

ORASURE TECHNOLOGIES INC

Form 424B5

July 09, 2012

**Table of Contents**

**The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

Filed pursuant to Rule 424(b)(5)

Registration No.: 333-168972

**SUBJECT TO COMPLETION, DATED JULY 9, 2012**

**PRELIMINARY PROSPECTUS SUPPLEMENT**

(To Prospectus dated August 30, 2010)

## Shares

**OraSure Technologies, Inc.**

### Common Stock

We are offering \_\_\_\_\_ shares of our common stock, par value \$0.000001 per share, at a public offering price of \$ \_\_\_\_\_ per share.

Our common stock is listed on the Nasdaq Global Select Market tier of The Nasdaq Stock Market LLC under the symbol OSUR . On July 6, 2012, the reported last sale price of our common stock on the Nasdaq Global Select Market was \$13.19 per share.

**Investing in our securities involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our common stock under the heading Risk Factors beginning on page S-11 of this 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 supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

Per Share      Total

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 424B5

Price to the public	\$	\$
Underwriting discounts	\$	\$
Proceeds, before expenses, to us	\$	\$

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to an additional \_\_\_\_\_ shares of our common stock from us. If the underwriters exercise this option in full, the total underwriting discounts will be \$ \_\_\_\_\_, and our total proceeds, before expenses, will be \$ \_\_\_\_\_.

The underwriters expect to deliver the shares of our common stock on or about July \_\_\_\_\_, 2012 through the book-entry facilities of The Depository Trust Company.

*Joint Book-Running Managers*

**Citigroup**

**Jefferies**

*Co-Managers*

**Canaccord Genuity**

**Stephens Inc.**

**ThinkEquity LLC**

**JMP Securities**

The date of this prospectus supplement is \_\_\_\_\_, 2012.

**Table of Contents**

**TABLE OF CONTENTS**

**Prospectus Supplement**

<u>About This Prospectus Supplement</u>	ii
<u>Prospectus Supplement Summary</u>	S-1
<u>The Offering</u>	S-10
<u>Risk Factors</u>	S-11
<u>Special Note Regarding Forward-Looking Statements</u>	S-12
<u>Use of Proceeds</u>	S-14
<u>Dilution</u>	S-15
<u>Underwriting</u>	S-16
<u>Description of Our Common Stock</u>	S-22
<u>Validity of Securities</u>	S-23
<u>Experts</u>	S-23
<u>Where You Can Find More Information</u>	S-23

**Prospectus**

<u>About This Prospectus</u>	1
<u>Who We Are</u>	3
<u>Risk Factors</u>	5
<u>Special Note Regarding Forward-Looking Statements</u>	5
<u>Ratio of Earnings to Fixed Charges</u>	7
<u>Use of Proceeds</u>	7
<u>The Securities We May Offer</u>	8
<u>Description of Common Stock and Preferred Stock</u>	8
<u>Description of Warrants</u>	12
<u>Description of Rights</u>	14
<u>Description of Debt Securities</u>	16
<u>Description of Units</u>	24
<u>Book-Entry Issuance</u>	25
<u>Plan of Distribution</u>	27
<u>Legal Matters</u>	29
<u>Experts</u>	29
<u>Incorporation By Reference</u>	29
<u>Where You Can Find More Information</u>	31

**Table of Contents**

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document contains two parts. The first part is this prospectus supplement, which describes the terms of the offering of shares of our common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, provides more general information about us and the securities offered hereby. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. To the extent there is a conflict between the information contained in this prospectus supplement or any free writing prospectus we may authorize to be delivered to you, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, you should rely on the information in this prospectus supplement or such free writing prospectus, as the case may be, provided that, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to such agreement and the third-party beneficiaries named therein, if any, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

**You should rely only on the information contained in this prospectus supplement, contained in the accompanying prospectus or incorporated herein and therein by reference, and any free writing prospectus we may authorize to be delivered to you. Neither we nor the underwriters have authorized anyone to provide you with information that is different. We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement, the accompanying prospectus and the offering of our securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus supplement and accompanying prospectus outside the United States. This prospectus supplement and accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation. The information contained, or incorporated by reference, in this prospectus supplement and contained, or incorporated herein by reference, in the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus, or of any sale of our securities. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents we have referred you to in the section entitled Where You Can Find More Information in this prospectus supplement and the accompanying prospectus and any free writing prospectus we may authorize to be delivered to you.**

Unless the context otherwise requires, in this prospectus supplement the Company, we, us, our and similar names refer to OraSure Technologies Inc. and its subsidiaries.

---

**Table of Contents**

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement and in the accompanying prospectus and in the documents we incorporate by reference herein and therein. This summary does not contain all the information you should consider before investing in shares of our common stock in this offering. You should carefully read this entire prospectus supplement and the entire accompanying prospectus, including the Risk Factors section beginning on page S-11 of this prospectus supplement and page 5 in the accompanying prospectus and the financial statements and the other information incorporated by reference in this prospectus supplement and the accompanying prospectus, before making an investment decision. If you invest in our securities, you are assuming a high degree of risk.*

**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. One of our products is currently sold in the over-the-counter ( OTC ) or consumer retail market 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 for infectious diseases, drugs of abuse or other conditions. However, 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 and dignified nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic marketplace.

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 Oragen® sample collection kit, provides an all-in-one system for the collection, stabilization, transportation and storage of DNA from saliva. DNAG serves customers in many countries worldwide, including many leading research universities and hospitals in the world.

**Recent Developments**

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 old and older.

The OraQuick® In-Home HIV Test is an over-the-counter version of our OraQuick ADVANCE® HIV 1/2 Antibody Test, the market leading rapid HIV test with millions of units sold since 2002 to hospitals, clinics, community-based organizations and physician offices. The In-Home Test has shown sensitivity of 92% and specificity of 99.98% in our clinical trials.

---

## **Table of Contents**

We believe the market opportunity for the HIV OTC test is approximately \$500 million at retail in the United States. The potential target population for the 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.

The OraQuick® In-Home HIV Test is expected to be available for purchase this October. 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. The term All Commodity Volume, or ACV, represents the dollar value share we expect to achieve in the stores projected to constitute the market for our product. 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](http://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.

We expect to build inventory for the anticipated launch of the OraQuick® In-Home HIV Test by October. We will also be increasing our sales and marketing spending as a result of the initial launch of this product. To support individuals that purchase and use our test, we have established a toll-free customer support center that operates on a 24/7, 365-day per year basis. Through the 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 we are a new participant in this space and have 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.

## **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 Improvements Amendment of 1988, or CLIA, to perform moderately complex tests. We have also received a CLIA waiver for use of the test with oral fluid and finger-stick and venous whole blood. As a result, the test can be used by numerous additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians' offices.

On the international front, we have obtained a CE mark for our OraQuick *ADVANCE*® test so that we can sell this product in Europe and other countries accepting the CE mark for commercialization and this product is registered in other countries. We have distributors in place for several countries and are seeking to increase awareness and expand our distribution network for this product throughout the world.

## **Table of Contents**

We believe that the OraQuick *ADVANCE*<sup>®</sup> 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<sup>®</sup> HCV Rapid Antibody Test*

Another test available on the OraQuick<sup>®</sup> platform is the OraQuick<sup>®</sup> HCV rapid antibody test. Like the OraQuick<sup>®</sup> 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<sup>®</sup> HCV test operates in substantially the same manner as the OraQuick<sup>®</sup> 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. In November 2011, we 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<sup>®</sup> 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.

The OraSure QuickFlu test is intended to be used as an aid in the rapid differential diagnosis of influenza and covers a broad range of influenza subtypes, including 2009 H1N1, with proven clinical detection spanning three flu seasons from 2007 through 2009. The test is highly accurate across all specimen types based on standard culture confirmation with demonstrated sensitivity for influenza Type A at 90% or greater. Additionally, in clinical studies a significant number of culture negative samples that were tested positive with the OraSure QuickFlu product were determined to be true positives by PCR (polymerase chain reaction) testing.

This product is manufactured for us under an agreement with Princeton BioMeditech Corporation. The OraSure QuickFlu test is currently available for sale in certain U.S. markets.

### *OraSure<sup>®</sup> Collection Device*

Our OraSure<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> collection device involves three steps:

Collection of an oral fluid specimen using the OraSure<sup>®</sup> device;

## **Table of Contents**

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. 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. Clinical studies for THC and barbiturate assays are in process.

The high-throughput assays will be distributed in the U.S. and internationally by OraSure and Roche pursuant to a commercialization agreement between the parties. Sales of the assays in the U.S. are expected to begin in 2012.

### *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.



## **Table of Contents**

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 Oragen® 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.

### *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.

## **Table of Contents**

### *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.

On July 3, 2012, we received FDA approval to sell our OraQuick® In-Home HIV Test in the United States OTC market. We have developed product packaging and labeling suitable for the OTC market and have in place a toll-free, 24/7, 365-day per year customer call center to provide additional information and referral support for consumers.

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

### *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 expected eventually to be used with the high-throughput drug assays jointly developed with Roche Diagnostics.

## **Table of Contents**

### *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.

### **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 and distributor promotions, 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. For more information about our revenues and long-lived assets attributable to U.S. and international customers, please see Note 12 to our consolidated financial statements incorporated by reference into this prospectus supplement.

### *Infectious Disease Testing*

We market the OraQuick *ADVANCE*<sup>®</sup> 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*<sup>®</sup> 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<sup>®</sup> HIV test in Europe and other foreign countries. We expect to increase the number of countries where this product is sold as we find new distributors and complete registrations in additional countries.

We market the OraSure<sup>®</sup> 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<sup>®</sup> test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure<sup>®</sup> device in the international public health market.

Based on the FDA approvals in place during most of 2011, our OraQuick<sup>®</sup> 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 agreements with Merck & Co. Inc. ( Merck ) to collaborate on the development and promotion of our OraQuick<sup>®</sup> HCV test. Under the terms of these agreements, we have been and in the future may be reimbursed by Merck for a portion of our costs to develop the test and obtain regulatory approvals. Merck is also providing detailing and other promotional support for the test in the physicians office market in the United States and internationally.

## **Table of Contents**

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.

### *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. In 2012, we expect to begin selling 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.

### *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. In 2011, we began selling 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.

## **Table of Contents**

We also promote use of the OraSure<sup>®</sup> 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<sup>®</sup> Western blot confirmatory test directly to insurance testing laboratories for use in confirming oral fluid specimens collected with our OraSure<sup>®</sup> device that initially test positive for HIV-1.

There exists a wide range of policy limits where our OraSure<sup>®</sup> product is being used. In general, many (but not all) of our insurance company customers use the OraSure<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 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.

**Table of Contents**

**THE OFFERING**

Issuer:	OraSure Technologies, Inc.
Common stock offered by us pursuant to this prospectus supplement	shares
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of common stock within 30 days of the date of this prospectus supplement.
Common stock estimated to be outstanding immediately after this offering*	shares ( shares if the underwriters exercise in full their option to purchase additional shares of common stock)
Use of Proceeds	We currently intend to use the net proceeds of this offering for general corporate purposes. See Use of Proceeds on page S-14 of this prospectus supplement.
Risk Factors	See Risk Factors beginning on page S-11 of this prospectus supplement and in our Annual Report on Form 10-K for the year ended December 31, 2011 for a discussion of factors you should consider carefully before deciding to invest in shares of our common stock.
Market for the common stock	Our common stock is quoted and traded on The Nasdaq Global Select Market under the symbol OSUR.

\* The number of shares of our common stock to be outstanding after this offering is based on 48,086,177 shares of common stock outstanding as of March 31, 2012. Unless specifically stated otherwise, the information in this prospectus supplement excludes:

5,738,559 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2012, at a weighted average exercise price of \$7.52 per share, of which options to purchase 3,735,271 shares of our common stock were then exercisable;

up to 702,571 shares reserved as of March 31, 2012 for future issuance upon settlement of restricted stock awards granted under our Stock Award Plan; and

an aggregate of 3,084,221 shares of our common stock reserved for future grants of stock options (or other similar equity instruments) under our Stock Award Plan (pursuant to which we assumed the obligation to issue shares for the then outstanding stock options granted under the Epitope, Inc. 1991 Stock Award Plan and the Agritope, Inc. 1992 Stock Award Plan, upon the merger of Epitope and STC into us on September 29, 2000), as of March 31, 2012.

**Table of Contents**

**RISK FACTORS**

Investing in our securities involves a high degree of risk and uncertainty. Please see the risk factors under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011, as such discussions may be amended or updated in subsequent reports filed by us with the SEC.

Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus. The risks and uncertainties we have described are not the only risks facing our company. Additional risks and uncertainties not presently known to us or that we currently deem to be immaterial may also affect our business operations. If any of such risks and uncertainties actually occurs, our business, financial condition and results of operations could be severely harmed. This could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

**Risks Related to this Offering**

*We will have broad discretion in how we use the proceeds, and we may use the proceeds in ways in which you and other stockholders may not agree with.*

We intend to use the net proceeds from this offering for general corporate purposes. Our management will have broad discretion in the application of the proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.

*Investors in this offering will suffer immediate and substantial dilution in the net tangible book value per share of our common stock.*

Because the price per share in this offering is substantially higher than the net tangible book value per share of common stock, investors in this offering will suffer immediate dilution in the net tangible book value per share of our common stock. Based on an offering price of \$      per share, if you purchase securities in this offering, you will suffer immediate dilution of approximately \$      per share in the net tangible book value of our common stock. See "Dilution" on page S-15 for a more detailed discussion of the dilution you will incur in connection with this offering.

**Risks Relating to the Commercialization of our Products**

*Our future success depends on our ability to commercialize the OraQuick® In-Home HIV Test*

Our future success 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 adoption of the product among the targeted consumer base, initiating and maintaining relationships with our suppliers and retailing partners, 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. Successful commercialization 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.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents incorporated herein and therein by reference 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, clinical development activities, 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 exclusive 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<sup>®</sup> 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 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 refinance outstanding debt under expiring credit facilities on acceptable terms or at all; 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. You should read this prospectus supplement, the accompanying prospectus and the documents that



**Table of Contents**

we incorporate by reference herein and therein completely and with the understanding that our actual future results may be materially different from what we expect. 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.

S-13

**Table of Contents**

**USE OF PROCEEDS**

We expect to receive net proceeds of approximately \$        from the sale of        shares of our common stock in this offering, or \$        if the underwriters exercise their option to purchase additional shares in full, based on a public offering price of \$        per share after deducting the estimated expense