

ORASURE TECHNOLOGIES INC

Form S-3

December 11, 2015

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As filed with the Securities and Exchange Commission on December 11, 2015

Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of

Incorporation or Organization)

36-4370966
(IRS Employer

Identification Number)

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

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

Jack E. Jerrett, Esquire

Senior Vice President, General Counsel and Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

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

COPIES TO:

Stephen Leitzell, Esquire

Dechert LLP

2929 Arch Street

Philadelphia, PA 19104-2808

(215) 994-2621

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. "

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

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

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

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

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

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

Large accelerated filer <input type="checkbox"/> "	Accelerated filer <input checked="" type="checkbox"/> 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 (4)
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	\$20,140 (5)

- (1) Not specified as to each class of securities to be registered hereunder pursuant to General Instruction II.D. to Form S-3 under the Securities Act of 1933, as amended.
- (2) Includes an indeterminate number of securities that may be issued from time to time in primary offerings or upon exercise, conversion or exchange of any securities registered hereunder that provide for exercise, conversion or exchange.
- (3) With respect to debt securities, excluding accrued interest and accrued amortization of discount, if any, to the date of delivery. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be equal to any such greater principal amount due at maturity, such aggregate principal amount not to exceed \$200,000,000 less the value of securities previously issued hereunder.
- (4) Includes \$200,000,000 aggregate principal amount of the Securities registered by the Registrant under Registration Statement No. 333-184190 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. 333-184190. 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 \$20,140 filing fee is fully offset by the \$22,920 registration fee that was paid, but not used, in connection with the Registrant's Registration Statement No. 333-184190 filed on September 28, 2012.

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

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

Subject to Completion, dated December 11, 2015

PROSPECTUS

\$200,000,000

Common Stock

Preferred Stock

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

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

Debt Securities

Units

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

Common Stock

Preferred Stock

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

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

Debt Securities

Units consisting of any of the foregoing in one or more series or issuances and their total offering price, in the aggregate, will not exceed \$200,000,000. This prospectus also covers common stock or preferred stock issuable upon exercise, conversion or exchange of warrants, rights and/or debt securities. We will provide the specific terms of any securities we actually offer for sale in supplements to this prospectus. **This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.** The net proceeds we expect to receive from such sales will be set forth in a prospectus supplement.

Our common stock is listed on the Nasdaq Global Select Market tier of The Nasdaq Stock Market LLC under the symbol OSUR . On December 2, 2015, the reported last sale price of our common stock on the Nasdaq Global Select Market was \$6.30 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.

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 (the SEC) 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 _____, 2015

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ABOUT THIS PROSPECTUS

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

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

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any prospectus supplement, any free writing prospectus or other written communication we may authorize to be delivered to you. We have not provided, and have not authorized anyone else to provide, you with different or additional information. This prospectus, any prospectus supplement, any free writing prospectus and any other written communication do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they specifically relate, nor does this prospectus, any

prospectus supplement, any free writing prospectus or any other written communication constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus or in the documents incorporated by reference herein, any prospectus supplement, any free writing prospectus or other written communication is accurate as of any date other than the date noted therein or, in the case of documents incorporated by reference, the filing date

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

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

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

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

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WHO WE ARE

General

Our business principally involves the development, manufacture, marketing and sale of diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. We manufacture and sell kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetics, clinical genetic testing, academic research, pharmacogenomics, personalized medicine, and animal genetics markets. Our diagnostic products include tests that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing.

Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, research universities, and commercial and industrial entities. One of our diagnostic products, the OraQuick® HCV rapid antibody test, is the first and only rapid HCV test approved by the U.S. Food and Drug Administration (FDA) for sale in the United States. In addition, our OraQuick® In-Home HIV test is the first and only rapid HIV test approved by the FDA for sale in the over-the-counter (OTC) or consumer retail market in the United States. We also sell OTC cryosurgical products to consumers in North America, Europe, Central and South America, and Australia.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers. We have targeted the use of oral fluid in many of our products as a differentiating factor and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

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 premarket authorization (PMA) approval from the FDA for the detection of antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick whole blood, venous whole blood and plasma. This test is available for use by laboratories located in the United States certified under the Clinical Laboratory Improvements Amendment of 1988, or CLIA, to perform moderately complex

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

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

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We believe that the OraQuick® device, because it is approved for detecting antibodies to both HIV-1 and HIV-2 in finger-stick and venous whole blood, oral fluid and plasma samples, provides a significant competitive advantage in the market for rapid HIV testing in the United States and elsewhere.

OraQuick® In-Home HIV Test

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

OraQuick® HCV Rapid Antibody Test

Another test available on the OraQuick® platform is the OraQuick® HCV rapid antibody test. Like the OraQuick® HIV test, this product is a qualitative test that can detect antibodies to the hepatitis C virus, or HCV, in a variety of sample types. The OraQuick® HCV test operates in substantially the same manner as the OraQuick® HIV test.

We have received FDA approval for use of the test in detecting HCV antibodies in venous whole blood and finger-stick whole blood specimens, making it the first and only 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. The OraQuick® HCV test has received a CE mark for use with oral fluid, venous whole blood, finger-stick whole blood, plasma and serum and is sold in Europe and other foreign countries.

OraSure QuickFlu® Rapid Flu A&B Test

The OraSure QuickFlu® rapid flu A&B test is an FDA 510(k) cleared rapid qualitative test for the detection of influenza (flu) Types A and B, including H1N1 viral infections. The test utilizes specimen collected with a nasal swab, nasopharyngeal swab or nasal aspirate/wash. A reagent is first inserted into a test cartridge, the specimen is added and the test is allowed to flow. Results are available in as little as ten minutes. This product is manufactured for us under an agreement with Princeton BioMeditech Corporation and is currently sold in certain U.S. markets.

OraSure® Collection Device

Our OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. This device consists of a small, treated cotton-fiber pad on a handle that is placed in a person's mouth for two to five minutes. The device collects oral mucosal transudate (OMT), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

The OraSure® collection device is FDA approved for use in the detection of HIV-1 antibodies and is a Class I medical device for the detection of cocaine and cotinine in oral fluid specimens. HIV-1 antibody detection using the OraSure® collection device involves three steps:

Collection of an oral fluid specimen using the OraSure® device;

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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.

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We believe that oral fluid testing has several significant advantages over blood or urine-based systems for infectious disease testing, for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a non-invasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and reducing the cost of administration by a trained health care professional.

Molecular Collection Systems

Our wholly-owned subsidiary, DNAG, sells a number of products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA and/or RNA from human and animal biologic samples. DNAG's lead product is sold under the Oragene® name and is used to collect DNA from human saliva. DNAG products are sold to commercial entities and 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 ease-of-use and reliability 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 and stable genetic samples, use of simple non-invasive collection methods, the ability to store and transport collected samples for extended periods at ambient temperatures and compatibility with fully-automated laboratory testing systems.

DNAG products historically have been sold primarily as Class I medical devices for use by research and academic institutions. DNAG has received FDA 510(k) clearance for the Oragene® Dx product which enables the Oragene® Dx product to be used with other FDA-cleared or exempt molecular diagnostic applications. A separate 510(k) clearance permits self-collection by consumers when the sample is to be tested with either an exempt or 510(k) cleared molecular tests. An application for 510(k) clearance of DNAG's ORAcollect product is currently pending with the FDA.

Intercept® Drug Testing System

A collection device that is substantially similar to the OraSure® device is sold by us under the name Intercept®, and is used to collect OMT for oral fluid drug testing. We have received FDA 510(k) clearance to use the Intercept® collection device with laboratory-based EIAs to test for drugs-of-abuse commonly identified by the National Institute for Drug Abuse (NIDA) as the NIDA-5 (i.e., tetrahydrocannabinol (THC or marijuana), cocaine, opiates, amphetamines/methamphetamines and phencyclidine (PCP), and for barbiturates, methadone and benzodiazepines. Each of these EIAs is also FDA 510(k) cleared for use with the Intercept® device. Our Intercept® device and oral fluid assays are sold in the U.S. primarily through laboratory distributors.

We believe that the Intercept® device has several advantages over competing urine and other drugs-of-abuse testing products, including its lower total testing cost, its non-invasive nature, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection

facilities and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow our customers to test for drug impairment and eliminate scheduling costs and inconvenience, thereby streamlining the testing process.

During 2014, we completed development of a next generation collection device, which we are marketing under the tradename Intercept i2 . This device offers several important advantages over our original Intercept[®] device, including a sample adequacy indicator that provides a visual prompt when the appropriate volume of oral fluid has been

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collected, the ability to collect a larger sample required by current laboratory testing protocols and a more optimized chemistry that results in improved recovery of the targeted drug analytes. The Intercept i2 device is currently being sold as a forensic use only device within the criminal justice and drug treatment markets along with a NIDA-5 panel of fully-automated high-throughput oral fluid drug assays that we distribute under an agreement with Thermo Fisher Scientific (Thermo Fisher).

Cryosurgical Systems (Skin Lesion Removal Products)

The Histofreezer[®] cryosurgical removal system is a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. The Histofreezer[®] product mixes three cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to a maximum of 50°C to 55°C. The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area by freezing. We have received 510(k) clearance for use of the Histofreezer[®] product to remove common warts and eight other types of benign skin lesions, and this product has been CE marked and registered for distribution in Canada, throughout Europe and in certain other foreign countries. In 2014, we began supplying this product on a private label basis for resale by one of our physician office distributors.

Internationally, we sell an OTC cryosurgical product through our distributor Genomma Labs (Genomma), under the POINTTS tradename, in Mexico and a number of South and Central American countries. We sell a CE marked cryosurgical wart removal product into the OTC foot care market in Europe, Australia and New Zealand through our distributor, Reckitt Benckiser (Reckitt), under the Scholl and Dr. Scholl trademarks. Reckitt is the owner of the Scholl and Dr. Scholl trademarks in countries outside North and South America. We also sell OTC cryosurgical products to retailers on a private label basis for the treatment of warts in the U.S. and for the treatment of both warts and skin tags in Canada.

Immunoassay Tests and Reagents

We develop and sell immunoassay tests in formats, known as MICRO-PLATE and AUTO-LYTE[®], to meet the specific needs of our customers. In 2014 we also began selling fully-automated high-throughput oral fluid drug assays developed under our agreement with Thermo Fisher.

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.

We entered into the agreement with Thermo Fisher in 2013 after terminating a similar agreement with Roche Diagnostics. Under our latest agreement, Thermo Fisher has agreed to develop and supply up to 12 fully-automated high-throughput oral fluid drug assays for use with our Intercept i2 device. Under the first phase of this agreement, we are selling a NIDA-5 panel of assays supplied by Thermo Fisher. The parties intend to complete development of several additional assays and obtain FDA 510(k) clearance of the Intercept i2 device for use with a 12-assay panel. We also intend to obtain CE mark and other regulatory approvals to enable us to sell our Intercept i2 collector and Thermo Fisher assays into Europe and other foreign countries.

The assays from Thermo Fisher will be optimized as needed to comply with new oral fluid guidelines expected to be issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the federally regulated market and certain other markets that follow Federal drug testing guidelines, none of which is currently served by

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OraSure. We believe the offering of an Intercept i2 device with a full menu of fully-automated high-throughput oral fluid assays will better meet the needs of our laboratory drug testing customers and allow us to compete more effectively against fully automated urine drug assays that dominate the drug testing market.

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

Infectious Disease Testing

We are continuing our efforts to develop and commercialize a rapid, point-of-care antigen test for the Ebola virus, using our OraQuick® technology platform. In July 2015, the Company received an FDA Emergency Use Authorization for its OraQuick® Ebola Rapid Antigen test. This authorization allows the use of this test for the duration of the U.S. Secretary of the Department of Health and Human Services (HHS) August 5, 2014 declaration regarding the emergency use of in vitro diagnostic tests for the detection of the Ebola virus.

In September 2015, the Biomedical Advanced Research Development Authority (BARDA) within HHS exercised an option to provide \$7.2 million in additional funding for our OraQuick® Ebola test. This funding will be used primarily for clinical and regulatory activities required to request FDA 510(k) clearance for this product. This option is part of the aggregate \$10.4 million funding contract we announced in June 2015. The three-year, multi-phased contract included an initial commitment of \$1.8 million and options for up to an additional \$8.6 million to fund certain clinical and regulatory activities. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are being performed.

In addition, during the third quarter of 2015 the Centers for Disease Control and Prevention (CDC) agreed to purchase approximately \$1.5 million of our OraQuick® Rapid Ebola test. This purchase is expected to be fulfilled by the end of 2015. The CDC is purchasing this product for field testing in West Africa. This is the second such purchase of this product for field testing by the CDC.

Molecular Collection Systems

The following new product initiatives are underway at DNAG:

OMNIgene GUT is a system for the collection, stabilization, transportation and storage of microbial DNA in stool samples. This product is being offered to academic researchers for early-stage testing in gut microbiome studies.

OMNIgene SPUTUM is a reagent for the liquefying, decontaminating, transporting and preserving of TB bacteria in sputum samples. OMNIgene SPUTUM is expected to improve laboratory and operational workflows, compared to current approaches, and improve overall test results. This product is being offered to TB laboratories for evaluation.

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PrepIT MAX for tuberculosis (TB) is a reagent for extraction of DNA from TB bacteria. This product is being offered for early-stage testing by TB researchers, clinical laboratories, and diagnostic developers who need to extract DNA from TB bacteria for molecular analysis.

HEMAgene BUFFY COAT is a reagent for stabilizing buffy coat, a derivative of whole blood, for ambient temperature transport and storage. An initial version of this product is being marketed to academic researchers that use buffy coat for DNA or RNA analysis.

These products represent potential, long-term market opportunities that we are still developing or are in the early stages of commercializing. Much of our activities for these products are currently centered around ensuring that early versions are being provided to key opinion leaders or early adopters in the relevant markets. We expect these products will enable researchers and other customers to improve their results through better and lower cost sample collection, stabilization and preservation.

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic arrangements and independent distributors. Our marketing strategy is to create or raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs, distributor promotions, telemarketing and the use of digital and social media in order to stimulate sales in each target market.

We market our products in the United States and internationally. Consolidated net revenues attributable to customers in the United States were \$82.3 million, \$77.2 million and \$67.5 million in 2014, 2013 and 2012, respectively. Consolidated net revenues attributable to international customers amounted to \$24.2 million, \$21.7 million and \$20.3 million, or 23%, 22% and 23% of our total revenues, in 2014, 2013 and 2012, respectively.

Infectious Disease Testing - Professional

We market the OraQuick *ADVANCE*[®] rapid HIV-1/2 antibody test directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, family planning clinics, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market, such as AIDS service organizations and various community-based organizations that are set up primarily for the purpose of encouraging and enabling HIV testing. We also sell our OraQuick *ADVANCE*[®] test directly to hospitals in the U.S. and through distributors into the U.S. physician office market and to clinics operated by certain consumer retailers. We have engaged two manufacturers representative organizations to assist with sales to U.S. physicians and retail clinics. Internationally, we distribute our OraQuick[®] HIV test in Europe and certain other foreign countries.

We market the OraSure[®] oral fluid collection device for HIV-1 testing, on its own and as a kit in combination with laboratory testing services. To better serve our public health customers, we have contracted a commercial laboratory to provide prepackaged OraSure[®] test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure[®] device in the international public health market.

Our OraQuick[®] HCV test is sold primarily to the same markets where our OraQuick[®] *ADVANCE* HIV test is sold, including public health organizations, hospitals, physicians and retail clinics. We also sell this test in Europe and other countries through distributors. Under an agreement with AbbVie, we are co-promoting our OraQuick[®] HCV test in certain U.S. markets, including general practitioners and certain specialty physicians, the professional trucking industry and retail pharmacies and clinics. Under this arrangement, AbbVie has agreed to detail our OraQuick[®] HCV

test in the physician markets and we pay AbbVie a fee for these detailing services. In addition, we have implemented a program for training physicians on our OraQuick® HCV test and we have developed and implemented a patient care database under this agreement.

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.

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Infectious Disease Testing - OTC

We sell our OraQuick® In-Home test in the U.S. retail or consumer market. Retailers carrying the product include CVS, Walgreens, Rite Aid, Wal-Mart and Kroger. The product is also available for purchase on-line through certain retailers and our website, www.oraquick.com. The primary target population for our HIV-OTC test is comprised of young, sexually active adults, with greater purchase intent found in high-risk sub groups, such as men who have sex with men, African Americans and Latino Americans. In 2014, we changed our promotional strategy by implementing a more cost-effective promotional approach focused on retail outlets and moved away from more expensive broad-based consumer advertising.

To support individuals that purchase and use our test, we have established a toll-free customer support center that operates on a 24-hour, 365-day per year basis. Through this center, consumers will have access to highly-trained, bi-lingual representatives who can answer questions about HIV/AIDS and the use of our test, and refer consumers to appropriate resources for follow-up confirmatory testing, counseling and medical treatment.

Molecular Collection Systems

DNAG primarily sells its products directly to its customers, primarily through its own internal sales force. In some countries distributors are used, particularly in the Asia-Pacific region. Over half of DNAG's employees work in the areas of sales, marketing, business development or product management. The significant majority of employees who deal directly with customers have molecular science backgrounds, which we believe is useful in selling and marketing molecular collection products, and more importantly, in identifying and evaluating new market and business opportunities.

Historically, most of DNAG's revenues have been derived from product sales into the academic and research markets. However, sales to commercial customers providing consumer genetics and clinical diagnostic services have been increasing and now account for a majority of DNAG's revenues. A significant portion of DNAG's sales are derived from repeat customers, in both markets. DNAG also has a number of established global customers in the livestock market, including breed associations and research institutions. A molecular collection product focused on the infectious disease research market is also sold by DNAG.

Substance Abuse Testing

Our substance abuse testing products are marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice and drug rehabilitation markets in the U.S. and in certain international markets.

We have entered into agreements for the distribution of our Intercept® collection device and associated MICRO-PLATE assays for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors and internationally for workplace, criminal justice and forensic toxicology testing through other distributors. We also market the Intercept® collection device on its own and as a kit in combination with laboratory testing services. To better serve our workplace customers, we have contracted with commercial laboratories to provide prepackaged Intercept® test kits, with prepaid laboratory testing and specimen shipping costs included.

The criminal justice market in the United States for our substance abuse testing products consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation offices, police forces, drug courts, prisons, drug treatment programs and community/family service programs. The forensic toxicology market consists of several hundred laboratories including federal, state and county crime

laboratories, medical examiner laboratories and reference laboratories.

As discussed above, we have also launched our next generation Intercept i2 collection device with a NIDA-5 panel of fully-automated high-throughput oral fluid assays developed with Thermo Fisher for the detection of PCP, THC, opiates, cocaine, methamphetamines and amphetamines. These products are currently sold into the criminal justice and drug treatment markets. We plan to obtain FDA 510(k) clearance of our Intercept i2 device for use with the NIDA-5 assay panel, along with an additional six fully-automated high-throughput assays in order to expand sales of this product line into the workplace testing market and other markets that require 510(k) cleared drug tests. We expect that the 510(k) cleared Intercept i2 device and related fully-automated high-throughput assays will eventually replace our original Intercept® collector and MICRO-PLATE assays in the drug testing market.

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We distribute our Q.E.D.[®] saliva alcohol test primarily through various distributors in the United States and internationally. The markets for alcohol testing are relatively small and fragmented with a broad range of legal and procedural barriers to entry. Markets range from law enforcement testing to workplace testing of employees in safety sensitive occupations. Typical usage situations include pre-employment, random, post-accident, reasonable-cause and return-to-duty testing.

Cryosurgical Systems

Most of our Histofreezer[®] sales occur in the United States to distributors that, in turn, resell the product to primary care physicians and podiatrists in the United States. Our major U.S. distributors include Cardinal Healthcare, McKesson Medical-Surgical, AmerisourceBergen Corporation, and Henry Schein. We have also engaged a manufacturers representative organization to help our U.S. distributors promote and sell Histofreezer[®]. In 2014, we began selling a private label version of our professional Histofreezer[®] product for resale by one of our U.S. distributors. 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 foot care 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. For several years, we have sold OTC cryosurgical products for the removal of both warts and skin tags under private label arrangements with retailers in Canada. In 2014, we began selling a private label version of our OTC product to several U.S. retailers.

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 Issue 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.

Corporate Information

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. and Epitope, Inc., and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our Company on September 29, 2000. Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015. Our telephone number is (610) 882-1820, and our website address is <http://www.orasure.com>. Information contained on our website is not incorporated into this registration statement. You can obtain more information regarding our business and industry by reading our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 12, 2015 and the other reports we file with the SEC.

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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. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and any prospectus supplement may contain, certain forward-looking statements, within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, losses, expenses or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, expected manufacturing performance, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include words, such as "believes," "expects," "anticipates," "intends," "plans," "estimates," "will," "should," "could," or similar expressions.

Factors that could cause or contribute to differences in our results and outcomes include, without limitation, those discussed in "Risk Factors" above, in our Annual Report on Form 10-K for the year ended December 31, 2014 and in our Quarterly Reports on Form 10-Q. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. These factors include, but are not limited to: ability to market and sell products, whether through our 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 the 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; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; 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; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; the impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of replacing distributors; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, 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 or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; 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 products and 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 OraSure's 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;

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adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and 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.

Readers should note that these risk factors may not be exhaustive. We operate in a continually changing business environment, and new or different risks emerge from time to time. Management cannot predict such new or different risks or the impact of such risks on our businesses. You should not rely unduly on these forward-looking statements, which are not a prediction of actual results and 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.

RATIO OF EARNINGS TO FIXED CHARGES

The following table sets forth our ratio of earnings to fixed charges for the periods indicated below (in thousands). We have not included a ratio of earnings to combined fixed charges and preferred stock dividends because we had no preferred stock outstanding.

	Nine Months Ended		Years ended December 31,			
	September 30, 2015	2014	2013	2012	2011	2010
Ratio of Earnings to Fixed Charges	29.0					
Deficiency in Earnings to Cover Fixed Charges	\$	\$ 4,248,667	\$ 11,940,481	\$ 16,490,688	\$ 9,687,939	\$ 3,499,263

Ratio of earnings to fixed charges is calculated by dividing earnings by fixed charges from operations for the periods indicated. For purposes of calculating the ratio of earnings to fixed changes, (i) earnings consist of our consolidated income from operations before income taxes and fixed charges and (ii) fixed charges consist of interest expense and the interest component of rental expense, as estimated by management. Earnings for the years ended December 31, 2014, 2013, 2012, 2011 and 2010 were inadequate to cover fixed charges and, accordingly, no ratio of earnings to fixed charges is disclosed for those periods.

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USE OF PROCEEDS

Except as may be 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.

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.

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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 November 3, 2015, we had 56,482,384 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

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.

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.

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