluid assay collaboration with Roche Diagnostics, which was recorded as a reduction of operating expenses in the current period.

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

(4) 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.

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 oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid 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 and tests that are processed in a laboratory. In September 2012, we began selling our OraQuick® In-Home HIV test, the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail 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 clinical genetic testing, academic research, pharmacogenomics, personalized medicine, 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 and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. Our over-the-counter ("OTC") HIV and cryosurgery products are sold to retail pharmacies and mass merchandisers and to consumers over the internet.

Current Consolidated Financial Results

During the year ended December 31, 2013, our consolidated net revenues were $98.9 million compared to $87.8 million for the year ended December 31, 2012. Net product revenues during the year ended December 31, 2013 increased 15% when compared to 2012, primarily due to sales of our OraQuick® In-Home HIV test, which was commercially launched during the third quarter of 2012. In December 2013, we recorded a favorable non-recurring $2.5 million net revenue adjustment to account for a change in the revenue recognition policy associated with this product. Also contributing to the increased net revenues for the year were higher sales from our molecular collection systems business, and higher international sales of our OraQuick® HCV and HIV tests. Licensing and product development revenues for 2013 decreased 70% primarily as a result of the absence of a $1.0 million milestone payment received in the first quarter of 2012 related to the achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Our consolidated net loss for the year ended December 31, 2013 was $11.2 million, or $0.20 per share, compared to a net loss of $15.1 million, or $0.29 per share, for the year ended December 31, 2012. Our loss for the current period included $18.8 million in advertising and promotional expenses associated with our OraQuick® In-Home HIV test, as compared to $9.9 million of similar expenses in 2012. Our current period loss also included an $8.3 million gain (recorded as a reduction to operating expenses) for a settlement payment received for the termination of our assay collaboration with Roche Diagnostics.

Cash provided by operating activities for the year ended December 31, 2013 was $8.4 million, compared to $5.4 million used during the year ended December 31, 2012 and included the $8.3 million settlement payment from Roche. As of December 31, 2013, we had $93.2 million in cash and cash equivalents compared to $87.9 million at December 31, 2012.

2013 Developments

OraQuick® In-Home HIV Test Revenue Recognition Change

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 have 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. For the year ended December 31, 2013, we recorded net revenues of $9.1 million related to our OraQuick® In-Home HIV test. Included in these net revenues was a $2.7 million gross revenue adjustment made in December 2013 to recognize previously deferred revenue, reduced by an estimated allowance for expected returns of $206,000.

Drugs-of-Abuse Assay Collaboration Agreements

On November 21, 2013, we terminated our assay collaboration agreement with Roche Diagnostics. Under the termination agreement, Roche paid us $8.3 million which was recorded as a reduction of operating expense on our consolidated statement of operations. Roche agreed to provide certain transitional product support services and will continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We have the right to stop the supply of assays prior to the end of this five-year period and could receive an additional payment from Roche of up to $5.5 million depending on how early in that five-year period the supply authorization is ended.

Concurrently with the termination of our agreement with Roche, we entered into a new agreement with Thermo Fisher for the development and supply of up to 12 homogeneous fully-automated oral fluid drugs-of-abuse assays. These assays will be used with a new version of our Intercept® collection device. Under this new agreement, a NIDA-5 panel of assays is expected to be initially sold with our new Intercept® device in the domestic criminal justice and forensics markets beginning in the second half of 2014. Eventually, the parties expect to complete development of several more assays and obtain FDA 510(k) clearance and approvals in certain foreign countries. The assays will be optimized as needed to comply with new oral fluid guidelines expected to be issued by the SAMHSA for the federally-regulated market and certain other markets that follow Federal drug testing guidelines, none of which are currently served by OraSure.

HCV Screening Grade Change

In June 2013, the U.S. Preventive Services Task Force (“USPSTF”) issued new recommendations giving HCV screening for both at-risk individuals and individuals born between 1945 and 1965 a ‘B’ grade. Under the

Affordable Care Act, preventive services that have received an “A” or “B” grade from the USPSTF must be covered by insurance policies without cost-sharing and will be part of essential health benefits for those individuals eligible for Medicare. These recommendations became effective in January 2014 and are expected to have a positive impact on testing for HCV over time, including with our OraQuick® HCV rapid antibody test.

Economic Outlook

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 current 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. In addition, these circumstances could adversely affect our access to liquidity that may be needed to conduct or expand our business, conduct future acquisitions or make other discretionary investments.

On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which was designed to reduce federal spending over the next 10 years by $2.5 trillion. Under that law, a select committee of Congress was tasked with identifying and recommending $1.2 trillion in spending cuts by late November 2011. Because the committee did not agree on spending cuts within that time frame, certain automatic cuts to discretionary, national defense and Medicare spending (often referred to as Federal sequestration) became effective on March 1, 2013. We cannot predict whether Congress will attempt to suspend or restructure the automatic budget cuts or what other deficit reduction initiatives may be proposed by Congress. Although their full impact is difficult to ascertain, the spending cuts implemented under this law have adversely affected, and are expected to continue to adversely affect our customers’ ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products.

Business Segments

We operate our business within two reportable segments: our “OSUR” business, which consists of the development, manufacture and sale of oral fluid diagnostic products, specimen collection devices, and medical devices used for the removal of benign skin lesions by cryosurgery; 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, 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, and commercial and industrial entities. Revenues from OSUR’s OTC products primarily result from sales to retail pharmacies and mass merchandisers and to consumers over the internet. OSUR also derives revenues from licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market, which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetic testing, as well as products sold into the academic research market, which consists of research laboratories, universities and hospitals.

Results of Operations

Year Ended December 31, 2013 Compared to December 31, 2012

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues generated by each of our business segments and net revenues generated by licensing and product development activities (dollars in thousands).

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2013	2012	% Change	2013	2012
OSUR	$77,936	$71,495	9%	78%	82%
DNAG	20,381	14,258	43	21	16
Net product revenues	98,317	85,753	15	99	98
Licensing and product development	623	2,067	(70)	1	2
Net revenues	$98,940	$87,820	13%	100%	100%

Consolidated net revenues increased 13% to $98.9 million in 2013 from $87.8 million in 2012. Net product revenues increased 15% during the year ended December 31, 2013 when compared to the year ended December 31, 2012, primarily as a result of higher sales of our infectious disease testing and molecular collection systems products. These increases were partially offset by lower sales of our substance abuse testing, insurance risk assessment, and cryosurgical systems products. Licensing and product development revenues decreased in the current year compared to the prior year primarily as a result of the absence of a $1.0 million milestone payment received in the first quarter of 2012 related to the achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Consolidated net revenues derived from products sold to customers outside the U.S. were $21.7 million and $20.3 million, or 22% and 23% of total net revenues, for the years ended December 31, 2013 and 2012, 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 generated by our OSUR segment in each of our principal markets and by licensing and product development activities (dollars in thousands).

Market	Year Ended December 31, Dollars 2013	Dollars 2012	% Change	Percentage of Total Net Revenues 2013	Percentage of Total Net Revenues 2012
Infectious disease testing	$50,961	$42,728	19%	65%	58%
Substance abuse testing	8,571	9,407	(9)	11	13
Cryosurgical systems	14,468	14,876	(3)	18	20
Insurance risk assessment	3,936	4,484	(12)	5	6
Net product revenues	77,936	71,495	9%	99	97%
Licensing and product development	623	2,067	(70)	1	3
Net revenues	$78,559	$73,562	7%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 19% to $51.0 million in 2013 from $42.7 million in 2012, primarily due to sales of our OraQuick® In-Home HIV test and higher sales of our OraQuick® HCV and HIV products in international markets.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during 2013 and 2012.

Market	Year Ended December 31, 2013	2012	% Change
Domestic HIV	$32,301	$34,265	(6)%
International HIV	3,365	3,061	10
Domestic OTC HIV	9,106	546	1,568
Net HIV revenues	44,772	37,872	18
Domestic HCV	2,847	2,805	1
International HCV	2,268	1,059	114
Net HCV revenues	5,115	3,864	32
Net OraQuick® revenues	$49,887	$41,736	20%

Domestic OraQuick® HIV sales decreased 6% to $32.3 million in 2013 from $34.3 million in 2012. This decrease was primarily caused by competition from other rapid and automated laboratory-based HIV tests and reductions in government funding. We expect that sales of our professional HIV product will continue to be challenged by these factors in future periods. International sales of our OraQuick® HIV test increased 10% to $3.4 million in 2013 from $3.1 million in 2012 primarily as a result of higher sales in Mexico, Africa, and Europe.

In 2013, we recorded $9.9 million in gross revenues from sales of our OraQuick® In-Home HIV test, including $2.7 million ($2.5 million, net of estimated returns) of previously deferred gross revenue recognized in December 2013 when we changed our revenue recognition policy for this product. These gross revenues were

partially offset by $764,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Sales during 2013 also included approximately $701,000 of direct sales to certain public health customers compared to $19,000 in 2012. We anticipate that some public health entities may continue to use a portion of their funding to purchase our OTC product in lieu of our or a competitor's professional rapid HIV testing product.

We began shipping our OraQuick® In-Home HIV test to the retail outlets at the end of September 2012. In 2012, we recorded $902,000 in gross revenues from product sales to retail customers either in a store or over the internet. These revenues were offset by $356,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances.

Domestic OraQuick® HCV sales remained flat at $2.8 million in 2013 and 2012. International sales of our OraQuick® HCV test increased 114% to $2.3 million in 2013 from $1.1 in 2012, primarily as a result of a first-time order from a multi-national humanitarian organization. We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. However, demand for our HCV product, particularly in the public health marketplace, has been, and will likely continue to be, 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.

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 decreased 9% to $8.6 million in 2013 from $9.4 million in 2012, as a result of lower sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during 2013 and 2012.

	Year Ended December 31,		
Market	2013	2012	% Change
Domestic	$5,693	$6,335	(10)%
International	500	706	(29)
Net Intercept® revenues	$6,193	$7,041	(12)%

Domestic Intercept® sales decreased 10% to $5.7 million in 2013 from $6.3 million in 2012. In 2011, our largest laboratory distributor began selling its own competing oral specimen collection device and a panel of oral fluid drug assays suitable for use on fully-automated high throughput homogenous processing systems. As a result, by the end of 2012, this distributor had significantly reduced its purchases of our Intercept® product line. Intercept® sales to this distributor were $67,000 for the year ended December 31, 2013 compared to $1.4 million for the year ended December 31, 2012. Intercept® sales in 2013 were also negatively impacted by the continued consolidation of drug testing laboratories.

International Intercept® sales decreased 29% to $500,000 in 2013 from $706,000 in 2012, as a result of lower purchases by our UK laboratory distributor, which totaled $316,000 in 2013 compared to $610,000 in 2012. In 2012, this UK distributor began selling its own competing oral specimen collection device and we expect this distributor to discontinue its purchases of our product in future periods.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased to $14.5 million for the year ended December 31, 2013 from $14.9 million for the year ended December 31, 2012.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during 2013 and 2012.

	Year Ended December 31,		
Market	2013	2012	% Change
Domestic professional	$ 6,020	$ 7,159	(16)%
International professional	1,441	1,462	(1)
International OTC	7,007	6,255	12
Net cryosurgical systems revenues	$14,468	$14,876	(3)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 16% to $6.0 million in 2013, compared to $7.2 million in 2012. This decrease was the result of higher distributor purchases made in the fourth quarter of 2012 in anticipation of price increases implemented in early January 2013, a decline in sales to the military during 2013 as a result of the U.S. withdrawal of troops overseas and lower sales to our Canadian distributor. International sales of Histofreezer® remained relatively flat at $1.4 million in 2013 and $1.5 million in 2012.

Sales of our OTC cryosurgical products during 2013 increased 12% to $7.0 million from $6.3 million in 2012. This increase was largely the result of higher sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser. In 2013, Genomma purchased $3.3 million compared to $2.7 million during 2012, largely due to increased sales into Brazil. Sales to Reckitt Benckiser increased to $3.6 million in 2013 from $3.3 million in 2012 as a result of higher sales in new geographic territories, partially offset by lower sales to existing markets resulting from a reallocation of advertising resources by the distributor.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 12% to $3.9 million in 2013 from $4.5 million in 2012, as a result of reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a "Simplified Issues" policy, pursuant to which lab-based testing is replaced by having applicants respond to a questionnaire about their behaviors.

Licensing and Product Development

Licensing and product development revenues for 2013 decreased 70% primarily as a result of the absence of a $1.0 million milestone payment received in the first quarter of 2012 related to the achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Also contributing to the decline in product development revenues in 2013 was a decrease in royalties received on domestic outsales of Merck's OTC cryosurgical wart removal product. Pursuant to a license and settlement agreement executed in January 2008, the receipt of royalties stopped in August 2013 when certain of our cryosurgical patents expired.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 43% to $20.4 million in 2013 from $14.3 million in 2012. Sales of Oragene® in the commercial market increased in 2013 primarily due to a substantial increase in orders received from an existing customer partially offset by lower sales in the academic research market in 2013 when compared to 2012 due to continued constrained research funding, particularly in North America.

CONSOLIDATED OPERATING LOSS

Consolidated gross margin was 59% in 2013 compared to 63% in 2012. This decrease was largely due to higher royalty expenses, an unfavorable change in product mix, and the absence of the $1.0 million HCV milestone payment which was received in 2012. These negative effects on gross margin were partially offset by an improvement in overhead absorption during 2013 when compared to the prior year period.

Consolidated operating loss decreased $4.1 million to $12.2 million in 2013, compared to $16.3 million in 2012. Our 2013 operating loss reflects the $8.3 million settlement payment received for the termination of our assay collaboration agreement with Roche Diagnostics partially offset by higher sales and marketing expenses associated with the promotion of our OraQuick® In-Home HIV test.

Operating Loss by Segment

OSUR Segment

OSUR's gross margin was 57% in 2013 compared to 62% in 2012. OSUR's 2013 margin was negatively impacted by higher lateral flow patent royalties on sales of our OraQuick® HIV products, an unfavorable change in product mix, and the absence of the $1.0 million HCV milestone payment received from Merck in the first quarter of 2012. The negative impact of these items was partially offset by an improvement in overhead absorption.

Research and development expenses declined 13% to $8.4 million in 2013 from $9.7 million in 2012, largely due to lower staffing costs and decreased spending on lab supplies. We expect OSUR's research and development costs will increase in 2014 when compared to 2013 levels.

Sales and marketing expenses increased 29% to $39.5 million in 2013 from $30.5 million in 2012. This increase was primarily the result of higher spending associated with advertising and promotional activities for our OraQuick® In-Home HIV test. During 2013, we launched three large promotional campaigns including one in association with Earvin "Magic" Johnson, a multi-city promotional campaign to encourage consumers to get tested for HIV, and another focused on increasing brand awareness among men who have sex with men and African American consumers. We also increased our use of radio, television, print and digital advertising. Advertising and promotional costs for our OraQuick® In-Home HIV test were $18.8 million in 2013, compared to $9.9 million in 2012. We expect 2014 sales and marketing expenses to decline from 2013 levels, as a result of lower spending on advertising and promotional activities related to the OraQuick® In-Home HIV test.

General and administrative expenses decreased 4% to $18.2 million in 2013 from $19.0 million in 2012 due to lower legal and consulting expenses, partially offset by higher staffing costs. We expect general and administrative expenses to increase in 2014 when compared to 2013 levels.

All the above contributed to OSUR's operating loss of $12.8 million, which included non-cash charges of $3.2 million for depreciation and amortization expense and $5.3 million for stock-based compensation expense.

DNAG Segment

DNAG's gross margin was 67% in 2013 compared to 68% in 2012. This decrease was primarily the result of increased sales to a lower margin commercial customer.

Research and development expenses decreased 7% to $2.6 million in 2013 from $2.8 million in 2012 due largely to lower staffing costs and amortization expense. Sales and marketing expenses increased 7% to $7.0 million in 2013 from $6.6 million in 2012 largely due to higher staffing costs and higher sales commission expenses. General and administrative expenses remained relatively flat at $3.4 million in 2013 as compared to $3.3 million in 2012. We expect DNAG's 2014 operating expenses to increase across all categories when compared to 2013 levels.

All of the above contributed to operating income of $687,000 for DNAG in 2013, which also included non-cash charges of $3.3 million for depreciation and amortization expense and $238,000 for stock-based compensation expense.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. net 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 OraSure's pre-tax loss in 2013 and 2012. A Canadian income tax benefit of $772,000 and $1.4 million was recorded in 2013 and 2012, respectively, which was associated with certain Canadian research and development and investment tax credits and the DNAG loss before income taxes in 2012. The Canadian income tax benefit is considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Year Ended December 31, 2012 Compared to December 31, 2011

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues generated by each of our business segments and net revenues generated by licensing and product development activities (dollars in thousands).

	Year Ended December 31,				
	Dollars		%	Percentage of Total Revenues	
	2012	2011	Change	2012	2011
OSUR	$71,495	$74,467	(4)%	82%	91%
DNAG	14,258	6,216	129	16	8
Net product revenues	85,753	80,683	6	98	99
Licensing and product development	2,067	1,198	73	2	1
Net revenues	$87,820	$81,881	7%	100%	100%

Consolidated net revenues increased 7% to $87.8 million in 2012 from $81.9 million in 2011. Net product revenues in 2012 included $14.3 million in net revenues from our molecular collection systems subsidiary, DNAG, compared to $6.2 million in 2011. Results for 2012 reflect a full twelve months of molecular collection systems sales, while 2011 results include only those revenues generated from the August 17, 2011 acquisition date of DNAG through year end.

Net product revenues increased 6% during the year ended December 31, 2012 when compared to the year ended December 31, 2011, primarily as a result of the higher molecular collection system sales and higher sales of our cryosurgical systems products. These increases were partially offset by lower sales of our infectious disease testing, substance abuse testing and insurance risk assessment products. Licensing and product development revenues also increased in 2012 as compared to the prior year.

Consolidated net revenues derived from products sold to customers outside the U.S. were $20.3 million and $14.2 million, or 23% and 17% of total net revenues, for the years ended December 31, 2012 and 2011, respectively. This increase was primarily caused by the inclusion of a full twelve months of revenues from DNAG. 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 operating results.

Net Revenues by Segment

OSUR Segment

The table below shows the amount of total net revenues (dollars in thousands) generated by our OSUR segment in each of our principal markets and by licensing and product development activities.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Revenues	
Market	2012	2011	Change	2012	2011
Infectious disease testing	$42,728	$44,691	(4)%	58%	59%
Substance abuse testing	9,407	12,498	(25)	13	16
Cryosurgical systems	14,876	12,046	23	20	16
Insurance risk assessment	4,484	5,232	(14)	6	7
Net product revenues	71,495	74,467	(4)	97	98
Licensing and product development	2,067	1,198	73	3	2
Net revenues	$73,562	$75,665	(3)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 4% to $42.7 million in 2012 from $44.7 million in 2011, primarily due to lower OraQuick® sales. OraQuick® sales totaled $41.7 million and $43.3 million for the years ended December 31, 2012 and 2011, respectively.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during 2012 and 2011.

Market	Year Ended December 31, 2012	2011	% Change
Domestic HIV	$34,265	$38,722	(12)%
International HIV	3,061	3,011	2
Domestic OTC HIV	546	—	N/A
Total HIV revenues	37,872	41,733	(9)
Domestic HCV	2,805	890	215
International HCV	1,059	672	58
Total HCV revenues	3,864	1,562	147
Net OraQuick® revenues	$41,736	$43,295	(4)%

Domestic OraQuick® HIV sales decreased 12% to $34.3 million in 2012 from $38.7 million in 2011. This decrease was due to changes in public health testing programs and their timing of purchases, reductions in government funding, price competition and a shift to automated laboratory-based blood tests by certain customers. International sales of our OraQuick® HIV test increased 2% to $3.1 million in 2012 from $3.0 million in 2011 as a result of higher sales in Africa due to changes in existing distributor order patterns.

We began shipping our OraQuick® In-Home HIV test to the retail outlets at the end of September 2012. We recorded $902,000 in gross revenues from product sales to retail customers either in a store or over the internet. These revenues were offset by $356,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles.

Domestic OraQuick® HCV sales increased to $2.8 million in 2012 from $890,000 in 2011 as result of broader adoption of our product by customers who are able to use a CLIA-waived product. We received a CLIA waiver for this product in November 2011, allowing us to sell our HCV product to many non-CLIA certified customers, such as outreach clinics, community-based organizations and physician offices. International sales of our OraQuick® HCV test increased 58% to $1.1 million in 2012 from $672,000 in 2011, largely as a result of higher sales into Latin America and Europe.

Substance Abuse Testing Market

Net substance abuse testing revenues decreased 25% to $9.4 million in 2012 from $12.5 million in 2011, as a result of lower sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during 2012 and 2011.

Market	Year Ended December 31, 2012	2011	% Change
Domestic	$6,335	$8,004	(21)%
International	706	1,912	(63)
Net Intercept® revenues	$7,041	$9,916	(29)%

Domestic Intercept® sales decreased 21% to $6.3 million in 2012 from $8.0 million in 2011. In 2011, our largest laboratory distributor began selling its own competing oral specimen collection device and a panel of oral fluid drug

assays suitable for use on fully-automated high throughput homogenous processing systems. As a result, by the end of 2012, this distributor had significantly reduced its purchases of our Intercept® product line. Intercept® sales to this distributor were $1.5 million for the year ended December 31, 2012 compared to $3.5 million for the year ended December 31, 2011.

International Intercept® sales decreased 63% to $706,000 in 2012 from $1.9 million in 2011, as a result of lower purchases by our UK laboratory distributor as it also has begun selling its own competing oral specimen collection device. Intercept® sales to this distributor were $610,000 for the year ended December 31, 2012 compared to $1.9 million in the year ended December 31, 2011.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased to $14.9 million for the year ended December 31, 2012 from $12.1 million for the year ended December 31, 2011.

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during 2012 and 2011.

	Year Ended December 31,		
Market	2012	2011	% Change
Domestic professional	$ 7,159	$ 6,775	6%
International professional	1,462	1,400	4
International OTC	6,255	3,871	62
Net cryosurgical systems revenues	$14,876	$12,046	23%

Sales of our Histofreezer® product to physicians' offices in the United States increased 6% to $7.2 million in 2012, compared to $6.8 million in 2011, due to the success of sales and promotional efforts by our distributors. During the year ended December 31, 2012, international sales of Histofreezer® increased 4% to $1.5 million compared to $1.4 million in the prior year, largely as a result of higher out-sales in Australia by our distributor in that new market.

Sales of our OTC cryosurgical products during 2012 increased 62% to $6.3 million from $3.9 million in 2011. This increase was largely the result of higher sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser.

In 2012, Genomma purchased $2.7 million compared to $990,000 during 2011. Early in 2011, the Mexican government placed limitations on the advertising Genomma could use for our product. At the same time, the Brazilian government also required changes to our package insert. Both of these events negatively impacted sales of our product to Genomma during 2011, but were resolved by the end of that year.

Sales to Reckitt Benckiser increased to $3.3 million in 2012 from $2.6 million in 2011 as a result of increased advertising and promotional activities and expansion into additional European countries.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 14% to $4.5 million in 2012 from $5.2 million in 2011, largely as a result of the loss of one of our larger customers who changed its underwriting methodologies in 2011.

Licensing and Product Development

Licensing and product development revenues increased 73% to $2.1 million in 2012 from $1.2 million in 2011. During the first quarter of 2012, we received a $1.0 million milestone payment as a result of our achievement of certain regulatory and commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in international markets. No such milestone payments were received in the prior year.

The remaining licensing revenues for these periods represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. In the latter half of 2011, the royalty rate decreased pursuant to the terms of our license.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues primarily represent sales of the Oragene® product line by our subsidiary, DNAG, which we acquired in August 2011. During 2012, net DNAG revenues included several new orders from large commercial customers as well as continued strong sales into the academic research market despite funding challenges in both Canada and the United States.

CONSOLIDATED OPERATING LOSS

Consolidated gross margin remained unchanged at 63% for both 2012 and 2011.

Consolidated operating loss increased $6.9 million to $16.3 million in 2012, compared to $9.4 million in 2011. The increased loss was primarily the result of higher sales and marketing expenses associated with the commercialization of our OraQuick® In-Home HIV test and the inclusion of a full year of DNAG operating expenses. These higher expenses were partially offset by lower research and development costs due to decreased clinical trial costs related to our OraQuick® In-Home HIV test.

Operating Loss by Segment

OSUR Segment

OSUR's gross margin was 62% in 2012 compared to 64% in 2011. OSUR's 2012 margin was negatively impacted by the overall decrease in sales volume which caused a decline in absorption of our labor and fixed overhead costs. This decline was partially offset by the beneficial impact of the $1.0 million HCV milestone payment received in the first quarter of 2012.

Research and development expenses declined 44% to $9.7 million in 2012 from $17.4 million in 2011, primarily as a result of lower clinical trial costs related to the development of our OraQuick® In-Home HIV test.

Sales and marketing expenses increased 52% to $30.5 million in 2012 from $20.1 million in 2011. This increase was primarily the result of approximately $9.9 million of spending associated with the commercialization of our OraQuick® In-Home HIV test.

General and administrative expenses remained flat at $19.0 million in both 2012 and 2011.

All the above contributed to OSUR's operating loss of $13.4 million, which included non-cash charges of $3.5 million for depreciation and amortization expense and $5.0 million of stock-based compensation expense.

DNAG Segment

DNAG's gross margin increased to 68% in 2012 from 50% in the comparable period of 2011. DNAG's 2011 gross margin included the impact of an $852,000 non-cash purchase accounting adjustment to mark up the acquired finished goods inventory to fair value. Gross margin for 2012 also included $1.3 million of intangibles amortization expense compared to $499,000 recorded for the period August 17, 2011 through December 31, 2011.

DNAG incurred $12.6 million in operating expenses during 2012 compared to $4.7 million incurred in 2011 from the August 17, 2011 acquisition date through December 31, 2011. Expenses for 2012 included $2.8 million of research and development costs, $6.6 million of sales and marketing costs and $3.3 million of general and administrative costs. Expenses for the period August 17, 2011 through December 31, 2011 included $1.0 million of research and development costs, $2.3 million of sales and marketing costs and $1.4 million of general and administrative costs.

All of the above contributed to DNAG's 2012 operating loss of $2.9 million, which included non-cash charges of $3.7 million for depreciation and amortization expense and $189,000 of stock-based compensation expense.

CONSOLIDATED INCOME TAXES

As of December 31, 2012, we believed the full valuation allowance established in 2008 against OSUR's total U.S. net deferred tax asset was appropriate as the facts and circumstances necessitating the allowance had not changed. As a result, no U.S. income tax benefit was recorded for OraSure's pre-tax loss in 2012. A Canadian income tax benefit of $1.4 million was recorded in 2012 which was associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit in 2012 was negatively impacted by a $428,000 adjustment to DNAG's deferred tax liability recorded in the second quarter to reflect a change in the enacted Canadian provincial tax rates.

Liquidity and Capital Resources

	December 31,	
	2013	2012
	(In thousands)	
Cash	$ 93,191	$ 87,888
Working capital	100,590	103,483

Our cash increased $5.3 million to $93.2 million at December 31, 2013 from $87.9 million at December 31, 2012. Our working capital decreased to $100.6 million at December 31, 2013 from $103.5 million at December 31, 2012.

During 2013, we generated $8.4 million in cash from operating activities. Our net loss of $11.2 million and deferred income tax benefit of $772,000 were largely offset by non-cash stock-based compensation expense of $5.6 million and depreciation and amortization expense of $6.5 million. Included in our net loss in 2013 was an $8.3 million gain recorded for cash received as a settlement payment received from Roche Diagnostics for the termination of our assay collaboration agreement. Also contributing to the cash generated in operating activities was a $5.4 million increase in accrued expenses and other liabilities due to higher year-end accruals for management incentive bonuses and royalty obligations, a $4.3 million decrease in accounts receivable resulting from the collection of outstanding balances due at the end of 2012, a $1.5 million increase in accounts payable related to year-end inventory purchases and advertising and marketing services associated with our OraQuick® In-Home HIV test, and a $1.3 million decrease in inventory associated with our OraQuick® In-Home HIV test. Offsetting these increases to cash was a $4.4 million decrease in deferred revenue resulting from the recognition of previously deferred OraQuick® In-Home HIV test revenues and the realization of certain customer prepayments.

We used a total of $2.5 million in investing activities during 2013 to acquire property and equipment. During the year ended December 31, 2014, we expect to invest approximately $4.0 million in capital expenditures, primarily to purchase additional equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was $420,000 in 2013, which resulted from the use of $829,000 for the repurchase of common stock related to the vesting of restricted shares partially offset by $409,000 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 timing and amount of promotional costs for our products including our OraQuick® In-Home HIV test, 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 time and cost of obtaining regulatory approvals, 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 ongoing economic downturn and other factors.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations as of December 31, 2013 (in thousands) for future payments under contracts and other contingent commitments, for the year 2014 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2014**	**2015**	**2016**	**2017**	**2018**	**Thereafter**
Operating leases[1]	$ 853	$ 438	$ 409	$ 6	$—	$—	$ —
Employment contracts[2]	2,943	2,072	581	290	—	—	—
Purchase obligations[3]	3,685	3,685	—	—	—	—	—
Minimum commitments under contracts[4]	2,292	500	500	500	500	292	—
Total contractual obligations	$9,773	$6,695	$1,490	$796	$500	$292	$ —

1 Represents payments required under our operating leases. See Note 13 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 13 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 13 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 13 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, 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 estimates, 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 tests, 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 commercial 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 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 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 have 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 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. All of these allowances are estimates established by management, based on currently available information which 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.

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.

Customer Sales Returns and Allowances. We do not grant product return rights to our customers, 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 experience of sales 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, 2013, the reserve for sales returns and allowances was $279. If actual product returns differ materially from our reserve, 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 $299,000 as of December 31, 2013. 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.

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. In 2013 and 2012, we wrote-off inventory which had a cost of $1.3 million in each year. During 2011, we wrote-off inventory which had a cost of $919,000. These write-offs were as 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 $63.9 million, or 35% of our total assets, as of December 31, 2013. 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, 2013 will exceed their book value. We did not recognize any impairment losses for the years ended December 31, 2013 or 2012. 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 values of the applicable reporting units with their aggregate carrying values, 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 the respective carrying values.

We performed our annual impairment assessment as of July 31, 2013 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 amount. We performed our last quantitative impairment test for goodwill as of July 31, 2012 and determined there was no impairment. That quantitative assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of $25,179) by approximately 13%. 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, 2013, we had federal NOL carryforwards of $73.3 million. The net deferred tax assets, before the valuation allowance, associated with these NOLs and other temporary differences was $37.6 million at December 31, 2013. In assessing the realizability of net 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. net 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 net deferred tax asset in the immediate future. Each year, we continued 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 against our net deferred tax assets as of December 31, 2013 and 2012 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 years ended December 31, 2013, 2012 and 2011, we recorded a Canadian income tax benefit of $772,000, $1.4 million and $869,000, respectively, associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes in 2012 and 2011. 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, 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, 2013, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada and Europe, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency were 5.0% of our total consolidated net revenues for the year ended December 31, 2013. We expect our international business will continue to grow and our exposure to fluctuations in foreign currency exchange rates may increase.

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, 2013. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2013 the Company's disclosure controls and procedures were adequate and effective to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

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

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (1992)* 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, 2013.

The effectiveness of our internal control over financial reporting as of December 31, 2013 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, 2013 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, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* 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.

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, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* 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, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2013, and our report dated March 14, 2014 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2014

ITEM 9B. Other Information.

Not applicable.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2014 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, "Corporate Governance—Committees of the Board—Audit Committee," "Executive Officers," "Item 1—Election of Directors" 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 caption, "Executive 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 "Executive Compensation—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," "Corporate Governance—Director Independence" and "Corporate Governance—Committees of the Board," 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," Item 2—Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Consolidated Financial Statement Schedules.

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

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

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, 2014.

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, 2014, 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
*GERALD M. OSTROV Gerald M. Ostrov	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)

Index to Consolidated Financial Statements

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, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2013. 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, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2013, 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, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2014 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2014

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

	December 31, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash	$ 93,191	$ 87,888
Accounts receivable, net of allowance for doubtful accounts of $299 and $285	12,957	17,469
Inventories	11,444	12,758
Prepaid expenses	1,712	1,719
Deferred income taxes	71	—
Other current assets	200	283
Total current assets	119,575	120,117
PROPERTY AND EQUIPMENT, net	17,933	18,546
INTANGIBLE ASSETS, net	22,226	27,207
GOODWILL	23,782	25,445
OTHER ASSETS	729	124
	$ 184,245	$ 191,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,834	$ 3,380
Deferred revenue	1,119	5,504
Accrued expenses	13,032	7,750
Total current liabilities	18,985	16,634
OTHER LIABILITIES	677	89
DEFERRED INCOME TAXES	3,437	4,401
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 55,632 and 55,281 shares issued and outstanding	—	—
Additional paid-in capital	338,674	333,522
Accumulated other comprehensive loss	(3,797)	(666)
Accumulated deficit	(173,731)	(162,541)
Total stockholders' equity	161,146	170,315
	$ 184,245	$ 191,439

See accompanying notes to the consolidated financial statements.

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

	For the years ended December 31,		
	2013	2012	2011
NET REVENUES:			
Product	$ 98,317	$ 85,753	$80,683
Licensing and product development	623	2,067	1,198
	98,940	87,820	81,881
COST OF PRODUCTS SOLD	40,351	32,249	30,164
Gross profit	58,589	55,571	51,717
OPERATING EXPENSES:			
Research and development	10,932	12,445	18,406
Sales and marketing	46,465	37,087	22,383
General and administrative	21,654	22,309	20,325
Gain on contract termination settlement	(8,300)	—	—
	70,751	71,841	61,114
Operating loss	(12,162)	(16,270)	(9,397)
INTEREST EXPENSE	—	(172)	(316)
OTHER INCOME (EXPENSE)	200	(70)	3
Loss before income taxes	(11,962)	(16,512)	(9,710)
INCOME TAX BENEFIT	(772)	(1,397)	(869)
NET LOSS	$(11,190)	$(15,115)	$ (8,841)
LOSS PER SHARE:			
BASIC	$ (0.20)	$ (0.29)	$ (0.19)
DILUTED	$ (0.20)	$ (0.29)	$ (0.19)
SHARES USED IN COMPUTING LOSS PER SHARE:			
BASIC	55,555	51,457	46,908
DILUTED	55,555	51,457	46,908

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	For the years ended December 31,		
	2013	2012	2011
NET LOSS	$(11,190)	$(15,115)	$ (8,841)
OTHER COMPEHENSIVE INCOME (LOSS)			
Currency translation adjustments	(3,131)	1,298	(1,729)
Other comprehensive income (loss)	(3,131)	1,298	(1,729)
COMPREHENSIVE LOSS	$(14,321)	$(13,817)	$(10,570)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2013, 2012 and 2011
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2011	46,226	$ —	$ 241,663	$ (235)	$ (138,585)	$ 102,843
Common stock issued upon exercise of options	880	—	4,783	—	—	4,783
Vesting of restricted stock	421	—	—	—	—	—
Purchase and retirement of treasury shares	(134)	—	(909)	—	—	(909)
Compensation cost for restricted stock	—	—	2,521	—	—	2,521
Compensation cost for stock option grants	—	—	1,582	—	—	1,582
Net loss	—	—	—	—	(8,841)	(8,841)
Currency translation adjustments	—	—	—	(1,729)	—	(1,729)
Balance at December 31, 2011	47,393	—	249,640	(1,964)	(147,426)	100,250
Common stock issued upon exercise of options	1,476	—	10,040	—	—	10,040
Vesting of restricted stock	454	—	—	—	—	—
Issuance of common stock for public equity offering	6,100		70,246	—	—	70,246
Purchase and retirement of treasury shares	(142)	—	(1,560)	—	—	(1,560)
Compensation cost for restricted stock	—	—	2,894	—	—	2,894
Compensation cost for stock option grants	—	—	2,262	—	—	2,262
Net loss	—	—		—	(15,115)	(15,115)
Currency translation adjustments	—	—	—	1,298	—	1,298
Balance at December 31, 2012	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 treasury 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	$ 0	$ 338,674	$ (3,797)	$ (173,731)	$ 161,146

See accompanying notes to the consolidated financial statements

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31		
	2013	2012	2011
OPERATING ACTIVITIES:			
Net loss	$(11,190)	$(15,115)	$ (8,841)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation	5,572	5,197	4,100
Depreciation and amortization	6,552	7,250	4,891
Deferred income taxes	(772)	(1,397)	(868)
Inventory purchase accounting step-up adjustment	—	16	852
Changes in assets and liabilities			
Accounts receivable	4,337	(220)	(3,377)
Inventories	1,268	(3,139)	(1,757)
Prepaid expenses and other assets	51	(99)	491
Accounts payable	1,510	(791)	911
Deferred revenue	(4,365)	4,178	112
Accrued expenses and other liabilities	5,422	(1,253)	492
Net cash provided by (used in) operating activities	8,385	(5,373)	(2,994)
INVESTING ACTIVITIES:			
Proceeds from maturities and redemptions of short-term investments	—	—	1,895
Acquisition of DNA Genotek Inc., net of cash acquired	—	—	(49,730)
Purchases of property and equipment	(2,462)	(2,019)	(2,505)
Net cash used in investing activities	(2,462)	(2,019)	(50,340)
FINANCING ACTIVITIES:			
Repayments of long-term debt	—	(7,292)	(500)
Proceeds from the issuance of common stock, net of expenses	—	70,246	—
Proceeds from exercise of stock options	409	10,040	4,783
Repurchase of common stock	(829)	(1,560)	(909)
Net cash (used in) provided by financing activities	(420)	71,434	3,374
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(200)	(32)	(5)
NET INCREASE (DECREASE) IN CASH	5,303	64,010	(49,965)
CASH, BEGINNING OF PERIOD	87,888	23,878	73,843
CASH, END OF PERIOD	$ 93,191	$ 87,888	$ 23,878

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts, unless otherwise indicated)

1. THE COMPANY:

We manufacture and market oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid 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 and tests that are processed in a laboratory. In September 2012, we began selling our OraQuick® In-Home HIV test, the first and only 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 testing, academic research, pharmacogenomics, personalized medicine, 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, and commercial and industrial entities. Our OTC HIV and cryosurgical products are sold to retail pharmacies and mass merchandisers, and to consumers over the internet.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of OraSure and its wholly-owned subsidiary, DNA Genotek Inc. ("DNAG" and, collectively with OraSure, the "Company"). All intercompany transactions and balances have been eliminated. Certain amounts have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies and accruals, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity and foreign currency markets, reductions in government funding, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Supplemental Cash Flow Information

On July 30, 2012, we repaid the balance of our long-term debt so we paid no interest during 2013. In 2012 and 2011, we paid interest of $199 and $318, respectively.

In 2013, we paid state income taxes of $27. In 2012, we paid foreign and state income taxes of $22. In 2011, we received a refund of $15 for federal and state income taxes, net of state taxes paid.

In 2013, 2012 and 2011, we recorded through the consolidated statements of operations an increase in our allowance for doubtful accounts of $18, $115 and $64, respectively.

Accounts Receivable

Accounts receivable have been reduced by an estimated allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as they become past due, the financial condition of our customers and our historical experience related to write-offs.

Inventories

Inventories are stated at the lower of cost or 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 factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. In addition to reserving for these items identified through specific identification procedures, we also reserve for unidentified scrap or spoilage under a fixed-formula methodology.

Property and Equipment

Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statement of operations.

Intangible Assets

Intangible assets consist of a customer list, patents and product rights, acquired technology, tradenames and non-compete agreements. Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. The customer list, acquired technology, tradenames and non-compete agreements were all part of our acquisition of DNAG in August 2011. Intangible assets are amortized using the straight-line method over their estimated useful lives of one to fifteen years.

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 values of the

applicable reporting units with their aggregate carrying values, 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 the respective carrying values.

We performed our annual impairment assessment as of July 31, 2013 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 amount. We performed our last quantitative impairment test for goodwill as of July 31, 2012 and determined there was no impairment. That quantitative assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of $25,179), of approximately 13%. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. As of December 31, 2013, we believe no indicators of impairment exist.

Impairment of Long-Lived Assets

We assess the recoverability of the affected long-lived assets, which include property and equipment and intangible assets, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows from the use and eventual disposition of the asset. If indicators of impairment exist, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets.

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 tests, 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 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 have 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. All of these allowances are estimates established by management, based on 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.

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.

Customer Sales Returns and Allowances

We do not grant product return rights to our customers, 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 experience of sales 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, 2013, the reserve for sales returns and allowances was $279. 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.

Deferred Revenue

We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue at December 31, 2013 and 2012 included customer prepayments of $1,119 and $1,880, respectively. As of December 31, 2012, it also included $3,700 related to OraQuick® In-Home HIV tests, representing the value of product held by those retailers or distributors having product return rights. As previously discussed, in December 2013 we recognized all of the previously deferred revenue related to our OraQuick® In-Home HIV test.

Customer and Vendor Concentrations

We had no significant concentrations (greater than 10%) in accounts receivable as of December 31, 2013. As of December 31, 2012, one of our customers, CVS Distribution, Inc., accounted for approximately 11% of our accounts receivable balance. We had no significant concentrations (greater than 10%) in revenues for the years ended December 31, 2013, 2012 or 2011.

We currently purchase certain products and critical components of our products from sole-supply vendors, and if these vendors are unable or unwilling to supply the required components and products, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development costs are charged to expense as incurred. Clinical trial expenses include costs associated with contract research organizations, or CROs. The invoicing from CROs can precede the services provided or can lag the service period by several months. Invoices paid prior to services being provided are recorded as a prepaid expense and then expensed appropriately as services are provided. We accrue the cost of services rendered but unbilled by CROs based on purchase order estimates provided by the CROs. Differences between actual and estimated clinical trial expenses recorded are generally not material and are adjusted for in the period in which they become known.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2013, 2012, and 2011, we incurred $17,142, $6,310, and $130, respectively, in advertising expenses. 2013 and 2012 expenses include costs associated with our OraQuick® In-Home HIV test which we began selling in the consumer retail market in the fourth quarter of 2012.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the fair value method. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue restricted stock, we issue new shares rather than purchase shares on the open market.

Income Taxes

We follow the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax basis of assets and liabilities, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates for the respective taxing jurisdiction that are expected to apply to taxable income in the years in which those temporary differences and operating loss and credit carryforwards are expected to be recovered, settled or utilized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We assess the realizability of our net deferred tax assets on a quarterly basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, we reduce our net deferred tax assets by a valuation allowance. The realization of the net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of our net operating loss carryforwards.

Foreign Currency Translation

The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in income in the period in which the change occurs.

Loss Per Share

Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. Common stock options and unvested restricted stock totaling 5,924, 5,314, and 6,296 shares were outstanding as of December 31, 2013, 2012 and 2011, respectively. As a result of our net losses for the years ended December 31, 2013, 2012 and 2011, these shares were excluded from the respective period's computation of diluted loss per share, as their inclusion would have been anti-dilutive.

Accumulated Other Comprehensive Loss

We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our balance sheet.

Our accumulated other comprehensive loss for 2013, 2012, and 2011 consisted of foreign currency translation adjustments.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. The ($3,131), $1,298 and ($1,729) currency translation adjustments recorded in 2013, 2012 and 2011, respectively, are largely the result of the translation of our Canadian operation's financial statements into U.S. dollars.

Fair Value of Financial Instruments

As of December 31, 2013 and 2012, the carrying values of cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1:	Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
Level 2:	Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
Level 3:	Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

We offer a nonqualified deferred compensation plan for highly compensated employees. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of December 31, 2013 and 2012 was $677 and $89, respectively, and was calculated using the quoted market price of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments.

3. BUSINESS COMBINATION:

On August 17, 2011 (the "Acquisition Date"), we acquired all of the outstanding capital stock of DNAG, pursuant to the terms of a Support Agreement dated July 25, 2011. The purchase price was $49,750 CDN ($50,467 in U.S. dollars at the Acquisition Date exchange rate) and was funded by OraSure with cash on hand. The purchase price consisted of $50,000 CDN ($50,710 million in U.S. dollars at the Acquisition Date exchange rate) less a $250 CDN ($254 U.S. dollars) working capital adjustment received in the fourth quarter of 2011. Of the original $50,000 CDN purchase price, $5,000 CDN (or $5,071 in U.S. dollars at the Acquisition Date exchange rate) was deposited in escrow pursuant to the related support agreement. The payment for the working capital adjustment was funded from the escrow account. Subject to certain adjustments and the processing of any indemnification claims, $1.9 million CDN was released from the escrow fund to the seller in February 2013 with the balance released in February 2014.

We have accounted for the acquisition of DNAG using the acquisition method of accounting. Under the acquisition method of accounting, the total purchase price is allocated to the tangible and identifiable intangible assets acquired and the liabilities assumed based upon their estimated fair values as of the Acquisition Date. The excess of the fair value of the consideration paid over the estimated fair value of the assets acquired and liabilities assumed was recorded as goodwill. For purposes of the purchase price allocation, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an

orderly transaction between market participants. The fair value guidance also requires that the fair value measurements reflect the assumptions market participants use in pricing an asset or liability based upon the best information available. Under the acquisition method of accounting, acquisition related transaction costs, such as success-based banking fees and professional fees, are not included as a component of consideration transferred, but rather are accounted for as expenses in the periods in which the costs are incurred.

During 2011, we incurred a total of $2,634 of acquisition related costs, including success-based investment banking fees and accounting, legal and other professional fees, related to the DNAG acquisition, all of which were expensed and included in general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2011.

The following table summarizes the allocation of the fair values of the assets acquired and the liabilities assumed at the Acquisition Date:

Current assets	$ 3,734
Property, plant and equipment	715
Other assets	760
Intangible assets	28,502
Goodwill	25,619
Total assets acquired	59,330
Current liabilities	(1,388)
Deferred tax liability	(7,475)
Total liabilities assumed	(8,863)
Purchase price	50,467
Less cash acquired	(737)
Net cash paid	$49,730

Included in the current assets acquired in the DNAG acquisition was inventory having an estimated fair value of $1,413. This fair value includes an $892 “step-up” adjustment to capitalize the estimated manufacturing profit in acquired finished goods inventory as of the Acquisition Date, of which we expensed $16 and $852 to cost of products sold during the years ended December 31, 2012 and 2011, respectively.

The results of operations associated with DNAG have been consolidated with those of the Company since the Acquisition Date. Total revenues of $6,216 and a net loss of $693, including $852 of inventory step-up as noted above, attributable to DNAG were recognized in the consolidated statement of operations for the year ended December 31, 2011.

The following unaudited condensed consolidated pro forma information sets forth the revenues, net loss and net loss per share of the Company for the year ended December 31, 2011, as if the acquisition had occurred on January 1, 2010. The unaudited pro forma information presented below is not necessarily indicative of the results that would have been attained had the transaction occurred at an earlier date, nor are these results necessarily indicative of future consolidated results of operations of the Company.

Total revenues	$ 89,966
Net loss	(10,911)
Loss per share:	
Basic and diluted	$ (0.23)

The supplemental pro forma results for the year ended December 31, 2011 exclude $2,634 of transaction costs incurred by OraSure that were recorded in operating expenses.

4. INVENTORIES:

	December 31, 2013	December 31, 2012
Raw materials	$ 6,700	$ 6,777
Work in process	833	393
Finished goods	3,911	5,588
	$11,444	$12,758

5. PROPERTY AND EQUIPMENT:

	December 31, 2013	December 31, 2012
Land	$ 1,118	$ 1,118
Buildings and improvements	16,977	16,589
Machinery and equipment	19,199	18,423
Computer equipment and software	6,443	5,989
Furniture and fixtures	1,731	1,692
Construction in progress	855	581
	46,323	44,392
Less accumulated depreciation	(28,390)	(25,846)
	$ 17,933	$ 18,546

Depreciation expense was $3,026, $3,347, and $2,934 for 2013, 2012, and 2011, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS:

The changes in goodwill are as follows:

	December 31, 2013	December 31, 2012
Balance as of January 1	$25,445	$24,740
Increase (decrease) related to foreign currency translation	(1,663)	705
Balance as of December 31	$23,782	$25,445

Intangible assets consist of the following:

	Amortization Period (Years)	December 31, 2013 Gross	Accumulated Amortization	Net
Customer list	10	$11,795	$ (2,701)	$ 9,094
Patents and product rights	3-10	10,449	(7,466)	2,983
Acquired technology	7	9,162	(2,952)	6,210
Tradename	15	4,521	(715)	3,806
Non-compete agreements	1-3	787	(654)	133
		$36,714	$ (14,488)	$22,226

	Amortization Period (Years)	December 31, 2012 Gross	Accumulated Amortization	Net
Customer list	10	$12,619	$ (1,673)	$10,946
Patents and product rights	3-10	10,449	(6,926)	3,523
Acquired technology	7	9,802	(1,829)	7,973
Tradename	15	4,837	(443)	4,394
Non-compete agreements	1-3	842	(471)	371
		$38,549	$ (11,342)	$27,207

Patents and products rights are made up of the following:

	December 31, 2013	2012
HIV-related	$ 1,900	$ 1,900
HCV-related	4,500	4,500
Lateral flow-related	1,500	1,500
Cryosurgery-related	2,549	2,549
	10,449	10,449
Less accumulated amortization	(7,466)	(6,926)
	$ 2,983	$ 3,523

Amortization expense for 2013, 2012, and 2011 was $3,526, $3,903, and $1,957, respectively.

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

2014	$3,394
2015	3,216
2016	3,216
2017	3,216
2018	3,212
Beyond	5,972

7. ACCRUED EXPENSES:

	December 31, 2013	2012
Payroll and related benefits	$ 5,827	$4,248
Royalties	4,374	1,948
Professional fees	749	413
Other	2,082	1,141
	$13,032	$7,750

8. LONG-TERM DEBT:

As of December 31, 2011, we had in place a $10,000,000 credit facility (the "Credit Facility"), as amended, with Comerica Bank ("Comerica"). Pursuant to the terms of the Credit Facility, principal and interest fixed at 4.15% per annum were payable monthly through August 27, 2012, at which time the remaining unpaid principal balance was payable. On July 30, 2012, we repaid the $7,042 principal balance outstanding under the Credit Facility and it was terminated.

9. INCOME TAXES:

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

	Years Ended December 31,		
	2013	2012	2011
United States	$(12,833)	$(13,515)	$(8,147)
Canada	871	(2,997)	(1,563)
	$(11,962)	$(16,512)	$(9,710)

The components of the income tax benefit for the years ended December 31, 2013, 2012 and 2011 are as follows:

	2013	2012	2011
Deferred			
Federal	$(4,280)	$(4,370)	$(2,674)
State	(323)	(272)	(273)
Canada	(772)	(1,397)	(869)
	(5,375)	(6,039)	(3,816)
Increase in valuation allowance	4,603	4,642	2,947
Total income tax benefit	$ (772)	$(1,397)	$ (869)

For the years ended December 31, 2013, 2012 and 2011, we recorded a foreign deferred tax benefit of $772, $1,397 and $869, respectively, associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes in 2012 and 2011. The income tax benefit associated with DNAG was considered realizable based upon the estimated scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG. The deferred tax benefit for the year ended December 31, 2012 was negatively impacted by a $428 adjustment to DNAG's deferred tax liability recorded in the second quarter of 2012 to reflect a change in the enacted Canadian provincial tax rates.

A reconciliation of the statutory United States federal income tax rate to our effective tax rate for each of the years ended December 31, 2013, 2012, and 2011 is as follows:

	2013	2012	2011
Statutory U.S. federal income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(1.6)	(1.2)	(1.9)
Canadian income taxes	(6.5)	(8.5)	(8.9)
Nondeductible expenses and other	(0.4)	1.0	5.3
U.S. research and development credits	—	(0.3)	(5.7)
Change in valuation allowance, federal and state	36.0	34.5	36.3
Effective tax rate	(6.5)%	(8.5)%	(8.9)%

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting purposes and tax purposes, and net operating loss and tax credit carryforwards. Significant components of our deferred tax assets (liabilities) as of December 31, 2013 and 2012 are as follows:

	2013	2012
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 25,751	$ 21,207
Inventories	1,531	1,781
Capitalized research and development costs	5,276	6,148
Accruals and reserves currently not deductible	2,048	1,205
Patent costs	865	1,202
Acquired intangible assets	(5,099)	(6,278)
Depreciation and amortization	(751)	(744)
Stock-based compensation	4,704	4,176
Investment tax credit carryforward	1,230	918
Research and development tax credit carryforward	2,076	2,378
Net deferred tax asset	37,631	31,993
Valuation allowance	(40,997)	(36,394)
Net deferred tax liability	$ (3,366)	$ (4,401)

In assessing the realizability of our net deferred tax asset, we consider all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOL carryforwards. In 2008, we established a full valuation allowance against our U.S. net deferred tax asset, and management believes the full valuation allowance is still appropriate as of December 31, 2013 and 2012 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state income tax benefit was recorded for the years ended December 31, 2013, 2012, or 2011.

Our Federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2018 - 2019	$16,377
2020 - 2024	16,398
2025 - 2031	14,476
2032 - 2033	26,030
	$73,281

The Tax Reform Act of 1986 contains provisions that limit the annual amount of NOLs available to be used in any given year in the event of a significant change in ownership. On September 29, 2000, two separate companies, STC Technologies, Inc. and Epitope, Inc., merged to form OraSure. A significant change in ownership, as defined by Section 382 of the Internal Revenue Code, occurred in connection with this merger. As such, the utilization of NOLs generated prior to September 29, 2000 is limited to approximately $13,700 per year. We do not believe that this limitation will have a material adverse impact on the utilization of our Federal NOL carryforwards in future years.

As of December 31, 2013, our gross unrecognized tax benefits totaled $2,051 and based upon the valuation allowance for our U.S. operations, the recognition of any tax benefit would not impact our effective tax rate.

We record interest and penalties related to unrecognized tax benefits as a component of income tax expense. Interest and penalties were immaterial in 2013, 2012 and 2011. As a result of our net operating loss carryforward position, we are subject to audit by the Internal Revenue Service since our inception, as well as by several state jurisdictions for the years ended December 31, 2001 through 2013.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2013	2012	2011
Balance as of January 1	$2,011	$2,015	$2,090
Additions based on tax positions related to the current period	—	—	53
Additions for tax positions of prior periods	40	67	19
Reductions for tax positions of prior periods	—	(71)	(147)
Balance as of December 31	$2,051	$2,011	$2,015

10. STOCKHOLDERS' EQUITY:

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue restricted stock, we normally issue new shares rather than purchase shares on the open market.

Under the terms of the Stock Plan, nonqualified options may be granted to eligible employees, including our officers at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may be either unlimited or have a specified period in which to vest and be exercised. To date, options generally have been granted with ten-year exercise periods and an exercise price not less than the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years.

As of December 31, 2013, 2,019 shares were available for future grants under the Stock Plan.

The fair value of each stock option was estimated on the date of the grant using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Years Ended December 31,		
Black-Scholes Option Valuation Assumptions	2013	2012	2011
Risk-free interest rate(1)	1.47%	0.99%	1.36%
Expected dividend yield	—	—	—
Expected stock price volatility(2)	51%	52%	54%
Expected life of stock options (in years)(2)	7	6	4

(1) Based on the constant maturity interest rate of U.S. Treasury securities whose term is consistent with the expected life of our stock options.
(2) Based upon historical experience.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2013, 2012 and 2011 was $3.58, $5.38 and $2.82, respectively.

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

	Years Ended December 31,		
	2013	2012	2011
Total compensation cost during the year	$2,694	$2,262	$1,579
Amounts capitalized into inventory during the year	(128)	(90)	(58)
Amounts recognized in cost of products sold for amounts previously capitalized	99	58	36
Amounts charged against income	$2,665	$2,230	$1,557

The aggregate intrinsic value of options exercised during the years ended December 31, 2013, 2012 and 2011 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $125, $6,961, and $2,490, respectively.

The following table summarizes the stock option activity under the Stock Plan:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding on January 1, 2011	5,504	$ 6.83		
Granted	1,143	6.78		
Exercised	(880)	5.44		
Expired	(163)	10.74		
Forfeited	(188)	8.11		
Outstanding on December 31, 2011	5,416	6.89		
Granted	783	11.18		
Exercised	(1,476)	6.80		
Expired	(12)	6.07		
Forfeited	(67)	7.49		
Outstanding on December 31, 2012	4,644	7.64		
Granted	984	6.94		
Exercised	(80)	5.07		
Expired	(82)	7.59		
Forfeited	(195)	7.87		
Outstanding on December 31, 2013	5,271	$ 7.54	6.0	$ 1,595
Vested or expected to vest as of December 31, 2013	5,152	$ 7.54	6.0	$ 1,591
Exercisable on December 31, 2013	3,705	$ 7.39	5.0	$ 1,555

As of December 31, 2013, there was $5,141 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.5 years.

Net cash proceeds from the exercise of stock options were $409, $10,040 and $4,783 for the years ended December 31, 2013, 2012 and 2011, respectively. As a result of our net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises for these periods.

The following table summarizes information about stock options outstanding as of December 31, 2013:

	Options outstanding			Options exercisable	
Range of exercise prices	Number Outstanding	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Exercise Price Per Share	Number Exercisable	Weighted-Average Exercise Price Per Share
$2.55 - $5.19	860	8.2	$ 4.47	846	$ 4.46
$5.60 - $6.37	396	4.9	5.79	279	5.73
$6.63	704	6.9	6.63	506	6.63
$6.67	1	4.2	6.67	1	6.67
$7.05	809	9.0	7.05	—	—
$7.33 - $8.20	833	3.0	8.00	773	8.05
$8.21 - $9.04	567	3.4	8.53	562	8.53
$9.05 - $10.99	415	2.0	9.63	411	9.62
$11.30	684	7.9	11.30	325	11.30
$12.14	2	4.6	12.14	2	12.14
	5,271	6.0	$ 7.54	3,705	$ 7.39

The Stock Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers, and our outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. Compensation cost of $2,878, $2,894 and $2,521 related to restricted shares was recognized during the years ended December 31, 2013, 2012 and 2011, respectively.

The following table summarizes restricted stock award activity under the Stock Plan:

	Shares	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2011	792	$ 5.28
Granted	527	6.53
Vested	(422)	5.47
Forfeited	(18)	6.63
Issued and unvested, December 31, 2011	879	5.91
Granted	259	11.31
Vested	(454)	5.56
Forfeited	(14)	7.77
Issued and unvested, December 31, 2012	670	8.19
Granted	438	6.30
Vested	(395)	7.81
Forfeited	(60)	8.27
Issued and unvested, December 31, 2013	653	$ 7.15
Issued and expected to vest, December 31, 2013	653	$ 7.15

As of December 31, 2013, there was $2,403 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 1.5 years.

In connection with the vesting of restricted shares during the years ended December 31, 2013, 2012 and 2011, we purchased and immediately retired 124, 142 and 134 shares with aggregate values of $829, $1,560 and $909, respectively, in satisfaction of minimum tax withholding obligations.

Share Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired in 2013, 2012 or 2011.

Public Equity Offering

On July 11, 2012, we completed a public offering of 6,100 common shares, at a price of $12.30 per share, raising $75,030 before expenses of the offering. In connection with the offering, we paid $4,502 in underwriting discounts and commissions and incurred $282 in additional offering expenses.

11. TERMINATION SETTLEMENT:

On November 21, 2013, we terminated our assay collaboration agreement with Roche Diagnostics (“Roche”). Pursuant to this termination agreement, Roche paid us $8,300 which was recorded as a reduction of operating expense on our consolidated statement of operations. Roche agreed to provide certain transitional product support services to us and will continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We have the right to stop the supply of assays prior to the end of this five-year period and could receive an additional payment from Roche of up to $5.5 million depending on how early in that five-year period the supply authorization is ended.

12. BUSINESS SEGMENT INFORMATION:

We operate our business within two reportable segments: our “OSUR” business, which consists of the development, manufacture and sale of oral fluid diagnostic products and specimen collection devices and the manufacture and sale of medical devices used for the removal of benign skin lesions by cryosurgery; and our molecular collection systems or “DNAG” business, which consists primarily of the manufacture, development and sale of oral fluid collection devices that are used to collect, stabilize and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold in 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. Revenues from OSUR’s OTC products primarily result from sales to retail pharmacies and mass merchandisers and to consumers over the internet. OSUR also derives revenues from licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal and livestock genetic testing, as well as products sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income (loss). We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues.

The following table summarizes segment information for the years ended December 31, 2013, 2012, and 2011:

	Years Ended December 31,		
	2013	2012	2011
Net revenues:			
OSUR	$ 78,559	$ 73,562	$75,665
DNAG	20,381	14,258	6,216
Total	$ 98,940	$ 87,820	$81,881
Operating income (loss):			
OSUR	$(12,849)	$(13,395)	$ (7,855)
DNAG	687	(2,875)	(1,542)
Total	$(12,162)	$(16,270)	$ (9,397)
Depreciation and amortization:			
OSUR	$ 3,225	$ 3,530	$ 3,550
DNAG	3,327	3,720	1,341
Total	$ 6,552	$ 7,250	$ 4,891
Capital expenditures:			
OSUR	$ 1,687	$ 1,794	$ 2,345
DNAG	775	225	160
Total	$ 2,462	$ 2,019	$ 2,505

	December 31,	
	2013	2012
Total assets:		
OSUR	$130,848	$137,258
DNAG	53,397	54,181
Total	$184,245	$191,439

Our products are sold principally in the United States, Canada and Europe.

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

	For the Years Ended December 31,		
	2013	2012	2011
United States	$77,194	$67,460	$67,644
Europe	11,081	10,131	7,506
Other regions	10,665	10,229	6,731
	$98,940	$87,820	$81,881

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

	December 31, 2013	December 31, 2012
United States	$16,925	$17,868
Canada	975	589
Other regions	33	89
	$17,933	$18,546

13. COMMITMENTS AND CONTINGENCIES:

Sublicense Agreement

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. Under the terms of this sublicense agreement, we are obligated to pay royalties based on a percentage of our net sales of certain products, which incorporate the technology covered by the licensed patents. Royalties are expensed as an element of cost of goods sold. Future minimum payments under this agreement are as follows:

2014	$ 500
2015	500
2016	500
2017	500
2018	292
	$2,292

Royalties from our commercial sale of products covered by the sublicense can be credited against these minimum royalty obligations.

Leases

We lease office space for our Canadian subsidiary and domestic warehouse facilities under operating lease agreements. Future payments required under these non-cancelable leases are as follows:

2014	$438
2015	409
2016	6
	$853

Rent expense for 2013, 2012 and 2011 was $600, $510, and $307, respectively.

Purchase Commitments

As of December 31, 2013, we had outstanding non-cancelable purchase commitments in the amount of $3,685 related to inventory, capital expenditures, and other goods or services.

Employment Agreements

Under terms of employment agreements with certain executive officers, which extend through 2016, we are required to pay each individual a base salary for continuing employment with us. The agreements require payments totaling $2,072, $581, and $290 in 2014, 2015, and 2016, respectively.

Litigation

From time-to-time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, based upon the advice of counsel, the outcomes of such actions are not expected to have a material adverse effect on our future financial position or results of operations.

14. RETIREMENT PLANS:

Substantially all of our U.S. employees are eligible to participate in the OraSure Technologies, Inc. 401(k) Plan (the "401(k) Plan"). The 401(k) Plan permits voluntary employee contributions to be excluded from an employee's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The 401(k) Plan also provides for us to match employee contributions up to $4 per year. Contributions to the 401(k) Plan, net of forfeitures, were $553, $592, and $533 in 2013, 2012, and 2011, respectively.

In addition to our 401(k) plan, we offer a nonqualified deferred compensation plan to permit eligible highly compensated employees of the Company to defer receipt and taxation of their compensation each year. We also may make discretionary contributions to the accounts of the participating employees in any amount either in cash or stock. Participants in the plan may not purchase OraSure stock as an investment vehicle. As of December 31, 2013 and 2012, the value of the assets associated with this plan was $677 and $89, respectively, and is included in other assets in our consolidated balance sheet. Our obligation related to the deferred compensation plan is included in other liabilities in our consolidated balance sheet. As of December 31, 2013 and 2012, our total obligation under this plan was $677 and $89, respectively.

Effective January 2, 2012, all regular full-time employees of DNAG are eligible to participate in the DNA Genotek Registered Retirement Savings Plan (the "RRSP"). The RRSP permits voluntary employee contributions to be excluded from an employee's current taxable income and receive tax preferred treatment with Revenue Canada. The RRSP also provides for DNAG to match employee contributions up to $2 per year. Contributions to the RRSP were $126 and $113 in 2013 and 2012, respectively.

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2013 and 2012. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein.

	2013 Results			
	Three months ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Net revenues	$ 21,164	$24,337	$ 24,671	$ 28,768 (1)
Costs and expenses	31,753	29,913	26,731	22,705 (2)
Operating income (loss)	(10,589)	(5,576)	(2,060)	6,063
Other income (expense), net	(47)	42	41	164
Income (loss) before income taxes	(10,636)	(5,534)	(2,019)	6,227
Income tax expense (benefit)	(410)	(249)	(127)	14
Net income (loss)	$(10,226)	$ (5,285)	$ (1,892)	$ 6,213
Earnings (loss) per share				
Basic	$ (0.18)	$ (0.10)	$ (0.03)	$ 0.11
Diluted	$ (0.18)	$ (0.10)	$ (0.03)	$ 0.11

(1) 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 tests.

(2) Includes an $8.3 million gain from the termination of the Company's oral fluid assay collaboration with Roche Diagnostics, which was recorded as a reduction of operating expenses in the current period.

	2012 Results			
	Three months ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Net revenues	$ 20,944	$22,616	$ 22,115	$ 22,145
Costs and expenses	24,596	26,156	25,043	28,295
Operating loss	(3,652)	(3,540)	(2,928)	(6,150)
Other income (expense), net	(120)	(113)	(35)	26
Loss before income taxes	(3,772)	(3,653)	(2,963)	(6,124)
Income tax benefit	(521)	(91)	(527)	(258)
Net loss	$ (3,251)	$ (3,562)	$ (2,436)	$ (5,866)
Loss per share				
Basic	$ (0.07)	$ (0.07)	$ (0.04)	$ (0.11)
Diluted	$ (0.07)	$ (0.07)	$ (0.04)	$ (0.11)

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INDEX TO EXHIBITS

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of OraSure Technologies, Inc. is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.2	Bylaws of OraSure Technologies, Inc., amended and restated as of August 18, 2008, are incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed August 22, 2008.
10.1	Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.*
10.2	Employment Agreement, dated as of June 22, 2004, between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.3	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Douglas A. Michels, is incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 19, 2008.*
10.4	Amendment No. 2 to Employment Agreement, dated as of December 15, 2010, between the Company and Douglas A. Michels, is incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.5	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Ronald H. Spair, is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.6	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Ronald H. Spair, is incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 19, 2008.*
10.7	Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Ronald H. Spair, is incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.8	Employment Agreement, dated September 23, 2005, between OraSure Technologies, Inc. and Stephen R. Lee, Ph.D., is incorporated herein by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed September 28, 2005.*
10.9	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Stephen R. Lee, Ph.D., is incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed December 19, 2008.*
10.10	Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Stephen R. Lee, Ph.D., is incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.11	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Jack E. Jerrett, is incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.12	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed December 19, 2008.*

Exhibit Number	Exhibit
10.13	Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.14	Employment Agreement, dated as of October 2, 2006, between Mark L. Kuna and OraSure Technologies, Inc., is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed October 5, 2006.*
10.15	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Mark L. Kuna, is incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed December 19, 2008.*
10.16	Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Mark L. Kuna, is incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.17	Employment Agreement, dated as of January 3, 2011, between the Company and Anthony Zezzo II is incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
10.18	Description of Non-Employee Director Compensation Policy, as amended as of November 14, 2011, is incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.19	Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.*
10.20	OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.21	Amended and Restated OraSure Technologies, Inc. Stock Award Plan, effective as of February 12, 2013 is incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012.*
10.22	Form of Restricted Share Grant Agreement (Executive Officers) is incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.23	Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.24	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.25	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.26	Description of the OraSure Technologies, Inc. 2013 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed April 16, 2013.*
10.27	Description of Long-Term Incentive Plan, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed April 16, 2013.*
10.28	OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed December 21, 2011.*

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Exhibit Number	Exhibit
10.28	Adoption Agreement related to OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed December 21, 2011.*
10.29	Settlement Agreement, effective as of November 17, 2009, by and among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
10.30	License Agreement, effective as of November 17, 2009, by and among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
10.32	Settlement and Restated Supply Agreement, dated as of November 18, 2013, between F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH, Roche Diagnostics Operations, Inc. and OraSure Technologies, Inc.**
21	Subsidiaries of the Registrant.
23	Consent of KPMG LLP.
24	Powers of Attorney.
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase document

* Management contract or compensatory plan or arrangement.

** Portions of this exhibit were omitted pursuant to an application for confidential treatment and filed separately with the Securities and Exchange Commission.

CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. SUCH OMISSIONS DENOTED WITH [***].

SETTLEMENT AND RESTATED SUPPLY AGREEMENT

between

F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel
Switzerland
– "FHLR" –

Roche Diagnostics GmbH
Sandhofer Strasse 116
68161 Mannheim
Germany
– "RDG" –

Roche Diagnostics Operations, Inc.
Hague Road
Indianapolis, IN
USA
– "RDO" –

FHLR, RDG and RDO collectively referred to as "Roche"

And

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
U.S.A.

– "OraSure" –

Dated as of November 18, 2013 (the "**Effective Date**"). OraSure, FHLR, RDG and RDO are referred to herein separately as a "**Party**" and collectively as the "**Parties**."

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WHEREAS, OraSure and RDO, RDG and FHLR entered into a Joint Development and Cross-License Agreement, dated August 14, 2008 (the "**Development Agreement**"), and OraSure and FHLR entered into a Commercialization and Supply Agreement, dated as of December 22, 2009 (the "**Commercialization Agreement**");

WHEREAS, by letter dated November 22, 2012, Roche notified OraSure that it is terminating both the Development Agreement and Commercialization Agreement and, by letter dated December 21, 2012, OraSure advised Roche that it believes Roche is not permitted to terminate such Agreements and the Parties have since then disagreed on the validity of the termination; and

WHEREAS, the Parties wish to settle such disputes amicably and restate their on-going relationship in one single agreement containing the terms and conditions set forth in this Settlement and Restated Supply Agreement (this "**Agreement**").

NOW, THEREFORE, in consideration of the mutual covenants and obligations contained herein and intending to be legally bound hereby, the Parties agree as follows.

1. DEFINITIONS

For the purpose of this Agreement, the terms set forth below shall be defined as follows:

Affiliate means

(a) an organization, which directly or indirectly controls a Party;

(b) an organization, which is directly or indirectly controlled by a Party;

(c) an organization, which is controlled, directly or indirectly, by the ultimate parent company of a Party.

Control as per (a) to (c) is defined as owning 50 % (fifty percent) or more of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization.

With respect to Roche the term "Affiliate" shall not include Chugai Pharmaceutical Co., Ltd, 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo, 103-8324, Japan, unless Roche opts for such inclusion by giving written notice to OraSure.

Agreement means this Agreement and all annexes hereto, in each case as amended from time to time.

Application means, with respect to an Immunoassay and a Platform, all know- how, specifications, methods, instructions, processes, software, or data for processing such Immunoassay with such Platform.

Business Day	means any day other than (a) Saturday or Sunday or (b) any statutory holiday in Germany, or holiday in the United States on which offices of the Federal Reserve Bank of Philadelphia are required to be closed.
Calibrators	means the calibrators and controls developed by OraSure under the Development Agreement for use in performing the Immunoassays on the Platforms, including all modifications and improvements to the calibrators and controls.
Calibrator Specifications	means the final specifications reflected in the FDA-approved or cleared application for each Calibrator, as attached hereto as **Exhibit B.**
Commercialization Agreement	means the Commercialization and Supply Agreement dated December 22, 2009, as amended.
Confidential Information	means the terms and conditions of this Agreement and all information and data, regardless of form, provided by a Party (the "**Disclosing Party**") to the other (the "**Receiving Party**") under the terms of this Agreement or regarding the purpose of this Agreement, either of a business or technical nature, and which information is clearly marked confidential or if disclosed orally is declared by the originator as confidential and summarized in writing within thirty (30) days from the day of disclosure.
Controlled	means, at any time with respect to a particular item, material, information or Intellectual Property Rights, that at such time a Party (a) owns or has a right or license to and (b) has the ability to make available and license or sublicense (as the case may be) to the other Party, such item, material, information or Intellectual Property Rights.
Development Agreement	means the Joint Development and Cross-License Agreement dated August 14, 2008.
DOA Detection	means the detection of drugs of abuse.
Effective Date	means the date first set forth above.
FDA	means the United States Food and Drug Administration or any successor agency having the administrative authority to regulate the sale or marketing of medical devices in the United States.
FHLR	means F. Hoffmann-La Roche Ltd or any successor.
Fully Automated	means, with respect to an Immunoassay, the suitability of such Immunoassay for processing on a fully automated laboratory instrument.
GMP	means the current good manufacturing practices as specified in the quality system regulations at 21 CFR Part 820 or similar regulatory laws of any applicable Regulatory Authority, as such regulatory laws are in effect at the time of design and/or manufacturing.

Immunoassay	means a homogenous Fully Automated immunoassay for DOA Detection in Oral Fluid for amphetamines, methamphetamine, cocaine, opiates and PCP, which have been developed by Roche under the Development Agreement and have received 510(k) clearance from the FDA.
Immunoassay Specifications	means the final specifications reflected in the FDA-approved or cleared application for each Immunoassay, attached hereto as **Exhibit A.**
Indemnified Party and Indemnifying Party	have the meanings set forth in Section 17.5.
Intellectual Property Rights	means all intellectual property rights and other proprietary rights, in any jurisdiction, whether registered or unregistered, including such rights in (a) patents, patent applications, inventions (whether or not patented or patentable) and other industrial property rights, (b) copyrights and other rights associated with works of authorship, (c) trade secrets rights, know-how (whether relating to, without limitation, development, processing, manufacture, use or operation), proprietary techniques, methodologies and processes, rights in confidential information and (d) trademarks, service marks, trade names and other product, service or company identifiers, including such rights in all applications, registrations, extensions, renewals, continuations, continuations-in-part, combinations, divisions and reissues of the foregoing.
Intercept® Device	means (a) the Oral Fluid collection device known as Intercept® developed, manufactured and owned by OraSure for use in DOA Detection, as such device exists as of the Effective Date, (b) the Second Generation Intercept® Device and/or (c) any other future versions or modifications or improvements of any of the foregoing.
Losses	means any losses, liabilities, claims, damages, settlements, judgments, awards, actions, suits and costs whatsoever, including reasonable attorneys' fees and disbursements and the costs of enforcing any indemnity granted under this Agreement.
Manufacturing Know-How	means, with respect to any Product, any proprietary or non-public know-how, data, information, non-patented inventions, methods, instructions, processes, formulae, expert opinions or similar items Controlled by a Party and used or developed for use in the manufacturing of such Product.
Manufacturing Records	has the meaning set forth in Section 13.2.

OCC	shall have the meaning set forth in Section 14.2.
Oral Fluid	means mucosal transudate, saliva, or other fluids extracted from the human oral cavity.
OraSure Applications	means the Applications to allow the Immunoassays to be used in connection with those Third Party Platforms allocated to OraSure in any Statement of Work attached as an exhibit to the Development Agreement.
OraSure Background IPR	means any Intellectual Property Right Controlled by OraSure or its Affiliates that: (a) directly relates to the scope of the Project, (b) is or was disclosed to Roche, utilized by either Party in connection with the Project or comprised within, practiced by, or relating to the manufacture or use of any Development (as defined in the Development Agreement) and (c) either (i) was Controlled by OraSure or its Affiliates prior to the commencement of the Project or (ii) during the term of the Development Agreement but wholly independent of the Project was developed or acquired by OraSure or its Affiliates (whether by assignment, under license or otherwise). Without limiting the foregoing, and notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that all Intellectual Property Rights in each of (x) the Antibodies (as defined in the Development Agreement) and Calibrators owned or Controlled by OraSure and in existence as of the effective date (including all related Know-How) of the Development Agreement, (y) the first generation of the Intercept® Device (including rights under US Patent Nos. 5,103,836, 5234001 and 5,335,673, the trademark “Intercept” and all related Know-How) and (z) the Second Generation Intercept® Device owned or Controlled by OraSure and in existence as of the effective date (including all related Know-How) of the Development Agreement constitute OraSure Background IPR.
OraSure Clone	shall have the meaning set forth in Section 9.1.
OraSure IPR	means OraSure Background IPR and such Project IPR comprised in (a) the Intercept® Device or the OraSure Applications or (b) any antibodies, Calibrators or improvements thereto developed solely by OraSure after the effective date of the Development Agreement.
OraSure Releasees and OraSure Releasors	shall have the meanings set forth in Article 19.
Party	means FHLR, RDG, RDO or OraSure.
Person	means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any governmental or agency or political subdivision thereof.

Platform	means a Fully Automated laboratory instrument suitable for processing one or more of the Immunoassays for DOA Detection.
Proceeding	means any claim, suit or proceeding.
Product	Means any Immunoassay or Calibrator.
Project	means (a) the design and development of the Immunoassays under the Development Agreement; (b) the development of a Second Generation Intercept® Device (as defined herein) under the Development Agreement to be used in conjunction with such Immunoassays; and (c) the marketing, commercialization, manufacture and distribution of such products under the Commercialization Agreement and this Agreement.
Project IPR	means, subject to the OraSure Background IPR and Roche Background IPR, any and all Intellectual Property Rights conceived, invented, developed or authored (including all such rights in and to Developments) in connection with the Project by any Party, whether alone or together with the other Party, from the time of the commencement of the Project and through the termination of this Agreement. For avoidance of doubt, the Project IPR includes any such Intellectual Property Rights conceived during the Project but reduced to practice after expiration or termination of this Agreement, or invented (as such term is defined under U.S. Patent law) during the Project but which is the subject of a patent application filed after expiration or termination of the Project.
Purchase Order	shall have the meaning set forth in Section 5.5.
Purchaser	means, with respect to a Product, the Party that is purchasing the Product from the other Party in exchange for payment of the applicable Transfer Price.
Quality Requirements	means, with respect to any Product, the quality standards, change procedures, and other practices and requirements set forth in **Exhibit C.**
RDG	means Roche Diagnostics GmbH or any successor.
RDO	means Roche Diagnostics Operations, Inc. or any successor.
Regulatory Authority	means, with respect to any country or jurisdiction, any governmental authority involved in granting approval of the investigation, manufacture, distribution, marketing, sale, pricing or reimbursement of the Products in that country or jurisdiction, including the FDA in the United States.
Representative	means, for any Party, any employee, director or agent of such Party.

Roche	means FHLR, RDG and RDO, collectively.
Roche Applications	means the Applications to allow the Immunoassays to be used in connection with the Roche Platforms and certain Hitachi and Olympus platforms.
Roche Background IPR	means any Intellectual Property Right Controlled by Roche or its Affiliates that: (a) directly relates to the scope of the Project, (b) is or was disclosed to OraSure, utilized by either Party in connection with the Project or comprised within, practiced by, or relating to the manufacture or use of any Development (as defined in the Development Agreement) and (c) either (i) was Controlled by Roche or its Affiliates prior to the commencement of the Project or (ii) during the Project Term (as defined in the Development Agreement) but wholly independent of the Project is or was developed or acquired by Roche or its Affiliates (whether by assignment, under license or otherwise). Without limiting the foregoing, and notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that all Intellectual Property Rights in the DAT Microparticle Technology (as defined in the Development Agreement) constitute Roche Background IPR.
Roche IPR	means Roche Background IPR and such Project IPR as is comprised in the Immunoassays and the Roche Applications or is related to any antibodies or improvements thereto developed solely by Roche after the effective date of the Development Agreement.
Roche Platform	means a Platform Controlled by Roche.
Roche Releasees and Roche Releasors	shall have the meanings set forth in Article 19.
Roche Trademarks	shall have the meaning set forth in Section 9.2.
Second Generation Intercept® Device	means the second generation of the Intercept® Device developed by OraSure and known as the Intercept® I2 Oral Fluid collection device, including any modifications or improvements to such device.
[***]	**[***]**
[***]	**[***]**
Supplier	means, with respect to a Product, the Party that is supplying the Product to the other Party in exchange for payment of the applicable Transfer Price.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Term	has the meaning set forth in Section 15.1.
Third Party	means a Person that is not a Party or an Affiliate of a Party.
Third Party Claim	has the meaning set forth in Section 17.1.
Transfer Price	means the applicable price set forth in Exhibits F-1 and F-2 to be paid by one Party to the other Party for the purchase of a Product.

2. TERMINATION OF PRIOR AGREEMENTS; ONGOING SUPPLY

2.1 Subject to the provisions of this Agreement, OraSure and Roche agree that all rights and obligations under the Development and the Commercialization Agreement terminate as of the Effective Date of this Agreement. For the avoidance of doubt, all previous agreements between the Parties shall be superseded by this Agreement. Notwithstanding the foregoing, (a) Section 4.1, 4.2, 4.5, 4.6, 4.7, and 4.8 of the Development Agreement shall survive the termination of the Development Agreement; (b) any Products previously supplied by one Party to the other under the Commercialization Agreement shall be subject to and covered by the terms of this Agreement; and (c) any "Confidential Information" (as that term is defined under the Development Agreement and Commercialization Agreement), received or used by the Parties prior to the Effective Date of this Agreement shall be deemed to be "Confidential Information," as that term is defined herein and such Confidential Information shall be subject to Article 16 hereof.

2.2 During the Term of this Agreement, Roche shall supply to OraSure the Immunoassays under the terms and conditions described in this Agreement.

2.3 During the Term of this Agreement, OraSure shall supply Roche with Calibrators under the terms and conditions described in this Agreement. Roche shall use the Calibrators provided hereunder solely for release testing performed in connection with the manufacture of Immunoassays purchased by OraSure under this Agreement.

3. ROCHE RIGHTS AND COVENANTS

3.1 Exclusivity. Except as provided below, during the Term of this Agreement and for two years after the expiration or earlier termination of this Agreement, Roche and its Affiliates shall not, directly or indirectly, enter into any written or oral agreement or other arrangement with, or assist, license, support or finance, any Third Party, with respect to the development, commercialization, marketing, manufacture or sale of any homogeneous Fully-Automated Oral Fluid immunoassays for use with an Oral Fluid collection device in DOA Detection and (b) will only sell, promote and use its homogeneous Fully-Automated Oral Fluid immunoassays (including the Immunoassays) with OraSure's Intercept® Device for DOA Detection and shall not engage in or sponsor any studies regarding or develop any materials that promote the use of the Immunoassays with any collection device other than the Intercept® Device for DOA Detection. Notwithstanding the foregoing, any technical assistance or support that Roche provides to an end-user customer by opening a reagent channel on a Roche

Platform for the use of an oral fluid immunoassay purchased by such end-user customer from OraSure or a Third Party shall not be considered a breach of this Section 3.1. Such assistance may include the supply of empty reagent cassettes to the end-user customer.

3.2 Assistance. Roche agrees to continue to provide assistance with respect to the OraSure Application for the Olympus 680 platform, as outlined in the letter dated M ay 27, 2013 from Roche to OraSure and attached hereto as Exhibit H.

3.3 Early Termination of Supply. Roche shall be entitled to terminate this Agreement and the foregoing supply obligation upon not less than thirty (30) days prior written notice once OraSure is able to purchase from a Third Party commercial quantities of alternative Fully-Automated Oral Fluid immunoassays for each of the drugs-of-abuse indicated above in the definition of "Immunoassays" and for THC that have received FDA 510(k) clearance for use with the Second Generation Intercept® Device.

3.4 Payments. Roche agrees to pay OraSure the amount of $8.3 million (eight million three hundred thousand U.S. Dollars) within thirty (30) days after the Effective Date of this Agreement.

In addition, in the event OraSure places its final binding Purchase Order for Immunoassays during any one of the following periods, Roche shall pay OraSure the indicated amount of additional compensation:

(a) On or prior to December 31, 2013, Roche shall pay to OraSure $6.0 million (six million U.S. Dollars);

(b) During the period January 1, 2014 to June 30, 2014, Roche shall pay to OraSure $5.5 million (five million five hundred thousand U.S. Dollars);

(c) During the period July 1, 2014 to September 30, 2016, Roche shall pay to OraSure $1.5 million (one and one-half million U.S. Dollars); or

(d) During the period October 1, 2016 to September 30, 2017, Roche shall pay to OraSure $750,000 (seven hundred fifty thousand U.S. Dollars).

Any amount due to OraSure under this Section 3.4 shall be paid by Roche within thirty (30) days after placement of OraSure's final Purchase Order to Roche. A final Purchase Order shall be deemed to have been placed by OraSure, upon Roche's receipt of a formal notice by OraSure together with a copy of such final Purchase Order.

3.5 Regulatory Approvals. Roche shall ensure commercially reasonable efforts to maintain in good standing all approvals received from Regulatory Authorities for the Immunoassays that are in effect as of the Effective Date, including all 510(k) clearances for the Immunoassays received from the FDA.

3.6 To the extent OraSure is able to obtain a supply of alternative homogeneous Fully Automated immunoassays for DOA Detection in Oral Fluid (other than the Immunoassays), OraSure shall endeavor in good faith to make those immunoassays

available for purchase by Roche so long as it is not precluded from doing so by contract. The terms for supply of such immunoassays to Roche shall be subject to mutual agreement by the Parties.

4. ORASURE RIGHTS AND COVENANTS

4.1 Immunoassays. OraSure shall have the right to market, distribute and sell the Immunoassays into any market without restriction, subject to compliance with applicable regulatory approvals and applicable law. For clarification purposes, OraSure shall be free, directly or indirectly, to enter into any agreement or other arrangement with, or assist, license, support or finance, any Third Party with respect to the development, commercialization, marketing, modification or sale of any homogeneous Fully-Automated Oral Fluid immunoassays for use with the Intercept® Device in DOA Detection.

4.2 Alternate Source. OraSure shall notify Roche as soon as practicable after one or more submissions to the FDA have been filed for clearance of immunoassays to be used with the Second Generation Intercept® Device for DOA Detection that are comparable to the Immunoassays.

5. SUPPLY TERMS

5.1 Immunoassays. During the Term of this Agreement, Roche agrees to manufacture and supply to OraSure the Immunoassays in accordance with the Immunoassay Specifications set forth in Exhibit A, the Quality Requirements set forth in Exhibit C, and the other requirements of this Agreement, in exchange for payment of the applicable Transfer Prices set forth in Exhibit F-1.

5.2 Calibrators. During the Term of this Agreement, OraSure agrees to manufacture and supply to Roche the Calibrators in accordance with the Calibrator Specifications set forth in Exhibit B, the Quality Requirements set forth in Exhibit C, and the other requirements of this Agreement, in exchange for payment of the applicable Transfer Prices set forth in Exhibit F-2.

5.3 Technical Support. Each Party shall provide and maintain, at its own expense, adequate support services and a staff properly trained in all aspects of its Products to provide the other Party and its customers such levels of technical support throughout the Term that are commercially reasonable in light of the then current and reasonably anticipated sales volumes of such Products. In particular, Roche shall provide technical support for the Immunoassays, the Roche Platforms and the Roche Applications to OraSure and all customers served by OraSure pursuant to this Agreement. Technical support required under this Section 5.3 will include, without limitation, responding to questions from customers and the other Party regarding the Products and providing to the other Party and its customers, at no additional charge, all reasonable training to appropriate personnel in the proper use of its Products.

5.4 Terms and Conditions. The terms and conditions of this Agreement and its Exhibits shall control all sales of all Products hereunder between the Parties. No different or additional terms and conditions on any purchase order, acknowledgment or other transmittal, whether a standard business form or otherwise, utilized by OraSure or

Roche in connection with the sale of Products to the other Party shall be construed or deemed to be an amendment of or supplement to this Agreement or otherwise binding on either OraSure or Roche.

5.5 Purchases of Product. The Purchaser may purchase Products from the Supplier by issuing binding purchase orders (each, a "**Purchase Order**") to the Supplier pursuant to the terms of this Agreement. Each Purchase Order shall be subject to Section 5.4 and shall state the quantity and type of Product to be purchased, delivery date(s), routing instructions, destination(s) and confirmation of the applicable Transfer Price hereunder. The Supplier shall indicate its acceptance or rejection of a Purchase Order within ten (10) Business Days after receipt; provided that the Supplier may reject a Purchase Order, in whole or in part, only if: (a) the Purchase Order fails to comply with the terms and conditions of this Agreement; or (b) the volume under the Purchase Order and all other accepted Purchase Orders covering the same period exceeds the volume in the Purchaser's then current forecast (delivered pursuant to Section 5.6) for such period by more than 50% (fifty percent). If requested by Purchaser following the Purchaser's receipt of the Supplier's rejection notice under clause (b) above, the Supplier will use commercially reasonable efforts to deliver the excess volume of the Products specified in the rejected Purchase Order, but the Supplier's failure to so deliver the excess volume shall not be a breach of this Agreement. In no event shall the Supplier be liable to any Third Party for the Supplier's failure to deliver the Products to the Purchaser by any delivery due date set forth in any Purchase Order.

5.6 Forecasts. As soon as practicable after the Effective Date, each Party shall provide to the other Party a written forecast of the Party's anticipated monthly requirements for each of the Products of the other Party during the subsequent twelve (12) months. Thereafter, no later than ten (10) days before the beginning of each calendar quarter during the Term, each Party shall provide the other Party with an additional, non-binding written forecast of the Party's anticipated monthly requirements for each of the Products of the other Party during the subsequent twelve (12) months. Notwithstanding the foregoing, the Parties agree that binding Purchase Orders shall be issued on a made-to-order basis.

6. SHIPMENT

6.1 Delivery Terms. Each Supplier shall ship its Products EX WORKS (Incoterms 2010) its respective facility. All risk of loss, damage, spoilage, improper storage, mishandling and negligence for all Product shall pass to Purchaser at the time of delivery to the shipper at Supplier's facility. For purposes of clarification, Roche agrees that it will ship Immunoassays to OraSure solely from Roche's facilities in Indianapolis, Indiana, U .S.A . or other U.S. locations.

6.2 Packaging. Each Supplier shall be responsible for boxing, crating, handling, storage and other packaging requirements for its Products prior to shipment. Each Supplier shall package, handle and otherwise prepare Product to be supplied for shipment in a manner that is: (a) in accordance with the applicable Product specifications and good commercial practice, (b) acceptable to common carriers for shipment, and (c) adequate to ensure safe arrival of the Products. All costs related to such boxing, crating, handling, storage and other packaging shall be borne by

the Supplier, except as provided below. Each Supplier shall arrange for transportation of its Products to the destination designated by the Purchaser, by a common carrier selected by the Purchaser. If the Purchaser requests non-standard packaging, the Supplier shall use reasonable efforts to accommodate that request and shall be entitled to charge an additional fee for such packaging in accordance with Supplier's then existing pricing policies. The Supplier shall ensure that all Products are suitably packed for shipment in the Supplier's standard containers and shall adhere, with regard to palettes or wooden packages to the rules of the International Plant protection Convention (IPPC) and meet the corresponding standard (ISPM No. 15).

6.3 Shipment Documents. The Supplier shall provide to the Purchaser, in advance of each shipment, all necessary information relating to such shipment, including without limitation, the identity of the carrier, flight number or similar information, scheduled arrival time and package identification number.

6.4 Product Identification. The delivered Products must be marked with Purchaser's Purchase Order number, Purchaser's catalogue number (in case of Roche: 11 digit), lot number, expiry date and quantity on the outside transport box, all packing slips and invoices in accordance with the applicable Specifications.

6.5 Certificate of Analysis. Supplier shall issue a certificate of analysis in respect of each batch of Product sold to the Purchaser, which – in addition to accompanying the delivery – shall be forwarded to Purchaser by facsimile. Each certificate of analysis shall include the results of testing performed by Supplier in accordance with its Quality Management System and shall confirm that the Product meets the applicable specifications. The expiration date on the certificate of analysis has to be given in the following format: year – month – last day of month (example: 2013-11-30). Purchaser shall be entitled to rely upon each Supplier certificate of analysis of the Product. Supplier shall provide Purchaser with any applicable validation certificates upon request.

7. PRODUCT WARRANTIES

7.1 Roche Limited Product Warranty. Roche warrants to OraSure that: (a) each Immunoassay, when shipped, will conform to the Immunoassay Specifications, the Quality Requirements and all other terms of the this Agreement, (b) at the time of delivery, title to each Immunoassay shall be delivered to OraSure free and clear of all liens or encumbrances, (c) none of the Immunoassays shall, at the time of delivery, be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321-394), or similar law of any other jurisdiction, and (d) each Immunoassay shall be new and shall be free from defects in materials and workmanship for a period equal to its stated shelf life (the "**Roche Warranty Period**").

7.2 OraSure Limited Product Warranty. OraSure warrants to Roche that: (a) each Calibrator, when shipped, will conform to the Calibrator Specifications, (b) at the time of delivery, title to each Calibrator shall be delivered to Roche free and clear of all liens or encumbrances, (c) no Calibrators shall, at the time of delivery, be adulterated or misbranded within the meaning of the Federal Food, Drug, and

Cosmetic Act, as amended (21 U.S.C. 321-394), or similar law of any other jurisdiction. and (d) each Calibrator shall be new and shall be free from defects in materials and workmanship for a period equal to its stated shelf life (the "**OraSure Warranty Period**").

7.3 Disclaimer of Warranty. The express representations and warranties set forth in this Article 7, in Article 11 and in Exhibit C are in lieu of all other representations and warranties, whether expressed or implied. Each party hereby disclaims any and all other representations and warranties of any kind, expressed or implied, whether arising from a course of dealing or usage of trade, including, without limitation, the implied warranties of merchantability, fitness for a particular purpose and non-infringement.

7.4 Warranty Remedies. During the Roche Warranty Period and the OraSure Warranty Period, the purchasing Purchaser shall have the right to reject the whole batch and the applicable Supplier shall replace, at its own expense, or at the Purchaser's option, refund or credit the purchase price of, any Product, as the case may be, that does not comply with the applicable limited warranty set forth in Sections 7.1 or 7.2 of this Agreement. The obligation to replace defective Products or provide a credit or refund pursuant to this Section 7.4 shall not apply to any Products that have been subjected to misuse, mishandling, storage in a manner inconsistent with labeling, neglect, modification or unusual physical or chemical stress after delivery to the Purchaser. Except for each Party's indemnification obligations under Article 17, this Section 7.4 states the Parties sole and exclusive remedy for failure of any Products to comply with the applicable limited warranty set forth in Sections 7.1 and 7.2.

8. PRICING; TERMS OF PAYMENT

8.1 Prices. Subject to the other provisions of this Section 8, the Transfer Prices for the Immunoassays and the Calibrators shall be as set forth in Exhibits F-1 and F-2, respectively.

8.2 Payment Terms. The Purchaser shall pay the Supplier all amounts due under this Agreement (other than those stated in Section 3.4) in U.S. Dollars no later than thirty (30) days from the date of the invoice from the Supplier for such amounts. Overdue amounts shall bear interest at a rate of one percent (1%) per month or such lower rate required by law, until paid. Payment of any amount by a Purchaser hereunder shall be made either by check or wire transfer to an account designated by the Supplier.

8.3 Taxes; Freight. Prices for the Products are EX WORKS (Incoterms 2010) the respective facility where the Products are shipped and are exclusive of all sales, use, ad valorem and other similar taxes, customs, duties and other similar imports, fees and governmental charges, and freight, shipping and insurance charges. Any such charges shall be the sole responsibility of the Purchaser.

8.4 Fixed Prices. Prices for Immunoassays and Calibrators shall be fixed for the Term of this Agreement.

9. INTELLECTUAL PROPERTY LICENSES

9.1 License Grant by OraSure.

(a) OraSure IPR. OraSure hereby grants Roche a non-exclusive, fully paid up, royalty-free, non-transferable license without the right to sublicense under the OraSure IPR, as necessary to perform Roche's manufacturing, importation and other obligations respecting the Immunoassays and the Calibrators under this Agreement.

(b) OraSure Clone. OraSure has transferred to Roche a clone for the production of certain cocaine antibodies (the "**OraSure Clone**"). OraSure hereby grants to Roche a non-exclusive fully paid up royalty-free, non-transferable limited license, without the right to sublicense, to use the OraSure Clone solely for the production of Immunoassays pursuant to this Agreement. Notwithstanding the foregoing, OraSure shall retain all right, title and interest in and to the OraSure Clone, subject to the limited license described above.

9.2 License Grant by Roche.

(a) Roche IPR. Roche hereby grants OraSure a non-exclusive, fully paid up, royalty-free, non-transferable limited license without the right to sublicense under the Roche IPR, as necessary to perform OraSure's marketing, manufacturing, distribution, importation and other obligations respecting the Immunoassays under this Agreement. It is expressly understood by the Parties that Roche has a non-exclusive license, without the right to sublicense, [***], and that no rights under that license shall be transferred or sub-licensed to OraSure under this Agreement, provided that to the extent OraSure makes, uses or sells the Immunoassays hereunder, such activity is being conducted on behalf of Roche and pursuant to Roche's "have made" and/or "have sold" rights under the aforementioned license.

(b) Roche Trademarks. Roche hereby grants OraSure a nonexclusive, fully paid up, royalty-free, non-transferable limited license to use Roche's trademarks, trade names and logos as provided on **Exhibit G** or identified in writing by Roche from time to time (the "**Roche Trademarks**") on labeling and promotional materials for the purpose of promoting and selling the Immunoassays in accordance with this Agreement. No labeling or promotional materials bearing the Roche Trademarks may be used without Roche's prior written approval, which shall not be unreasonably withheld but shall be conditioned upon OraSure maintaining the distinctiveness of the trademarks of each Party and including a tag line that indicates that OraSure's use of the Roche Trademarks is pursuant to a license from Roche. Notwithstanding anything herein to the contrary, OraSure's use of the Roche Trademarks shall be conditioned upon OraSure's compliance with Roche's then-

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

current quality standards, which standards Roche may update from time to time by written notice to OraSure, it being understood that OraSure may use up any packaging, labeling or promotional material that it has at the time of the update, either in stock or in process. Roche consents to OraSure's use of all promotional, marketing and training materials for the Immunoassays that have been previously developed and approved by the Parties. For the avoidance of doubt, Roche shall have no obligation to provide any such material to OraSure.

9.3 No Other Rights; Allocation of Goodwill; Quality Control. Except for the licenses granted in this Article 9, neither Party shall acquire any right, title, or interest in any trademark, trade name, or logo, including foreign translations thereof, or any copyright, patent or other intellectual property of the other Party by reason of this Agreement.

10. THIRD PARTY LICENSE

10.1 Compliance. Roche represents and warrants that Roche and its Affiliates will comply with the terms of [***], with respect to the Immunoassays, including payment of all royalties thereunder with respect to sales of the Immunoassays (whether sold separately or otherwise in combination with other products or equipment) by Roche or its Affiliates to OraSure or other customers. Roche represents and warrants that it will pay royalties under [***] based on OraSure's net sales invoiced to its customers in the United States.

10.2 Report. OraSure agrees co-operate and to provide its net sales information for Immunoassays as reasonably requested by Roche to allow Roche to comply with its obligations towards the licensor under [***].

11. REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties by Roche. Roche represents and warrants as of the Effective Date and during the Term as follows:

(a) Organization and Authority. It is a corporation validly existing and in good standing under the laws of the state or country of its organization or formation. It has full corporate power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. All corporate acts and other proceedings required to authorize such execution, delivery, and consummation have been duly and properly taken and obtained.

(b) Enforceability. This Agreement has been duly executed and delivered by Roche and constitutes legal, valid, and binding obligations of Roche enforceable against Roche in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization and other similar laws and equitable principles relating to or limiting creditors' rights generally.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) No Conflicts. The execution, delivery and performance of this Agreement by Roche does not violate the provisions of, or constitute a breach or default under (i) the articles of incorporation or any other applicable corporate or organic documents of Roche or (ii) any material contract to which Roche may be bound.

(d) Non-Infringement. Other than rights granted to Roche by OraSure under this Agreement and the Development Agreement, to the knowledge of Roche, Roche Controls all Intellectual Property Rights necessary to fulfill its duties and obligations pursuant to this Agreement. To the knowledge of Roche, the sale, distribution or use of the Immunoassays by the Parties as contemplated hereunder will not infringe or misappropriate the Intellectual Property Rights of any Third Party.

11.2 Representations and Warranties of OraSure. OraSure represents and warrants as of the Effective Date and during the Term as follows:

(a) Organization and Authority. It is a corporation validly existing and in good standing under the laws of the State of Delaware, U.S.A. It has full corporate power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. All corporate acts and other proceedings required to authorize such execution, delivery, and consummation have been duly and properly taken and obtained.

(b) Enforceability. This Agreement has been duly executed and delivered by OraSure and constitutes legal, valid, and binding obligations of OraSure enforceable against OraSure in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization and other similar laws and equitable principles relating to or limiting creditors' rights generally.

(c) No Conflicts. The execution, delivery and performance of this Agreement by OraSure does not violate the provisions of, or constitute a breach or default under (i) the articles of incorporation or any other applicable corporate or organic documents of OraSure or (ii) any material contract to which OraSure may be bound.

(d) Non-Infringement. Other than rights granted to OraSure by Roche under this Agreement and the Development Agreement, to the knowledge of OraSure, OraSure Controls all Intellectual Property Rights necessary to fulfill its duties and obligations pursuant to this Agreement.

11.3 No Re-packaging or Re-Labeling. Neither Party shall re-package or re-label Products purchased from the other; provided that Products can be aggregated and packaged in shipping boxes or containers with labeling approved by the other Party.

12. RECALLS; COMPLAINTS

12.1 Recall. Each Party shall immediately notify the other Party in writing should it become aware of any defect or condition that may render any Product unsafe to use or in violation of any applicable requirement of law or that may constitute a deviation from the warranties made in Articles 7 or 11 or Exhibit C. Upon the determination of the Supplier to recall the affected Product, the Parties shall carry out any recall or replacement in full compliance with applicable laws and regulations and in the manner agreed upon between the Parties in as expeditious a manner as possible and in such a way as to cause the least disruption and to preserve customer goodwill and the reputation of the affected Product and the Parties. Each Party shall reimburse the other Party in full for all reasonable, direct costs of the recall or replacement of a Product it supplied hereunder, but only if the recall or replacement results from a defect in the manufacture, packaging, or labeling of the Product or from any breach of warranty by such Party, and not from any action taken or omitted by the other Party. The direct costs for which a Party shall reimburse the other Party shall be limited to out-of-pocket costs, such as mailing and printing costs and other amounts paid to Third Parties. Neither Party shall have liability to the other Party (or others) for indirect costs of the recall or replacement, such as lost profits, employee time, or overhead. Notwithstanding the foregoing, Purchaser shall have the right to request a recall of the Product if Purchaser, in good faith, believes a Recall is warranted. In such case, Supplier shall consider in good faith whether or not to recall the Product.

12.2 Complaints. Each Party shall notify the other Party promptly of the receipt of any complaints about such other Party's Products and shall forward all complaints to the other Party or its local Affiliate of other Party as soon as practicable after receipt by the Party. Each Party shall have primary responsibility for investigating, responding and reporting to all such complaints relating to its Products. Each Party shall cooperate with the other Party, as necessary and useful, to investigate and respond to such complaints.

13. RECORDS AND AUDIT RIGHTS

13.1 Records of Sales. OraSure shall maintain accurate and complete records of each sale and use of the Immunoassays. Each Party shall comply with all record-keeping requirements imposed by the FDA or other regulatory or governmental authorities. Each Party promptly shall disclose to the other Party any records required to be maintained under this Section 13.1, including such records as may be necessary for the other Party to comply with all regulatory approvals obtained for the import, marketing, sale, use or distribution of the Products and other requirements of the FDA.

13.2 Manufacturing Records. In compliance with applicable laws, GM P and its own internal quality systems, each Party shall maintain reproducible records of all information, data and documentation relating to its manufacturing processes, its Products, the Quality Requirements, and the applicable Specifications and its performance under this Agreement (the "**Manufacturing Records**"), including, without limitation, incoming quality control tests and/or inspection reports, final inspection reports, certificates of analysis or compliance, batch records, design records, written policies and procedures, test results, reports, correspondence, memoranda, safety information and information relating to recalls until five (5) years after the expiration or early termination of this Agreement.

13.3 Audit of Manufacturing Records. Within five (5) Business Days after a request is made by either Party, the other Party's manufacturing processes, Products and Manufacturing Records shall be open to audit, inspection, examination and evaluation during normal working hours and at reasonable intervals, by the requesting Party or its authorized representatives to the extent reasonably necessary to evaluate the other Party's compliance with applicable laws and/or other requirements in connection with its performance under this Agreement. Without limiting the generality of the foregoing, the Party being audited shall permit the requesting Party or its authorized representative, subject to reasonable confidentiality restrictions, to enter the manufacturing, packaging, and quality control facilities to inspect and audit all the manufacturing processes (including equipment, facilities, operations and procedures), Products (including by sampling of such Products) and Manufacturing Records (including Records relating to quality assurance and regulatory compliance as they pertain to the Product(s) or to the system support and processes used to manufacture, process and/or package the Product(s)). For the purpose of such audits, inspections, examinations, and evaluations, the requesting Party or its authorized representatives shall have access to such manufacturing processes, Products and Manufacturing Records beginning on the Effective Date and continuing until five (5) years after the termination or expiration of this Agreement. In addition, the Party being audited shall provide adequate and appropriate workspace for the requesting Party or its authorized representatives to conduct such audits, inspections, examinations and evaluations

14. SECURING OF SUPPLY – RISK MANAGEMENT

14.1 Raw Materials. Supplier shall maintain such stock of raw materials and packaging sufficient to ensure Purchaser's prospective three months requirement of Products.

14.2 Failure to Supply. As soon as practicable after the Effective Date, the Parties shall establish an Operations Coordination Committee **(**"**OCC**"), which shall include representatives from each Party's operations and supply chain management organizations. The OCC shall meet (by phone or in person) at least on a quarterly basis in locations alternately selected by each Party to discuss (a) Product supply performance for each Party; (b) the maintenance of minimum safety stocks for each Party for both finished Products and critical raw materials; (c) the performance and robustness of each Party's manufacturing processes and any identifiable risks to Product supply; and (d) any manufacturing process non-conformances or deviations experienced by either Party which could create a risk to Product supply. Each Party shall cooperate with the other and provide information reasonably required for the OCC to perform its functions under this Section 14.2. The OCC will evaluate potential risks to Product supply and develop action plans to avoid supply interruptions and customer backorders. The OCC shall meet more frequently than quarterly if necessary in order to address critical supply issues or to resolve or prevent potential supply problems. If either Party is unable to correct or prevent a supply interruption, the OCC will determine in good faith plans to resolve such problems, including the potential transfer of one or more manufacturing processes to a Third Party or another location managed by an affected Party. Each Party may appoint a Project Logistics Manager from its organization and, upon the appointing Party's request, such Manager will be permitted to work at the other Party's manufacturing facilities for periods of time

to be reasonably determined by the OCC. Each Project Logistics Manager shall assist the OCC in scheduling and conducting meetings and performing its functions hereunder.

15. DURATION; TERMINATION

15.1 Term. The term of this Agreement will commence on the Effective Date and shall expire on the 5th (fifth) anniversary of the Effective Date unless terminated earlier pursuant to Sections 15.2, 15.3 or 3.3 (the "Term").

15.2 Termination for Cause. This Agreement may be terminated as follows:

(a) Termination for Breach. Either Party may terminate this Agreement: (i) sixty (60) days following written notice if the other Party is in breach of any material obligation under this Agreement, where such breach is capable of being cured and the breaching Party fails to cure the breach within such sixty (60) day period and (ii) immediately upon written notice if the other Party is in breach of any material obligations under this Agreement and such breach is incapable of being cured.

(b) Failure to Pay. Either Party may terminate this Agreement if the other Party has failed to pay timely any amounts due under this Agreement which non-payment is not cured within thirty (30) days of receipt of written notice of such non-payment, provided that the Agreement shall not be terminated if the other Party's failure to pay all or any portion of any invoice is base on such Party's good faith dispute regarding the invoice.

(c) Insolvency. Either Party may terminate this Agreement immediately upon written notice in the event that bankruptcy, insolvency, dissolution or liquidation proceedings of any nature are instituted by or against the other Party, the other Party makes an assignment of its assets for the benefit of its creditors or the other Party discontinues all or a significant part of the business operations of the other Party that are material to the performance of such Party's obligations under this Agreement.

(d) Attempted Assignment. Either Party may terminate this Agreement immediately upon written notice upon the occurrence of an attempted assignment or transfer by the other Party that is prohibited by Section 20.1.

(e) Force Majeure Event. Either Party may terminate on thirty (30) days written notice if a Party is subject to force majeure event, as described in Section 20.13, that has extended or is reasonably likely to extend for a continuous period of at least 180 days.

15.3 Termination for Infringement. Either Party may terminate this Agreement upon thirty (30) days written notice pursuant if a Third Party asserts or threatens any bona fide claim, suit or action asserting that any of the manufacture, marketing, import, sale or use of any of such Party's Products infringes upon any Intellectual Property Rights of such Third Party and the Party responsible for the manufacture

of such Products reasonably determines after consultation with outside legal counsel that the other options provided in Section 17.4 are not commercially practicable.

15.4 Events Upon Termination. Upon termination or expiration of this Agreement:

(a) Following termination of this Agreement, OraSure may continue selling any inventory of the Immunoassays remaining in its possession after such termination.

(b) Roche shall cease to produce antibodies from the OraSure Clone and, at OraSure's request, either destroy the OraSure Clone or return the OraSure Clone to OraSure or its designee.

(c) Except as otherwise provided under this Section 15.4, this Agreement shall become void and have no further effect, without liability on the part of either Party hereto, provided that neither Party shall be relieved from any obligation already accrued prior to the effective date of such expiration or termination, nor from any liability for a breach of this Agreement occurring prior to such effective date of such expiration termination.

(d) Articles 7, 9, 10, 11, 12, 13, 16, 17, 18, 19 and 20 and Sections 3.1 and 15.4 of this Agreement shall survive any expiration or termination of this Agreement.

16. CONFIDENTIALITY

16.1 Confidential Treatment. During the Term of this Agreement and for a period of five (5) years thereafter, each Party agrees not to disclose any of the other Party's Confidential Information to any Third Party or use any such Confidential Information for any purpose other than the performance or enforcement of this Agreement, except as permitted hereunder, without first obtaining the other Party's prior written consent.

Each Party further agrees to take all practicable steps to ensure that any such Confidential Information shall not be used by its Affiliates, Representatives or advisors, except under same terms of confidentiality as stated herein. Each Party shall be responsible for any breach of this Article 16 by any of its Affiliates, Representatives or advisors.

16.2 Exceptions. The above provision of confidentiality and non-use shall not apply to that part of such Confidential Information which the receiving Party is clearly able to demonstrate:

(a) was fully in its possession prior to receipt from the other; or has been independently developed as shown by respective documents; or

(b) was in the public domain at the time of receipt from the other; or

(c) became part of the public domain through no default of the receiving Party, its Affiliates, Representatives or advisors; or

(d) was lawfully received from some Third Party having a right of further disclosure; or

(e) is required to be disclosed by law or applicable government regulations.

16.3 Disclosure. A receiving Party may disclose the other Party's Confidential Information pursuant to applicable law (including applicable securities laws and regulations and the rules of any stock exchange) or subpoena or other governmental order or process only if the receiving Party, if legally permitted, provides the disclosing Party with prompt written notice of such requirement sufficient to give the disclosing Party the opportunity to seek a protective order, injunction or other measure to limit or prevent the disclosure of its Confidential Information. Any such disclosure shall be limited to such portions of the Confidential Information that the receiving Party's legal counsel advises is required under the applicable law, subpoena or order or process.

16.4 Return or Destruction of Confidential Information. Upon expiration or earlier termination of this Agreement, the receiving Party shall, upon request, promptly deliver to the disclosing Party all Confidential Information of the disclosing Party, together with all copies thereof, in the possession, custody or control of the receiving Party or, alternatively, with the written consent of the disclosing Party, destroy all such Confidential Information and certify such destruction in writing to the disclosing Party; provided, however, that the receiving Party may retain a list that contains general descriptions of the information it has returned or destroyed to facilitate the resolution of any controversies after the disclosing Party's Confidential Information is returned.

17. INDEMNIFICATION

17.1 OraSure Indemnity. OraSure shall, at its sole expense, defend, indemnify and hold harmless Roche and its Affiliates and their respective Representatives and permitted successors and assigns from and against all Losses incurred as a result of or in connection with any Third Party claim, suit or action (a "**Third Party Claim**"): (a) for bodily injury, personal injury, death and property damage caused by a Calibrator, or caused by the negligence of OraSure or any person for whose actions OraSure is legally liable; (b) arising out of a breach by OraSure of any of its representations and warranties set forth in Sections 7.2 or 11.2 of this Agreement and Exhibit C; or (c) asserting that any of the manufacture, marketing, sale, import or use of the Calibrators infringes upon, or constitutes a misappropriation of, such Third Party's Intellectual Property Rights; provided, however, that in each case OraSure shall have no liability to Roche for any Losses to the extent that such Losses resulted from or arose out of: (i) the negligence or misconduct of Roche or any person for whose actions Roche is legally liable; (ii) a breach by Roche of any of its representations or warranties set forth in Sections 7.1 or 11.1 of this Agreement or Exhibit C; or (iii) any event or occurrence for which Roche has an indemnification obligation under Section 17.2.

17.2 Roche Indemnity. Roche shall, at its sole expense, defend, indemnify and hold harmless OraSure and its Affiliates and their respective Representatives, permitted successors and assigns from and against all Losses incurred as a result of or in

connection with any Third Party Claim: (a) for bodily injury, personal injury, death and property damage caused by any Immunoassay, or caused by the negligence of Roche or any person for whose actions Roche is legally liable; (b) arising out of a breach by Roche of any of its representations and warranties set forth in Sections 7.1 or 11.1 of this Agreement or Exhibit C; (c) asserting that any of the manufacture, marketing, sale, import or use of the Immunoassays infringes upon, or constitutes a misappropriation of, such Third Party's Intellectual Property Rights; or (d) arising out of any claim that any of the Roche Trademarks constitutes an infringement or dilution of a Third Party's trademark rights; provided, however, that in each case Roche shall have no liability to OraSure for any Losses to the extent that such Losses resulted from or arose out of: (i) the negligence or misconduct of OraSure or any person for whose actions OraSure is legally liable; (ii) a breach by OraSure of any of its representations or warranties set forth in Sections 7.2 or 11.2 of this Agreement or Exhibit C; or (iii) any event or occurrence for which OraSure has an indemnification obligation under Section 17.1.

17.3 Indemnification Limitation. Notwithstanding Sections 17.1 and 17.2, no Party shall have an indemnification obligation with respect to a claim that the combination of the Immunoassays, the Roche Platforms, the Calibrators and the Intercept® Device (and not such respective Products individually) infringes a Third Party's patent rights.

17.4 Additional Rights for Claims of Infringement. Without limitation of any rights and obligations of OraSure and Roche under this Article 17, if a Third Party asserts or threatens any claim, suit or action asserting that any of the manufacture, marketing, import, sale or use of any Product infringes upon any Intellectual Property Rights of such Third Party, then the Supplier of such Product shall, at its election, either (a) procure a license for the other Party to continue selling and distributing the infringing Product, (b) modify such Product to make it non-infringing, (c) obtain a license from the Third Party and make an appropriate adjustment to the applicable Transfer Price, acceptable to the other Party, for the infringing Product hereunder to reflect any additional royalties payable by the other Party to such Third Party, or (d) if none of the foregoing is commercially practicable, terminate this Agreement.

17.5 Indemnification Procedures. If any Proceeding is commenced against a Party entitled to indemnification under Section 17.1 or Section 17.2 (the "**Indemnified Party**"), written notice thereof shall be given to the Party that is obliged to give the indemnification (the "**Indemnifying Party**") as soon as reasonably possible. If, after such notice, the Indemnifying Party acknowledges that this Agreement applies with respect to such claim, the Indemnifying Party shall be entitled, if it so elects, in a written notice promptly delivered to the Indemnified Party, but in no event less than thirty (30) days prior to the date on which a response to such claim is due, to immediately take control of the defense and investigation of such claim. The Indemnified Party shall cooperate, at the Indemnifying Party's cost, in all reasonable respects with the Indemnifying Party and its attorneys in the investigation, trial and defense of such claim and any appeal arising therefrom; provided, however, that the Indemnified Party may, at its own cost and expense, participate, through its attorneys or otherwise, in such investigation, trial and defense of such claim and any appeal arising therefrom. No settlement of a claim

or other Proceeding shall be entered into without the consent of the Indemnified Party which consent shall not be unreasonably withheld or delayed. If, after investigation of the facts known at the time, the Indemnifying Party disputes its obligation to indemnify the Indemnified Party: (a) the Parties shall cooperate to ensure that timely and adequate defense of the claim is provided, (b) all defense costs shall initially be shared equally, and (c) the dispute between the Parties regarding the Indemnifying Party's obligation to indemnify shall be resolved in accordance with the provisions of Section 20.8; provided that if such dispute between the Parties is finally resolved in favor of the Indemnifying Party, all such defense costs shall be borne by the Indemnified Party, and if the matter is finally resolved in favor of the Indemnified Party, all such defense costs shall be borne by the Indemnifying Party.

17.6 Limitations on Liability. Except with respect to any damages or settlements amounts paid by an indemnified party to a third party that are subject to an indemnification obligation of the other party hereunder, or any direct claim for intellectual property infringement or misappropriation that may be asserted by one party against the other, neither party shall be liable for any special, incidental, consequential, indirect, enhanced or punitive damages arising in any way out of this agreement, however caused and on any theory of liability. This limitation will apply even if the other party has been advised of the possibility of such damage

18. NOTICES

18.1 Notice. Any notice required or permitted to be given hereunder shall be sent in writing by registered or certified airmail, postage prepaid, return receipt requested, or by facsimile or hand delivery addressed to the Party to whom it is to be given as follows:

If to	Roche: F. Hoffmann-La Roche Ltd Corporate Legal Department (CLL) Grenzacherstrasse 124 4070 Basel Switzerland Attention: Head Legal Diagnostics Facsimile No. +41 61 68 81396
With a copy to:	Roche Diagnostics International Ltd Forrenstrasse 2 6340 Rotkreuz Switzerland Attention: Lifecycle Leader Core Reagents Roche Professional Diagnostics Facsimile No. +41 41 798 7387
If to OraSure:	OraSure Technologies, Inc. 220 East First Street Bethlehem, PA 18015 Facsimile: (610) 882-2275 Attention: President Facsimile No. 610-882-2275

With a copy to: OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
Facsimile: (610) 882-2275
Attention: General Counsel
Facsimile No. 610-882-2275

or to such other address or addresses as may from time to time be given in writing by either Party to the other pursuant to the terms hereof.

18.2 Effective Notice. Any notice given in accordance with this Article shall be effective upon receipt by the Party to whom it is addressed.

19. MUTUAL RELEASES

19.1 Release by Roche: Except as provided in Section 2.1 and subject to OraSure's compliance with the terms hereof, Roche, for itself and on behalf of its Affiliates, predecessors, successors and assigns (hereinafter in this Section 19.1 individually and collectively referred to as the "**Roche Releasors**"), fully and forever releases and discharges OraSure and its Affiliates, and each of their respective predecessors, successors, assigns, officers, directors, employees, agents, attorneys, advisors and shareholders (hereinafter individually and collectively referred to in this Section 19.1 as the **"OraSure Releasees**"), of and from any and all claims, controversies, actions, causes of action, suits, debts, accounts, bonds, covenants, contracts, agreements, promises, demands, damages, judgments, executions, costs, expenses, charges, liabilities, sums of money, doings, omissions, losses, exposures, and obligations of any kind whatsoever, at law or in equity, direct or indirect, known or unknown, matured or unmatured, that the Roche Releasors, or any of them, ever had, now has, or may have in the future by reason of, arising out of, or relating to any matter or cause whatsoever related to the Development Agreement or the Commercialization Agreement existing or occurring from the beginning of the world until the Effective Date of this Agreement.

19.2 Release by OraSure. Except as provided in Section 2.1 and subject to Roche's compliance with the terms hereof, OraSure, for itself and on behalf of its Affiliates, predecessors, successors and assigns (hereinafter in this Section 19.2 individually and collectively referred to as the "**OraSure Releasors**"), fully and forever releases and discharges Roche and its Affiliates, and their respective predecessors, successors, assigns, officers, directors, employees, agents, attorneys, advisors, distributors and shareholders (hereinafter individually and collectively referred to in this Section 19.2 as the "**Roche Releasees**"), of and from any and all claims, controversies, actions, causes of action, suits, debts, accounts, bonds, covenants, contracts, agreements, promises, demands, damages, judgments, executions, costs, expenses, charges, liabilities, sums of money, doings, omissions, losses, exposures, and obligations of any kind whatsoever, at law or in equity, direct or indirect, known or unknown, matured or unmatured, that the OraSure Releasors, or any of them, ever had, now has, or may have in the future by reason of, arising out of, or

relating to any matter or cause whatsoever related to the Development Agreement or the Commercialization Agreement existing or occurring from the beginning of the world until the Effective Date of this Agreement.

20. MISCELLANEOUS

20.1 Assignment. This Agreement shall not be assigned by either Party without the prior written consent of the other Party. Such consent shall not be unreasonably withheld. Notwithstanding the foregoing, (a) Roche may assign or delegate at its sole discretion its rights and obligations under this Agreement, in whole or in part to any of its Affiliates, without any such prior written consent, but shall remain liable hereunder notwithstanding such assignment and (b) OraSure may assign or delegate at its sole discretion its rights and obligations under this Agreement, without such prior written consent, to any Person that succeeds to all or substantially all of its business or assets by purchase or sale, merger, consolidation or otherwise or acquires the line of business to which this Agreement relates ("**OraSure Assignee**"). Each Party promptly shall provide written notice to the other Party of any assignment or delegation of this Agreement. Any assignment or delegation of this Agreement in violation of this Section 20.1 shall be null and void, ab initio. If an OraSure Assignee is a company that develops and/or sells in vitro diagnostic assays and/or equipment and which generates sales of such assays and/or equipment in excess of $500,000,000 (five hundred million) U.S. Dollars) in any given calendar year, such OraSure Assignee shall not be entitled to sell Immunoassays under any Roche trademark and label and Roche shall be obligated to supply Immunoassays in accordance with this Agreement only under such OraSure Assignee's own trademark and label.

20.2 Compliance with Laws. Each Party shall comply in all material respects with, and give all notices required by, all applicable laws of any governmental authority bearing on such Party's performance of this Agreement as existing on the Effective Date and/or as enacted or amended during the Term hereof, including, without limitation, all requirements relating to human health, safety, animal derived materials, and the environment. In no instance shall either Party promote the Products in a manner that is inconsistent with existing regulatory clearances or approvals, or in a manner that shall cause the Products to become adulterated or misbranded under U.S. law or similar laws in any other jurisdiction. Each Party shall notify the other Party if it becomes aware of any non-compliance by it of any material requirement under applicable law and shall take all appropriate action necessary to comply with such applicable laws.

20.3 Compliance with Import and Export Regulations. Each Party acknowledges that Products delivered under this Agreement may be subject to export control laws and export or import regulations. Each Party is responsible for and agrees to comply strictly with all such laws and regulations and acknowledges that it has the responsibility to obtain licenses to export, re-export, or import as may be required.

In any case the applicable Supplier has to inform the Purchaser about the respective numbers/codes of the Products, software or technology according to the EU Dual Use List and/or the US Commerce Control List or any other EU and US export control regulation e.g. Weapons- or Munitions List etc. Further, the applicable Supplier shall notify the Purchaser about the percentage (%) of the US originated contents in the Products, software or technologies/services.

20.4 Entire Agreement. This Agreement and its attachments constitute the entire understanding between the Parties with respect to the subject matter hereof, and supersedes and replaces all prior agreements, understandings, writings and discussions between the Parties relating to said subject matter, except if explicitly exempted in this Agreement.

20.5 Amendments; Waivers. This Agreement may be amended and any of its terms or conditions may be waived only by a written instrument executed by both Parties, or, in the case of a waiver, by the Party waiving compliance. The failure of either Party at any time to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any instance shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

20.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and permitted assigns.

20.7 Governing Law; Jurisdiction. This Agreement shall in all respects regarding substantive law be governed by and construed in accordance with the laws of the State of New York, U.S.A, exclusively, as such laws shall be in effect from time to time, and such laws shall also be applied to all disputes, claims and other proceedings which may arise hereunder or relating hereto, in the event of arbitration, court proceedings or otherwise, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the State of New York, U.S.A. The Parties agree that any disputes arising hereunder shall be resolved pursuant to Section 20.8. To the extent any dispute is not subject to Section 20.8, the Parties each hereby submit to the exclusive jurisdiction of federal and state courts in the State of New York, U.S.A. for the purposes of any suit, action or other proceeding relating to such dispute. Each Party further agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth above shall be effective service of process for any action, suit or proceeding in New York, U.S.A. with respect to any matters to which it has submitted to jurisdiction in this Section. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or state courts of the State of New York, U.S.A., and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

20.8 Dispute Resolution.

(a) Attempt to Settle. Except as otherwise provided in this Section 20.8 below, in the event of any controversy or claim arising out of, relating to or in connection with any provision of this Agreement or the rights or obligations of the Parties hereunder, the Parties will try to settle their differences amicably between themselves as contemplated herein. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party. Promptly following such notice, representatives of the Parties shall meet in person at a mutually agreeable location to negotiate in good faith a resolution to the dispute within the thirty (30) day period following the notice. If the executive officers are unable to promptly resolve such disputed matter within the said thirty (30) days, either Party may initiate arbitration proceedings in accordance with Section 20.8 hereof.

(b) Arbitration. The Parties agree that if the dispute is unresolved after following the procedure in Section 20.8(a), then either Party may initiate binding arbitration in accordance with the commercial arbitration rules of the American Arbitration Association ("AAA") then in force by providing written notice to the other Party informing the other Party of such intention and the issues to be resolved. The Parties shall agree upon and appoint three (3) arbitrators within thirty (30) days after the notice of arbitration is received, or if the Parties are unable to agree the arbitrators shall be selected in accordance with the applicable rules of the AAA. Such arbitrators shall have appropriate experience in the medical diagnostics industry and be independent of each of the Parties. The Parties shall use their best efforts to conclude the arbitration within six (6) months after the arbitrators have been appointed. Each arbitrator selected in accordance with this Section 20.8(b) shall be required to acknowledge his or her intention and availability to meet the Parties' desire that a final decision be issued with respect to the dispute within six (6) months from the selection of the last arbitrator. The place of arbitration shall be New York City, New York, U.S.A. The costs of arbitration, including administrative and arbitrator fees, shall be shared equally by the Parties, provided that each Party shall bear the expenses of its witnesses, counsel and other experts. The award or decision of the arbitrators shall be in writing and shall be final and binding upon the Parties. Judgment upon the award or decision may be entered in any court having jurisdiction, or application may be made to such court for judicial acceptance of the award and/or an order of enforcement as the case may be.

(c) Equitable Relief. Nothing in this Agreement shall be deemed as preventing any Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect any Party's name, proprietary information, Confidential Information or other Intellectual Property Rights or as contemplated by Section 20.16.

20.9 Severability. The Parties agree that if any part, term or provision of this Agreement shall be found illegal or in conflict with any valid controlling law, the validity of the remaining provisions shall not be affected thereby. In the event the legality of any provision of this Agreement is brought into question because of a decision by a

Court of competent jurisdiction of any country in which this Agreement applies, the Parties will discuss in order to revise or delete the provision in question so as to comply with the decision of said Court.

20.10 Headings. Headings and titles in this Agreement are for convenience purposes only and shall not in any way influence the construction, performance and enforcement of any of its provisions.

20.11 No Partnership or Agency. Nothing in this Agreement and no action taken by the Parties pursuant to this Agreement shall constitute, or be deemed to constitute, a partnership, agency, association, joint venture, or other cooperative entity. The Parties acknowledge that they are independent contractors and neither Party has the right or power, express or implied, to make any commitments of any kind on behalf of the other Party without prior written consent of the other Party.

20.12 Further Assurances. Each Party shall from time to time, at the request and cost of the other, now or at any time in the future, execute all documents and do all such acts and things as may be necessary or desirable to give full effect to this Agreement.

20.13 Force Majeure. Neither Party shall be liable for any failure or delay in its performance under this Agreement due to causes that are beyond its reasonable control, including acts of God, acts of civil or military authority, fires, epidemics, floods, earthquakes, riots, wars, sabotage, labor shortages or disputes, and governmental actions; provided that the delayed Party: (i) promptly gives the other Party written notice of such cause, and in any event within fifteen (15) days of discovery thereof, and (ii) uses its reasonable efforts to correct such failure or delay in its performance. The delayed Party's time for performance or cure under Section 15.2 shall be extended for a period equal to the duration of the cause.

20.14 No Third-Party Beneficiaries. Except as expressly provided herein, nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

20.15 Counterparts. This Agreement may be signed in one or more identical original or facsimile counterparts, each of which shall be treated as an original but all of which, when taken together, shall constitute one and the same instrument. This Agreement may be translated into other languages, but the English version of this Agreement shall at all times control.

20.16 Irreparable Harm. Each Party acknowledges and agrees that, in the event of any threatened or actual breach by it of any provision of this Agreement, the other Party shall suffer immediate and irreparable injury not fully compensable by monetary damages and for which the other Party may not have an adequate remedy at law. Accordingly, each Party agrees that if the other Party institutes an action or proceeding to enforce any provisions of this Agreement, the other Party shall be entitled to injunctive or other equitable relief as may be necessary or appropriate to enjoin, prevent or curtail any such breach or threatened breach, without the posting of any bond or security. The foregoing shall be in addition to and without prejudice to such other rights as each Party may have under this Agreement, at law or in equity.

20.17 Publication. The Parties agree to publicly announce the principal terms of this Agreement following execution and to cooperate in the preparation and timing of one or more press releases to effect such announcement.

20.18 Rules of Construction.

(a) Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in the event an ambiguity or a question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

(b) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined, and derivative forms of any capitalized term defined herein shall have meanings correlative to the meaning specified herein. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” The word “will” shall be construed to have the same meaning and effect as the word “shall.” The word “any” shall mean “any and all” unless otherwise clearly indicated by context. “$” as used in this Agreement means the lawful currency of the United States. Where either Party’s consent is required hereunder, except as otherwise specified herein, such Party’s consent may be granted or withheld in such Party’s sole discretion.

(c) Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) references to this Agreement include all Exhibits, which are incorporated herein and made part hereof, and any duly executed amendments to the foregoing; (iii) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (iv) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (v) the words “herein” “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (vi) all references herein to Articles, Sections, or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, or Exhibits of this Agreement.

20.19 Annexes. The following annexes shall form integral parts of this Agreement:

Exhibit A	Immunoassay Specifications
Exhibit B	Calibrator Specifications
Exhibit C	Quality Requirements for Products
Exhibit D	intentionally omitted
Exhibit E	Chemical Change Notification
Exhibit F-1	Immunoassay Transfer Prices
Exhibit F-2	Calibrators Transfer Prices
Exhibit G	Roche Trademarks
Exhibit H	Roche Letter to OraSure Dated May 27, 2013

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the day and year first above written.

ORASURE TECHNOLOGIES, INC.

By: /s/ Ronald H. Spair
Name: Ronald H. Spair
Title: CFO and COO

ROCHE DIAGNOSTICS OPERATIONS, INC.

By: _____
Name: _____
Title: _____

ROCHE DIAGNOSTICS GMBH

By: /s/ Jean-Claude Gottraux
Name: Jean-Claude Gottraux
Title: Head of Roche Professional Diagnostics

By: /s/ Claudia Böckstiegel
Name: ppa Claudia Böckstiegel
Title: Head Legal Professional Diagnostics

F. HOFFMANN – LA ROCHE LTD

By: /s/ Claus-Joerg Ruetsch
Name: Claus-Joerg Ruetsch
Title: Head Legal Diagnostics

By: /s/ Juan Cortizo
Name: ppa Juan Cortizo
Title: Legal Counsel

Exhibit A

Immunoassay Specifications

1	Use	Specification
1.1	Intended Use	[***]
1.2	Business/markets	[***]
1.4	Controls / Calibrators (2 levels / 6 levels)	[***] [***] [***] [***] [***] [***] [***] [***]
1.5	Equipment / Applications	[***] [***] [***]
1.6	Panels / Assays Developed	[***] [***] [***] [***] [***]
2	Performance Characteristics	
2.1	Analytical Sensitivity/ (Limit of Detection)	[***]
2.2	Specificity Compared to Mass Spectrometry	[***]
2.3	Sensitivity Compared to Mass Spectrometry	[***]
2.4	Method Comparison	[***]
2.5	Resolution (Control Levels)	[***]
2 .6	Cutoff (Phase 1) Amphetamine Methamphetamine/ MDMA Cocaine (BZE) Opiates Phencyclidine (PCP)	[***] [***] [***] [***] [***] [***]
2.8	Cross Reactivity	
	Amphetamines	[***] [***] [***] [***] [***] [***] [***] [***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

		[***]
		[***]
		[***]
		[***]
		[***]
	Methamphetamine/MDMA	[***]
		[***]
		[***]
		[***]
		[***]
		[***]
	Cocaine	[***]
		[***]
		[***]
		[***]
	Opiates	[***]
		[***]
		[***]
		[***]
		[***]
	Phencyclidine (PCP)	[***]
		[***]
2.9	Calibrators Target Analytes	
	Amphetamine	
	Methamphetamine/ MDMA	
	Cocaine	[***]
	Opiates	[***]
	Phencyclidine (PCP)	[***]
		[***]
		[***]
2.10		
	Calibrator Levels	[***]
	Amphetamine	[***]
	Methamphetamine	[***]
	Cocaine (BZE)	[***]
	Opiates (Morphine)	[***]
	PCP	[***]
2.11	Control Levels	[***]
	Amphetamine	[***]
	Methamphetamine	[***]
	Cocaine (BZE)	[***]
	Opiates (Morphine)	[***]
	PCP	[***]

2.12	Precision Semi-quantitative	Intra-Assay	Inter-Assay
	Amphetamines	[***]	[***]
		[***]	[***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

	Methamphetamine	[***] [***]	[***] [***]
	Cocaine	[***] [***]	[***] [***]
	Opiates	[***] [***]	[***] [***]
	PCP	[***] [***]	[***] [***]
3	Stability		
3.1	Reagents - Shelf Life (2 - 8C)	[***] [***]	
3.2	Calibrators – Shelf Life (2 - 8C)	[***]	
3.3	Control – Shelf Life (2 - 8C)	[***]	
3.4	Reagents – Onboard Stability	[***]	
3.5	Controls Stability - Open Bottle[***]		
3.6	Calibrator Stability - Open Bottle[***]		
3.7	Sample– Intercept device	[***] [***]	
4	Regulatory Requirements		
4.1	Approval Requirements	[***]	

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit B

Calibrator Specifications

DAT Oral Fluid Calibrators and Controls

Formulation of product	[***]
Matrix of product	[***]
Handling of product	[***]
Source of added components	[***]
Size of components	[***] [***]
Bottle material	[***]
Storage conditions	[***]
Acceptance cirteria	[***]
Real time	[***]
Stress	[***]
Shipping category	[***]
Minimum expiration date	[***]
Opened/reclosed bottle	[***]
Performance – typical analyte concentration	[***] [***] [***] [***] [***] [***] [***] [***] [***] [***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Specifications	Requirements
1 OF DAT Cal 0	
1.a. Appearance	[***]
1.b. Drug Analyte • None (Negative) – Assay testing	[***]
2 OF DAT Cal A 1	
2.a. Appearance	[***]
2.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]

Specifications	Requirements
3 OF DAT Cal A 2	
3.a. Appearance	[***]
3.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]

Specifications	Requirements
4 OF DAT Cal A 3	
4.a. Appearance	[***]
4.b. Drug Analyte	

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]
Specifications	Requirements
5 OF DAT Cal A 3	
5.a. Appearance	[***]
5.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]
Specifications	Requirements
6 OF DAT Cal A 3	
6.a. Appearance	[***]
6.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Specifications	Requirements
1 OF DAT Control 0	
1.a. Appearance	[***]
2 OF DAT Control Set A POS	
2.a. Appearance	[***]
2.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]

Specifications	Requirements
3 OF DAT Control Set A NEG	
3.a. Appearance	[***]
3.b. Drug Analyte	
• Phencyclidine (PCP) • LC/MS/MS Assay testing	[***] [***]
• Benzoylecgonine • LC/MS/MS Assay testing	[***] [***]
• Morphine • LC/MS/MS Assay testing	[***] [***]
• Methamphetamine • LC/MS/MS Assay testing	[***] [***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit C

Quality Requirements for Products

1. Roles. Supplier shall comply with all laws applicable to a manufacturer of finished medical devices, including without limitation, pre-market notification and quality system requirements, if applicable.

2. Compliance with Quality Assurance and Quality System Regulations. Supplier represents and warrants as follows: (a) the manufacturing processes used to produce its Products comply with all applicable laws. Supplier further represents and warrants that Supplier shall maintain purchasing controls in accordance with all applicable laws and shall establish and maintain procedures to ensure that Supplier's subcontractors, vendors and manufacturers comply with all such applicable laws. Supplier shall provide Provider with any applicable validation certificates upon request. Supplier represents and warrants that an installation qualification, operational qualification, and performance qualification has been performed on the manufacturing processes for the Products in accordance with GM P. Without limiting the warranty in this Paragraph, Supplier warrants that none of its Products, at the time of delivery, are adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321-394), or similar law of any other jurisdiction.

3. Incoming Quality Control Tests/Inspections. Supplier shall perform appropriate incoming quality control tests and/or inspections to determine that the quality of the component parts and/or raw materials used in the manufacture of its Product(s) meets Supplier's requirements. Supplier shall keep complete, accurate, and reproducible records of all data relating to such component parts and/or raw materials. Supplier shall maintain an appropriate system for auditing its subcontractors, vendors or manufacturers (if any).

4. Final Inspection of Lots. Supplier shall use statistical or other appropriate sampling to inspect every lot of its Product(s) to be delivered to Provider for compliance with the applicable Specifications and the other terms and conditions of this Agreement prior to shipment, and shall issue a certificate of compliance in a form reasonably satisfactory to Provider in respect thereof.

5. Reports, Complaints and Inquiries from Governmental Authority.

(a) Adverse Event Reports. Supplier shall be responsible for reporting adverse device events, malfunctions, incidents, near incidents and other reportable events for its Product(s) to relevant Regulatory Authorities pursuant to the applicable laws of any jurisdiction in which the Product is marketed or sold, including the FDA's medical device reporting requirements set forth in 21 C.F.R. Part 803. Provider shall provide such assistance and information as Supplier reasonably requests to fulfill its reporting obligations for the Product. Supplier shall maintain files and records as required by 21 C.F.R. 803 (or similar provisions of other applicable laws). Any adverse experience information obtained by a Party with respect to the other Party's Products shall be reported to the other Party, by telephone or by facsimile within three (3) Business Days after initial receipt of any such information: provided, however, any report of a serious adverse event or any

report of a death shall be reported to the other Party by telephone within twenty-four (24) hours after receipt of the information and by facsimile within forty-eight (48) hours after receipt of the information.

(b) Inquiries from Regulatory Authority. If either Supplier or Provider receives notice of an inspection, audit, or inquiry by a Regulatory Authority relating to the Product(s), arising from the any activities under this Agreement, or concerning either Party's compliance with applicable laws in connection with its activities under this Agreement, the Party receiving such notice of inspection, audit, or inquiry will notify the other Party as soon as possible, but in no event later than forty-eight (48) hours after receipt of such notice or notification, and provide to the other Party, within seventy-two (72) hours, copies of any documents received from or supplied to the Regulatory Authority that are relevant to the inspection or inquiry. Supplier and Provider agree to cooperate reasonably with each other during any inspection, investigation or other inquiry, including providing information and/or documentation as requested by the Regulatory Authority.

6. Regulatory Approval. Supplier represents and warrants to Provider that Supplier will use commercially reasonable efforts to obtain and maintain any existing marketing approvals or clearances for the Products required by applicable Regulatory Authorities in the United States and other applicable jurisdictions. Supplier hereby grants to Provider the fully paid-up right during the Term of this Agreement to use any and all regulatory approvals and clearances related to the Products owned by or licensed to Supplier. Provider shall have a right of reference to any and all technical, scientific and clinical data in any application for marketing approval or clearance for the Product.

7. Supplier Corrective Action Request. If, during the Term of this Agreement, Provider reasonably identifies an issue that may affect the quality of a Product(s), its components or raw materials, Supplier's manufacturing processes or quality control processes or procedures, Provider may at its sole discretion, issue to Supplier a Supplier Correction Action Request (each a "SCAR"). Within fifteen (15) Business Days after the issue date of the SCAR, Supplier shall deliver to Provider a detailed response to the SCAR (a "SCAR Response"). If final closure and verification on the issue or issues identified in the SCAR cannot be achieved within fifteen (15) Business Days of Supplier's receipt of the SCAR, as part of the SCAR Response, Supplier shall submit to Provider an action plan detailing its proposed plan to correct the issues identified in the SCAR. Provider shall have the right to review and propose revisions to any such action plans. Following Provider's approval and Supplier's initial implementation of the corrective action plan, Supplier shall provide bi-weekly status reports, upon reasonable request, to Provider until final verification of the corrective action is accomplished and Provider accepts the corrective action by written notice to Supplier.

8. Regulatory Documentation. Supplier shall accurately prepare and maintain all necessary and customary records as required by law, including without limitation records related to the manufacturing processes undertaken by Supplier pursuant to this Agreement in compliance with all applicable laws. Provider shall have access to and the right to review such records, upon request and without charge, in order to ensure compliance with this Agreement.

9. Violations. Supplier shall notify Provider as soon as practicable after becoming aware of any violation of any applicable laws or Quality Requirements, relating to its Product(s), the manufacturing processes, or otherwise relating to or arising out of Supplier's activities pursuant to this Agreement.

Exhibit E

Chemical Change Notification- CCN

PROCEDURE FOR USE OF CHEMICAL CHANGE NOTIFICATION FOR

ROCHE DIAGNOSTICS PRODUCTS PRODUCED BY OEM-PARTNER

Information required by RDO from the OEM-Partner concerning changes in device(s) chemical change notification Procedure (CC N)

1. Preliminary remarks

Any planned changes in device on behalf of the OEM-Partner must be notified to RDO at least 2 to 3 months prior to the change. On receiving notification a CCN-procedure will be started at RDO. Alterations in device specification as agreed to in any previous contract, are not a constituent part of the CCN-procedure. Such alterations require special agreement and consent by both parties.

In the case of any alteration(s) the OEM-partner must provide evidence that the change in the device makes no change to the product specification or quality (validation, verification). It remains the privilege of RDO to make any necessary comments concerning the aforementioned alterations. If judged necessary by RDO further experimental evidence must be provided by the OEM-partner. The first two production lots, produced following an alteration in the device, must have all necessary quality control examinations. These examinations must be carried out by the OEM - partner.

2. List of planned device changes, about which RDO must be informed in advance:

- Changes in manufacturing facilities, methods or quality procedures
- Changes in principle of operation, ingredients, principle of operation, or physical layout of the device
- Change of critical raw materials
- Change of supplier of critical compounds
- Labeling changes
- Changes in packaging
- Changes in the sterilization procedures
- Changes of the expiration date of the device
- Changes in the stability of the device

3. Partners responsible at RDO

Window person in QA RDO

CHEMICAL CHANGE NOTIFICATION REPORT

CCN-REPORT

Company: _____

Product Name: _____

Material Number: _____

Originator and Dept.: _____ Date: _____

Description of intended change: _____

_____

Reason(s) for intended change: _____

_____

Validation/verification of intended change: _____

_____

Risk assessment for intended change: _____

_____

Plan date for implementation: _____

Departmental Approval: _____ Date: _____

_____ Accept

The change has no effect on product specification (attach data)

final disposition approval (authorized persons):

Research and Development _____ Date: _____

Re-engineering Development _____ Date: _____

Production: _____ Date: _____

Quality Assurance: _____ Date: _____

The change is accepted by RDO ☐

The change is not accepted by RDO ☐

Exhibit F-1

Immunoassay Transfer Prices

	[***]	[***]	[***]
Amphetamine	[***]	[***]	[***]
Methamphetamine	[***]	[***]	[***]
Cocaine	[***]	[***]	[***]
Opiates	[***]	[***]	[***]
PCP	[***]	[***]	[***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit F-2

Calibrators & Controls Transfer Prices

	Roche Cat.-No.	OraSure Cat.-No.	Product name	Description	Packaging	Transfer Price to Roche
	[***]	[***]	[***]	[***]	[***]	[***]
CALIBRATORS	[***]	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]	[***]
CONTROLS	[***]	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]	[***]

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit G

Roche Trademarks

COBAS®

cobas®

cobas c

MODULAR

Exhibit H

Roche Letter to OraSure Dated

May 27, 2013

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
Facsimile: (619) 882-2275
Attention: Douglas A. Michels, President

May 27, 2013

Joint Development and Cross-License Agreement between OraSure Technologies. Inc. and Roche Diagnostics Operations, Inc., Roche Diagnostics GmbH and F. Hoffmann-La Roche Ltd dated June 15, 2008 ("Development Agreement") Request for assistance with Olympus 680 applications

Dear Mr. Michels

Following our last discussion in Chicago, we have carefully reviewed OraSure's request for assistance with Olympus 680 applications.

While we maintain our position as communicated in Roche's notice of termination dated November 22, 2012 and disagree with the view that OraSure response letter dated December 21, 2012, we are willing to work on this specific application process with OraSure.

We currently estimate that the sequence of next steps will be as follows:

- Finalization of documents (protocols and reporting templates) at Roche takes about 1 week.
- As soon as application data are available from OTI Roche needs approximately 3 months for the compilation and review of application reports and labeling changes.

Please note that our agreement to support OraSure in this matter is made without prejudice and does not constitute an acknowledgement of any contractual obligation.

Please contact Randy Pritchard, should you have further questions. We look forward to continuing our discussions to reach a mutually-agreeable solution as to the state of our relationship.

Roche Diagnostics GmbH Diagnostics Division Legal Department

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49 621 759 0; Telefax +49 621 759 2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

Sincerely,
Roche Diagnostics GmbH

/s/ Jean-Claude Gottraux
Jean - Claude Gottraux
Head of Roche Professional Diagnostics

/s/ Claudia Böckstiegel
ppa. Claudia Böckstiegel
Head Legal Professional Diagnostics

Copy to
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
Facsimile: (619) 882-2275
Attention: General Counsel

Exhibit 21

Subsidiaries of the Registrant

Subsidiary	Place of Incorporation/ Organization
DNA Genotek Inc.	Canada

Exhibit 23

Consent of Independent Registered Public Accounting Firm

The Board of Directors
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-3 (No. 333-184190) and Form S-8 (No. 333-118385, No. 333-102235, No. 333-50340, No. 333-48662, No. 333-138814, No. 333-151077 and No. 333-176315) of OraSure Technologies, Inc. of our reports dated March 14, 2014, with respect to the consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2012, and the effectiveness of internal control over financial reporting as of December 31, 2013, which reports appear in the December 31, 2013 annual report on Form 10-K of OraSure Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2014

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ *Douglas A. Michels*
Signature

Douglas A. Michels
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Michael Celano
Signature

Michael Celano
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Ronny B. Lancaster
Signature

Ronny B. Lancaster
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Gerald M. Ostrov
Signature

Gerald M. Ostrov
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Charles W. Patrick
Signature

Charles W. Patrick
Print Name

POWER OF ATTORNEY

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IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Roger L. Pringle
Signature

Roger L. Pringle
Print Name

POWER OF ATTORNEY

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IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Ronald H. Spair
Signature

Ronald H. Spair
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Stephen S. Tang, Ph.D.
Signature

Stephen S. Tang, Ph.D.
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Mark L. Kuna, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2013, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 10, 2014.

/s/ Douglas G. Watson
Signature

Douglas G. Watson
Print Name

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2014

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2014

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

March 14, 2014

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

March 14, 2014