

ORASURE TECHNOLOGIES INC
Form S-3/A
December 17, 2012
Table of Contents

As filed with the Securities and Exchange Commission on December 17, 2012

Registration No. 333-184190

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

Amendment No. 2 to FORM S-3 REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of)

36-4370966
(IRS Employer)

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

Incorporation or Organization)

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. "

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

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.

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.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

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 <input type="checkbox"/>	Accelerated filer	x
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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)(6)

- (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.

(6) Previously paid.

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.

Table of Contents

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 December 17, 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**

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

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 December 12, 2012, the reported last sale price of our common stock on the Nasdaq Global Select Market was \$7.29 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.

Table of Contents

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

Table of Contents**TABLE OF CONTENTS**

<u>ABOUT THIS PROSPECTUS</u>	1
<u>WHO WE ARE</u>	3
<u>RISK FACTORS</u>	11
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	11
<u>RATIO OF EARNINGS TO FIXED CHARGES</u>	13
<u>USE OF PROCEEDS</u>	13
<u>THE SECURITIES WE MAY OFFER</u>	14
<u>DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK</u>	14
<u>DESCRIPTION OF WARRANTS</u>	18
<u>DESCRIPTION OF RIGHTS</u>	20
<u>DESCRIPTION OF DEBT SECURITIES</u>	22
<u>DESCRIPTION OF UNITS</u>	30
<u>BOOK-ENTRY ISSUANCE</u>	31
<u>PLAN OF DISTRIBUTION</u>	33
<u>LEGAL MATTERS</u>	35
<u>EXPERTS</u>	35
<u>INCORPORATION BY REFERENCE</u>	36
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	37

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

Table of Contents

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.

Table of Contents

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 Oragen® 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.

Financial Performance

We have experienced annual net losses since 2008. For the fiscal years ended December 31, 2011, 2010 and 2009, we have experienced annual net losses of \$8.8 million, \$3.5 million and \$7.8 million, respectively. For the nine months ended September 30, 2012, we experienced a net loss of \$9.2 million and as of September 30, 2012 we had an accumulated deficit of \$156.7 million. There can be no assurance that we will be able to achieve or sustain profitability in the future.

Competition, unfavorable economic conditions, funding uncertainty and other factors have affected sales of our products in the past, and certain of these factors may continue to negatively affect product sales in the future. In addition, we expect a substantial increase in our sales and marketing expenditures as a result of the commercialization of our OraQuick® In-Home HIV test. Sales and marketing expenditures for this product are expected to be in excess of \$4.2 million during the fourth quarter of 2012. Expenditures for the full year 2013 are expected to substantially exceed aggregate annual 2012 levels, with the heaviest spend projected for the first half of the year. These additional costs will negatively impact our future operating results.

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

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

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.

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

Table of Contents

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 expired in September 2012 and will not be renewed. We are also in discussions with Merck regarding the termination of our international agreement. Termination of these agreements is not expected to have a material impact on sales of our OraQuick[®] HCV test, either in the U.S. or in international markets.

We have distribution rights to an FDA 510(k) cleared rapid flu A&B test, which we market under our proprietary OraSure QuickFlu tradename. Under our agreement with the supplier of this product, we are permitted to sell this product into the U.S. hospital and public health markets.

Infectious Disease Testing OTC

The OraQuick[®] In-Home test has been available for purchase in the U.S. retail or consumer market since October 2012. Retailers carrying the product include CVS, Walgreens, Rite Aid and Kroger. The product is also available for purchase on-line through certain retailers and our website, www.oraquick.com. 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. We also began our national public relations and advertising campaign in connection with the OraQuick[®] launch.

Table of Contents

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 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.

Table of Contents

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

Table of Contents

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.

RISK 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 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® 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

Table of Contents

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.

Table of Contents**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):

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

Deficiency in Earnings to Cover Fixed Charges \$ 10,371,391 \$ 9,687,939 \$ 3,499,263 \$ 8,417,497 \$ 8,786,471

Fixed charges consist of interest expense and the interest component of rental expense, as estimated by management. Earnings for the nine months ended September 30, 2012 and for the years ended December 31, 2011, 2010, 2009 and 2008 were inadequate to cover fixed charges and, accordingly, no ratio of earnings to fixed charges is disclosed for those periods.

USE OF PROCEEDS

Except as otherwise described in the applicable prospectus supplement, the net proceeds from the sale of the securities offered hereunder will be added to our general funds and used for general corporate purposes, which may include, but are not limited to:

ongoing research and development activities;

commercialization of new products;

potential acquisitions;

capital expenditures;

patent license fees;

debt service and retirement; and

general working capital.

The amounts and timing of our actual expenditures for each purpose may vary significantly depending upon numerous factors, including the status of our research and product and clinical development efforts, regulatory approvals, competition, marketing and sales activities, the market acceptance of any products introduced by us, and economic or other conditions. Pending such uses, we intend to invest the net proceeds of this offering in short-term, investment grade, interest-bearing securities.

Table of Contents

THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements and any related free writing prospectuses, summarize the material terms and provisions of the various types of securities that we may offer. Prices for such securities will be determined by market conditions at the time of offering. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange or market, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

shares of our common stock;

shares of our preferred stock;

debt securities, in one or more series;

warrants to purchase any of the securities listed above;

rights to purchase any of the securities listed above; and/or

units consisting of one or more of the foregoing.

In this prospectus, we will refer to the common stock, preferred stock, warrants, rights, debt securities and units, collectively, as securities. The total dollar amount of all securities that we may issue will not exceed \$200,000,000. This prospectus may not be used to communicate a sale of securities unless it is accompanied by a prospectus supplement.

If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. For the complete terms of our common stock or preferred stock, please refer to our certificate of incorporation, as amended from time to time, the applicable certificate of designation, and our bylaws, as amended from time to time. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any common stock or preferred stock offered under that prospectus supplement may differ from the terms described below.

Under our certificate of incorporation, our authorized capital stock consists of 120,000,000 shares of common stock, par value \$0.000001 per share, and 25,000,000 shares of preferred stock, par value \$0.000001 per share. As of December 12, 2012, we had 55,264,651 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

Voting. For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in his or her name. Subject to applicable law and any preferential rights we may grant to the holders of preferred stock, if any is outstanding, holders of our common stock will have all voting power. Our common stock does not have cumulative voting rights.

- 14 -

Table of Contents

Dividends. If our board of directors declares a dividend, holders of common stock will receive payments from our funds that are legally available to pay dividends. However, this dividend right is subject to any preferential dividend rights we may grant to the holders of preferred stock, if any is outstanding. We have never paid, and we do not anticipate declaring or paying, any cash dividends on shares of our common stock in the foreseeable future.

Liquidation and Dissolution. If we are liquidated or dissolve, the holders of our common stock will be entitled to share ratably in all the assets that remain after we pay our liabilities and any amounts we may owe to the holders of preferred stock, if any is outstanding.

Other Rights and Restrictions. Holders of our common stock do not have preemptive rights, and they have no right to convert their common stock into any other securities. Our common stock is not subject to redemption by us. The rights, preferences and privileges of holders of our common stock are subject to the rights of the holders of any series of preferred stock which we may designate in the future. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer his or her shares of common stock. If we issue shares of common stock under this prospectus and any applicable prospectus supplement, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing. Our common stock is listed on the NASDAQ Global Select Market tier under the symbol OSUR.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is Computershare Shareowner Services LLC (formerly known as BNY Mellon Shareowner Services LLC).

Preferred Stock

General. Our certificate of incorporation authorizes the issuance of up to 25,000,000 shares of preferred stock, par value \$0.000001 per share. We may issue, from time to time in one or more series, the terms of which may be determined at the time of issuance by our board of directors, without further action by our stockholders, shares of preferred stock and such shares may include voting rights, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The shares of each series of preferred stock shall have preferences, limitations and relative rights, including voting rights, identical with those of other shares of the same series and, except to the extent provided in the description of such series, of those of other series of preferred stock.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our board of directors to issue preferred stock could discourage, delay or prevent a takeover or change in control.

The description of the terms of a particular series of preferred stock in the applicable prospectus supplement will not be complete. You should refer to the applicable certificate of designation for complete information regarding a series of preferred stock. The prospectus supplement will also contain a description of U.S. federal income tax consequences relating to the preferred stock, if material.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to that particular series of preferred stock, including, where applicable:

the series designation, stated value and liquidation preference of such preferred stock and the number of shares offered;

the offering price;

the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;

any redemption or sinking fund provisions;

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

the amount that shares of such series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;

the terms and conditions, if any, on which shares of such series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;

- 15 -

Table of Contents

the voting rights, if any, of shares of such series in addition to those set forth under the caption entitled, "Voting Rights" below;

the status as to reissuance or sale of shares of such series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;

the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us, of our common stock or of any other class of our stock ranking junior to the shares of such series as to dividends or upon liquidation (including, but not limited to, at such times as there are arrearages in the payment of dividends or sinking fund installments);

the conditions and restrictions, if any, on the creation of Company indebtedness, or on the issue of any additional stock ranking on a parity with or prior to the shares of such series as to dividends or upon liquidation; and

any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of such preferred stock.

If we issue shares of preferred stock under this prospectus and any related prospectus supplement, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Voting Rights. The General Corporation Law of Delaware provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Transfer Agent and Registrar. The transfer agent and registrar for any series of preferred stock will be set forth in the applicable prospectus supplement.

Other. Our issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock could have the effect of decreasing the market price of our common stock.

Certain Effects of Authorized But Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including raising additional capital through future public offerings, facilitating corporate acquisitions or paying a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or the DGCL, which, subject to certain exceptions and limitations, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless:

(i)

prior to such date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

Table of Contents

- (ii) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (for the purposes of determining the number of shares outstanding under the DGCL, those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer are excluded from the calculation); or
- (iii) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

For purposes of Section 203, a business combination includes:

- (i) any merger or consolidation involving the corporation and the interested stockholder;
- (ii) any sale, lease, exchange, mortgage, transfer, pledge or other disposition (in one transaction or a series of transactions) of 10% or more of the aggregate market value of all assets or outstanding stock of the corporation involving the interested stockholder;
- (iii) subject to certain exceptions, any transaction which results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- (iv) any transaction involving the corporation which has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- (v) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any person or entity who, together with the person's or entity's affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

Selected Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation provides that the number of directors shall be as determined by the board of directors from time to time, but shall be at least three and not more than twelve. It further provides that directors may be removed only for cause, and then only by the affirmative vote of the holders of at least a majority of all outstanding voting stock entitled to vote in an election of directors. These provisions, in conjunction with the provision of the certificate of incorporation authorizing the board of directors to fill vacant directorships, will prevent stockholders from removing incumbent directors without cause and filling the resulting vacancies with their own nominees.

Our certificate of incorporation further provides that the board of directors will be divided into three classes, with each class containing as nearly as possible one-third of the total number of directors and the members of each class serving for staggered three-year terms. At each annual meeting of our stockholders, the number of directors equal to the number of the class whose term expires at the time of such meeting will be elected to hold office until the third succeeding annual meeting of stockholders. This provision could make it more difficult for stockholders to take control of the board of directors.

Table of Contents

Our certificate of incorporation provides that stockholders may act only at an annual or special meeting of stockholders and may not act by written consent unless such consent is unanimous. Special meetings of the stockholders can be called only by our Chairman of the Board, President, or board of directors pursuant to a resolution approved by a majority of the whole board of directors. This provision will prevent stockholders from removing board members by calling a special meeting of stockholders without the consent of the Chairman of the Board, the President or the board of directors.

Our bylaws contain provisions (i) requiring that advance notice be delivered to us of any business to be brought by a stockholder before any meeting of stockholders and (ii) establishing procedures to be followed by stockholders in nominating persons for election to the board of directors. Generally, such advance notice provisions provide that written notice must be given to us by a stockholder, with respect to director nominations or stockholder proposals, not less than 90 nor more than 120 days prior to the meeting (except that if less than 100 days notice or prior public disclosure of the date of the meeting is given or made to stockholders, then notice by the stockholder, to be timely, must be received within 10 days of the date on which notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs). Such notice must set forth specific information regarding such stockholder and such business or director nominee, as described in the bylaws.

Our certificate of incorporation authorizes the board of directors to take into account (in addition to any other considerations which the board of directors may lawfully take into account) in determining whether to take or to refrain from taking corporate action on any possible acquisition proposals, including proposing any related matter to our stockholders, the long-term as well as short-term interests of our company and its stockholders, including the possibility that these may be best served by the continued independence of our company, customers, employees and other constituencies and any subsidiaries, as well as the effect upon communities in which we do business. In considering the foregoing and other pertinent factors, the board of directors is not required, in considering our best interests, to regard any particular corporate interest or the interest of any particular group affected by such action as a controlling interest.

Certain provisions of the certificate of incorporation and bylaws, including those described above, may only be amended by stockholders upon the affirmative vote of the holders of at least two-thirds of the outstanding voting capital stock entitled to vote on such amendment.

The preceding provisions could have the effect of discouraging, delaying or making more difficult certain attempts to acquire us or to remove incumbent directors even if a majority of our stockholders believe the attempt to be in their or our best interests. The foregoing summaries are qualified in their entirety by reference to our certificate of incorporation and bylaws, copies of which are incorporated by reference into the registration statement of which this prospectus is a part.

Stockholder Rights Plan

We currently do not have a stockholder rights plan in place.

Stock Options and Restricted Stock

As of December 12, 2012, a total of 4,656,668 options to purchase shares of our common stock had been granted and remained outstanding and unexercised under our stock option plans and there were 676,777 shares of restricted stock that had been granted and remain unvested. As of that date, there were 3,105,228 shares of our common stock available for future grants under our Stock Award Plan.

DESCRIPTION OF WARRANTS

The following is a general description of the terms of the warrants we may issue from time to time unless we provide otherwise in the prospectus supplement. Particular terms of any warrants we offer will be described in the prospectus supplement relating to such warrants. There are currently no warrants to purchase shares of common stock outstanding.

Table of Contents

General Terms

We may issue warrants to purchase common stock, preferred stock, debt securities and/or units in one or more series. Warrants may be issued independently or together with other securities and may be attached to, or separate from, such securities. We will issue each series of warrants under a separate warrant agreement to be entered into between us and a warrant agent. The warrant agent will act solely as our agent and will not assume any obligation or relationship of agency for or with holders or beneficial owners of warrants.

A prospectus supplement will describe the particular terms of any series of warrants we may issue, including some or all of the following:

the title and aggregate number of the warrants;

the price or prices at which the warrants will be issued and the currency or currencies in which the price of the warrants may be payable;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;

in the case of warrants to purchase common stock or preferred stock, the type of stock and number of shares of stock purchasable upon exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the date on which the right to exercise the warrants will commence and the date on which such right will expire (subject to any extension);

whether the warrants will be issued in registered form or bearer form;

if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

if applicable, the procedures for adjusting the exercise price and number of shares of common stock or preferred stock purchasable upon the exercise of each warrant upon the occurrence of certain events, including stock splits, reverse stock splits, combinations, subdivisions or reclassifications of common stock or preferred stock;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

information with respect to book-entry procedures, if any;

the terms of the securities issuable upon exercise of the warrants;

if applicable, a discussion of certain U.S. Federal income tax considerations; and

any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Table of Contents

We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

Exercise of Warrants

Each warrant will entitle the holder to purchase for cash such common stock, preferred stock and/or units at the exercise price or such principal amount of debt securities as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the warrants offered thereby. Warrants may be exercised as set forth in the prospectus supplement beginning on the date specified therein and continuing until the close of business on the expiration date set forth in the prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of payment and a warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the securities purchasable upon such exercise. If less than all of the warrants represented by such warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Prior to exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise any voting rights or, in the case of warrants to purchase debt securities, the right to receive principal, premium, if any, or interest payments, on the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture.

Enforceability of Rights By Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

DESCRIPTION OF RIGHTS

The following is a general description of the terms of the rights we may issue from time to time unless we provide otherwise in the applicable prospectus supplement. Particular terms of any rights we offer will be described in the prospectus supplement relating to such rights.

General

We may issue rights to purchase common stock, preferred stock, debt securities or units. Rights may be issued independently or together with other securities and may or may not be transferable by the person purchasing or receiving

Table of Contents

the rights. In connection with any rights offering to our stockholders, we may enter into a standby underwriting, backstop or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. In connection with a rights offering to our stockholders, we would distribute certificates evidencing the rights and a prospectus supplement to our stockholders on or about the record date that we set for receiving rights in such rights offering.

The applicable prospectus supplement will describe the following terms of any rights we may issue, including some or all of the following:

the title and aggregate number of the rights;

the subscription price or a formula for the determination of the subscription price for the rights and the currency or currencies in which the subscription price may be payable;

if applicable, the designation and terms of the securities with which the rights are issued and the number of rights issued with each such security or each principal amount of such security;

the number or a formula for the determination of the number of the rights issued to each stockholder;

the extent to which the rights are transferable;

in the case of rights to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one right;

in the case of rights to purchase common stock or preferred stock, the type of stock and number of shares of stock purchasable upon exercise of one right;

the date on which the right to exercise the rights will commence, and the date on which the rights will expire (subject to any extension);

if applicable, the minimum or maximum amount of the rights that may be exercised at any one time;

the extent to which such rights include an over-subscription privilege with respect to unsubscribed securities;

if applicable, the procedures for adjusting the subscription price and number of shares of common stock or preferred stock purchasable upon the exercise of each right upon the occurrence of certain events, including stock splits, reverse stock splits, combinations, subdivisions or reclassifications of common stock or preferred stock;

the effect on the rights of any merger, consolidation, sale or other disposition of our business;

the terms of any rights to redeem or call the rights;

information with respect to book-entry procedures, if any;

the terms of the securities issuable upon exercise of the rights;

if applicable, the material terms of any standby underwriting, backstop or other purchase arrangement that we may enter into in connection with the rights offering;

if applicable, a discussion of certain U.S. Federal income tax considerations; and

any other terms of the rights, including terms, procedures and limitations relating to the exchange and exercise of the rights.

Table of Contents

Exercise of Rights

Each right will entitle the holder to purchase for cash or other consideration such shares of stock or principal amount of securities at the subscription price as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the rights offered thereby. Rights may be exercised as set forth in the applicable prospectus supplement beginning on the date specified therein and continuing until the close of business on the expiration date set forth in the prospectus supplement relating to the rights offered thereby. After the close of business on the expiration date, unexercised rights will become void.

Upon receipt of payment and a subscription certificate properly completed and duly executed at the corporate trust office of the subscription agent or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the securities purchasable upon such exercise. If less than all of the rights represented by such subscription certificate are exercised, a new subscription certificate will be issued for the remaining rights. If we so indicate in the applicable prospectus supplement, holders of the rights may surrender securities as all or part of the exercise price for rights.

We may determine to offer any unsubscribed offered securities directly to stockholders, persons other than stockholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby underwriting, backstop or other arrangements, as set forth in the applicable prospectus supplement.

Prior to exercising their rights, holders of rights will not have any of the rights of holders of the securities purchasable upon subscription, including, in the case of rights to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise any voting rights or, in the case of rights to purchase debt securities, the right to receive principal, premium, if any, or interest payments, on the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture.

DESCRIPTION OF DEBT SECURITIES

The following is a general description of the terms of debt securities we may issue from time to time unless we provide otherwise in the applicable prospectus supplement. Particular terms of any debt securities we offer will be described in the prospectus supplement relating to such debt securities.

As required by Federal law for all bonds and notes of companies that are publicly offered, any debt securities we issue will be governed by a document called an indenture. An indenture is a contract between us and a financial institution acting as trustee on behalf of the holders of the debt securities, and is subject to and governed by the Trust Indenture Act of 1939, as amended. The trustee has two main roles. First, the trustee can enforce holders' rights against us if we default. There are some limitations on the extent to which the trustee acts on holders' behalf, described in the second paragraph under Description of Debt Securities Events of Default. Second, the trustee performs certain administrative duties, such as sending interest and principal payments to holders.

Because this section is a summary, it does not describe every aspect of any debt securities we may issue or the indenture governing any such debt securities. Particular terms of any debt securities we offer will be described in the prospectus supplement relating to such debt securities, and we urge you to read the applicable indenture, which will be filed with the SEC at the time of any offering of debt securities, because it, and not this description, will define the rights of holders of such debt securities.

A prospectus supplement will describe the particular terms of any series of debt securities we may issue, including some or all of the following:

the designation or title of the series of debt securities;

the total principal amount of the series of debt securities, the denominations in which the offered debt securities will be issued and whether the offering may be reopened for additional securities of that series and on what terms;

Table of Contents

the percentage of the principal amount at which the series of debt securities will be offered;

the date or dates on which principal will be payable;

the rate or rates (which may be either fixed or variable) and/or the method of determining such rate or rates of interest, if any;

the date or dates from which any interest will accrue, or the method of determining such date or dates, and the date or dates on which any interest will be payable;

the terms for redemption, extension or early repayment, if any;

the currencies in which the series of debt securities are issued and payable;

whether the amount of payments of principal, interest or premium, if any, on a series of debt securities will be determined with reference to an index, formula or other method and how these amounts will be determined;

the place or places of payment, transfer, conversion and/or exchange of the debt securities;

the provision for any sinking fund;

any restrictive covenants;

events of default;

whether the series of debt securities are issuable in certificated form;

any provisions for legal defeasance or covenant defeasance;

whether and under what circumstances we will pay additional amounts in respect of any tax, assessment or governmental charge and, if so, whether we will have the option to redeem the debt securities rather than pay the additional amounts (and the terms of this option);

any provisions for convertibility or exchangeability of the debt securities into or for any other securities;

whether the debt securities are subject to subordination and the terms of such subordination;

any listing of the debt securities on any securities exchange;

if applicable, a discussion of certain U.S. Federal income tax considerations, including those related to original issue discount, if applicable; and

any other material terms.

The debt securities may be secured or unsecured obligations. Unless the prospectus supplement states otherwise, principal, interest and premium, if any, will be paid by us in immediately available funds.

General

The indenture may provide that any debt securities proposed to be sold under this prospectus and the applicable prospectus supplement relating to such debt securities (offered debt securities) and any debt securities issuable upon conversion or exchange of other offered securities (underlying debt securities) may be issued under the indenture in one or more series.

Table of Contents

For purposes of this prospectus, any reference to the payment of principal of, or interest or premium, if any, on, debt securities will include additional amounts if required by the terms of the debt securities.

Debt securities issued under an indenture, when a single trustee is acting for all debt securities issued under the indenture, are called the indenture securities. The indenture may also provide that there may be more than one trustee thereunder, each with respect to one or more different series of securities issued thereunder. See Description of Debt Securities Resignation of Trustee below. At a time when two or more trustees are acting under an indenture, each with respect to only certain series, the term indenture securities means the one or more series of debt securities with respect to which each respective trustee is acting. In the event that there is more than one trustee under an indenture, the powers and trust obligations of each trustee described in this prospectus will extend only to the one or more series of indenture securities for which it is trustee. If two or more trustees are acting under an indenture, then the indenture securities for which each trustee is acting would be treated as if issued under separate indentures.

We refer you to the applicable prospectus supplement relating to any debt securities we may issue from time to time for information with respect to any deletions from, modifications of or additions to the Events of Default or covenants that are described below, including any addition of a covenant or other provision providing event risk or similar protection, that will be applicable with respect to such debt securities.

We have the ability to issue indenture securities with terms different from those of indenture securities previously issued and, without the consent of the holders thereof, to reopen a previous issue of a series of indenture securities and issue additional indenture securities of that series unless the reopening was restricted when that series was created.

Conversion and Exchange

If any debt securities are convertible into or exchangeable for other securities, the related prospectus supplement will explain the terms and conditions of the conversion or exchange, including the conversion price or exchange ratio (or the calculation method), the conversion or exchange period (or how the period will be determined), if conversion or exchange will be mandatory or at the option of the holder or us, provisions for adjusting the conversion price or the exchange ratio and provisions affecting conversion or exchange in the event of the redemption of the underlying debt securities. These terms may also include provisions under which the number or amount of other securities to be received by the holders of the debt securities upon conversion or exchange would be calculated according to the market price of the other securities as of a time stated in the prospectus supplement.

Payment and Paying Agents

We will pay interest to the person listed in the applicable trustee's records as the owner of the debt security at the close of business on a particular day in advance of each due date for interest, even if that person no longer owns the debt security on the interest due date. That day, often approximately two weeks in advance of the interest due date, is called the record date. Because we will pay all the interest for an interest period to the holders on the record date, holders buying and selling debt securities must work out between themselves the appropriate purchase price. The most common manner is to adjust the sales price of the debt securities to prorate interest fairly between buyer and seller based on their respective ownership periods within the particular interest period. This prorated interest amount is called accrued interest.

Events of Default

Holders of debt securities of any series will have rights if an Event of Default occurs in respect of the debt securities of such series and is not cured, as described later in this subsection.

Table of Contents

The term Event of Default in respect of the debt securities of any series means any of the following:

we do not pay the principal of, or any premium on, a debt security of the series on its due date;

we do not pay interest on a debt security of the series within 30 days of its due date;

we do not deposit any sinking fund payment in respect of debt securities of the series on its due date and we do not cure this default within five days;

we remain in breach of a covenant in respect of debt securities of the series for 90 days after we receive a written notice of default stating we are in breach. The notice must be sent by either the trustee or holders of at least 25% of the principal amount of debt securities of the series;

we file for bankruptcy or certain other events of bankruptcy, insolvency or reorganization occur; and

any other Event of Default occurs in respect of debt securities of the series described in the prospectus supplement.

An Event of Default for a particular series of debt securities does not necessarily constitute an Event of Default for any other series of debt securities issued under the same or any other indenture. The trustee may withhold notice to the holders of debt securities of any default, except in the payment of principal, premium or interest, if it considers the withholding of notice to be in the best interests of the holders.

Remedies if an Event of Default Occurs

If an Event of Default has occurred and has not been cured or waived, the trustee or the holders of not less than 25% in principal amount of the debt securities of the affected series may declare the entire principal amount of all the debt securities of that series to be due and immediately payable. This is called a declaration of acceleration of maturity. A declaration of acceleration of maturity may be canceled by the holders of a majority in principal amount of the debt securities of the affected series if the default is cured or waived and certain other conditions are satisfied.

Except in cases of default, where the trustee has some special duties, the trustee typically is not required to take any action under an indenture at the request of any holders unless the holders offer the trustee reasonable protection from expenses and liability (called an indemnity). If reasonable indemnity is provided, the holders of a majority in principal amount of the outstanding debt securities of the relevant series may direct the time, method and place of conducting any lawsuit or other formal legal action seeking any remedy available to the trustee. The trustee may refuse to follow those directions in certain circumstances.

Before a holder is allowed to bypass the trustee and bring its own lawsuit or other formal legal action or take other steps to enforce its rights or protect its interests relating to any debt securities, the following must occur:

the holder must give the trustee written notice that an Event of Default has occurred and remains uncured;

the holders of at least 25% in principal amount of all outstanding debt securities of the relevant series must make a written request that the trustee take action because of the default and must offer reasonable indemnity to the trustee against the cost and other liabilities of taking that action;

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

the trustee must not have taken action for 60 days after receipt of the above notice and offer of indemnity; and

the holders of a majority in principal amount of the debt securities must not have given the trustee a direction inconsistent with the above notice during that 60-day period.

However, a holder is entitled at any time to bring a lawsuit for the payment of money due on its debt securities on or after the due date.

- 25 -

Table of Contents

Each year, we will furnish to each trustee a written statement of certain of our officers certifying that to their knowledge we are in compliance with the indenture and the debt securities, or else specifying any default.

Waiver of Default

The holders of a majority in principal amount of the relevant series of debt securities may waive a default for all such series of debt securities. If this happens, the default will be treated as if it had not occurred. No one can waive a payment default on a holder's debt security, however, without the holder's approval.

Merger or Consolidation

Under the terms of an indenture, we may be permitted to consolidate or merge with another entity. We may also be permitted to sell all or substantially all of our assets to another entity. However, typically we may not take any of these actions unless all the following conditions are met:

if we do not survive such transaction or we convey, transfer or lease our properties and assets substantially as an entirety, the acquiring company must be a corporation, limited liability company, partnership or trust, or other corporate form, organized under the laws of any state of the United States or the District of Columbia, any country comprising the European Union, the United Kingdom or Japan and such company must agree to be legally responsible for our debt securities, and, if not already subject to the jurisdiction of any state of the United States or the District of Columbia, the new company must submit to such jurisdiction for all purposes with respect to the debt securities and appoint an agent for service of process;

alternatively, we must be the surviving company;

immediately after the transaction no Event of Default will exist;

we must deliver certain certificates and documents to the trustee; and

we must satisfy any other requirements specified in the prospectus supplement relating to a particular series of debt securities.

Modification or Waiver

There are three types of changes we may make to an indenture and the debt securities issued thereunder.

Changes Requiring Approval

First, there are changes that we cannot make to debt securities without specific approval of all of the holders. The following is a list of the types of changes that may require specific approval:

change the stated maturity of the principal of or rate of interest on a debt security;

reduce any amounts due on a debt security;

reduce the amount of principal payable upon acceleration of the maturity of a security following a default;

at any time after a change of control has occurred, reduce any premium payable upon a change of control;

change the place or currency of payment on a debt security (except as otherwise described in the prospectus or prospectus supplement);

impair the right of holders to sue for payment;

- 26 -

Table of Contents

adversely affect any right to convert or exchange a debt security in accordance with its terms;

reduce the percentage of holders of debt securities whose consent is needed to modify or amend the indenture;

reduce the percentage of holders of debt securities whose consent is needed to waive compliance with certain provisions of the indenture or to waive certain defaults;

modify any other aspect of the provisions of the indenture dealing with supplemental indentures, modification and waiver of past defaults, changes to the quorum or voting requirements or the waiver of certain covenants; and

change any obligation we have to pay additional amounts.

Changes Not Requiring Approval

The second type of change does not require any vote by the holders of the debt securities. This type is limited to clarifications and certain other changes that would not adversely affect holders of the outstanding debt securities in any material respect, including the addition of covenants and guarantees. We also do not need any approval to make any change that affects only debt securities to be issued under the indenture after the change takes effect.

Changes Requiring Majority Approval

Any other change to the indenture and the debt securities may require the following approval:

if the change affects only one series of debt securities, it must be approved by the holders of a majority in principal amount of that series; and

if the change affects more than one series of debt securities issued under the same indenture, it must be approved by the holders of a majority in principal amount of all of the series affected by the change, with all affected series voting together as one class for this purpose.

The holders of a majority in principal amount of all of the series of debt securities issued under an indenture, voting together as one class for this purpose, may waive our compliance obligations with respect to some of our covenants in that indenture. However, we cannot obtain a waiver of a payment default or of any of the matters covered by the bullet points included above under Description of Debt Securities Modification or Waiver Changes Requiring Approval.

Further Details Concerning Voting

When taking a vote on proposed changes to the indenture and the debt securities, we expect to use the following rules to decide how much principal to attribute to a debt security:

for original issue discount securities, we will use the principal amount that would be due and payable on the voting date if the maturity of these debt securities were accelerated to that date because of a default;

for debt securities whose principal amount is not known (for example, because it is based on an index), we will use a special rule for that debt security described in the related prospectus supplement; and

for debt securities denominated in one or more foreign currencies, we will use the U.S. dollar equivalent. Debt securities will not be considered outstanding, and therefore not eligible to vote, if we have deposited or set aside in trust money for their payment or redemption. Debt securities will also not be eligible to vote if they have been fully defeased as described later under Description of Debt Securities Defeasance Legal Defeasance.

Table of Contents

We generally will be entitled to set any day as a record date for the purpose of determining the holders of outstanding indenture securities that are entitled to vote or take other action under the indenture. If we set a record date for a vote or other action to be taken by holders of one or more series, that vote or action may be taken only by persons who are holders of outstanding indenture securities of those series on the record date and must be taken within 11 months following the record date.

Book-entry and other indirect holders will need to consult their banks or brokers for information on how approval may be granted or denied if we seek to change the indenture or the debt securities or request a waiver.

Defeasance

The following provisions will be applicable to each series of debt securities unless we state in the applicable prospectus supplement that the provisions of covenant defeasance and legal defeasance will not be applicable to that series.

Covenant Defeasance

We can make the deposit described below and be released from some of the restrictive covenants in the indenture under which the particular series was issued. This is called *covenant defeasance*. In that event, the holders would lose the protection of those restrictive covenants but would gain the protection of having money and government securities set aside in trust to repay holders' debt securities. If applicable, a holder also would be released from the subordination provisions described under *Description of Debt Securities Indenture Provisions Subordination* below. In order to achieve covenant defeasance, we must do the following:

If the debt securities of the particular series are denominated in U.S. dollars, we must deposit in trust for the benefit of all holders of such debt securities a combination of money and U.S. government or U.S. government agency notes or bonds that will generate enough cash to make interest, principal and any other payments on the debt securities on their various due dates;

We may be required to deliver to the trustee a legal opinion of our counsel confirming that, under current U.S. Federal income tax law, we may make the above deposit without causing the holders to be taxed on the debt securities any differently than if we did not make the deposit and just repaid the debt securities ourselves at maturity; and

We must deliver to the trustee certain documentation stating that all conditions precedent to covenant defeasance have been complied with.

If we accomplish covenant defeasance, holders can still look to us for repayment of the debt securities if there were a shortfall in the trust deposit or the trustee is prevented from making payment. In fact, if one of the remaining Events of Default occurred (such as our bankruptcy) and the debt securities became immediately due and payable, there might be a shortfall. Depending on the event causing the default, holders may not be able to obtain payment of the shortfall.

Legal Defeasance

As described below, we can legally release ourselves from all payment and other obligations on the debt securities of a particular series (called *legal defeasance*), (1) if there is a change in U.S. Federal tax law that allows us to effect the release without causing the holders to be taxed any differently than if the release had not occurred, and (2) if we put in place the following other arrangements for holders to be repaid:

If the debt securities of the particular series are denominated in U.S. dollars, we must deposit in trust for the benefit of all holders of such debt securities a combination of money and U.S. government or U.S. government agency notes or bonds that will generate enough cash to make interest, principal and any other payments on the debt securities on their various due dates;

Table of Contents

We may be required to deliver to the trustee a legal opinion confirming that there has been a change in current U.S. Federal tax law or an Internal Revenue Service ruling that allows us to make the above deposit without causing the holders to be taxed on the debt securities any differently than if we did not make the deposit and just repaid the debt securities ourselves at maturity. Under current U.S. Federal tax law, the deposit and our legal release from the debt securities would be treated as though we paid each holder its share of the cash and notes or bonds at the time the cash and notes or bonds were deposited in trust in exchange for its debt securities and holders would recognize gain or loss on the debt securities at the time of the deposit; and

We must deliver to the trustee a legal opinion and officers' certificate stating that all conditions precedent to legal defeasance have been complied with.

If we ever did accomplish legal defeasance, as described above, holders would have to rely solely on the trust deposit for repayment of the debt securities. Holders could not look to us for repayment in the unlikely event of any shortfall. Conversely, the trust deposit would most likely be protected from claims of our lenders and other creditors if we ever became bankrupt or insolvent. If applicable, holders would also be released from the subordination provisions described later under Description of Debt Securities Indenture Provisions Subordination.

Resignation of Trustee

Each trustee may resign or be removed with respect to one or more series of indenture securities provided that a successor trustee is appointed to act with respect to such series. In the event that two or more persons are acting as trustee with respect to different series of indenture securities under the indenture, each of the trustees will be a trustee of a trust separate and apart from the trust administered by any other trustee.

Indenture Provisions Subordination

Upon any distribution of our assets upon our dissolution, winding up, liquidation or reorganization, the payment of the principal of (and premium, if any) and interest on any indenture securities denominated as subordinated debt securities is to be subordinated to the extent provided in the indenture in right of payment to the prior payment in full of all Senior Indebtedness (defined below), but our obligation to holders to make payment of the principal of (and premium, if any) and interest on such subordinated debt securities will not otherwise be affected. In addition, no payment on account of principal (or premium, if any), interest or sinking fund, if any, may be made on such subordinated debt securities at any time unless full payment of all amounts due in respect of the principal (and premium, if any), interest and sinking fund, if any, on Senior Indebtedness has been made or duly provided for in money or money's worth.

In the event that, notwithstanding the foregoing, any payment from us is received by the trustee in respect of subordinated debt securities or by the holders of any of such subordinated debt securities before all Senior Indebtedness is paid in full, the payment or distribution must be paid over to the holders of the Senior Indebtedness or on their behalf for application to the payment of all the Senior Indebtedness remaining unpaid until all the Senior Indebtedness has been paid in full, after giving effect to any concurrent payment or distribution to the holders of the Senior Indebtedness. Subject to the payment in full of all Senior Indebtedness, the holders of such subordinated debt securities will be subrogated to the rights of the holders of the Senior Indebtedness to the extent of payments made to the holders of the Senior Indebtedness out of the distributive share of such subordinated debt securities.

By reason of this subordination, in the event of a distribution of our assets upon our insolvency, certain of our senior creditors may recover more, ratably, than holders of any subordinated debt securities. The related indenture will provide that these subordination provisions will not apply to money and securities held in trust under the defeasance provisions of the indenture.

Senior Indebtedness will be defined in an applicable indenture as the principal of (and premium, if any) and unpaid interest on:

our indebtedness (including indebtedness of others guaranteed by us), whenever created, incurred, assumed or guaranteed, for money borrowed (other than indenture securities issued under the indenture and denominated as subordinated debt securities), unless in the instrument creating or evidencing the same or under which the same is outstanding it is provided that this indebtedness is not senior or prior in right of payment to the subordinated debt securities; and

renewals, extensions, modifications and refinancings of any of such indebtedness.

Table of Contents

The prospectus supplement accompanying any series of indenture securities denominated as subordinated debt securities will set forth the approximate amount of our Senior Indebtedness outstanding as of a recent date.

Trustee

We intend to name the indenture trustee for each series of indenture securities in the related prospectus supplement.

Certain Considerations Relating to Foreign Currencies

Debt securities denominated or payable in foreign currencies may entail significant risks. These risks include the possibility of significant fluctuations in the foreign currency markets, the imposition or modification of foreign exchange controls and potential illiquidity in the secondary market. These risks will vary depending upon the currency or currencies involved and will be more fully described in the applicable prospectus supplement.

DESCRIPTION OF UNITS

The following is a general description of the terms of the units we may issue from time to time unless we provide otherwise in the applicable prospectus supplement. Particular terms of any units we offer will be described in the prospectus supplement relating to such units.

General

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The applicable prospectus supplement may describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and

whether the units will be issued in fully registered or global form.

The applicable prospectus supplement will describe the terms of any units. The preceding description and any description of units in the applicable prospectus supplement does not purport to be complete and is subject to and is qualified in its entirety by reference to the unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such units.

We will describe in the applicable prospectus supplement the terms of the series of units, including the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately, the relevant provisions of any agreement governing the units and any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

Table of Contents

The provisions described in this section, as well as those described under Description of Common and Preferred Stock, Description of Warrants, Description of Rights and Description of Debt Securities will apply to each unit and to any common stock, preferred stock, warrants, rights and debt securities included in each unit, respectively.

BOOK-ENTRY ISSUANCE

Unless otherwise indicated in the applicable prospectus supplement, securities will be issued in the form of one or more global certificates, or global securities, registered in the name of a depository or its nominee. Unless otherwise indicated in the applicable prospectus supplement, the depository will be The Depository Trust Company, or DTC. DTC has informed us that its nominee will be Cede & Co. Accordingly, we expect Cede & Co. to be the initial registered holder of all securities that are issued in global form. No person that acquires a beneficial interest in those securities will be entitled to receive a certificate representing that person's interest in the securities except as described herein or in the applicable prospectus supplement. Unless and until definitive securities are issued under the limited circumstances described below, all references to actions by holders of securities issued in global form will refer to actions taken by DTC upon instructions from its participants, and all references to payments and notices to holders will refer to payments and notices to DTC or Cede & Co., as the registered holder of these securities.

DTC has informed us that it is a limited-purpose trust company organized under the New York Banking Law, a banking organization within the meaning of the New York Banking Law, a member of the Federal Reserve System, a clearing corporation within the meaning of the New York Uniform Commercial Code, and a clearing agency registered pursuant to the provisions of Section 17A of the Securities Exchange Act of 1934, as amended (the Exchange Act). DTC holds and provides asset servicing for U.S. and non-U.S. equity issues, corporate and municipal debt issues and money market instruments that DTC's participants deposit with DTC. DTC also facilitates the post-trade settlement among DTC's participants of sales and other securities transactions in deposited securities, through electronic computerized book-entry transfers and pledges between DTC's participants' accounts, thereby eliminating the need for physical movement of certificates. DTC's participants include both U.S. and non-U.S. securities brokers and dealers, banks, trust companies, clearing corporations and certain other organizations. DTC is a wholly owned subsidiary of the Depository Trust & Clearing Corporation, or DTCC. DTCC is the holding company for DTC, Global Select Securities Clearing Corporation and Fixed Income Clearing Corporation, all of which are registered clearing agencies. DTCC is owned by the users of its regulated subsidiaries. Access to the DTC system is also available to others such as both U.S. and non-U.S. securities brokers and dealers, banks, trust companies and clearing corporations that clear through or maintain a custodial relationship with a DTC participant, either directly or indirectly. The DTC rules applicable to its participants are on file with the SEC.

Persons that are not participants or indirect participants but desire to purchase, sell or otherwise transfer ownership of, or other interests in, securities may do so only through participants and indirect participants. Under a book-entry format, holders may experience some delay in their receipt of payments, as such payments will be forwarded by our designated agent to Cede & Co., as nominee for DTC. DTC will forward such payments to its participants, who will then forward them to indirect participants or holders. Holders will not be recognized by the relevant registrar, transfer agent, trustee or warrant agent as registered holders of the securities entitled to the benefits of our certificate of incorporation, as amended, or the applicable indenture or warrant agreement. Beneficial owners that are not participants will be permitted to exercise their rights only indirectly through and according to the procedures of participants and, if applicable, indirect participants.

Under the rules, regulations and procedures creating and affecting DTC and its operations as currently in effect, DTC will be required to make book-entry transfers of securities among participants and to receive and transmit payments to participants. DTC rules require participants and indirect participants with which beneficial securities owners have accounts to make book-entry transfers and receive and transmit payments on behalf of their respective account holders.

Because DTC can act only on behalf of

participants, who in turn act only on behalf of participants or indirect participants; and

certain banks, trust companies and other persons approved by it,

Table of Contents

the ability of a beneficial owner of securities issued in global form to pledge such securities to persons or entities that do not participate in the DTC system may be limited due to the unavailability of physical certificates for these securities.

DTC has advised us that DTC will take any action permitted to be taken by a registered holder of any securities under our certificate of incorporation or the relevant indenture or warrant agreement only at the direction of one or more participants to whose accounts with DTC such securities are credited.

Unless otherwise indicated in the applicable prospectus supplement, a global security will be exchangeable for the relevant definitive securities registered in the names of persons other than DTC or its nominee only if:

DTC notifies us that it is unwilling or unable to continue as depository for that global security or if DTC ceases to be a clearing agency registered under the Exchange Act when DTC is required to be so registered;

we execute and deliver to the relevant registrar, transfer agent, warrant agent and/or trustee an order complying with the requirements of the applicable indenture or warrant agreement that the global security will be exchangeable for definitive securities in registered form; or

there has occurred and is continuing a default in the payment of any amount due in respect of the securities or, in the case of debt securities, an event of default or an event that, with the giving of notice or lapse of time, or both, would constitute an event of default with respect to these debt securities.

Any global security that is exchangeable under the preceding sentence will be exchangeable for securities registered in such names as DTC directs.

Upon the occurrence of any event described in the preceding paragraph, DTC is generally required to notify all participants of the availability of definitive securities. Upon DTC surrendering the global security representing the securities and delivery of instructions for re-registration, the registrar, transfer agent, trustee or warrant agent, as the case may be, will reissue the securities as definitive securities, and then such persons will recognize the holders of such definitive securities as registered holders of securities entitled to the benefits of our certificate of incorporation or the relevant indenture and/or warrant agreement.

Redemption notices will be sent to Cede & Co., as the registered holder of the global securities. If less than all of a series of securities are being redeemed, DTC will determine the amount of the interest of each direct participant to be redeemed in accordance with its then current procedures.

Except as described above, the global security may not be transferred except as a whole by DTC to a nominee of DTC or by a nominee of DTC to DTC or another nominee of DTC or to a successor depository we appoint. Except as described above, DTC may not sell, assign, transfer or otherwise convey any beneficial interest in a global security evidencing all or part of any securities unless the beneficial interest is in an amount equal to an authorized denomination for these securities.

The information in this section concerning DTC and DTC's book-entry system has been obtained from sources that we believe to be accurate, but we assume no responsibility for the accuracy thereof. None of OraSure, any registrar and transfer agent, trustee or warrant agent, or any agent of any of them, will have any responsibility or liability for any aspect of DTC's or any participant's records relating to, or for payments made on account of, beneficial interests in a global security, or for maintaining, supervising or reviewing any records relating to such beneficial interests.

Secondary trading in notes and debentures of corporate issuers is generally settled in clearing-house or next-day funds. In contrast, beneficial interests in a global security, in some cases, may trade in the DTC's same-day funds settlement system, in which secondary market trading activity in those beneficial interests would be required by DTC to settle in immediately available funds. There is no assurance as to the effect, if any, that settlement in immediately available funds would have on trading activity in such beneficial interests. Also, settlement for purchases of beneficial interests in a global security upon the original issuance of this security may be required to be made in immediately available funds.

Table of Contents

Considerations Relating to Euroclear and Clearstream

Euroclear and Clearstream are securities clearing systems in Europe. Both systems clear and settle securities transactions between their participants through electronic, book-entry delivery of securities against payment.

Euroclear and Clearstream may be depositaries for a global security. In addition, if DTC is the depositary for a global security, Euroclear and Clearstream may hold interests in the global security as participants in DTC. As long as any global security is held by Euroclear or Clearstream, as depositary, you may hold an interest in the global security only through an organization that participates, directly or indirectly, in Euroclear or Clearstream. If Euroclear or Clearstream is the depositary for a global security and there is no depositary in the United States, you will not be able to hold interests in that global security through any securities clearance system in the United States. Payments, deliveries, transfers, exchanges, notices and other matters relating to the securities made through Euroclear or Clearstream must comply with the rules and procedures of those systems. Those clearing systems could change their rules and procedures at any time. OraSure does not have control over those systems or their participants and assumes no responsibility for their activities. Transactions between participants in Euroclear or Clearstream, on one hand, and participants in DTC, on the other hand, when DTC is the depositary, would also be subject to DTC's rules and procedures.

Special Timing Considerations for Transactions in Euroclear and Clearstream

Investors will be able to make and receive through Euroclear and Clearstream payments, deliveries, transfers, exchanges, notices and other transactions involving any securities held through those clearing systems only on days when those systems are open for business. These clearing systems may not be open for business on days when banks, brokers and other institutions are open for business in the United States.

In addition, because of time-zone differences, U.S. investors who hold their interests in the securities through these clearing systems and wish to transfer their interests, or to receive or make a payment or delivery or exercise any other right with respect to their interests, on a particular day may find that the transaction will not be effected until the next business day in Luxembourg or Brussels, as applicable. Thus, investors who wish to exercise rights that expire on a particular day may need to act before the expiration date. In addition, investors who hold their interests through both DTC and Euroclear or Clearstream may need to make special arrangements to finance any purchases or sales of their interests between the U.S. and European clearing systems, and those transactions may settle later than would be the case for transactions within one clearing system.

PLAN OF DISTRIBUTION

We may sell the securities being offered hereby in one or more of the following ways from time to time:

through agents to the public or to investors;

to underwriters for resale to the public or to investors;

directly to investors; or

through a combination of any of these methods of sale.

The distribution of the securities may be effected from time to time in one or more transactions:

at a fixed price, or prices, which may be changed from time to time;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; and

at negotiated prices.

Table of Contents

We will set forth in a prospectus supplement the terms of the offering of securities, including:

the name or names of any agents or underwriters;

the purchase price of the securities being offered and the proceeds we will receive from the sale;

any over-allotment options under which underwriters may purchase additional securities from us;

any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;

any initial public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchanges or markets on which such securities may be listed.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase the securities will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the securities if they purchase any of the securities.

In compliance with the guidelines of the Financial Industry Regulatory Authority, the maximum compensation to the underwriters or dealers in connection with the sale of our securities pursuant to this prospectus and the accompanying supplement to this prospectus may not exceed 8 percent of the aggregate offering price of the securities as set forth on the cover page of any prospectus supplement.

We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for soliciting these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment). We or one of our affiliates may loan or pledge securities to a financial institution or other third party that in turn may sell the securities using this prospectus. Such financial institution or third party may transfer its short position to investors in our securities or in connection with a simultaneous offering of other securities offered by this prospectus or otherwise.

Table of Contents

To facilitate an offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In those circumstances, such persons would cover such over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Trading Markets and Listing Of Securities

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is listed on The Nasdaq Global Select Market. We may elect to list any other class or series of securities on any exchange or market, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

Passive Market Marking

Any underwriters who are qualified market makers on The Nasdaq Global Select Market may engage in passive market making transactions in the securities on The Nasdaq Global Select Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security. If all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

Blue Sky Restrictions on Resale

After you purchase our securities under this registration statement, you will need to comply with state securities laws, also known as Blue Sky laws, with regard to secondary sales in certain states in the United States. All states offer a variety of exemptions from registration for secondary sales. Many states, for example, have an exemption for secondary trading of certain securities registered under Section 12(b) of the Securities Exchange Act of 1934. Your broker will be able to advise you about which states exempt our securities from registration for secondary sales.

LEGAL MATTERS

The validity of the securities we are offering by this prospectus will be passed upon for us by Dechert LLP, Princeton, New Jersey.

EXPERTS

The consolidated financial statements of OraSure Technologies, Inc. as of December 31, 2011 and 2010, and for each of the years in the three-year period ended December 31, 2011, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2011 have been incorporated by reference herein and in the registration statement in reliance upon the reports of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report on the effectiveness of internal control over financing reporting as of December 31, 2011 contains an explanatory paragraph that states that OraSure Technologies, Inc. acquired DNA Genotek Inc. during 2011 and management excluded from its assessment of the effectiveness of OraSure Technologies, Inc.'s internal control over financial reporting as of

Table of Contents

December 31, 2011, DNA Genotek Inc. s internal control over financial reporting associated with total assets of \$56,534,999 (44.2% of total assets, of which \$51,059,969 represents goodwill and intangibles) and total revenues of \$6,215,929 (7.6% of total revenues), included in the consolidated financial statements of OraSure Technologies, Inc. and subsidiaries as of and for the year ended December 31, 2011. KPMG s audit of internal control over financial reporting of OraSure Technologies, Inc. also excluded an evaluation of internal control over financial reporting of DNA Genotek Inc.

INCORPORATION BY REFERENCE

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act of 1933. As permitted by the SEC s rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

The SEC allows us to incorporate by reference into this prospectus certain information that we file with it. This means that we can disclose important information to you by referring you to another document that we filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information in this prospectus. You should read the information incorporated by reference because it is an important part of this prospectus.

We incorporate by reference the following documents that we have filed or may file with the SEC (but we do not incorporate by reference any documents or portions of documents that we furnish to or are otherwise not deemed filed with the SEC):

1. Our Annual Report on Form 10-K for the year ended December 31, 2011;
2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012;
3. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012;
4. Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012;
5. Our Current Report on Form 8-K filed on January 3, 2012;
6. Our Current Report on Form 8-K filed on February 8, 2012;
7. Our Current Report on Form 8-K filed on February 27, 2012;
8. Our Current Report on Form 8-K filed on April 4, 2012;
9. Our Current Report on Form 8-K filed on April 20, 2012;
10. Our Current Report on Form 8-K filed on May 2, 2012;

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

11. Our Current Report on Form 8-K filed on May 16, 2012;
12. Our Current Report on Form 8-K filed on May 25, 2012;
13. Our Current Report on Form 8-K filed on July 3, 2012;
14. Our Current Report on Form 8-K filed on July 5, 2012;
15. Our Current Report on Form 8-K filed on July 9, 2012;
16. Our Current Report on Form 8-K filed on July 11, 2012;
17. Our Current Report on Form 8-K filed on August 7, 2012;
18. Our Current Report on Form 8-K filed on November 7, 2012;
19. Our Current Report on Form 8-K filed on November 28, 2012;
20. Our Definitive Proxy Statement and additional definitive proxy soliciting materials filed April 5, 2012; and

Table of Contents

21. The description of our capital stock contained in Exhibit 99 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

We incorporate by reference the documents listed above and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 between (i) the date of the initial registration statement and prior to the effectiveness of the registration statement or (ii) the date of this prospectus and the termination of the offering of securities described in this prospectus; provided, however, that notwithstanding the foregoing, unless specifically stated to the contrary, none of the information that is not deemed filed with the SEC, including information furnished under Items 2.02 or 7.01 of any Current Report on Form 8-K, will be incorporated by reference into, or otherwise included in, this prospectus. These documents may also be accessed on our website at www.orasure.com. Information contained in, or accessible through, our website is not a part of this prospectus.

If you request, either orally or in writing, we will provide you with a copy of any or all documents which are incorporated by reference. We will provide such documents to you free of charge, but will not include any exhibits, unless those exhibits are incorporated by reference into the document. You should address written requests for documents as follows:

Corporate Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

Any statements contained in a document incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus (or in any other subsequently filed document which also is incorporated by reference in this prospectus) modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed to constitute a part of this prospectus except as so modified or superseded.

Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 8-K and 10-K reports to the SEC. Also note that we provide a cautionary discussion of risks and uncertainties relevant to our business in the Risk Factors section of this prospectus. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed here could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

WHERE YOU CAN FIND MORE INFORMATION

We make periodic filings and other filings required to be filed by us as a reporting company under Sections 13 and 15(d) of the Exchange Act. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, our SEC filings, including the registration statement, are also available to the public at no cost from the SEC's website at <http://www.sec.gov>.

Table of Contents

ORASURE TECHNOLOGIES, INC.

\$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

PROSPECTUS

, 2012

This prospectus only provides you with a general description of the securities that we may offer. Each time we sell securities, we will provide a prospectus supplement that contains specific information about the terms of those securities. You should read both this prospectus and any prospectus supplement together with the additional information described under the Sections entitled, **Incorporation by Reference** and **Where You Can Find More Information**.

Table of Contents**Part II****Information Not Required In Prospectus****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth the various expenses in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates except the Securities and Exchange Commission registration fee.

SEC registration fee	\$ 22,920
Listing fees	(1)
Transfer agent and registrar fees and expenses	(1)
Legal fees and expenses	(1)
Printing fees and expenses	(1)
Accounting fees and expenses	(1)
Blue Sky fees and expenses	(1)
Miscellaneous fees and expenses	(1)
Total	\$ (1)

- (1) These fees will be dependent on the type of securities offered and number of offerings and, therefore, cannot be estimated at this time. In accordance with Rule 430B, additional information regarding estimated fees and expenses will be provided at the time information as to an offering is included in a prospectus supplement.

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director, officer, employee or agent of the corporation or another enterprise if serving at the request of the corporation. Depending on the character of the proceeding, a corporation may indemnify against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding if the person indemnified acted in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. In the case of an action by or in the right of the corporation, no indemnification may be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine that, despite the adjudication of liability, such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper. Section 145 further provides that to the extent a director, officer, employee or agent of a corporation has been successful in the defense of any action, suit or proceeding referred to above, or in the defense of any claim, issue or matter therein, he or she shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection therewith.

Delaware law authorizes a corporation to limit or eliminate the personal liability of its directors for monetary damages for breach of a director's fiduciary duty of care. Delaware law further enables corporations to limit available relief to equitable remedies such as injunction or rescission. Absent the limitations authorized by Delaware law, directors are accountable for monetary damages for conduct constituting gross negligence in the exercise of their duty of care. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Accordingly, our directors will not be personally liable to us or our stockholders for monetary damages for breach of a fiduciary duty as a director, except for liability for breach of the duty of loyalty, for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, for the

Table of Contents

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware, or for any transaction in which a director has derived an improper personal benefit.

Our bylaws require us to indemnify to the fullest extent permitted by Delaware law any person who is a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that such person is or was our director, officer, employee or agent, or is serving as a director, officer, employee or agent of another enterprise at our request. Indemnification is not, however, permitted under the bylaws unless the person acted in good faith and in a manner that such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal action or proceeding, that such person had no reasonable cause to believe such person's conduct was unlawful. The bylaws further provide that we shall not indemnify any person for any liabilities or expenses incurred by such person in connection with an action, suit or proceeding by or in the right of OraSure Technologies in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless and only to the extent that the court in which the action, suit or proceeding is brought determines that the person is entitled to indemnity for such expenses. The indemnification provided by the bylaws is not exclusive of any other rights to which those seeking indemnification may be otherwise entitled.

We have entered into indemnification agreements with certain of our directors and officers. The indemnification agreements provide that we will indemnify these directors and officers against all liabilities and expenses actually and reasonably incurred in connection with any action, suit or proceeding (including an action by or in the right of OraSure Technologies) to which any of them is, was or at any time becomes a party, or is threatened to be made a party, by reason of their status as a director or officer, or by reason of their serving or having served at the request or on behalf of OraSure Technologies as a director, officer, trustee or in any other comparable position of any other enterprise to the fullest extent allowed by law.

We have also obtained director's and officer's liability insurance.

Item 16. List of Exhibits

The exhibits filed as part of this registration statement are as follows:

Exhibit	Description
1.1*	The form of underwriting agreement.
4.1	Certificate of Incorporation of OraSure Technologies is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
4.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
4.3	Bylaws of OraSure Technologies, as amended and restated as of August 18, 2008, are incorporated by reference to Exhibit 3 to the Company's current Report on Form 8-K filed August 22, 2008.
4.4	Specimen certificate representing shares of OraSure Technologies \$.000001 par value Common Stock is incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 8, 2000.
4.5*	Form of warrant agreement and warrant certificate.
4.6*	Form of rights certificate.
4.7.1	Form of indenture to be entered into between registrant and a trustee acceptable to the registrant. (1)
4.7.2	Form of debt securities (included in Exhibit 4.7.1). (1)
4.8*	Form of certificate of designation with respect to any preferred stock issued hereunder and the related form of preferred stock certificate.
4.9*	Form of unit agreement and unit certificate.
5.1	Opinion of Dechert LLP regarding legality of securities being registered. (1)
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges. (1)
23.1	Consent of KPMG LLP.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form S-3/A

- 23.2 Consent of Dechert LLP (included in its Opinion filed as Exhibit 5.1 hereto).
- 24.1 Powers of Attorney (included on signature page). (1)
- 25.1** Statement of Eligibility of Trustee

Table of Contents

- * To be filed by amendment or as an exhibit to a document filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.
- ** To be filed separately pursuant to Section 305(b)(2) of the Trust Indenture Act of 1939, as amended, and the appropriate rules and regulations thereunder.
- (1) Previously filed.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that the undertakings set forth in paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, as amended, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933, as amended, to any purchaser:
 - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

Table of Contents

- (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933, as amended, to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) In the event that rights or warrants are to be offered to existing security holders and any securities not taken by the security holders are to be offered to the public, the undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

Table of Contents

(d) Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Act"), may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(e) If and when applicable, the undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, OraSure Technologies, Inc. certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in Bethlehem, Pennsylvania on December 17, 2012.

OraSure Technologies, Inc.

By: */s/ Douglas A. Michels*
 Douglas A. Michels
 President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons on December 17, 2012 in the capacities indicated below.

Signature	Title
<i>/s/ Douglas A. Michels</i> Douglas A. Michels	President, Chief Executive Officer (Principal Executive Officer) and Director
<i>/s/ Ronald H. Spair</i> Ronald H. Spair	Chief Financial Officer, Chief Operating Officer (Principal Financial Officer) and Director
<i>/s/ Mark L. Kuna</i> Mark L. Kuna	Senior Vice President Finance and Controller (Principal Accounting Officer)
*	Director
Michael Celano	
*	Director
Gerald M. Ostrov	
*	Director
Ronny B. Lancaster	
*	Director
Charles W. Patrick	
*	Director
Roger L. Pringle	
*	Director
Stephen S. Tang, Ph.D	
*	Director
Douglas G. Watson	

*By: */s/ Jack E. Jerrett*
 Jack E. Jerrett

Attorney-in-fact

Table of Contents

EXHIBIT INDEX

Exhibit	Description
1.1*	The form of underwriting agreement.
4.1	Certificate of Incorporation of OraSure Technologies is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
4.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
4.3	Bylaws of OraSure Technologies, as amended and restated as of August 18, 2008, are incorporated by reference to Exhibit 3 to the Company's current Report on Form 8-K filed August 22, 2008.
4.4	Specimen certificate representing shares of OraSure Technologies \$.000001 par value Common Stock is incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 8, 2000.
4.5*	Form of warrant agreement and warrant certificate.
4.6*	Form of rights certificate.
4.7.1	Form of indenture to be entered into between registrant and a trustee acceptable to the registrant. (1)
4.7.2	Form of debt securities (included in Exhibit 4.7.1). (1)
4.8*	Form of certificate of designation with respect to any preferred stock issued hereunder and the related form of preferred stock certificate.
4.9*	Form of unit agreement and unit certificate.
5.1	Opinion of Dechert LLP regarding legality of securities being registered. (1)
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges. (1)
23.1	Consent of KPMG LLP.
23.2	Consent of Dechert LLP (included in its Opinion filed as Exhibit 5.1 hereto).
24.1	Powers of Attorney (included on signature page). (1)
25.1**	Statement of Eligibility of Trustee

* To be filed by amendment or as an exhibit to a document filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

** To be filed separately pursuant to Section 305(b)(2) of the Trust Indenture Act of 1939, as amended, and the appropriate rules and regulations thereunder.

(1) Previously filed.