ORASURE TECHNOLOGIES INC
Form S-3
September 28, 2012
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As filed with the Securities and Exchange Commission on September 28, 2012

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification Number)**

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Jack E. Jerrett, Esquire

Senior Vice President, General Counsel and Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

COPIES TO:

Ella DeTrizio, Esquire

Dechert LLP

902 Carnegie Center

Suite 500

Princeton, New Jersey 08540-6531

(609) 955-3200

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement, as determined by market conditions and other factors.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)(2)	Proposed Maximum Aggregate Offering Price (1)(3)	Amount of Registration Fee
Common Stock, par value $0.000001 per share		
Preferred Stock		
Warrants to purchase common stock, preferred stock, debt securities or units		
Rights to purchase common stock, preferred stock, debt securities or units		
Debt securities		
Units		
Total	$200,000,000(4)	$22,920(5)

(1) Not specified as to each class of securities to be registered hereunder pursuant to General Instruction II.D. to Form S-3 under the Securities Act of 1933, as amended.

(2) Includes an indeterminate number of securities that may be issued from time to time in primary offerings or upon exercise, conversion or exchange of any securities registered hereunder that provide for exercise, conversion or exchange.

(3) With respect to debt securities, excluding accrued interest and accrued amortization of discount, if any, to the date of delivery. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be equal to any such greater principal amount due at maturity, such aggregate principal amount not to exceed $200,000,000 less the value of securities previously issued hereunder.

(4) Includes $74,970,000.00 aggregate principal amount of the Securities registered by the Registrant under Registration Statement No. 333-168972 and not previously sold, which Securities are consolidated in this Registration Statement pursuant to Rule 429. All registration fees in connection with such unsold amount of Securities have previously been paid under Registration Statement No. 333-168972. The total amount registered under this Registration Statement as so consolidated as of the date of this filing is $200,000,000.

(5) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended. The $22,920.00 filing fee is offset by $2,096.56 of the registration fee that was paid, but not used, in connection with the Registrant s Registration Statement No. 333-168972 filed on August 20, 2010.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT THAT SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated September 28, 2012

PROSPECTUS

$200,000,000

Common Stock

Preferred Stock

Warrants to Purchase Common Stock, Preferred Stock, Debt Securities or Units

Rights to Purchase Common Stock, Preferred Stock, Debt Securities or Units

Debt Securities

Units

We may offer and sell, from time to time, in one or more offerings, any combination of:

Common Stock

Preferred Stock

Warrants to Purchase Common Stock, Preferred Stock, Debt Securities or Units

Rights to Purchase Common Stock, Preferred Stock, Debt Securities or Units

Debt Securities

Units consisting of any of the foregoing

in one or more series or issuances and their total offering price, in the aggregate, will not exceed $200,000,000. This prospectus also covers common stock or preferred stock issuable upon exercise, conversion or exchange of warrants, rights and/or debt securities. We will provide the specific terms of any securities we actually offer for sale in supplements to this prospectus. **This prospectus may not be used to sell securities**

unless accompanied by a prospectus supplement. The net proceeds we expect to receive from such sales will be set forth in a prospectus supplement.

Our common stock is listed on the Nasdaq Global Select Market tier of The Nasdaq Stock Market LLC under the symbol OSUR. On September 25, 2012, the reported last sale price of our common stock on the Nasdaq Global Select Market was $10.64 per share. None of the other securities offered for sale are currently publicly traded. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement.

Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

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INVESTING IN OUR SECURITIES INVOLVES VARIOUS RISKS. SEE THE DISCUSSION OF RISK FACTORS ON PAGE [11] OF THIS PROSPECTUS. ADDITIONAL RISKS ASSOCIATED WITH AN INVESTMENT IN OUR SECURITIES MAY BE DESCRIBED IN THE ACCOMPANYING PROSPECTUS SUPPLEMENT.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2012

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ABOUT THIS PROSPECTUS

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission (the SEC). By using a shelf registration statement, we may offer and sell, from time to time over the next three years, in one or more offerings, any combination of the securities described in this prospectus in a total dollar amount that does not exceed $200,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement, as appropriate. You should read both this prospectus and any prospectus supplement, including all documents incorporated herein or therein by reference, together with additional information described under Incorporation By Reference and Where You Can Find More Information.

For further information about our business and the securities, you should refer to the registration statement and its exhibits. The exhibits to our registration statement contain the full text of certain contracts and other important documents we have summarized in this prospectus. Since these summaries may not contain all the information that you may find important in deciding whether to purchase the securities we may offer, you should review the full text of these documents.

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any prospectus supplement, any free writing prospectus or other written communication we may authorize to be delivered to you. We have not provided, and have not authorized anyone else to provide, you with different or additional information. This prospectus, any prospectus supplement, any free writing prospectus and any other written communication do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they specifically relate, nor does this prospectus, any prospectus supplement, any free writing prospectus or any other written communication constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus or in the documents incorporated by reference herein, any prospectus supplement, any free writing prospectus or other written communication is accurate as of any date other than the date noted therein or, in the case of documents incorporated by reference, the filing date

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thereof, regardless of its time of delivery, and you should not consider any information in this prospectus or in the documents incorporated by reference herein, any prospectus supplement, any free writing prospectus or other written communication to be investment, legal or tax advice. We encourage you to consult your own counsel, accountant and other advisors for legal, tax, business, financial and related advice regarding an investment in our securities.

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under the caption Where You Can Find More Information.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through a combination of these methods. We and our agents reserve the sole right to accept or reject, in whole or in part, any proposed purchase of securities. The prospectus supplement, which we will provide to you each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities and any applicable fee, commission or discount arrangements with them. See the information described below under the caption Plan of Distribution.

As used in this prospectus, OraSure, Company, we, our and us refer to OraSure Technologies, Inc. and its consolidated subsidiaries, unless stated otherwise or the context requires otherwise.

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WHO WE ARE

General

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, and other medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which 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. For several years, we have sold one of our products in the over-the-counter (OTC) or consumer retail market in North America, Europe, Central and South America, and Australia.

In August 2011, we completed the acquisition of DNA Genotek Inc. (DNAG), a company based in Ottawa, Canada. DNAG manufactures and sells oral fluid collection kits that are used to collect samples of genetic material (DNA and RNA) for molecular testing in the academic research, clinical, pharmacogenomics, personalized medicine, animal and livestock genetics markets. DNAG s lead product, the Oragene® sample collection kit, provides an all-in-one system for the collection, stabilization, transportation and storage of DNA in saliva. DNAG serves customers in many countries worldwide, including many leading research universities and hospitals in the world.

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 HIV-1 and HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 minutes. 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 test was approved by the FDA for use by individuals who are 17 years and older.

Products

Our current business includes the following principal products:

OraQuick® Rapid HIV Test

OraQuick® is our rapid point-of-care test platform designed to test oral fluid, whole blood (i.e., both finger-stick and venous), plasma and serum samples for the presence of various antibodies or analytes. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When blood, plasma or serum is to be tested, a loop collection device is used to collect a drop of the specimen and mix it in the developer solution, after which the collection pad is inserted into the solution and allowed to develop. In all cases, the specimen and developer solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a screening test and generally requires a confirmation test where an initial positive result is obtained.

This product is sold under the OraQuick *ADVANCE*® name in North America, Europe and certain other countries and under the OraQuick® name in other developing countries. The test has received PMA approval from the FDA for the detection of antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick whole blood, venous whole blood and plasma. This test is available for use by laboratories located in the United States certified under the Clinical Laboratory

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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® 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.

OraQuick® In-Home HIV Test

The OraQuick® In-Home HIV Test is an over-the-counter version of our OraQuick ADVANCE® HIV 1/2 Antibody Test. We have received FDA approval to sell this product in the U.S. OTC market. The In-Home Test operates in the same manner as the OraQuick ADVANCE® test, except that it has product labeling and instructions designed for consumers. In addition, we have in place a toll free, 24/7, 365-day per year customer call center to provide additional information and referral support for consumers.

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.

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.

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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.

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 have jointly developed with Roche Diagnostics a series of homogeneous fully-automated oral fluid drugs of abuse assays to be used with oral fluid samples collected with our Intercept® device. These assays use Roche s KIMs (kinetic interaction of micro-particles in solution) technology and will 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. FDA 510(k) clearance has been received for assays to detect PCP, opiates, cocaine, methamphetamines and amphetamines.

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

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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, under the POINTTS tradename, in Mexico and a number of South and Central American countries. We also sell a CE marked cryosurgical wart removal product into the OTC footcare market in Europe, Australia and New Zealand through our distributor, Reckitt Benckiser (Reckitt), under the Scholl and Dr. Scholl trademarks. Reckitt is the owner of the Scholl and Dr. Scholl trademarks in countries outside North and South America. 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.

Molecular Collection Systems

Our wholly-owned subsidiary, DNAG, sells a number of products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA and/or RNA from human and animal biologic samples. DNAG s lead product is sold under the Oragene® name and is used to collect DNA from human saliva. DNAG products are currently sold to thousands of academic and research customers in many countries worldwide.

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

We believe these products provide significant advantages over competing DNA and RNA collection methods such as blood collection or buccal swabs, particularly in human genetic applications. Benefits include the reliable collection of high quality genetic samples, use of simple non-invasive collection methods, the ability to store and transport collected samples for extended periods at ambient temperatures and compatibility with fully-automated laboratory testing systems.

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.

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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 OraQuick® has significant potential as a point-of-care testing platform 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 will be 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, such as viral hepatitis and certain sexually transmitted diseases.

Several new products based on the OraQuick® technology platform are in varying stages of evaluation. A second generation rapid HIV-1/2 antibody test, which we believe will provide improved performance compared to our current product, and several assays for certain other infectious diseases are being considered.

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. This new version of our Intercept® device is also intended eventually to be used with the high-throughput drug assays jointly developed with Roche Diagnostics.

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

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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.

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 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 $67.6 million, $63.5 million and $62.2 million in 2011, 2010 and 2009, respectively. Revenues attributable to international customers amounted to $14.2 million, $11.5 million and $14.8 million, or 17%, 15% and 19% of our total revenues, in 2011, 2010 and 2009, respectively.

Infectious Disease Testing Professional

We market the OraQuick *ADVANCE*® rapid HIV-1/2 antibody test directly to customers in the U.S. 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 market. We have engaged two manufacturers representative organizations to assist with sales to U.S. physicians. Internationally, we distribute our OraQuick® HIV test in Europe and 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.

Based on the FDA approvals in place during most of 2011, our OraQuick® HCV test had been sold primarily to customers operating CLIA-certified laboratories. In late 2011, we received a CLIA waiver for this product, which has enabled us to expand sales to non-CLIA certified settings, primarily in the U.S. public health and physician office markets. 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 will expire in September 2012 and we do not believe this agreement will be renewed. The expiration of this domestic agreement is not expected to have a material impact on U.S. sales of our OraQuick® HCV test. With the expiration of this agreement, we will be permitted to sell our test to other companies that participate in the HCV therapeutic market.

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 will be sold into the retail or consumer market in the United States. The potential target population for an HIV OTC test is expected to be comprised primarily 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.

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The OraQuick® In-Home HIV Test is expected to be available for purchase beginning in October 2012. We expect to have product in more than 30,000 retail outlets throughout the country at launch, with an 85% All Commodity Volume for this initial placement. An 85% All Commodity Volume, or ACV, means we expect to have product in stores that represent 85% of the dollar sales volume for the product category applicable to the OraQuick® In-Home HIV Test. We anticipate having broad distribution of our OraQuick® In-Home HIV Test in the highest value retail outlets representing our primary market for this test. The product will also be available for purchase on-line through retailers and our website, www.oraquick.com.

In order to meet these distribution goals, we have established vendor relationships with key retailers, such as Wal-Mart, Walgreens, CVS, Rite Aid and Kroger. We will also be distributing product through several large drug wholesalers and additional food retailers.

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 track record of returns, we will initially only recognize revenue 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.

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. In some cases, we assist our laboratory customers in customizing their testing services by selling them equipment required to test oral fluid specimens collected with the Intercept® device. 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. We intend to sell the cleared assays as part of our Intercept® drug testing system into the workplace, criminal justice, hospital and government markets in collaboration with Roche Diagnostics.

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.

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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, Physicians Sales & Service, AmerisourceBergen Corporation, and Henry Schein. We have also engaged two manufacturers representative organizations to help our U.S. distributors promote and sell Histofreezer®. Internationally, we sell the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

We distribute cryosurgical wart removal products in the OTC footcare market in Europe, Australia and New Zealand through our distributor, Reckitt Benckiser, under its Scholl and Dr. Scholl tradenames, and in the OTC markets in Mexico and several Central and South American countries under the POINTTS tradename through our distributor, Genomma Labs. 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.

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. Finally, a molecular collection product focused on the infectious disease testing market was launched by DNAG in mid-2011.

Corporate Information

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. and Epitope, Inc., and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our Company on September 29, 2000. Our principal offices

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are located at 220 East First Street, Bethlehem, Pennsylvania 18015. Our telephone number is (610) 882-1820, and our website address is http://www.orasure.com. Information contained on our website is not incorporated into this registration statement. You can obtain more information regarding our business and industry by reading our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 14, 2012 and the other reports we file with the Securities and Exchange Commission, or SEC.

R ISK FACTORS

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors contained in the applicable prospectus supplement and any related free writing prospectus, and in our most recent Annual Report on Form 10-K, or any updates in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in this prospectus or incorporated by reference into this prospectus and any applicable prospectus supplement, before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or a part of your investment.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and any prospectus supplement may contain, forward-looking statements regarding us and our business, financial condition, results of operations and prospects. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. Such forward-looking statements include those which express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. We have based these forward-looking statements on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown which could cause actual results and developments to differ materially from those expressed or implied in such statements. Words such as expects, anticipates, intends, plans, believes, seeks, estimates, and similar expressions are intended to identify forward-looking statements, but are not the exclusi means of identifying forward-looking statements. These forward-looking statements include statements about our financial condition and performance, markets, product demand, distribution arrangements, research and development, the commercialization of new products, clinical development programs, litigation, and regulatory submissions and approvals.

Factors that could cause or contribute to differences in our results and outcomes include, without limitation, those discussed in Risk Factors above and in our Annual Report on Form 10-K for the year ended December 31, 2011. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company s products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company s acquisition of DNA Genotek; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products, including the OraQuick® In-Home HIV Test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product

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components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions.

You should not rely unduly on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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RATIO OF EARNINGS TO FIXED CHARGES

The following table sets forth the computation of our ratio of earnings to fixed charges for the periods indicated below (in thousands):

	Six Months Ended June 30, 2012	Years ended December 31, 2011	2010	2009	2008	2007
Ratio of Earnings to Fixed Charges						8.2