ORASURE TECHNOLOGIES INC
Form 10-K
March 13, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT

TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2012

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File No. 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(610) 882-1820

(Registrant s Telephone Number, Including Area Code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock $0.000001 par value per share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes x No ¨

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

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

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

(Do not check if a smaller reporting company)

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

State the aggregate market value of the voting and non-voting common equity held by nonaffiliates, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant s most recently completed second fiscal quarter (June 30, 2012): $535,010,265

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 11, 2013: 55,518,043 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2013 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 is sold in the over-the-counter (OTC) or consumer retail markets in the United States and we sell a cryosurgical product 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 also manufacture and sell kits that are used to collect, stabilize, and store samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock 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 several countries worldwide, including many leading research universities and hospitals.

On July 3, 2012, the U.S. Food and Drug Administration (FDA) issued a pre-market approval (PMA) for our OraQuick® In-Home HIV Test for sale directly to consumers in the OTC market, making it the first and only rapid OTC HIV test approved in the U.S. The OraQuick® In-Home HIV Test can detect antibodies to both

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HIV-1 and HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 minutes. This test was approved following extensive clinical trials conducted during the past several years. In September 2012, we began selling this product to consumers.

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.	PMA approved 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

	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

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Product	Description	Regulatory Status	Commercial Status
OraSure QuickFlu Rapid Flu A&B Test	A rapid, point-of-care qualitative test for antibodies to influenza (flu) Types A and B, including H1N1 infections, with results available in 10 minutes.	FDA 510(k) cleared for use with nasal swab, nasopharyngeal swab and nasal aspirate/wash.	Marketed
OraSure®	Oral fluid collection device for 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 mark 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
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.	Marketed
		Registered in various other countries.	
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

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Product	Description	Regulatory Status	Commercial Status
Intercept®	Oral fluid collection device for oral fluid drugs of abuse (DOA) testing in a laboratory setting.	FDA 510(k) cleared for use with MICRO-PLATE DOA assays.	Marketed
		CE marked and registered in certain countries.	Marketed
MICRO-PLATE DOA Assays	Used to detect the following drugs in an oral fluid sample collected with Intercept® device: tetrahydrocannabinol (THC or marijuana), cocaine, opiates, amphetamines, methamphetamines, phencyclidine (PCP), benzodiazepines, barbiturates and methadone.	Nine drug assays FDA 510(k) cleared.	Marketed
		Assays CE marked and registered in certain countries.	Marketed
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 of PCP, opiates, cocaine, methamphetamines and amphetamines assays with Intercept® collection device.	Marketed
Cryosurgical Systems Professional	Cryosurgical (freezing) system for the removal of warts and other benign skin lesions, marketed under the Histofreezer® tradename primarily to the physicians office market.	Nine indications FDA 510(k) cleared.	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

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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 and is OraSure s newest product. We have received FDA approval to sell this test in the U.S. OTC market on July 3, 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 for sale in certain U.S. markets.

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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. In addition, we have received a CE mark for the OraSure® device and our cocaine and cotinine assays, all of which are sold through distributors in Canada, the United Kingdom, Mexico and certain other foreign countries.

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 each product is designed for. 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.

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DNAG products historically have been sold primarily as Class I medical devices for use by research and academic institutions. DNAG has received FDA 510(k) clearance for the Oragene® Dx product and began marketing this product to clinical diagnostics and personalized medicine customers in the U.S. during 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 have received a CE mark for the Intercept® device and our oral fluid assays and distribute these products in Canada, the United Kingdom and Mexico.

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 have experienced significant delays in completing development of the assays under our collaboration, primarily because Roche has not been able to obtain FDA 510(k) clearance of a THC assay. Although the other assays that comprise a NIDA-5 panel have received FDA clearance, the THC assay is needed to offer a complete NIDA-5 panel required by our customers. The inability to obtain this clearance has limited our ability to commercialize these initial assays and has delayed development of assays beyond the NIDA-5 panel. As a result, we are in discussions with Roche about the THC assay and the future of our collaboration.

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

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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. In 2011, we began selling 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.

Products Under Development

OraQuick® Platform

We believe that the OraQuick® point-of-care testing platform has significant potential for clinics and other public health entities, hospitals, physicians offices and other markets. Because the OraQuick® platform is simple to use and can operate in a non-invasive manner with oral fluid, we believe it is suitable for use by consumers without the assistance of a doctor or other medical professional. We also believe that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV and HCV, including certain sexually transmitted diseases. Several new products based on the OraQuick® technology platform are being evaluated.

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OraSure®/Intercept® Applications

Oral mucosal transudate, or OMT, contains many constituents found in blood and serum, although in lower concentrations. We believe the OraSure® and Intercept® devices are a platform technology with a wide variety of potential applications, where laboratory testing is available. For example, the OraSure® device may be useful for the collection of a variety of antibodies or markers for infectious diseases or conditions in addition to HIV-1, such as antibodies to viral hepatitis.

Since January 2011, the Drug Testing Advisory Board (DTAB) has been evaluating oral fluid as a potential alternative specimen to be permitted under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (the Guidelines). The Guidelines govern workplace drug testing of federally-regulated workers. Based on its evaluation, DTAB has recommended that oral fluid be included as an alternative specimen in the Guidelines, and the Substance Abuse and Mental Health Services Administration has approved this recommendation. If and when issued in final form, these regulations will likely require certain modifications to our Intercept® product in order to permit its use by federal workers. As a result, we are developing modifications to the Intercept® collection device that we anticipate will be required by these regulations or otherwise desired by our customers.

Molecular Collection Systems

Molecular testing in both the research and clinical diagnostics markets continues to evolve at a rapid pace. As a result, we expect to continue development activities designed to modify the capabilities and fit of the DNAG products to meet the evolving needs of existing and potential molecular testing market applications. To address unique customer needs, we will continue to develop new chemical and/or physical platforms as needed by our customers. DNAG has a number of development projects underway to expand its product offerings in three primary market segments human genetics, infectious disease testing and animal testing.

Research and Development

In 2012, our research and development activities focused primarily on clinical and regulatory activities related to the PMA application for FDA approval of our OraQuick® In-Home HIV test, development of next generation versions of our OraQuick® HIV and Intercept® products 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 $12.4 million in 2012 (including $2.8 million of DNAG expenses), $18.4 million in 2011 (including $1.0 million of DNAG expenses since the August 2011 acquisition) and $13.2 million in 2010. 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 $67.5 million, $67.6 million and $63.5 million in 2012, 2011 and 2010, respectively. Revenues attributable to international customers amounted to $20.3 million, $14.2 million and $11.5 million, or 23%, 17% and 15% of our total revenues, in 2012, 2011 and 2010, 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.

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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, hospitals, physicians and retail clinics. We also sell this test in Europe and other countries through distributors.

We previously entered into domestic and international collaboration agreements with Merck & Co. Inc. (Merck), under which Merck agreed to detail our OraQuick® HCV product to physician offices. The initial term of our domestic agreement expired in September 2012 and was not renewed. We have also terminated our international agreement with Merck. Termination of these agreements is not expected to have a material impact on sales of our OraQuick® HCV test, either in the U.S. or in international markets.

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

The OraQuick® In-Home test has been available for purchase in the U.S. retail or consumer market since September 2012. 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 began a national public relations and advertising campaign in late 2012.

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.

Our revenue recognition practices with respect to the OraQuick® In-Home HIV Test will initially be different than those customarily used in the consumer package goods industry. Because this is a new product for which we do not have a historical record of returns, we will initially recognize revenue only upon the consummation of a sale to the retail customer either in a store or over the internet. We are working with our retail distribution partners to gain access to out-sales data to obtain greater transparency into the effectiveness of our launch and the actual uptake of our product in the hands of the consumer.

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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 revenues have been derived from product sales into the academic and research markets. A significant portion of DNAG s sales is derived from repeat customers. The clinical diagnostic market for human genetics is still in its early stages with only a few diagnostic customers currently using DNAG s products. DNAG 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, the FDA has issued 510(k) clearances for the use of fully-automated high-throughput oral fluid assays for the detection of PCP, opiates, cocaine, methamphetamines and amphetamines with oral fluid samples collected with our Intercept® device. Due to significant development delays under our agreement with Roche Diagnostics, particularly with respect to the assay for THC, the parties are currently in discussions regarding the future of our development and commercialization collaboration.

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 HBOC, Physician Sales & Service (PSS), AmerisourceBergen Corporation, and Henry

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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. In 2012, the OraQuick® rapid HIV testing products, the cryosurgical systems products, and our Oragene® product line accounted for total revenues of $37.9 million, $14.9 million and $14.3 million, 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 and $40.0 million, $11.9 million and $11.2 million in 2010, respectively.

We had no individual customers who accounted for more than 10% of our total revenues in 2012, 2011 or 2010.

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.

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OSUR revenues consist primarily of product sold into the United States and internationally to various clinical laboratories, hospital, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. OSUR also derives revenues from licensing and production development activities. DNAG revenues consist of product sold into the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock 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., 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.

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DNAG has engaged two third-party 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, 2012, we had 313 full-time employees (including 71 employees at our subsidiary, DNAG). Of this total, there were 111 in sales, marketing and client services; 32 in research and development; 121 in operations, manufacturing, quality control, information systems, purchasing and shipping; 18 in quality assurance and regulatory affairs; and 32 in administration and finance. This compares to 308 employees as of December 31, 2011. 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 they 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;
- Price;
- 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 tests 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.

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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 recently 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 our 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. One of these competitors has received 510(k) clearance of its product. This 510(k) cleared product is being offered by

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one of our large laboratory distributors. This distributor has stopped purchasing our Intercept® product. Internationally, our distributor in the United Kingdom has reduced its Intercept® purchases as it transitions to selling its own oral fluid collection device and assays.

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 ten 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 2013 to December 2026. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

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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 these 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.

One of the lateral flow patent licenses was obtained as part of a patent infringement litigation settlement with Alere (formerly Inverness Medical) in 2009. Under that license, we have paid royalties on net sales of our OraQuick® HIV and HCV professional products and the royalty rate on our OraQuick® HIV professional product has increased beginning in 2013.

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, six 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 May 2030.

We have four United States patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products, and we have pending patent applications related to these products in the United States and in certain foreign countries. These patents expire from August 2013 to September 2025. 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 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

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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, certain 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.

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 may be granted within that 90-day period, in some cases as much as a year or more 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, 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, often requiring one year or more, and may include requests for additional data and facility inspections before approval is granted, if at all.

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.

Every company that manufactures medical devices distributed in the United States must comply with the FDA s Quality System Regulations (QSRs). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. In complying with

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the QSRs, manufacturers must continue to expend time, money and effort in the area of production and quality to ensure full technical compliance. Companies are also subject to other post-market and general requirements, including restrictions imposed on marketed products, promotional standards and requirements for recordkeeping and reporting of certain adverse reactions. 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. 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 warning letters, monetary penalties, suspension or withdrawal of regulatory approvals, operating restrictions, total or partial suspension of production, injunctions, product recalls, seizure of products and criminal prosecution.

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.

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 is a pre-requisite to use of the CE mark and indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution. The CE mark is a European Union (EU) requirement to sell products that fall under the scope of the Medical Devices Directive (MDD) and the In Vitro Diagnostic Directive (IVDD). The CE mark is evidence that the manufacturer and the product meet the requirements of all applicable directives, including the MDD and IVDD.

We received authorization to use the CE mark for the OraQuick *ADVANCE*® HIV-1/2 test, the OraQuick® HCV test, the OraSure® and Intercept® collection devices, our Histofreezer® product line, our OTC cryosurgical removal product and certain of the Oragene® collection kits sold by DNA Genotek.

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

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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 a person;
- The furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental 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 programs.

Our products are or may be purchased by customers that will seek or receive reimbursement under Medicare, Medicaid or other governmental programs. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid or other governmental 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 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 and 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, 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. 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.

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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 pay, offer to pay or authorize the 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 materials and wastes.

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

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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 could 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 can 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 advertizing 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.

Although we believe that we have adequate processes in place to ensure compliance with these requirements, the FDA or other regulatory bodies could force us or our distributors to stop manufacturing, selling, exporting or promoting our products if it concludes that we are out of compliance with applicable regulations. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could be adversely affected if their operations are determined to be out of compliance. The FDA and other regulatory bodies could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing and selling such products. 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

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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 and we may be harmed.

In August 2012, the SEC adopted a new rule requiring disclosure of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by public companies. The new rule, which is effective for calendar year 2013 reporting and requires a disclosure report to be filed by May 31, 2014, will require companies to disclose and report whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The new rule could

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affect sourcing at competitive prices and availability in sufficient quantities of minerals used in the manufacture of our products. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be significant costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs and delays associated with possible changes to products, processes, regulatory approvals, or sources of supply as a consequence of such verification and/or potential supplier change activities. We may not be able to sufficiently verify the origins of the relevant minerals used in our products, which may harm our reputation. In addition, we may encounter challenges in satisfying those customers who require that all of the components of its products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so, or are only able to do so at a higher price.

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 wide spread 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,

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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 2012, 2011 and 2010, we incurred $12.4 million (including $2.8 million of DNAG expenses), $18.4 million (including $1.0 million of DNAG expenses since the August 17, 2011 acquisition) and $13.2 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 can be required before any regulatory authority will review them. As noted above, regulatory authorities may not approve these products for commercial sale or can 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 successfully commercialize our OraQuick® In-Home HIV test and increase sales of our OraQuick® HCV test. 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.

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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 risk factors, 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, 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.

In August 2011, we acquired DNAG with the expectation that the acquisition would result in benefits to both companies. However, we may not realize the financial, tax and other benefits of the acquisition to the extent, or in the timeframe, anticipated. For example, the acquisition could result in the loss of key employees, diversion of each company s management s attention, the disruption or interruption of, or the loss of momentum in, each company s ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect either company s ability to maintain relationships with customers, licensors, collaborators, partners, suppliers and employees. In addition, DNAG may not perform in a manner consistent

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with our expectations. These factors and others could negatively impact our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company.

Our Revenues Could be Affected by Third-Party Reimbursement Policies and Potential Cost Constraints.

The end-users of our products include hospitals, physicians and other healthcare providers. Use of our products could be adversely impacted if 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.

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 governmental 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 we expect will include 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 products. For example,

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several years ago, the CDC issued guidelines recommending routine HIV screening for all people ages 13 to 64, with more frequent testing for people at higher risk. These recommendations have resulted in increased HIV testing, including with our OraQuick *ADVANCE*® HIV-1/2 test. The CDC also issued guidelines with respect to HCV testing in 2012. The issuance of new testing guidelines, or changes in existing guidelines, and the manner in which these new or changed guidelines are interpreted and applied by healthcare practitioners, could have a positive or negative impact on the degree to which our OraQuick® rapid HIV and HCV testing products are used. New or changed 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 certain other products 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 and will remain in effect unless Congress takes further action. 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 new law could 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

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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.

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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.

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

Although we intend to pursue some product opportunities independently, opportunities that require 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.

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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.

We will 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. 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. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our 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.

Our industry is characterized by a large number of patents, claims of which 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.

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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 significantly affecting 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.

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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

A Market for Our Products May Not Develop.

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, an 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 an OraQuick® HCV test. As such, there can be no assurance that any products will obtain market acceptance and fill the market need that is perceived to exist.

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 genetic and other 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

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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 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 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. Moreover, 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 are more effective than ours or take market share from our products through more effective marketing or competitive pricing, our revenues, margins and operating results could be adversely affected.

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, 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 are expected to be substantial for the foreseeable future. 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 failure of our supplier for this product to obtain a CLIA waiver, which we believe is important to expand sales, particularly in the public health market;
- 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.

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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 be Sued for Product Liabilities 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 recently 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.

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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 intend to increase revenue derived from international sales of our products. Our international sales accounted for $20.3 million or 23% of total revenues in 2012, $14.2 million or 17% of total revenues in 2011 and $11.5 million or 15% of total revenues in 2010. In addition, as a result of our acquisition of DNAG, we now have a direct presence 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;

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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 for the manufacture of a portion of our OraQuick® HIV-1/2 tests in Thailand, 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

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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.

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, 2012, the Company had an accumulated deficit of $162.5 million. Even though we achieved profitability several 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 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 success and revenue growth of our new subsidiary, DNAG, and the sales of its Oragene® product line;
- The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick *ADVANCE*® HIV-1/2 test will replace our OraSure® collection device for HIV-1 testing or sales of our cryosurgical wart removal products in OTC markets will replace sales of our Histofreezer® product to physicians offices or other professional markets;
- 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

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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 less than estimated customer demand or other factors, including continued volatility and disruption in economic conditions, 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 and 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;

Allowance for uncollectible accounts receivable;

Reserve for inventory write-downs;

Stock-based compensation;

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

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. However, 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 2012, DNAG reported total revenues of U.S. $14.3 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

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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.

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 National 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 ceased, 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;

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The performance of our business, including our efforts to commercialize the OraQuick® In-Home HIV test;

Clinical results with respect to our products or those of our competitors;

Status of clinical studies and pending submissions for required regulatory approvals;

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;

Additions or departures of key personnel;

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 these 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 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.

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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, such as DNAG, 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.

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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 $400,000 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.

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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,			
	2012		2011	
	High	Low	High	Low
First Quarter	$ 11.78	$ 9.17	$ 7.87	$ 5.81
Second Quarter	12.28	8.90	9.00	7.06
Third Quarter	14.01	9.39	10.10	6.29
Fourth Quarter	11.34	6.56	9.96	7.52

On March 4, 2013, there were 485 holders of record and approximately 12,500 holders in street name of our Common Stock, and the closing price of our Common Stock was $5.42 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 2,956 shares to satisfy minimum tax withholding obligations during the three months ended December 31, 2012. No shares were repurchased under our $25.0 million share repurchase program during the same period.

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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, 2007 through December 31, 2012. The graph assumes that $100 was invested on December 31, 2007 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 the NASDAQ Stock Market. 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.

	12/07	12/08	12/09	12/10	12/11	12/12
OraSure Technologies, Inc.	**100.00**	**41.39**	**57.14**	**64.68**	**102.47**	**80.76**
NASDAQ Composite	**100.00**	**59.03**	**82.25**	**97.32**	**98.63**	**110.78**
NASDAQ Biotechnology	**100.00**	**93.40**	**103.19**	**113.89**	**129.12**	**163.33**

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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,				
	2012	**2011 [2]**	**2010**	**2009**	**2008**
Operating Results:					
Net revenues	$ 87,820	$ 81,881	$ 75,015	$ 77,026	$ 71,104
Costs and expenses	104,090	91,278	78,369	85,819	82,551
Operating loss	(16,270)	(9,397)	(3,354)	(8,793)	(11,447)
Other income (expense), net	(242)	(313)	(143)	357	2,699
Income tax provision (benefit)	(1,397)	(869)		(622)	22,527[3]
Net loss	(15,115)	(8,841)	(3,497)	(7,813)	(31,275)[3]
Basic and diluted loss per share	$ (0.29)	$ (0.19)	$ (0.08)	$ (0.17)	$ (0.67)
Shares used in computing basic and diluted loss per share	51,457	46,908	46,187	45,878	46,550
Cash Flow:					
Cash flows (used in) provided by operating activities	$ (5,373)	$ (2,994)	$ 3,887	$ (293)	$ (2,460)

	December 31,				
	2012	**2011 [2]**	**2010**	**2009**	**2008**
Financial Position:					
Cash, cash equivalents, and short-term investments	$ 87,888[1]	$ 23,878	$ 75,738	$ 79,670	$ 82,523
Working capital	103,483	30,860	77,808	89,435	90,936
Total assets	191,725	127,861	122,520	126,991	131,918
Long-term debt, excluding current portion				7,792	8,301
Accumulated deficit	(162,541)	(147,426)	(138,585)	(135,088)	(127,275)
Stockholders equity	170,315	100,250	102,843	103,807	108,325

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

2 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.

3 Includes an income tax provision of $25,978 resulting from the establishment of a full valuation allowance on our net deferred tax assets.

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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 are a leader in 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. 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 the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail market. DNAG, a Canadian subsidiary acquired on August 17, 2011, manufactures and sell kits that are used to collect, stabilize, and store samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. One of our cryosurgery products is sold in the over-the-counter or consumer retail market in North America, Europe, Central and South America, and Australia. 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.

Current Consolidated Financial Results

During the year ended December 31, 2012, our consolidated net revenues were $87.8 million compared to $81.9 million for the year ended December 31, 2011. Net product revenues during the year ended December 31, 2012 increased 6% when compared to 2011, primarily as a result of the inclusion of DNAG revenues for all of 2012. Full-year 2012 net revenues from our molecular collection systems subsidiary were $14.3 million, compared to $6.2 million in 2011 for the period from the August 17, 2011 acquisition date through December 31, 2011. Licensing and product development revenues for 2012 increased as a result of a $1.0 million milestone payment received from our achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck. The initial term of our domestic collaboration agreement with Merck expired in September 2012 and was not renewed. We are also in the process of terminating our international agreement with Merck. Termination of these agreements is not expected to have a material impact on sales of our OraQuick® HCV test, either in the U.S. or in international markets. The milestone payment was partially offset by a decrease in the royalty rate paid to us on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008.

Our consolidated net loss for the year ended December 31, 2012 was $15.1 million, or $0.29 per share, compared to a net loss of $8.8 million, or $0.19 per share, for the year ended December 31, 2011. Our loss for the current period included $9.9 million in costs associated with the commercialization of our OraQuick® In-Home HIV test. Our consolidated net loss for the year ended December 31, 2011 included $2.6 million of transaction costs associated with the acquisition of DNAG and $7.9 million of clinical trial spending related to our OraQuick® In-Home HIV test.

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Cash used in operating activities for the year ended December 31, 2012 was $5.4 million, compared to $3.0 million used during the year ended December 31, 2011. As of December 31, 2012, we had $87.9 million in cash and cash equivalents compared to $23.9 million at December 31, 2011. During 2012, we completed a public offering of 6,100,000 shares of our common stock and received $70.2 million in proceeds, net of offering expenses. On July 30, 2012, we repaid the $7.1 million principal balance outstanding under our $10.0 million credit facility with Comerica Bank. During 2011, we used $53.0 million of our cash to fund the DNAG acquisition and related transaction expenses.

2012 Developments

OraQuick® In-Home HIV Test

On July 3, 2012, the FDA issued a pre-market approval of our OraQuick® In-Home HIV Test for sale directly to consumers in the OTC market, making it the first and only rapid HIV OTC test approved in the U.S. The OraQuick® In-Home HIV Test can detect antibodies to both HIV-1 and HIV-2 with an oral swab with results in as little as 20 minutes, providing a confidential in-home testing option to consumers. It is the first rapid diagnostic test for any infectious disease that has been approved by the FDA for sale over the counter. This test was approved following extensive clinical trials conducted during the past several years.

The OraQuick® In-Home HIV Test has been available for purchase by consumers since September 2012 throughout the country, at retailers such as 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.

We began our national public relations and advertising campaign in connection with the September product launch. These activities substantially increased our sales and marketing expenses during the fourth quarter of 2012 and are expected to continue to substantially increase sales and marketing expenses in 2013.

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.

Our revenue recognition practices with respect to the OraQuick® In-Home HIV Test initially will be different than those customarily used in the consumer package goods industry. Because this is a new product for which we do not have a historical record of returns, we will initially recognize revenue only upon the consummation of a sale to the retail customer either in a store or over the internet.

Public Offering of Common Stock

On July 11, 2012, we completed a public offering of 6,100,000 shares of our common stock, at a price of $12.30 per share, resulting in total proceeds of $75.0 million before expenses of the offering. In connection with the offering, we paid $4.5 million in underwriting discounts and commissions and incurred $282,000 in additional offering expenses.

Economic Outlook

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

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In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. One example is the Affordable Care Act, the Federal healthcare reform law enacted in 2010. The Affordable Care Act imposes a 2.3% excise tax on certain transactions, including U.S. sales of many medical devices, which will include domestic non-retail sales of some of our products. This new tax became effective in January 2013 and will have a negative impact on our gross margin.

Also, 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 became effective on March 1, 2013. Although the full impact is uncertain, the spending cuts implemented under this new law could adversely affect our customers ability to purchase our 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 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 products sold into 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. OSUR also derives revenues from licensing and product development activities. DNAG revenues consist of products sold into the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets.

Results of Operations

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

CONSOLIDATED NET REVENUES

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

	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. The current year 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 through year end.

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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.

	Year Ended December 31,		
Market	2012	2011	% Change
Domestic HIV	$ 34,265	$ 38,722	(12)%
International HIV	3,061	3,011	2
Domestic OTC HIV	546		N/A
Domestic HCV	2,805	890	215
International HCV	1,059	672	58
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

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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. While we believe the CLIA waiver provides an expanded opportunity for sales growth, demand for our HCV product 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 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.

We previously entered into domestic and international collaboration agreements with Merck, under which Merck agreed to detail our OraQuick® HCV product to physician offices. The initial term of our domestic agreement expired in September 2012 and was not renewed. We have also terminated our international agreement with Merck. Termination of these agreements is not expected to have a material impact on sales of our OraQuick® HCV test, either in the U.S. or in international markets.

Sales of our OraSure® oral fluid collection device decreased 30% to $865,000 in 2012 from $1.2 million in 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® or our OraQuick® In-Home HIV tests. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid. As such, we expect that sales of our OraSure® device will continue to decline in the future.

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.

	Year Ended December 31,		
Market	**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 stopped purchasing 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.

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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. We expect sales to this distributor to remain flat in 2013. 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.

During 2006, in an effort to expand our Intercept® product line and meet the needs of our laboratory customers, we entered into a joint development agreement with Roche Diagnostics to develop a series of homogeneous fully-automated oral fluid drugs of abuse assays. FDA 510(k) clearance has since been received for assays to detect PCP, opiates, cocaine, methamphetamines and amphetamines. However, we have experienced significant delays in completing development of the assays under our collaboration, primarily because Roche has not been able to obtain FDA clearance of a THC assay. A THC assay is needed to offer a complete NIDA-5 panel of assays required by our customers. The inability to obtain clearance of this assay has also delayed development of assays beyond the NIDA-5 panel. We are in discussions with Roche about the THC assay and the future of our collaboration.

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**
Professional domestic	$ 7,159	$ 6,775	6%
Professional international	1,462	1,400	4
Over-the-counter	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 same period of 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. Our distribution contract with Reckitt Benckiser has expired and we are currently negotiating the final terms of the renewal of this agreement.

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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. Royalties under this license will no longer be payable after certain of our cryosurgical patents expire in August 2013.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues primarily represent sales of the Oragene® product line by our subsidiary, DNA Genotek, 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.

Beginning in January 2013 and continuing through February 2015, sales of our OraQuick® product into the professional market are subject to an increase in certain lateral flow patent royalties under a litigation settlement we agreed to in 2009. In addition, also beginning in January 2013, certain of our product revenues are subject to a 2.3% medical device excise tax imposed under the Affordable Care Act. The higher royalties and new excise tax will negatively impact gross margins in 2013 and beyond.

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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. We expect OSUR s research and development costs in 2013 will remain flat when compared to 2012 levels.

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. We expect 2013 sales and marketing expenses to increase from 2012 levels as we continue to invest in advertising and promotional costs for this product.

General and administrative expenses remained flat at $19.0 million in both 2012 and 2011. We expect general and administrative expenses in 2013 to decline slightly when compared to 2012.

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. We expect 2013 research and development expense and sales and marketing expense to increase slightly when compared to 2012 levels. General and administrative expenses in 2013 are expected to remain flat.

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

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 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 for the current year was negatively impacted by a $428,000 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. 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.

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Year Ended December 31, 2011 Compared to December 31, 2010

CONSOLIDATED NET REVENUES

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

	Year Ended December 31, 2011,				
	Dollars		%	Percentage of Total Revenues	
	2011	2010	Change	2011	2010
OSUR	$ 74,467	$ 71,199	5%	91%	95%
DNAG	6,216		100	8	
Net product revenues	80,683	71,199	13	99	95
Licensing and product development	1,198	3,816	(69)	1	5
Net revenues	$ 81,881	$ 75,015	9%	100%	100%

Consolidated net revenues increased 9% to $81.9 million (including $6.2 million attributable to operations of DNAG) in 2011 from $75.0 million in 2010. Excluding revenue attributable to DNAG, our net product revenues increased 5% during the year ended December 31, 2011 when compared to the year ended December 31, 2010. Increased sales of our infectious disease testing, substance abuse testing and cryosurgical systems products were partially offset by lower sales of our insurance risk assessment products. The higher net product revenues were partially offset by a $2.6 million reduction in licensing and product development revenues during 2011 as compared to 2010.

Consolidated net revenues derived from products sold to customers outside the United States were $14.2 million and $11.5 million or 17% and 15% of total revenues for the years ended December 31, 2011 and 2010, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currencies was not material to our operating results.

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.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Revenues	
Market	2011	2010	Change	2011	2010
Infectious disease testing	$ 44,691	$ 41,738	7%	60%	59%
Substance abuse testing	12,498	11,671	7	17	16
Cryosurgical systems	12,046	11,965	1	16	17
Insurance risk assessment	5,232	5,825	(10)	7	8
Net product revenues	$ 74,467	$ 71,199	5%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 7% to $44.7 million in 2011. OraQuick® sales totaled $43.3 million and $40.1 million for the years ended December 31, 2011 and 2010, respectively.

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The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during 2011 and 2010.

	Year Ended December 31,		
Market	2011	2010	% Change
Domestic HIV	$ 38,722	$ 38,172	1%
International HIV	3,011	1,800	67
Domestic HCV	890	46	1,835
International HCV	672	119	465
Net OraQuick® revenues	$ 43,295	$ 40,137	8%

Domestic OraQuick® HIV sales remained relatively flat at $38.7 million for the twelve months ended December 31, 2011 compared to $38.2 million for the twelve months ended December 31, 2010. International sales of our OraQuick® HIV test increased 67% to $3.0 million for the year ended December 31, 2011 from $1.8 million for the year ended December 31, 2010. This increase was largely the result of an improved funding environment as certain private and government customers were able to fund purchases.

OraQuick® net revenues for 2011 included $1.6 million of sales of our OraQuick® HCV test, compared to $165,000 in 2010. We received a CLIA waiver for this product in November 2011, enabling us to sell our HCV product to many other non-CLIA certified customers, such as outreach clinics, community-based organizations and physician offices.

Sales of our OraSure® oral fluid collection device decreased 23% from $1.6 million in 2010 to $1.2 million in 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 7% from $11.7 million in 2010 to $12.5 million in 2011, as a result of higher domestic 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 2011 and 2010.

	Year Ended December 31,		
Market	2011	2010	% Change
Domestic	$ 8,004	$ 7,274	10%
International	1,912	1,976	(3)
Net Intercept® revenues	$ 9,916	$ 9,250	7%

Domestic Intercept® sales increased 10% from $7.3 million in 2010 to $8.0 million in 2011. This increase was largely the result of increased interest in oral fluid testing as well as growth achieved in the workplace market as hiring conditions began to improve when compared to 2010.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) remained flat at $12.0 million for the years ended December 31, 2011 and 2010.

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The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during 2011 and 2010.

	Year Ended December 31,		
Market	**2011**	**2010**	**% Change**
Professional domestic	$ 6,775	$ 5,967	14%
Professional international	1,400	1,385	1
Over-the-counter	3,871	4,613	(16)
Net cryosurgical systems revenues	$ 12,046	$ 11,965	1%

Sales of our Histofreezer® product to physicians offices in the United States increased 14% to $6.8 million in 2011, compared to $6.0 million in 2010, as a result of higher market penetration resulting from the continued efforts of our manufacturers sales representatives, improved focus by our distributors and an increase in sales to governmental entities. In early 2010, we signed agreements with two manufacturers sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these agreements, over 40 additional sales representatives have been working with our physicians office distributors throughout the Unites States.

Sales of Histofreezer® in the international market remained flat at $1.4 million in 2011 and 2010.

During the year ended December 31, 2011, our OTC cryosurgical sales decreased 16% primarily due to a decline in sales to our Latin American distributor, Genomma. Genomma had purchases totaling $1.0 million in 2011, compared to $2.0 million in 2010. In late 2010, the Mexican government placed limitations on the advertising Genomma could use for our product. In addition, during the first quarter of 2011, Genomma informed us of some changes required by the Brazilian government to our package insert, which have since been made. Both events negatively impacted sales of our product during 2011.

Sales to our European OTC distributor Reckitt Benckiser remained flat at $2.6 million in 2011 and 2010.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 10% from $5.8 million in 2010 to $5.2 million in 2011, as a result of variability in the timing of orders, general softness in the life insurance market, and the adoption by some underwriters of a Simplified Issues policy. This is a policy where lab-based testing is replaced by having applicants respond to a questionnaire about their behaviors. Two of our larger customers adopted this new policy form in 2011.

Licensing and Product Development

Licensing and product development revenues decreased 69% to $1.2 million in 2011 from $3.8 million in 2010. During 2010, we received $2.0 million in milestone payments 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 Europe.

The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008.

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DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues primarily represent sales of DNAG s Oragene® product line in the molecular diagnostics and research markets. The $6.2 million in net revenues reflect DNAG sales from the August 17, 2011 acquisition date through December 31, 2011. During the fourth quarter of 2011, DNAG shipped $1.5 million of product to its largest customer, which historically has made bulk purchases once a year.

CONSOLIDATED OPERATING LOSS

Consolidated operating loss increased $6.0 million to $9.4 million in 2011, compared to $3.4 million in 2010. The increased loss was primarily caused by higher research and development expenses due to increased clinical trial costs related to our OraQuick® HIV OTC test and higher general and administrative expense resulting from the transaction costs associated with the DNAG acquisition and increased amortization expense associated with the intangible assets acquired in the DNAG acquisition. Consolidated gross margin was 63% for both 2011 and 2010.

Operating Loss by Segment

OSUR Segment

OSUR s gross margin was 64% in 2011 compared to 63% in 2010. OSUR s 2011 margin benefited from improved product mix, more efficient manufacturing operations, lower direct labor costs, improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. The 2010 margin benefited from the $2.0 million in HCV milestone payments received during that period.

Research and development expenses increased 32% from $13.2 million in 2010 to $17.4 million in 2011, primarily as a result of a $6.2 million increase in clinical trial costs related to the development of our OraQuick® HIV OTC test. Higher clinical trial costs related to our OraQuick® HIV OTC test were partially offset by lower clinical trial costs related to the development of our OraQuick® HCV test.

Sales and marketing expenses declined 3% to $20.1 million in 2011 from $20.7 million in 2010. This decrease was primarily the result of lower consulting expenses.

General and administrative expenses increased 13% to $19.0 million in 2011 from $16.8 million in 2010, primarily as a result of $2.6 million in transaction costs associated with the DNAG acquisition.

DNAG Segment

DNAG s gross margin for the period from August 17, 2011 through December 31, 2011 was 50% and reflects the impact of a $852,000 non-cash purchase accounting adjustment to mark up the acquired finished goods inventory to fair value. DNAG s gross margin also included approximately $499,000 of amortization expense related to the acquisition.

DNAG incurred $4.7 million in operating expenses during 2011. This included $1.0 million of research and development costs, $2.3 million of sales and marketing expenses and $1.4 million of general and administrative expenses. The DNAG expenses also included a total of $714,000 of amortization expense related to the acquisition.

CONSOLIDATED INCOME TAXES

In 2011, we continued our evaluation of whether the full valuation allowance established in 2008 against OSUR s total U.S. net deferred tax asset is still appropriate and concluded that the full valuation allowance remained appropriate as the facts and circumstances since the establishment of the allowance had not changed.

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As a result, no U.S. income tax benefit was recorded for OSUR s pre-tax loss in 2011. In connection with the DNAG acquisition, a deferred income 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. A Canadian income tax benefit of $869,000 was also recorded in 2011 associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

Liquidity and Capital Resources

	December 31,	
	2012	2011
	(In thousands)	
Cash	$ 87,888	$ 23,878
Working capital	103,483	30,860

Our cash increased $64.0 million to $87.9 million at December 31, 2012 from $23.9 million at December 31, 2011, primarily due to receipt of $70.2 million in net proceeds from a secondary public offering of our common stock completed during the third quarter of 2012. Our working capital also increased to $103.5 million at December 31, 2012 from $30.9 million at December 31, 2011.

During 2012, we used $5.4 million in cash to finance our operating activities. Our net loss of $15.1 million and deferred income tax benefit of $1.4 million were partially offset by non-cash stock-based compensation expense of $5.2 million and depreciation and amortization of $7.2 million. Additional uses of cash in operating activities included a $296,000 increase in accounts receivable, a $3.1 million increase in inventory largely due to the stocking of our OraQuick® In-Home HIV tests and a $791,000 decrease in accounts payable. Accrued expenses decreased $1.2 million due to lower year-end accruals for management incentive bonuses, professional fees and other miscellaneous expenses. Offsetting these uses of cash was a $4.3 million increase in deferred revenue primarily related to the initial pipeline orders of our OraQuick® In-Home test by retailers in late September 2012.

We used a total of $2.0 million in investing activities during 2012 to acquire property and equipment. During the year ended December 31, 2013, 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 provided by financing activities was $71.4 million in 2012, which primarily resulted from the $70.2 million of net proceeds received from our secondary offering of 6.1 million shares of common stock in July 2012 and $10.0 million in proceeds received from the exercise of stock options. These increases in cash were partially offset by $7.3 million in loan principal repayments and $1.6 million used for the repurchase of common stock related to the vesting of restricted shares.

On July 30, 2012, we repaid the $7.0 million principal balance outstanding under our $10.0 million credit facility with Comerica Bank and this facility has been terminated.

Our current cash balance is expected to be sufficient to fund our current operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, 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, the timing and amount of costs to commercially launch new products including our OraQuick® In-Home HIV Test, market acceptance of new products, competing technological and market developments, the impact of the ongoing economic downturn and other factors.

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Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations as of December 31, 2012 (in thousands) for future payments under contracts and other contingent commitments, for the year 2013 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2013**	**2014**	**2015**	**2016**	**2017**	**Thereafter**
Operating leases[1]	$ 738	$ 480	$ 243	$ 9	$ 6	$	$
Employment contracts[2]	2,949	2,201	748				
Purchase obligations[3]	2,511	2,511					
Minimum commitments under contracts[4]	2,792	500	500	500	500	500	292
Total contractual obligations	$ 8,990	$ 5,692	$ 1,491	$ 509	$ 506	$ 500	$ 292

1 Represents payments required under our operating leases. See Note 12 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 12 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 12 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 12 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, 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. We do not grant price protection or product return rights (other than for our OraQuick® In-Home HIV Tests, which we began to sell in the third quarter of 2012) 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.

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Our revenue practices with respect to the OraQuick® In-Home HIV Test will initially be different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue can not be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV Test is a new product for which we do not have a historical record of returns, we do not believe we can reasonably determine a return rate at this time. As a result we do not recognize revenue upon shipment to the retail trade. For these product shipments, we invoice the retailer or distributor, record deferred revenue at gross invoice sales price, and classify the cost basis of the product held by the retailer or distributor as a component of inventory. Initially, we will only recognize revenue upon the consummation of a sale to the retail customer either in a store or over the internet. We expect to apply a more traditional revenue recognition policy such that revenue is recognized following shipment to the retailer or distributor when we believe we have sufficient data to develop reasonable estimate of the level of expected returns based upon historical returns.

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

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.

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 $285,000 as of December 31, 2012. 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 2012, we wrote-off inventory which had a cost of $1.3 million. During 2011 and 2010, we wrote-off inventory which had a cost of $919,000 and $918,000, respectively. 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.

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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 was 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 $71.2 million, or 37% of our total assets, as of December 31, 2012. 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, 2012 will exceed their book value. We did not recognize any impairment losses for the years ended December 31, 2012 or 2011. 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. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Performance of goodwill impairment testing permits us to first 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 the annual impairment test for goodwill as of July 31, 2012 and determined there was no impairment. Our 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, including projected revenue growth, 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 be performed annually in the fiscal third quarter, or sooner if a triggering event occurs.

Deferred Tax Assets and Liabilities. At December 31, 2012, we had federal NOL carryforwards of $60.6 million. The net deferred tax assets, before a full valuation allowance, associated with these NOLs and other temporary differences was $32.0 million at December 31, 2012. In assessing the realizability of net

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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, 2012 and 2011 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, 2012 and 2011, we recorded a Canadian income tax benefit of $1.4 million and $869,000, respectively, associated with DNAG s loss before income taxes and certain Canadian research and development and investment tax credits. 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, 2012, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada, Europe and Africa, which are subject

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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 6.7% of our total consolidated net revenues for the year ended December 31, 2012 (including revenues from DNAG). We expect the DNAG 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, 2012. Based on that evaluation, the Company s management, including such officers, concluded that as of December 31, 2012 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* 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, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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(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, 2012, based on criteria established in *Internal Control Integrated Framework* 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, 2012, based on criteria established in *Internal Control Integrated Framework* 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, 2012 and 2011, 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 our report dated March 13, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 13, 2013

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ITEM 9B. Other Information.

Not applicable.

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PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2013 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.

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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.

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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 13, 2013.

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 13, 2013, by the following persons on behalf of the Registrant and in the capacities indicated.

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

	*Douglas G. Watson	Director

Douglas G. Watson

*By:	/s/ Jack E. Jerrett	
	Jack E. Jerrett	
	(Attorney-in-Fact)	

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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, 2012 and 2011, 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. 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, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, 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, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2013 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 13, 2013

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31, 2012	2011
ASSETS		
CURRENT ASSETS:		
Cash	$ 87,888	$ 23,878
Accounts receivable, net of allowance for doubtful accounts of $285 and $170	17,545	17,159
Inventories	12,758	9,621
Prepaid expenses	1,719	1,682
Other current assets	493	496
Total current assets	120,403	52,836
PROPERTY AND EQUIPMENT, net	18,546	19,855
INTANGIBLE ASSETS, net	27,207	30,383
GOODWILL	25,445	24,740
OTHER ASSETS	124	47
	$ 191,725	$ 127,861
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$	$ 7,292
Accounts payable	3,380	4,142
Deferred revenue	5,580	1,318
Accrued expenses	7,960	9,224
Total current liabilities	16,920	21,976
OTHER LIABILITIES	89	
DEFERRED INCOME TAXES	4,401	5,635
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued		
Common stock, par value $.000001, 120,000 shares authorized, 55,281 and 47,393 shares issued and outstanding		
Additional paid-in capital	333,522	249,640
Accumulated other comprehensive loss	(666)	(1,964)
Accumulated deficit	(162,541)	(147,426)
Total stockholders equity	170,315	100,250
	$ 191,725	$ 127,861

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	For the years ended December 31,		
	2012	**2011**	**2010**
NET REVENUES:			
Product	$ 85,753	$ 80,683	$ 71,199
Licensing and product development	2,067	1,198	3,816
	87,820	81,881	75,015
COST OF PRODUCTS SOLD	32,249	30,164	27,655
Gross profit	55,571	51,717	47,360
OPERATING EXPENSES:			
Research and development	12,445	18,406	13,192
Sales and marketing	37,087	22,383	20,728
General and administrative	22,309	20,325	16,794
	71,841	61,114	50,714
Operating loss	(16,270)	(9,397)	(3,354)
INTEREST EXPENSE	(172)	(316)	(316)
OTHER INCOME (EXPENSE)	(70)	3	173
Loss before income taxes	(16,512)	(9,710)	(3,497)
INCOME TAX BENEFIT	(1,397)	(869)	
NET LOSS	$ (15,115)	$ (8,841)	$ (3,497)
LOSS PER SHARE:			
BASIC	$ (0.29)	$ (0.19)	$ (0.08)
DILUTED	$ (0.29)	$ (0.19)	$ (0.08)
SHARES USED IN COMPUTING LOSS PER SHARE:			
BASIC	51,457	46,908	46,187
DILUTED	51,457	46,908	46,187

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	For the years ended December 31,		
	2012	2011	2010
NET LOSS	$ (15,115)	$ (8,841)	$ (3,497)
OTHER COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments	1,298	(1,729)	(4)
Other comprehensive income (loss)	1,298	(1,729)	(4)
COMPREHENSIVE LOSS	$ (13,817)	$ (10,570)	$ (3,501)

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

For the years ended December 31, 2012, 2011 and 2010

(in thousands)

	Common Stock		Additional	Accumulated Other		
	Shares	Amount	Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Total
Balance at January 1, 2010	45,930	$	$ 239,126	$ (231)	$ (135,088)	$ 103,807
Common stock issued upon exercise of options	3		8			8
Vesting of restricted stock	429					
Purchase and retirement of treasury shares	(136)		(709)			(709)
Compensation cost for restricted stock			2,354			2,354
Compensation cost for stock option grants			884			884
Net loss					(3,497)	(3,497)
Currency translation adjustments				(4)		(4)
Balance at December 31, 2010	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

See accompanying notes to the consolidated financial statements

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	For the years ended December 31,		
	2012	2011	2010
OPERATING ACTIVITIES:			
Net loss	$ (15,115)	$ (8,841)	$ (3,497)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Stock-based compensation	5,197	4,100	3,229
Depreciation and amortization	7,250	4,891	3,012
Deferred income taxes	(1,397)	(868)	
Inventory purchase accounting step-up adjustment	16	852	
Changes in assets and liabilities			
Accounts receivable	(296)	(3,377)	1,219
Inventories	(3,139)	(1,757)	1,499
Prepaid expenses and other assets	(99)	491	1,413
Accounts payable	(791)	911	(472)
Deferred revenue	4,254	112	(722)
Accrued expenses and other liabilities	(1,253)	492	(1,794)
Net cash (used in) provided by operating activities	(5,373)	(2,994)	3,887
INVESTING ACTIVITIES:			
Proceeds from maturities and redemptions of short-term investments		1,895	2,841
Acquisition of DNA Genotek Inc., net of cash acquired		(49,730)	
Payments for patents and product rights			(4,500)
Purchases of property and equipment	(2,019)	(2,505)	(2,106)
Net cash used in investing activities	(2,019)	(50,340)	(3,765)
FINANCING ACTIVITIES:			
Repayments of long-term debt	(7,292)	(500)	(510)
Proceeds from the issuance of common stock, net of expenses	70,246		
Proceeds from exercise of stock options	10,040	4,783	8
Repurchase of common stock	(1,560)	(909)	(709)
Net cash provided by (used in) financing activities	71,434	3,374	(1,211)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(32)	(5)	(2)
NET INCREASE (DECREASE) IN CASH	64,010	(49,965)	(1,091)
CASH, BEGINNING OF PERIOD	23,878	73,843	74,934
CASH, END OF PERIOD	$ 87,888	$ 23,878	$ 73,843

See accompanying notes to the consolidated financial statements.

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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. 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. In September 2012 we began selling our rapid point-of-care HIV test 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 academic research, clinical genetic testing, 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 in saliva. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. One of our cryosurgery products has been sold in the over-the-counter or consumer retail markets in North America, Europe, Central and South America and Australia.

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.

Use of Estimates

The preparation of 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, 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

In 2012, 2011 and 2010, we paid interest of $199, $318, and $340, respectively. In 2010, we capitalized interest of $20. No interest was capitalized in 2012 or 2011.

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 2010, we received a federal income tax refund of $597 related to refundable alternative minimum taxes paid in previous years, and we paid state income taxes of $12.

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In 2012 and 2011, we recorded through the consolidated statements of operations an increase in our allowance for doubtful accounts of $115 and $64, respectively. In 2010, we recorded through the consolidated statement of operations a decrease in our allowance for doubtful accounts of $115. We had write-offs of $36 against the allowance for doubtful accounts in 2010. We had no material write-offs against the allowance for doubtful accounts in 2012 or 2011.

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. Performance of goodwill impairment testing permits 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

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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 test for goodwill as of July 31, 2012 and determined there was no impairment. Our 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 be performed annually in the fiscal third quarter, or sooner if a triggering event occurs.

Impairment of Long-Lived Assets

If indicators of impairment exist, 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 impairment is indicated, 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. We do not grant price protection or product return rights (other than for our OraQuick® In-Home HIV tests, which we began to sell in the third quarter of 2012) 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.

Our revenue practices with respect to the OraQuick® In-Home HIV test will initially be different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue can not be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV test is a new product for which we do not have a historical record of returns, we do not believe we can reasonably determine a return rate at this time. As a result we do not recognize revenue when we ship to the retail trade. For these product shipments, we invoice the retailer or distributor, record deferred revenue at gross invoice sales price, and classify the cost basis of the product held by the retailer or distributor as a component of inventory. Initially, we will only recognize revenue upon the consummation of a sale to the retail customer either in a store or over the internet. We expect to apply a more traditional revenue recognition policy such that revenue is recognized following shipment to the retailers or distributors when we believe we have sufficient data to develop a reasonable estimate of the level of expected returns.

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

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.

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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.

Deferred Revenue

We record deferred revenue when funds are received prior to the recognition of the associated revenue and also when shipments of our OraQuick® In-Home HIV test are made to the retailers or distributors who have product return rights. Deferred revenue at December 31, 2012 and 2011 included customer prepayments of $1,880 and $1,318, 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.

Customer and Vendor Concentrations

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 accounts receivable as of December 31, 2011 or in revenues for the years ended December 31, 2012, 2011 or 2010.

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 substantial delays in the delivery of our products to our customers and increased costs. Furthermore, 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 expenses 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 2012, 2011, and 2010, we incurred $6,310, $130, and $223, respectively, in advertising expenses. 2012 expenses include advertising associated with our OraQuick® In-Home HIV test which we began selling in the consumer retail market in the fourth quarter.

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.

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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 5,314, 6,296, and 6,296 shares were outstanding as of December 31, 2012, 2011 and 2010, respectively. As a result of our net losses for the years ended December 31, 2012, 2011 and 2010, these shares were excluded from the respective periods computations 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 2012, 2011, and 2010 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 $1,298 and ($1,729) currency translation adjustments recorded in 2012 and 2011, respectively, are largely the result of the translation of our Canadian operation s financial statements into U.S. dollars.

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Fair Value of Financial Instruments

As of December 31, 2012 and 2011, 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).

Effective January 3, 2012, we implemented 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. The fair value of the plan assets as of December 31, 2012 was $89 and was calculated using the market price of the mutual funds as of that date. All investments in the plan are classified as trading securities and measured as Level 1 instruments.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

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 to be released in February 2014.

The acquisition of DNAG strengthens OraSure s leadership in oral fluid diagnostics, by providing OraSure with a complementary portfolio of products that enable easy and reliable collection, stabilization, transportation and storage of high quality nucleic acid (DNA and RNA) samples. These samples can then be used for a wide range of research and diagnostic applications.

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

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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 years ended December 31, 2011 and 2010, 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.

	Years Ended December 31,	
	2011	2010
Total revenues	$ 89,966	$ 89,303
Net loss	(10,911)	(4,842)
Loss per share:		
Basic and diluted	$ (0.23)	$ (0.10)

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.

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4. INVENTORIES:

	December 31, 2012	2011
Raw materials	$ 6,777	$ 5,768
Work in process	393	497
Finished goods	5,588	3,356
	$ 12,758	$ 9,621

5. PROPERTY AND EQUIPMENT:

	December 31, 2012	2011
Land	$ 1,118	$ 1,118
Buildings and improvements	16,589	16,532
Machinery and equipment	18,423	17,428
Computer equipment and software	5,989	5,167
Furniture and fixtures	1,692	1,669
Construction in progress	581	438
	44,392	42,352
Less accumulated depreciation	(25,846)	(22,497)
	$ 18,546	$ 19,855

Depreciation expense was $3,347, $2,934, and $2,510 for 2012, 2011, and 2010, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS:

The changes in goodwill are as follows:

	December 31, 2012	2011
Balance as of January 1	$ 24,740	$
Goodwill from DNAG acquisition		25,619
Increase (decrease) related to foreign currency translation	705	(879)
Balance as of December 31	$ 25,445	$ 24,740

Intangible assets consist of the following:

	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
		$ 38,550	$ (11,342)	$ 27,207

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	Amortization Period (Years)	December 31, 2011 Gross	Accumulated Amortization	Net
Customer list	10	$ 12,270	$ (441)	$ 11,829
Patents and product rights	3-10	10,449	(6,386)	4,063
Acquired technology	7	9,531	(482)	9,049
Tradename	15	4,703	(117)	4,586
Non-compete agreements	1-3	1,021	(165)	856
		$ 37,974	$ (7,591)	$ 30,383

Patents and products rights are made up of the following:

	December 31, 2012	2011
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	(6,926)	(6,386)
	$ 3,523	$ 4,063

Amortization expense for 2012, 2011, and 2010 was $3,903, $1,957, and $502, respectively.

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

2013	$ 3,616
2014	3,483
2015	3,300
2016	3,300
2017	3,300
Beyond	10,208

7. ACCRUED EXPENSES:

	December 31, 2012	2011
Payroll and related benefits	$ 4,248	$ 4,867
Royalties	1,948	1,986
Professional fees	413	835
Other	1,351	1,536
	$ 7,960	$ 9,224

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 this Credit Facility and this Credit Facility has been terminated.

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9. INCOME TAXES:

Loss before income tax benefit consists of the following:

	2012	2011	2010
United States	$ (13,515)	$ (8,147)	$ (3,497)
Canada	(2,997)	(1,563)	
	$ (16,512)	$ (9,710)	$ (3,497)

The components of the income tax provision (benefit) for the years ended December 31, 2012, 2011 and 2010 are as follows:

	2012	2011	2010
Deferred			
Federal	$ (4,370)	$ (2,674)	$ (1,215)
State	(272)	(273)	(92)
Canada	(1,397)	(869)	
	(6,039)	(3,816)	(1,307)
Increase in valuation allowance	4,642	2,947	1,307
Total income tax benefit	$ (1,397)	$ (869)	$

For the years ended December 31, 2012 and 2011 we recorded an income tax benefit of $1,397 and $869, respectively, associated with DNAG s loss before income taxes and certain Canadian research and development and investment tax credits. 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 income tax benefit for the current 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, 2012, 2011, and 2010 is as follows:

	2012	2011	2010
Statutory U.S. federal income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(1.2)	(1.9)	(0.9)
Canadian income taxes	(8.5)	(8.9)	
Nondeductible expenses and other	1.0	5.3	6.8
U.S. research and development credits	(0.3)	(5.7)	(9.7)
Change in valuation allowance, federal and state	34.5	36.3	37.8
Effective tax rate	(8.5)%	(8.9)%	%

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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 total deferred tax asset as of December 31, 2012 and 2011 are as follows:

	2012	2011
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 21,207	$ 16,286
Inventories	1,781	1,216
Capitalized research and development costs	6,148	6,489
Accruals and reserves currently not deductible	2,123	1,968
Patent costs	1,202	1,552
Acquired intangible assets	(6,278)	(6,635)
Depreciation and amortization	(744)	(1,019)
Stock-based compensation	4,176	4,157
Research and development tax credit carryforward	2,378	2,103
Net deferred tax asset	31,993	26,117
Valuation allowance	(36,394)	(31,752)
Net deferred tax liability	$ (4,401)	$ (5,635)

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 recorded an income tax charge to establish a full valuation allowance against our total U.S. net deferred tax asset. During the subsequent years, 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 maintained a full valuation allowance against our net deferred tax assets as of December 31, 2012 and 2011 associated with our U.S. operations.

Our Federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2018-2019	$ 16,273
2020-2024	16,397
2025-2031	14,476
2032	13,407
	$ 60,553

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 our Company. 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, 2012, our gross unrecognized tax benefits totaled $1,922 and based upon the valuation allowance for the 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

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and penalties were immaterial in 2012, 2011 and 2010. 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 2012.

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

	2012	2011	2010
Balance as of January 1	$ 2,015	$ 2,090	$ 2,045
Additions based on tax positions related to the current period		53	52
Additions for tax positions of prior periods	67	19	
Reductions for tax positions of prior periods	(160)	(147)	(7)
Balance as of December 31	$ 1,922	$ 2,015	$ 2,090

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 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, 2012, 3,105 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	**2012**	**2011**	**2010**
Risk-free interest rate[1]	0.99%	1.36%	1.89%
Expected dividend yield			
Expected stock price volatility[2]	52%	54%	54%
Expected life of stock options (in years)[3]	6	4	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) Expected stock price volatility is based upon historical experience.
(3) Expected life of stock options is based upon historical experience.

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The weighted-average grant date fair value of stock options granted during the years ended December 31, 2012, 2011 and 2010 was $5.38, $2.82 and $2.24, respectively.

Amounts recognized in the financial statements related to stock options were as follows:

	Years Ended December 31,		
	2012	2011	2010
Total compensation cost during the year	$ 2,262	$ 1,579	$ 877
Amounts capitalized into inventory during the year	(90)	(58)	(40)
Amounts recognized in cost of products sold for amounts previously capitalized	58	36	63
Amounts charged against income	$ 2,230	$ 1,557	$ 900

The aggregate intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $6,961, $2,490, and $9, 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, 2010	5,432	$ 7.09		
Granted	709	5.15		
Exercised	(3)	2.81		
Forfeited	(634)	7.19		
Outstanding on December 31, 2010	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	6.4	$ 2,805
Vested or expected to vest as of December 31, 2012	4,595	$ 7.62	6.3	$ 2,800
Exercisable on December 31, 2012	3,115	$ 7.10	5.3	$ 2,285

As of December 31, 2012, there was $5,125 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 $10,040, $4,783 and $8 for the years ended December 31, 2012, 2011 and 2010, 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.

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The following table summarizes information about stock options outstanding as of December 31, 2012:

	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	467	11.1	$ 3.70	434	$ 3.69
$5.19 $5.60	646	5.5	5.32	499	5.35
$5.72 $6.37	128	7.9	5.96	63	5.98
$6.63	743	8.1	6.63	328	6.63
$6.67 $8.06	574	5.1	7.74	481	7.82
$8.18 $8.28	673	2.8	8.23	666	8.23
$8.33 $9.56	594	3.4	9.23	567	9.25
$9.78 $10.99	83	3.3	10.26	77	10.23
$11.30	730	9.1	11.30		
$12.14	6	9.5	12.14		
	4,644	6.4	$ 7.64	3,115	$ 7.10

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 $2,894, $2,521 and $2,354 related to restricted shares was recognized during the years ended December 31, 2012, 2011 and 2010, 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, 2010	820	$ 5.44
Granted	454	5.19
Vested	(429)	5.51
Forfeited	(53)	5.15
Issued and unvested, December 31, 2010	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
Issued and expected to vest, December 31, 2012	670	$ 8.19

As of December 31, 2012, there was $2,989 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 1.6 years.

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In connection with the vesting of restricted shares during the years ended December 31, 2012, 2011 and 2010, we purchased and immediately retired 142, 134 and 136 shares with aggregate values of $1,560, $909 and $709, 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 2012, 2011 or 2010.

Public Equity Offering

On July 11, 2012, we completed a public equity 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. 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 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 consist primarily of products sold in the United States and internationally to various clinical laboratories, hospital, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. In the fourth quarter of 2012, OSUR began selling a product in the domestic OTC marketplace. OSUR also derives revenues from licensing and product development activities. DNAG revenues consist primarily of products sold into the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets.

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 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.

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The following table summarizes segment information for the years ended December 31, 2012, 2011, and 2010. During the year ended December 31, 2010 we operated within only one reportable segment.

	Years Ended December 31,		
	2012	2011	2010
Net revenues:			
OSUR	$ 73,562	$ 75,665	$ 75,015
DNAG	14,258	6,216	
Total	$ 87,820	$ 81,881	$ 75,015
Operating loss:			
OSUR	$ (13,395)	$ (7,855)	$ (3,354)
DNAG	(2,875)	(1,542)	
Total	$ (16,270)	$ (9,397)	$ (3,354)
Depreciation and amortization:			
OSUR	$ 3,530	$ 3,550	$ 3,012
DNAG	3,720	1,341	
Total	$ 7,250	$ 4,891	$ 3,012
Capital expenditures:			
OSUR	$ 1,794	$ 2,345	$ 2,106
DNAG	225	160	
Total	$ 2,019	$ 2,505	$ 2,106

	December 31,	
	2012	2011
Total assets:		
OSUR	$ 137,544	$ 71,326
DNAG	54,181	56,535
Total	$ 191,725	$ 127,861

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,		
	2012	2011	2010
United States	$ 67,460	$ 67,644	$ 63,520
Europe	10,131	7,506	6,493
Other regions	10,229	6,731	5,002
	$ 87,820	$ 81,881	$ 75,015

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

	December 31,	
	2012	2011
United States	$ 17,868	$ 18,954
Canada	589	706
Other regions	89	195
	$ 18,546	$ 19,855

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12. 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. Future minimum payments under this agreement are as follows:

2013	$ 500
2014	500
2015	500
2016	500
2017	500
Thereafter	292
	$ 2,792

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 warehouse facilities under operating lease agreements. Future payments required under these non-cancelable leases are as follows:

2013	$ 480
2014	243
2015	9
2016	6
	$ 738

Rent expense for 2012, 2011 and 2010 was $510, $307, and $163, respectively.

Purchase Commitments

As of December 31, 2012, we had outstanding non-cancelable purchase commitments in the amount of $2,511 related to inventory, capital expenditures, and other goods or services.

Employment Agreements

Under terms of employment agreements with certain executive officers, extending through 2014, we are required to pay each individual a base salary for continuing employment with us. The agreements require payments totaling $2,201 and $748 in 2013 and 2014, 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.

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13. 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 $4,000 per year. Contributions to the 401(k) Plan, net of forfeitures, were $592, $533, and $597 in 2012, 2011, and 2010, respectively.

In addition to our existing 401(k) plan, effective January 3, 2012, we implemented 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 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, 2012, the value of the assets associated with the plan was $89 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, 2012, our total obligation under this plan was $89.

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 $2,000 per year. Contributions to the RRSP were $113 in 2012.

14. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2012 and 2011. 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.

	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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	2011 Results Three months ended			
	March 31, 2011	June 30, 2011	September 30, 2011[1]	December 31, 2011[1]
Net revenues	$ 17,414	$ 19,064	$ 21,714	$ 23,689
Costs and expenses	19,967	21,423	25,919	23,970
Operating loss	(2,553)	(2,359)	(4,205)	(281)
Other expense, net	(45)	(79)	(29)	(158)
Loss before income taxes	(2,598)	(2,438)	(4,234)	(439)
Income tax benefit			(315)	(554)
Net income (loss)	$ (2,598)	$ (2,438)	$ (3,919)	$ 115
Income (loss per share)				
Basic	$ (0.06)	$ (0.05)	$ (0.08)	$
Diluted	$ (0.06)	$ (0.05)	$ (0.08)	$

(1) Includes the results of operations of DNA Genotek Inc. from the acquisition date of August 17, 2011, as well as $2,534 and $100 of transaction costs associated with the acquisition recorded in the three months ended September 30, and December 31, 2011, respectively.

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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, 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.*

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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.*
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. 2012 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company s Current Report on Form 8-K filed April 20, 2012.*
10.27	OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K filed December 21, 2011.*
10.28	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.*

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Exhibit Number	Exhibit
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.
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.