ORASURE TECHNOLOGIES INC Form S-3 December 11, 2015 Table of Contents

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 36-4370966 (IRS Employer

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:

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. "

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

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

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

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

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

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

Large accelerated filer "	Accelerated filer	Х
Non-accelerated filer " (Do not check if a smaller reporting company)	Smaller reporting company	

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)(2)	Proposed Maximum Aggregate Offering Price (1)(3)	Amount of Registration Fee (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.

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

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	1
WHO WE ARE	3
RISK FACTORS	11
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	11
RATIO OF EARNINGS TO FIXED CHARGES	12
<u>USE OF PROCEEDS</u>	13
<u>THE SECURITIES WE MAY OFFER</u>	13
DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK	14
DESCRIPTION OF WARRANTS	18
DESCRIPTION OF RIGHTS	20
DESCRIPTION OF DEBT SECURITIES	21
DESCRIPTION OF UNITS	29
<u>BOOK-ENTRY ISSUANCE</u>	30
<u>PLAN OF DISTRIBUTION</u>	33
LEGAL MATTERS	35
<u>EXPERTS</u>	35
INCORPORATION BY REFERENCE	35
WHERE YOU CAN FIND MORE INFORMATION	36
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 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

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.

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 OraQuictin-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.

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;

Screening of the specimen for HIV-1 antibodies at a laboratory with an enzyme immunoassay (EIA) screening test approved by the FDA for use with the OraSure[®] device; and

Laboratory confirmation of any positive screening test results with our oral fluid Western blot HIV-1 confirmatory test (described below).

A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested.

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

Molecular Collection Systems

Our wholly-owned subsidiary, DNAG, sells a number of products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA and/or RNA from human and animal biologic samples. DNAG s lead product is sold under the Oragene[®] name and is used to collect DNA from human saliva. DNAG products are 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 Oragen® 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 Interent departure, including a sample adequacy indicator that provides a visual prompt when the appropriate volume of oral fluid has been

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

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.

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.

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, <u>www.oraquick.com</u>. 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.

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 Histofreeze[®]. 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 <u>http://www.orasure.com</u>. 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.

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. 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;

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 September 30,		Years	ended Decemb	er 31,		
	2015	2014	2013	2012	2011	2010	
Ratio of Earnings to Fixe	d						
Charges	29.0						
Deficiency in Earnings to	1						
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 period	s.	-				

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.

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

<u>Voting</u>. 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.

<u>Dividends</u>. 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.

<u>Liquidation and Dissolution</u>. 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.

<u>Other Rights and Restrictions</u>. 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.

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

Preferred Stock

<u>General</u>. 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;

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;

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.

<u>Voting Rights</u>. 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.

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

<u>Other</u>. 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;
- (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.

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 days 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, including the interests of the stockholders of the Company, as a dominant or controlling interest or factor.

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 have not adopted a stockholder rights plan, but our board of directors reserves the right to do so at any time.

Stock Options and Restricted Stock

As of December 2, 2015, a total of 6,225,955 options to purchase shares of our common stock had been granted and remained outstanding and unexercised under our stock option plans and there were 700,106 shares of restricted stock that had been granted and remain unvested. As of that date, there were 3,682,339 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.

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.

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 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.

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 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;

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.

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

Table of Contents

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.

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;

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.

Each year after the issuance of any such debt securities, 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;

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

Table of Contents

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.

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;

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 principal of (and premium, if 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, 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. 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

Table of Contents

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.

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 depositary or its nominee. Unless otherwise indicated in the applicable prospectus supplement, the depositary 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,

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 depositary 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 depositary 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.

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. 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 reallowed 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 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.

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 markers 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, Philadelphia, Pennsylvania.

EXPERTS

The consolidated financial statements of OraSure Technologies, Inc. as of December 31, 2014 and 2013, and for each of the years in the three-year period ended December 31, 2014 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2014 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.

INCORPORATION BY REFERENCE

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act of 1933, as amended. 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 considered to be a part of this prospectus, and information in documents that we file later with the SEC will automatically update and supersede information contained in documents filed earlier with the SEC or contained in this prospectus or a prospectus supplement. 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, 2014;
- 2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015;

Table of Contents

- 3. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015;
- 4. Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015;
- 5. Our Current Report on Form 8-K filed on March 31, 2015;
- 6. Our Current Report on Form 8-K filed on May 14, 2015; and
- 7. 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 Exchange Act 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 http://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

OraSure is subject to the information requirements of the Exchange Act, and it files unaudited quarterly and audited annual reports, proxy and information statements and other information with the SEC. You may read and copy all or any portion of the reports, proxy and information statements or other information OraSure files at the SEC s principal office in Washington, D.C., and copies of all or any part thereof may be obtained from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, D.C. 20549, after payment of fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information on operation of the public reference rooms. The SEC also maintains an Internet site which provides online access to reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at the address http://www.sec.gov. In addition, OraSure

posts its filed documents on its website at <u>http://www.orasure.com</u>. Except for the documents incorporated by reference into this prospectus, the information on OraSure s website is not part of this prospectus.

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

_____, 2015

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.

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, other than underwriting fees and commissions. All of the amounts shown are estimates except the Securities and Exchange Commission registration fee.

SEC registration fee	\$20,140
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)

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 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 indemnify 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.
- 3.1 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.
- 3.2 Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
- 3.3 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.
- 4.1 Specimen certificate representing shares of OraSure Technologies \$0.000001 par value Common Stock.
- 4.2* Form of warrant agreement and warrant certificate.
- 4.3* Form of rights certificate.
- 4.4.1 Form of indenture to be entered into between registrant and a trustee acceptable to the registrant.
- 4.4.2 Form of debt securities (included in Exhibit 4.4.1).

- 4.5* Form of certificate of designation with respect to any preferred stock issued hereunder and the related form of preferred stock certificate.
- 4.6* Form of unit agreement and unit certificate.
- 5.1 Opinion of Dechert LLP regarding legality of securities being registered.
- 12.1 Statement of Computation of Ratio of Earnings to Fixed Charges.
- 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).
- 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.

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 paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if 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 <u>bona fide</u> 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

- (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 <u>bona fide</u> 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.

(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.

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 11, 2015.

OraSure Technologies, Inc.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ronald H. Spair, Mark L. Kuna and Jack E. Jerrett, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the undersigned and in his or her name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to the registration statement and sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462 promulgated under the Securities Act of 1933, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons on December 11, 2015 in the capacities indicated below.

Signature	Title
/s/ Douglas A. Michels Douglas A. Michels	President, Chief Executive Officer (Principal Executive Officer) and Director
/s/ Ronald H. Spair Ronald H. Spair	Chief Financial Officer, Chief Operating Officer (Principal Financial Officer) and Director
/s/ Mark L. Kuna Mark L. Kuna	Senior Vice President Finance and Controller (Principal Accounting Officer)
/s/ Michael Celano Michael Celano	Director
/s/ Ronny B. Lancaster Ronny B. Lancaster	Director
/s/ Charles W. Patrick	Director

Charles W. Patrick

/s/ Roger L. Pringle Roger L. Pringle

/s/ Stephen S. Tang, Ph.D Stephen S. Tang, Ph.D

/s/ Douglas G. Watson Douglas G. Watson Director

Director

Director

EXHIBIT INDEX

Exhibit	Description				
1.1*	The form of underwriting agreement.				
3.1	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.				
3.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.				
3.3	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.				
4.1	Specimen certificate representing shares of OraSure Technologies \$0.000001 par value Common Stock.				
4.2*	Form of warrant agreement and warrant certificate.				
4.3*	Form of rights certificate.				
4.4.1	Form of indenture to be entered into between registrant and a trustee acceptable to the registrant.				
4.4.2	Form of debt securities (included in Exhibit 4.4.1).				
4.5*	Form of certificate of designation with respect to any preferred stock issued hereunder and the related form of preferred stock certificate.				
4.6*	Form of unit agreement and unit certificate.				
5.1	Opinion of Dechert LLP regarding legality of securities being registered.				
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges.				
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).				
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.

font-size: 10pt"> 93% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the Purchase Agreement, or (ii) the portion of the trading day of the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum; or the closing sale price of our common stock on the purchase date.

In the case of both Regular Purchases and Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. However, per the Purchase Agreement, we cannot issue or sell, and Lincoln Park cannot purchase or acquire, any shares of common stock pursuant to the Purchase Agreement which would result in Lincoln Park beneficially owning more than 9.99% of our outstanding common stock.

Minimum Purchase Price

Under the Purchase Agreement, we have set a floor price of \$0.35 per share. Lincoln Park shall not purchase any shares of our common stock on any day that the closing sale price of our common stock is below the floor price. The floor price will be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such event, the floor price will be the lower of (i) the adjusted price and (ii) \$1.00.

Events of Default

Events of default under the Purchase Agreement include the following:

the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

suspension by our principal market of our common stock from trading for a period of three consecutive business days;

the de-listing of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Market, the NASDAQ Global Select Market, the NASDAQ Capital Market, the NYSE MKT, the NYSE Arca, the OTC Bulletin Board or the OTCQX operating by the OTC Markets Group, Inc. (or nationally recognized successor thereto);

the transfer agent's failure for three business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the Purchase Agreement;

any breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreement which has or which could have a material adverse effect on us subject to a cure period of five business days;

any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or

if at any time we are not eligible to transfer our common stock electronically or a material adverse change in our business, financial condition, operations or prospects has occurred.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park's control, we cannot submit any Regular Purchase notice or Accelerated Purchase notice to Lincoln Park under the Purchase Agreement.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

All 5,150,000 shares registered in this offering which have been or may be sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on September 4, 2015. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Except with respect to the 850,000 shares of common stock already issued to Lincoln Park pursuant to the Purchase Agreement, Lincoln Park may ultimately purchase all, some or none of the 5,150,000 shares of common stock registered in this offering. If we sell these shares to Lincoln Park, Lincoln Park may sell all, some or none of such shares. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$10,000,000 of our common stock, exclusive of the 250,000 shares issued to Lincoln Park as a commitment fee (which 250,000 shares are part of this offering). During the year ended December 31, 2015, we issued and sold 300,000 shares to Lincoln Park pursuant to the Purchase Agreement, and during January 2017, we issued and sold an additional 300,000 shares to Lincoln Park pursuant to the Purchase Agreement. The number of

shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The following table sets forth the amount of additional gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

Assumed Average Purchase Price Per Share		Number of Additional Registered Shares to be Issued if Full Purchase (1)(2)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln		Proceeds from the Sale of Shares to Lincoln Park Under the \$10M Purchase	
\$ 0.35	(4)	4,300,000	Park (3) 8.4	%	Agreement \$1,505,000	
\$ 0.50	. /	4,300,000	8.4	%	\$2,150,000	
\$ 0.75		4,300,000	8.4	%	\$3,225,000	
\$ 1.00		4,300,000	8.4	%	\$4,300,000	
\$ 1.50		4,300,000	8.4	%	\$6,450,000	

Although the Purchase Agreement provides that we may sell up to \$10,000,000 of our common stock to Lincoln (1) Park, we are only registering 5,150,000 shares under this prospectus, which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering.

The number of registered shares to be issued excludes the 250,000 commitment shares because no proceeds will be (2) attributable to such commitment shares. Also excludes the 300,000 shares of common stock issued and sold to Lincoln Park during the year ended December 31, 2015 pursuant to the Purchase Agreement and the 300,000 shares of common stock issued and sold to Lincoln Park during January 2017 pursuant to the Purchase Agreement.

The denominator is based on 54,160,548 shares outstanding as of March 31, 2017, adjusted to include the number of shares set forth in the adjacent column which we would have sold to Lincoln Park at the applicable assumed average purchase price per share. The numerator does not include the 250,000 shares issued to Lincoln Park as commitment shares in connection with this offering, but does include the aggregate 600,000 shares of common stock issued and sold to Lincoln Park during the year ended December 31, 2015 and during January 2017 pursuant to the Purchase Agreement, and is based on the number of shares registered in this offering to be issued under the Purchase Agreement at the applicable assumed purchase price per share set forth in the adjacent column. Per the Purchase Agreement, we cannot issue or sell, and Lincoln Park cannot purchase or acquire, any shares of common stock pursuant to the Purchase Agreement which would result in Lincoln Park beneficially owning more than 9.99% of our outstanding common stock.

Under the Purchase Agreement, we may not sell and Lincoln Park may not purchase any shares on a day in which (4) the closing sale price of our common stock is below \$0.35, as may be adjusted in accordance with the Purchase Agreement.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive gross proceeds of up to \$10,000,000 under the Purchase Agreement. As of March 31, 2017, we have received gross proceeds of \$248,610 under the Purchase Agreement. We estimate that the total net proceeds to us from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will be up to \$9,940,000 over an approximately 36-month period, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under the Purchase Agreement and taking into account other estimated fees and expenses. If we elect to issue and sell more than the 5,150,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders and may involve additional fees and expenses not currently estimable. See "Plan of Distribution" elsewhere in this prospectus for more information.

We have used, and expect to use, any proceeds that we receive under the Purchase Agreement to fund sales and marketing activities, and for general corporate purposes. The amounts and timing of our actual expenditures will depend on numerous factors, including our revenue from filter sales, and the amount of proceeds actually raised from sales under the Purchase Agreement. Accordingly, our management will have significant flexibility in applying any net proceeds that we receive pursuant to the Purchase Agreement.

SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Lincoln Park, of shares of common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement, as described in greater detail below. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on July 24, 2015 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the selling stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have sold or may sell to Lincoln Park under the Purchase Agreement. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

The following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder, and reflects its holdings as of March 31, 2017. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 54,160,548 shares of our common stock actually outstanding as of March 31, 2017.

Selling Stockholder	Shares Beneficially Owned Before this Offering		Percentage of Outstanding Shares Beneficially Owned Before this Offering		Shares to be Sold in this Offering Assuming The Company issues the Maximum Number of Shares Under the Purchase Agreement	Percentage of Outstanding Shares Beneficially Owned After this Offering
Lincoln Park Capital Fund, LLC (1)	1,805,454	(2)	3.3	%(3)	5,150,000 (4)	*

* denotes less than 1%

Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope (1) and Scheinfeld have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Lincoln Park Capital, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(2)

Table of Contents

Represents (i) 930,454 shares of our common stock held by Lincoln Park, and (ii) warrants to purchase 875,000 shares of our common stock held by Lincoln Park. The registration statement that includes this prospectus does not cover 150,000 shares of common stock held by Lincoln Park prior to July 24, 2015, 800,000 shares of common stock purchased by Lincoln Park in March 2017, or the 875,000 shares of common stock that may be issued upon exercise of the warrants. See the description under the heading "The Lincoln Park Transaction" for more information about the Purchase Agreement.

Based on 54,160,548 outstanding shares of our common stock as of March 31, 2017. Although we may at our discretion elect to issue to Lincoln Park up to an aggregate amount of \$10,000,000 of our common stock under the (3)Purchase Agreement, other than the aggregate 600,000 shares issued and sold to Lincoln Park pursuant to the Purchase Agreement during the year ended December 31, 2015 and during January 2017, such shares are not included in determining the percentage of shares beneficially owned before this offering.

Represents (i) 250,000 shares of our common stock issued to Lincoln Park on July 24, 2015 as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement, (ii) an aggregate 600,000 shares issued and sold to Lincoln Park pursuant to the Purchase Agreement during the year ended December 31,

(4)2015 and during January 2017, and (iii) 4,300,000 additional shares that we may sell to Lincoln Park pursuant to the Purchase Agreement. If we elect to issue and sell more than the 5,150,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

ordinary brokers' transactions;

transactions involving cross or block trades;

through brokers, dealers, or underwriters who may act solely as agents;

"at the market" into an existing market for the common stock;

in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

in privately negotiated transactions; or

any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions. In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such indemnity is unavailable, to contribute amounts required to be paid in the securities are from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park.

Our common stock is quoted on the OTCQB under the symbol "NEPH".

DIVIDEND POLICY

We have neither paid nor declared dividends on our common stock since our inception. We do not anticipate paying any dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our board of directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our board of directors may deem relevant. Additionally, our ability to pay future dividends may be restricted by the terms of any debt financing, tax considerations and applicable law.

MARKET FOR OUR COMMON STOCK

Our common stock is quoted on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, under the symbol "NEPH." The following table sets forth the high and low bid and ask prices for our common stock as reported on the OTCQB for each quarter listed. Such over the counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
March 31, 2015	\$0.96	\$0.50
June 30, 2015	\$0.80	\$0.49
September 30, 2015	\$0.77	\$0.37
December 31, 2015	\$0.43	\$0.20
March 31, 2016	\$0.40	\$0.22
June 30, 2016	\$0.57	\$0.24
September 30, 2016	\$0.60	\$0.25
December 31, 2016	\$0.45	\$0.26
March 31, 2017	\$0.60	\$0.31

As of March 17, 2017, there were approximately 64 holders of record and approximately 2,650 beneficial holders of our common stock.

On April 13, 2017, the last reported sale price of our common stock on the OTCQB was \$.38 per share.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion includes forward-looking statements about our business, financial condition, and results of operations, including discussions about management's expectations for our business. These statements represent projections, beliefs and expectations based on current circumstances and conditions and in light of recent events and trends, and you should not construe these statements either as assurances of performances or as promises of a given course of action. Instead, various known and unknown factors are likely to cause our actual performance and management's actions to vary, and the results of these variances may be both material and adverse. A list of the known material factors that may cause our results to vary, or may cause management to deviate from its current plans and expectations, is included herein under "Risk Factors" and Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2016. The following discussion should also be read in conjunction with the consolidated financial statements and notes included herein.

Business Overview

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration ("HDF") systems. Our filters, which are generally classified as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate, and used in hospitals for the prevention of infection from water borne pathogens, such as legionella and pseudomonas. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites and endotoxins.

Our ultrafilters OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patient with end stage renal disease ("ESRD"). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis ("HD"). We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

The following trends, events and uncertainties may have a material impact on our potential sales, revenue and income from operations:

the market acceptance of our products in the United States and of our technologies and products in each of our target markets;

our ability to effectively and efficiently manufacture, market and distribute our products;

our ability to sell our products at competitive prices which exceed our per unit costs;

the consolidation of dialysis clinics into larger clinical groups; and

the current U.S. healthcare plan is to bundle reimbursement for dialysis treatment which may force dialysis clinics to change therapies due to financial reasons.

To the extent we are unable to succeed in accomplishing the foregoing, our sales could be lower than expected and dramatically impair our ability to generate income from operations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and was effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. Early adoption was not permitted. In August, 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of the Effective Date". The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting periods within that fiscal year. Earlier application is permitted only as of fiscal years beginning after December 31, 2016, including interim reporting periods with that fiscal year. We are currently reviewing the revised guidance and assessing the potential impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. We do not believe that the adoption of ASU 2015-11 will have a significant impact on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, "Balance Sheet Classification of Deferred Taxes," that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We do not believe that the adoption of ASU 2015-17 will have a significant impact on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases", that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-08, "Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," which clarifies the implementation guidance on principal versus agent considerations. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting," which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for us beginning in the first quarter of fiscal year 2017. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, "Identifying Performance Obligations and Licensing," which clarifies the implementation guidance for performance obligations and licensing. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, "Narrow Scope Improvements and Practical Expedients," which clarifies the accounting for certain aspects of guidance issued in ASU 2014-09, including assessing collectability and noncash consideration. The clarifications in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments," which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2020. Early adoption is our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Classification of Certain Cash Receipts and Cash Payments," which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-17, "Restricted Cash," which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, "Clarifying the Definition of a Business," which clarifies the definition of a business in a business combination. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, "Simplifying the Test for Goodwill Impairment," which simplifies the test for goodwill impairment. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual goodwill impairments tests after January 1, 2017. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in their report on our consolidated financial statements included in this prospectus which expressed doubt as to our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. However, there can be no assurance that we will be able to do so. Our recurring operating losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management's subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this prospectus, we believe that the following accounting policies require the application of significant judgments and estimates.

Revenue Recognition

Revenue is recognized in accordance with Accounting Standards Codification ("ASC") Topic 605. Four basic criteria must be met before revenue can be recognized: (i) persuasive evidence that an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured.

We recognize revenue related to product sales when delivery is confirmed by our external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by us. Shipments for all products are currently received directly by our customers.

We are recognizing the remaining deferred revenue under the Bellco license agreement on a straight line basis over the remaining eighty-four month expected obligation period which ends on December 31, 2021. Any difference between payments received and recognized revenue is reported as deferred revenue.

Deferred revenue on the accompanying December 31, 2016 consolidated balance sheet is approximately \$348,000 and is related to the Bellco license agreement. We have recognized approximately \$2,728,000 of revenue related to this license agreement to date and approximately \$69,000 for the year ended December 31, 2016, resulting in \$348,000 being deferred over the remainder of the expected obligation period. We amortize the deferred revenue monthly over the expected obligation period which ends on December 31, 2021. As a result, expected revenue to be recognized will be approximately \$70,000 in each of the next five years.

Stock-Based Compensation

The fair value of stock options is recognized as stock-based compensation expense in net income. We calculate employee stock-based compensation expense in accordance with ASC 718. We account for stock option grants to consultants under the provisions of ASC 505-50, and as such, these stock options are revalued at each reporting period through the vesting period. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

Warrants

We account for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for modification of the warrant exercise price under certain conditions are accounted for as derivative liabilities. We classify derivative warrant liabilities on the balance sheet as a liability, which is revalued using a binomial options pricing model at each balance sheet date subsequent to the initial issuance. A binomial options pricing model requires the input of highly subjective assumptions including expected stock price volatility and the estimated life of each award. The changes in fair value of the derivative warrant liabilities resulting from their remeasurement at each balance sheet date are recorded in current period earnings.

Accounts Receivable

We provide credit terms to our customers in connection with purchases of our products. We periodically review customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect our best estimate of potential losses.

Inventory Reserves

Our inventory reserve requirements are based on factors including the products' expiration date and estimates for the future sales of the product. If estimated sales levels do not materialize, we will make adjustments to our assumptions for inventory reserve requirements.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves identifying services which have been performed on our behalf, and the level of service performed and the associated cost incurred for such service as of each balance sheet date in our consolidated financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for the preclinical development of our products, the manufacturing of clinical materials, and clinical trials, as well as legal and accounting services provided by professional organizations. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Results of Operations

Fluctuations in Operating Results

Table of Contents

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our annual results of operations will be impacted for the foreseeable future by several factors including the progress and timing of expenditures related to our research and development efforts, marketing expenses related to product launches, timing of regulatory approval of our various products and market acceptance of our products. Due to these fluctuations, we believe that the period to period comparisons of our operating results are not a good indication of our future performance.

The Fiscal Year Ended December 31, 2016 Compared to the Fiscal Year Ended December 31, 2015

Revenues

Total revenues for the year ended December 31, 2016 were approximately \$2,320,000 compared to approximately \$1,944,000 for the year ended December 31, 2015. The increase of approximately \$376,000, or 19%, was primarily driven by an increase in the number of filters sold in 2016 versus in 2015.

Cost of Goods Sold

Cost of goods sold was approximately \$1,026,000 for the year ended December 31, 2016 compared to approximately \$884,000 for the year ended December 31, 2015. The increase of approximately \$142,000, or 16%, in cost of goods sold was primarily related to an increase in the number of filters sold.

Research and Development

Research and development expenses were approximately \$1,079,000 and \$826,000 for the years ended December 31, 2016 and December 31, 2015, respectively. This increase of approximately \$253,000, or 31%, is primarily due to an increase in full-time research and development employees.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$230,000 for the year ended December 31, 2016 compared to approximately \$212,000 for the year ended December 31, 2015, representing an increase of approximately 8% related to equipment expenditures for the year ended December 31, 2016.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$2,854,000 for the year ended December 31, 2016 compared to approximately \$3,443,000 for the year ended December 31, 2015, representing a decrease of \$589,000, or 17%. The decrease was primarily due to a decrease in legal and auditor expenses of approximately \$280,000, a decrease in regulatory expenses of approximately \$220,000, which were incurred in 2015 related to standard operating procedure updates, a decrease in severance expense of approximately \$175,000 incurred in 2015 and a decrease of approximately \$120,000 in direct compensation and investor relations expenses. These decreases were partially offset by an increase in selling, general and administrative personnel of approximately \$280,000.

Interest Expense

The table below summarizes interest expense for the years ended December 31, 2016 and 2015:

	2016	2014
Interest related to unsecured long-term note payable	\$77,000	\$ -
Amortization of debt discount – unsecured long-term note payable	53,000	-
Interest – outstanding payables due to a vendor	42,000	41,000
Other	-	1,000
Total interest expense	\$172,000	\$42,000

Interest Income

Interest income of approximately \$5,000 for the year ended December 31, 2016 is as result of interest income recognized on a lease receivable.

Change in Fair Value of Warrant Liability

We classified certain warrants as liabilities at their fair value and adjusted the warrant liability to fair value at each reporting period. This liability was subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our consolidated statement of operations and comprehensive income (loss). The fair value of such warrants issued was estimated using a binomial options pricing model. The change in fair value of the warrant liability resulted in income of approximately \$2,099,000 for the year ended December 31, 2015. These liability classified warrants were exercised in full on September 29, 2015.

Warrant Modification Expense

During the year ended December 31, 2015, the modification of the exercise price of the liability-classified warrants resulted in an increase in the warrant liability, immediately before exercise, of approximately \$1,761,000.

Other Income/Expense

Other expense for the year ended December 31, 2016 of approximately \$4,000 is related to foreign currency gains of approximately \$2,000 and miscellaneous other income of approximately \$2,000. Other income of approximately \$37,000 for the year ended December 31, 2015 is due to foreign currency gains.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2016 or 2015.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2016 and 2015 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,		
Liquidity and capital resources	2016	2015	
Cash	\$275	\$1,248	
Other current assets	989	1,216	
Working capital	369	1,505	
Stockholders' equity	667	2,664	

Our future liquidity sources and requirements will depend on many factors, including:

the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;

the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;

the continued progress in, and the costs of, clinical studies and other research and development programs;

the costs involved in filing and enforcing patent claims and the status of competitive products; and

the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

We expect to put our current capital resources to the following uses:

for the marketing and sales of our water-filtration products;

to pursue business development opportunities with respect to our chronic renal treatment system; and

for working capital purposes.

We operate under an Investment, Risk Management and Accounting Policy adopted by our board of directors. Such policy limits the types of instruments or securities in which we may invest our excess funds: U.S. Treasury Securities; Certificates of Deposit issued by money center banks; Money Funds by money center banks; Repurchase Agreements; and Eurodollar Certificates of Deposit issued by money center banks. This policy provides that our primary objectives for investments shall be the preservation of principal and achieving sufficient liquidity to meet our forecasted cash requirements. In addition, provided that such primary objectives are met, we may seek to achieve the maximum yield available under such constraints.

At December 31, 2016, we had an accumulated deficit of approximately \$120,285,000, and we expect to incur additional operating losses from operations in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue.

On June 7, 2016, we received gross proceeds of approximately \$1,187,000 in connection with the issuance of unsecured promissory notes and warrants.

On December 23, 2015, we received proceeds of approximately \$688,000 in connection with our offer to holders of certain warrants of the opportunity to exercise their warrants at a temporarily reduced cash exercise price. Warrant holders elected to exercise warrants to purchase an aggregate of 3,442,521 shares of our common stock at the reduced cash exercise price of \$0.20 per share, providing a total of \$688,000 in gross proceeds to us. Of the 3,442,521 shares issued, 2,782,577 are held by Lambda. The warrants that were not exercised pursuant to the offer to exercise remained in effect through the original expiration date, with an exercise price of \$0.40 per share of common stock.

On September 29, 2015, we entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda. Pursuant to the Amendment, we agreed to reduce the current exercise price of the Class D Warrant issued to Lambda on November 14, 2007 (together with all amendments thereto entered into prior to the Amendment, the "Warrant") representing the right to purchase 11,742,100 shares of our common stock by 50%, to \$0.15 per share, in exchange for Lambda's agreement to exercise such Warrant in its entirety. Upon exercise of the Warrant, we issued 11,742,100 shares of common stock to Lambda and received approximately \$1.76 million in cash proceeds from Lambda. Following such exercise, no Class D Warrants remain outstanding.

On July 24, 2015, we entered into a purchase agreement, together with a registration rights agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Under the terms and subject to the conditions of the purchase agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to \$10.0 million in shares of our common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 200,000 shares depending upon the closing sale price of the common stock. However, in no event shall these purchases be more than \$500,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price as set forth in the purchase agreement. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a purchase the closing sale price of the common stock is not below the threshold price as set forth in the purchase agreement. Our sales of shares of common stock to Lincoln Park under the purchase agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then-outstanding shares of the common stock. In connection with the Purchase Agreement, we issued to Lincoln Park 250,000 shares of common stock for no proceeds. The fair value of the 250,000 shares of common stock issued was approximately \$163,000 and was recorded as a commitment fee. Pursuant to the Purchase Agreement, in year ended December 31, 2015, we issued and sold an additional 300,000 shares of common stock to Lincoln Park at a per share price of \$0.45, resulting in gross proceeds of \$135,000.

On May 18, 2015, we raised gross proceeds of \$1.23 million through the private placement of 1,834,299 units of our securities. Each unit consisted of one share of our common stock and a five-year warrant to purchase one-half of one share of our common stock. The purchase price for each unit was \$0.67. The 917,149 warrants issued are exercisable at a price of \$0.85 per share.

On February 19, 2014, we entered into the First Amendment to License Agreement (the "First Amendment") with Bellco, which amends the License Agreement, entered into as of July 1, 2011. Pursuant to the First Amendment, both parties agreed to extend the term of the License Agreement through December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at our discretion, result in conversion of the license to non-exclusive status. We have agreed to reduce the fixed royalty payment payable to us for the period beginning on January 1, 2015 through and including December 31, 2021. Bellco will pay us a

royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, $\notin 1.75$ (approximately \$1.91) per unit; thereafter, $\notin 1.25$ (approximately \$1.36) per unit. In addition, we received a total of $\notin 450,000$ (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that we pursue a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, we will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.

On April 23, 2012, we entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica, an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products (collectively, the "Filtration Products"), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, we agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$1,000,000) for the years 2012, 2013 and 2014, respectively. Our aggregate purchase commitments totaled approximately €1,200,000 (approximately \$1,300,000) and €999,000 (approximately \$1,119,000) for the years ended December 31, 2016 and 2015, respectively. For calendar years 2017 through 2022, annual minimum amounts will be mutually agreed upon between Medica and us. We have not yet formalized an agreed upon minimum purchase level for 2017 with Medica. In exchange for the license, we paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013. As part of the agreement, we have granted to Medica 300,000 options to purchase our common stock which will vest over the first three years of the agreement. As of September 2013, we have an understanding with Medica whereby we have agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

As of the date of this prospectus, we expect that our existing cash balances and projected increase in product sales from the launch of new products, as well as the approximately \$1.2 million raised in a PIPE offering in March 2017, will allow us to fund our operations at least into 2018, if not longer, depending on the timing and market acceptance of our new products. This assumption excludes the impact of future cash receipts from recurring operations. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in us. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$2,112,000 for the year ended December 31, 2016 compared to approximately \$3,815,000 for the year ended December 31, 2015. Our net loss was approximately \$3,027,000 for the year ended December 31, 2016 compared to a net loss of approximately \$3,426,000, excluding the noncash impacts of the change in fair value of the warrant liability and the warrant modification, for the year ended December 31, 2015, a decrease of approximately \$399,000.

The most significant items contributing to the net decrease of approximately \$1,703,000 in cash used in operating activities during the year ended December 31, 2016 compared to the year ended December 31, 2015 are highlighted below:

our inventory decreased by approximately \$103,000 during the 2016 period compared to an increase of approximately \$405,000 during the 2015 period as a result of managing inventory levels;

our accounts receivable increased by approximately \$17,000 during the 2016 period compared to an increase of approximately \$302,000 during the 2015 period as a result of timing of receipts;

our prepaid expenses and other current assets increased by approximately \$10,000 during the 2016 period compared to an increase of approximately \$144,000 during the 2015 period as a result of decreased deposits;

our accounts payable decreased approximately \$76,000 during the 2016 period compared to a decrease of approximately \$176,000 during the 2015 period as a result of the timing of payments; and

our accrued expenses increased approximately \$51,000 during the 2016 period compared to an decrease of approximately \$69,000 during the 2015 period as a result of the timing of payments.

Net cash used in investing activities was approximately \$45,000 and \$13,000 for the years ended December 31, 2016 and 2015, respectively, as a result of the purchase of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2016 resulted from net proceeds of approximately \$1,187,000 from the issuance of unsecured notes payable and approximately \$1,000 of proceeds resulting from the exercise of warrants.

Net cash provided by financing activities for the year ended December 31, 2015 of approximately \$3,791,000 resulted from net proceeds of approximately \$1,340,000 resulting from the issuance of common stock and approximately \$2,451,000 of proceeds resulting from the exercise of warrants.

Contractual Obligations and Commercial Commitments

The following table summarizes our approximate minimum contractual obligations and commercial commitments as of December 31, 2016:

	Payments Due in Period				
	Total	Within 1 Year	Years 2 - 3	Years 4 - 5	More than 5 Years
Leases ¹	\$240,000	\$116,000	\$118,000	\$6,000	\$ -
Employment Contracts ²	550,000	240,000	310,000	-	-
Total	\$790,000	\$356,000	\$428,000	\$6,000	\$

¹In addition to lease obligations for office space, obligations include a lease for various office equipment which expires in 2020.

²Relates to employment agreement with Daron Evans, the Company's President and Chief Executive Officer, entered into on April 15, 2015 for a term of four years.

BUSINESS

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration ("HDF") systems. Our filters, which are generally classified as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate, and are used in hospitals for the prevention of infection from water-borne pathogens, such as legionella and pseudomonas. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites and endotoxins.

Our OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease ("ESRD"). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis ("HD"). We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Our Products

Presently, we have two core product lines: HDF Systems and Ultrafiltration Products

HDF Systems

The current standard of care in the United States for patients with chronic renal failure is HD, a process in which toxins are cleared via diffusion. Patients typically receive HD treatment at least 3 times weekly for 3-4 hours per treatment. HD is most effective in removing smaller, easily diffusible toxins. For patients with acute renal failure, the current standard of care in the United States is hemofiltration ("HF"), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD. However, HF treatment is performed on a daily basis, and typically takes 12-24 hours.

Hemodiafiltration ("HDF") is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the United States, HDF is much more prevalent in Europe and is performed in a growing number of patients. Clinical experience and literature show the following clinical and patient benefits of HDF:

Enhanced clearance of middle and large molecular weight toxins

Improved survival - up to a 35% reduction in mortality risk

Reduction in the occurrence of dialysis-related amyloidosis

Reduction in inflammation

Reduction in medication such as EPO and phosphate binders

Improved patient quality of life

Reduction in number of hospitalizations and overall length of stay

However, like HF, HDF can be resource intensive and can require a significant amount of time to deliver one course of treatment.

We have developed a modified approach to HDF that we believe is more patient-friendly, is less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration ("mid-dilution HDF") system and it consists of our OLpūr H2H Hemodiafiltration Module ("H2H Module"), our OLpūr MD 220 Hemodiafilter ("HDF Filter") and our H2H Substitution Filter ("Dialysate Filter").

The H2H Module utilizes a standard HD machine to perform on-line hemodiafiltration therapy. The HD machine controls and monitors the basic treatment functions, as it would normally when providing HD therapy. The H2H Module is a free-standing, movable device that is placed next to either side of an HD machine. The H2H Module is connected to the clinic's water supply, drain, and electricity.

The H2H Module utilizes the HDF Filter and is very similar to a typical hollow fiber dialyzer assembled with a single hollow fiber bundle made with a high-flux (or high-permeability) membrane. The fiber bundle is separated into two discrete, but serially connected blood paths. Dialysate flows in one direction that is counter-current to blood flow in Stage 1 and co-current to blood flow in Stage 2.

In addition to the HDF Filter, the H2H Module also utilizes a Dialysate Filter during patient treatment. The Dialysate Filter is a hollow fiber, ultrafilter device that consists of two sequential (redundant) ultrafiltration stages in a single housing. During on-line HDF with the H2H Module, fresh dialysate is redirected by the H2H Module's hydraulic (substitution) pump and passed through this dual-stage ultrafilter before being infused as substitution fluid into the extracorporeal circuit. Providing ultrapure dialysate is crucial for the success of on-line HDF treatment.

Our HDF System is cleared by the FDA to market for use with an ultrafiltration controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States. Our on-line mid-dilution HDF system is the only on-line mid-dilution HDF system of its kind to be cleared by the FDA to date.

In May 2014, DaVita Healthcare Partners initiated an evaluation of our HDF System to treat patients at DaVita's North Colorado Springs Clinic. In February 2015, we announced that, in the course of the evaluation, DaVita informed Nephros that they would require additional validation of the system. Nephros and DaVita agreed upon a protocol for the additional validation work which was completed in March 2015. We do not believe that DaVita will restart the evaluation in the near term.

In March 2015, we announced that the Renal Research Institute ("RRI"), a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. As of June 2016, our HDF Systems had performed over 1,200 patient treatments. Over the last 18 months of commercial use, we have gathered direct feedback from users of our HDF System to help improve our system and our training methodology. In January 2016, we updated our training procedures and rolled out a software update, which was focused on improving the system's alignment with nurse work flow. In June 2016, after approximately 5 months of successfully completed patient treatments with the updated software, we concluded the evaluation project with RRI.

Vanderbilt University began treating patients with our HDF Systems early in 2017. Our goal over the next 12-18 months is to develop a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of (a) improving the quality of life for the patient, (b) reducing overall expenditure compared to other dialysis modalities, (c) minimizing the impact on nurse work flow at the clinic, and (d) demonstrating the pharmacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. In addition, we are in the process of developing version 2.0 of our HDF System, which will enable us to manufacture at scale, as well as potentially reduce the per treatment cost of performing HDF.

Ultrafiltration Products

Our ultrafiltration products target a number of markets.

Hospitals and Other Healthcare Facilities: Filtration of water to be used for patient washing and drinking as an aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeons' hands.

Dialysis Centers - Water/Bicarbonate: Filtration of water or bicarbonate concentrate used in hemodialysis devices.

Military and Outdoor Recreation: Individual water purification devices used by soldiers and backpackers to produce drinking water in the field, as well as filters customized to remote water processing systems.

Commercial Facilities: Filtration of water for washing and drinking including use in ice machines and soda fountains.

Our Target Markets

Hospitals and Other Healthcare Facilities. According to the American Hospital Association approximately 5,700 hospitals, with approximately 915,000 beds, treated over 35 million patients in the United States in 2013. The U.S. Centers for Disease Control and Prevention estimates that healthcare associated infections ("HAI") occurred in approximately 1 out of every 25 hospital patients. HAIs affect patients in a hospital or other healthcare facility, and are not present or incubating at the time of admission. They also include infections acquired by patients in the hospital or facility but appearing after discharge, and occupational infections among staff. Many HAIs are waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities. The Affordable Care Act, which was passed in March 2010, puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce the potential for HAIs. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the point of delivery, for example, from sinks and showers.

On October 28, 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters as medical devices for use in the hospital setting. The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of a surgeon's hands. The filters are not intended to provide water that can be used as a substitute for United States Pharmacopeia ("USP") sterile water.

In May 2015, we received a warning letter from the FDA resulting from an October 2014 inspection. In the letter, the FDA alleged deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter did not restrict our ability to manufacture, produce or ship any of our products, nor did it require the withdrawal of any product from the marketplace. In August 2015, we received a subsequent letter from the FDA noting that it had received our response correspondence detailing our completed corrective actions. The corrective actions included revisions to our standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection. In April 2016, we received a third letter from the FDA noting that the FDA noting that the GDA noting that the FDA noting that the four data the completed its evaluation of our corrective actions and that, based on its evaluation, it appeared that we had addressed the deficiencies specified in the May 2015 warning letter.

In June 2015, the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. ("ASHRAE") approved Standard 188-2015, "Legionellosis: Risk Management for Building Water Systems". We believe the approval of ASHRAE 188-2015 ("S188") as a national standard will have a positive impact on point of delivery filtration market. The S188 applies to any human occupied building that is not a single family residence; requires the building to have a

plan to control for waterborne infection; requires heat, chemical or both cleaning in the event of a suspected or confirmed presence of legionella; and recommends point-of-use filters in areas of high risk. We are enhancing our efforts to support our distributors by developing and delivering focused sales training to their sales forces on the use of our filters to support an overall program of infection risk prevention; and by, whenever possible, doing joint sales calls with our distributors on potential hospital customers to both serve as a product expert and to field train their sales representatives.

In April 2016, we announced that we received 510(k) clearance from the FDA to market our S100 Point of Use filter. We began shipping our S100 Point of Use in the third quarter of 2016, and ramped up to full production by the end of 2016.

In December 2016, we announced that we received 510(k) clearance from the FDA to market our HydraGuardTM 10" Ultrafilter. We expect to begin shipping HydraGuardTM 10" Ultrafilter in the second quarter of 2017, ramping to full production in the third quarter of 2017.

In the third quarter of 2017, we expect to launch a flushable version of the HydraGuard[™] 10" Ultrafilter.

The complete hospital infection control product line, including in-line, point of use and cartridge filters, can be viewed on our website at <u>http://www.nephros.com/infection-control/</u>. We are not including the information on our website as a part of, or incorporating it by reference into, this report.

Dialysis Centers - Water/Bicarbonate. To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate. Water and bicarbonate concentrate are essential ingredients for making dialysate, the liquid that removes waste material from the blood. According to the American Journal of Kidney Diseases, there are approximately 6,300 dialysis clinics in the United States servicing approximately 430,000 patients annually. We estimate that there are over 100,000 hemodialysis machines in operation in the United States.

Medicare is the main payer for dialysis treatment in the U.S. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate concentrate quality set by the Association for the Advancement of Medical Instrumentation ("AAMI"), the American National Standards Institute ("ANSI") and the International Standards Organization ("ISO"). We anticipate that the stricter standards approved by these organizations in 2009 will be adopted by Medicare in the near future.

Published studies have shown that the use of ultrapure dialysate can reduce the overall need for erythropoietin stimulating agents ("ESA"), expensive drugs used in conjunction with HD. By reducing the level of dialysate contaminants, specifically cytokine-inducing substances that can pass into a patient's blood stream, the stimulation of inflammation-inducing cytokines is reduced, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient's responsiveness to erythropoietin ("EPO") is enhanced, consequently the overall need for ESAs is reduced.

We believe that our DSU-D and SSU-D ultrafilters are attractive to dialysis centers because they exceed currently approved and newly proposed standards for water and bicarbonate concentrate purity, assist in achieving those standards and may help dialysis centers reduce costs associated with the amount of ESA required to treat a patient. These in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine, or are installed as polishing filters for portable reverse osmosis ("RO") water systems.

In March 2016, we launched the SSUmini product, developed to provide a lower cost ultrafiltration solution for water and bicarbonate flowrates of 0.5 gallons per minutes ("GPM") or less. The SSUmini can be used as a polish filter for small, portable RO water systems or on bicarbonate concentrate lines in dialysis clinics with centralized bicarbonate concentrate systems.

In March 2017, we announced that we received 510(k) clearance from the FDA to market our EndoPurTM 10" Endotoxin filter, which is designed to fit in the existing cartridge hosing of a dialysis clinic's large RO water system. We expect to begin shipping the EndoPurTM 10" Endotoxin filter in the second quarter of 2017, and the 20" and 30" versions of the filter by the third quarter of 2017.

Military and Outdoor Recreation. Water is a key requirement for the soldier to be fully mission-capable. The availability of water supplies and immediate on-site water purification is critical to enhance the ability to operate in any environment. Currently, the military is heavily reliant on the use of bottled water to support its soldiers in the field. Bottled water is not always available, is very costly to move, is resource intensive, and is prone to constant supply disruptions. Soldiers conducting operations in isolated and rugged terrain must be able to use available local water sources when unable to resupply from bulk drinking water sources or bottled water. Therefore, the soldier needs the capability to purify water from indigenous water sources in the absence of available potable water. Soldiers must have the ability to remove microbiological contaminants in the water to Environmental Protection Agency ("EPA") specified levels.

We developed our individual water treatment device ("IWTD") in both in-line and point-of-use configurations. Our IWTD allows a soldier in the field to derive drinking water from any fresh water source. This enables the soldier to remain hydrated, which will maintain mission effectiveness and unit readiness, and extend mission reach. Our IWTD is one of the few portable filters that has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by U.S. Army Public Health Command and U.S. Army Test and Evaluation Command for deployment.

On May 6, 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC ("CamelBak"). Under this Sublicense Agreement, we granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the IWTD. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay us a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay us a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to us, and if such fees are not met or exceeded, we may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. During the fiscal year ended December 31, 2016, we recognized royalty revenue of \$10,000 related to the Sublicense Agreement with CamelBak.

In 2015, we began working with multiple companies developing portable water purification systems designed to provide potable water in remote locations. Specifically, we have provided flushable filter prototypes to these companies for validation as one potential component in systems that employ multiple technologies to purify water from streams, lakes and rivers.

Commercial and Industrial Facilities. In 2014, we launched NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water to be used for non-medical drinking and washing in non-transient non-community water systems, or commercial facilities. The NanoGuard-D and NanoGuard-S trap particulates greater than 0.005 microns in size and can be used as a component of a facility water treatment system, or to filter water used in ice machines and soda fountains.

In November 2015, we announced a strategic partnership with Biocon 1, LLC ("Biocon 1"). Biocon 1's AETHER® Water Systems technology, which includes patented water filtration media and water filtration products, provides solutions for customers to address all contaminate issues and to provide clean-tasting, sediment-free, scale-free, and bacteria-free water for the food service industry. AETHER® Water Systems are used with ice machines, coffee stations, and soda fountains in hotels, casual dining restaurants, fast food restaurants and convenience stores. As part of the collaboration, we have access to Biocon 1's anti-scale and related water filtration technology to develop filter products for the medical industry. In March 2016, we shipped the first lot of filter cartridges to Biocon 1 for inclusion with its AETHER® line of filtration products.

While our EndoPurTM ultrafilter cartridge platform was designed initially for use in the dialysis setting, we are working with our distributors to identify other opportunities for our ultrafilters to provide value to customers in multiple commercial and industrial settings. The NanoGuard-C, a cartridge ultrafilter that inserts into standard 10", 20", 30" and 40" housings, is now available; and we expect that the NanoGuard-F, a flushable cartridge ultrafilter available in 10" and 20" sizes, will be available for broad distribution in the second quarter of 2017.

Many potential customers in the commercial and industrial space currently utilize an Everpure® manifold system. The NanoGuard-E, a version of our ultrafilter that plugs into an Everpure® housing system, is now available.

Over the last few years, we have been developing a high-throughput, auto-flushing filter system capable of handling 25 GPM, or greater, through our proprietary 0.005 micron fiber membrane. The flushable filter system is designed to remove submicron particulates in closed loop water systems, including cooling systems for data centers and hot water return loops in commercial buildings. Initial data suggests the ability to remove both organic and inorganic particulates. We have released a limited number of systems to specific customers for additional testing and validation.

Small, flushable 2.5 and 5 GPM filter systems have potential utility as a point-of-entry water purification system in restaurants, convenience stores and households. We offered flushable systems to a limited set of customers in 2016, and expect to offer these system to a broad set of commercial and industrial customers starting in the second quarter of 2017.

In the third quarter of 2017, we expect to launch a lead filtration system that will address both soluble and particulate lead in potable water, with the ability to treat up to 10,000 gallons of water between filter change-outs.

Going forward, as we grow our water filtration business, we will be exploring opportunities for new applications for our filter products and will be open to evaluating new potential partnerships to expand our water filtration foot print. Our strategic distribution partners who place our filters in hospitals and medical facilities, also support a wide range of commercial and industrial customers. We believe that our existing distributor relationships will facilitate growth in filter sales outside of the medical industry.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 1997. Our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey, 07661, and our telephone number is (201) 343-5202. We also have an office in Dublin, Ireland. For more information about Nephros, please visit our website at <u>www.nephros.com</u>.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred significant losses in operations in each quarter since inception. In addition, we did not generate positive cash flow from operations for the years ended December 31, 2016 and 2015. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our commitments, we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

Manufacturing and Suppliers

We do not, and do not intend to in the near future, manufacture any of our products and components. With regard to the OLpūr MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, as amended by the first amendment dated February 19, 2014, with Bellco S.r.l. ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD190, MD220). Pursuant to the First Amendment, we and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. In addition, under the agreement, as amended by the first amendment, we granted Bellco a license to manufacture, market and sell these products under its own name, label and CE mark in Italy, France, Belgium, Spain, Canada, Denmark, Finland, Norway and Sweden on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom, Greece, Brazil, China, Korea, Mexico and the Netherlands and, upon our written approval, other European countries where we do not sell these products as well as non-European countries.

In April 2012, we entered into a license and supply agreement with Medica S.p.A., an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products, and to engage in an exclusive supply arrangement for the filtration products. Under the license and supply Agreement, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, excluding Italy, during the term of the agreement.

Sales and Marketing

Under the Bellco license agreement, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label and CE mark in the territory, as defined in the license agreement. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated territory.

Our New Jersey office oversees global sales and marketing activity of our ultrafilter products. We work with multiple distributors for our ultrafilter products in the dialysis water market and the hospital water market. In the food service market, Biocon 1 has the exclusive right to distribute our custom filter cartridge developed for the AETHER [®] Water System. For each prospective market for our ultrafilter products, we are pursuing alliance opportunities for joint product development and/or distribution. Our ultrafilter manufacturer in Europe shares certain intellectual property rights with us for one of our Dual Stage Ultrafilter ("DSU") designs.

Research and Development

Our research and development efforts continue on several fronts directly related to our current product lines. On the water filter business, we are continually working with existing and potential distributors of ultrafilter products to develop solutions to meet customer needs. On the HDF System business, we are working with our current customers to develop version 2.0 of the HDF System. For the years ended December 31, 2016 and 2015, we spent approximately \$1,079,000 and \$826,000, respectively, on research and development activities.

Major Customers

For the years ended December 31, 2016 and 2015, four customers accounted for 55% and 67%, respectively, of our revenues.

As of December 31, 2016 and 2015, four customers accounted for 59% and 73%, respectively, of our accounts receivable.

Competition

With respect to the water filtration market, we expect to compete with companies that are well entrenched in the water filtration domain. These companies include Pall Corporation (now wholly owned by Danaher Corporation), which manufactures end-point water filtration systems, as well as 3M, Siemens and Everpure®. Our methods of competition in the water filtration domain include:

developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;

offering unique attributes that illustrate our product reliability, "user-friendliness," and performance capabilities;

selling products to specific customer groups where our unique product attributes are mission-critical; and

pursuing alliance opportunities for joint product development and distribution.

The dialyzer and renal replacement therapy market is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical goals of nephrologists, improve patient outcomes and remain cost-effective for payers.

We compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG and Baxter International Inc., currently two of the primary machine manufacturers in hemodialysis. At present, Fresenius Medical Care AG and Baxter International Inc. also manufacture HDF machines that are not currently approved in the United States.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis products include Baxter International Inc., Fresenius Medical Care AG, Asahi Kasei Medical Co. Ltd., B. Braun Melsungen AG, Nipro Medical Corporation Ltd., Nikkiso Co., Ltd., Terumo Medical Corporation and Toray Medical Co., Ltd.

Other competitive considerations include pharmacological and technological advances in preventing the progression of ESRD in high-risk patients such as those with diabetes and hypertension, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants.

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of competing in the ESRD marketplace to include:

continuing our efforts to develop, have manufactured and sell products which, when compared to existing products, perform more efficiently and are available at prices that are acceptable to the market;

displaying our products and providing associated literature at major industry trade shows in the United States;

initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;

pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities; and

entering into license agreements similar to the Bellco S.r.l. agreement to expand market share.

Intellectual Property

Patents

Table of Contents

We protect our technology and products through patents and patent applications. In addition to the United States, we also applied for patents in other jurisdictions, such as the European Patent Office, Canada and Japan, to the extent we deem appropriate. We have built a portfolio of patents and applications covering our products, including their hardware design and methods of hemodiafiltration.

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge" have claims that cover the OLpur MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have issued patents on our water filtration products and applications in process to cover various applications in residential, commercial, and remote environments.

As of December 31, 2016, we have twenty-three issued U.S. patents, one issued Eurasian patent, seven Mexican patents, four South Korean patents, three Russian patents, six Chinese patents, nine French patents, nine German patents, five Israeli patents, seven Italian patents, three Spanish patents, nine United Kingdom patents, fourteen Japanese patents, three Hong Kong patents, ten Canadian patents, one Australian patent, two patents in Brazil, one patent in Sweden and one patent in the Netherlands. Our issued U.S. patents expire between 2018 and 2033. In addition, we have two pending patent applications in Canada, two pending patent applications in the European Patent Office, and one pending patent application in Brazil. Our pending patent applications relate to a range of filter technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance and ensure performance.

Trademarks

As of December 31, 2016, we secured registrations of the trademarks H2H and OLpūr in the European Union and OLpūr in the United States. We have also filed trademark applications for PATHOGUARD, NANOGUARD, and ENDOPUR in the United States and the European Union.

Governmental Regulation

The research and development, manufacturing, promotion, marketing and distribution of our ESRD therapy products in the United States, Europe and other regions of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and analogous agencies.

United States

The FDA regulates the manufacture and distribution of medical devices in the United States pursuant to the FDCA. All of our ESRD therapy products are regulated in the United States as medical devices by the FDA under the FDCA. Under the FDCA, medical devices are classified in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

Class I devices are medical devices for which general controls are deemed sufficient to ensure their safety and effectiveness. General controls include provisions related to (1) labeling, (2) producer registration, (3) defect notification, (4) records and reports and (5) quality service requirements, or QSR.

Class II devices are medical devices for which the general controls for the Class I devices are deemed not sufficient to ensure their safety and effectiveness and require special controls in addition to the general controls. Special controls include provisions related to (1) performance and design standards, (2) post-market surveillance, (3) patient registries and (4) the use of FDA guidelines.

Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before a new medical device can be introduced to the market, FDA clearance of a pre-market notification under Section 510(k) of the FDCA or FDA clearance of a pre-market approval, or PMA, application under Section 515 of

the FDCA must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process.

For any devices cleared through the Section 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require a new Section 510(k) pre-market notification submission. Accordingly, if we do obtain Section 510(k) pre-market clearance for any of our ESRD therapy and DSU products, we will need to submit another Section 510(k) pre-market notification if we significantly affect that product's safety or effectiveness through subsequent modifications or enhancements.

In July 2009, we received FDA clearance of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

In April 2012, we announced that 510(k) clearance was received from the FDA to market the OLpūr H2H Module and OLpūr MD 220 Hemodiafilter for use with a UF controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States.

In October 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters; in April 2016, we announced that we received 510(k) clearance from the FDA to market our S100 Point of Use Filter; in December 2016, we announced that we received 510(k) clearance from the FDA to market our HydraGuardTM 10" Ultrafilter; and in March 2017, we announced that we received 510(k) clearance from the FDA to market our market our EndoPurTM 10" Endotoxin.

The FDCA requires that medical devices be manufactured in accordance with the FDA's current QSR regulations which require, among other things, that:

the design and manufacturing processes be regulated and controlled by the use of written procedures;

the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;

any deficiencies in the manufacturing process or in the products produced be investigated;

detailed records be kept and a corrective and preventative action plan be in place; and

manufacturing facilities be subject to FDA inspection on a periodic basis to monitor compliance with QSR regulations.

If violations of the applicable QSR regulations are noted during FDA inspections of our manufacturing facilities or the manufacturing facilities of our contract manufacturers, there may be a material adverse effect on our ability to produce and sell our products.

In addition to the requirements described above, the FDCA requires that:

all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;

information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the

malfunction were to recur; and

certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive 93/42/EEC. The European Union directive applies to both the manufacturer's quality assurance system and the product's technical design and discusses the various ways to obtain approval of a device (dependent on device classification), how to properly CE Mark a device and how to place a device on the market.

The regulatory approach necessary to demonstrate to the European Union that the organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices requires the certification of a full quality management system by a notified body. Initially, we engaged TÜV Rheinland of North America, Inc. ("TÜV Rheinland") as the notified body to assist us in obtaining certification to the International Organization for Standardization ("ISO"), 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

European Union requirements for products are set forth in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. A company demonstrates conformity to these requirements, with respect to a product, by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

Once a manufacturer's full quality management system is determined to be in compliance with ISO 13485/2003 and other statutory requirements, and the manufacturer's products conform to harmonized European standards, the notified body will recommend and document such conformity. The manufacturer will receive a CE marking and ISO certifications, and then may place a CE mark on the relevant products. The CE mark, which stands for Conformité Européenne, demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported to, or sold or distributed within, the European Union.

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms to the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. In April 2010, we changed our notified body from TÜV Rheinland to BSI America, Inc. and expanded our scope to include design and development and production of water filters.

Under the Bellco license agreement, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label and CE mark in the stated territory. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated territory.

Regulatory Authorities in Regions Outside of the United States and the European Union

We also plan to sell our ESRD therapy products in foreign markets outside the United States that are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. In November 2007 and May 2011, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpūr MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the Canadian approval of our OLpūr MD220 Hemodiafilter and DSU products, we have not obtained any regulatory approvals to sell any of our products outside of the United States and the European Union and there is no assurance that any such clearance or certification will be issued.

Reimbursement

In both domestic markets and markets outside of the United States, sales of our ESRD therapy products will depend in part, on the availability of reimbursement from third-party payers. In the United States, ESRD providers are

reimbursed through Medicare, Medicaid and private insurers. In countries other than the United States, ESRD providers are also reimbursed through governmental and private insurers. In countries other than the United States, the pricing and profitability of our products generally will be subject to government controls. Despite the continually expanding influence of the European Union, national healthcare systems in its member nations, including reimbursement decision-making, are neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government.

Product Liability and Insurance

The production, marketing and sale of our products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our products in the amount of \$2 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.

Some of our existing and potential agreements with manufacturers of our products and components of our products do or may require us (1) to obtain product liability insurance or (2) to indemnify manufacturers against liabilities resulting from the sale of our products. If we are not able to maintain adequate product liability insurance, we will be in breach of these agreements, which could materially adversely affect our ability to produce our products. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

Employees

As of December 31, 2016, we employed a total of 10 employees, 9 of whom are full time and 1 who is employed on a part-time basis. We also have engaged 2 consultants on an ongoing basis. Of the 12 total employees and consultants, 3 are employed in a sales/marketing/customer support capacity, 4 in general and administrative and 5 in research and development.

Properties

Our U.S. facilities are located at 41 Grand Avenue, River Edge, New Jersey, 07661 and consist of approximately 4,688 square feet of space. The current rental agreement expires in November 2018 with a monthly cost of approximately \$9,000. We use these facilities to house our corporate headquarters and research facilities.

Our office space in Europe are currently located at Ulysses House, Foley Street, Dublin, Ireland. The lease agreement was entered into on August 1, 2016 and is for a twelve month term.

We use these facilities to house our accounting, operations and customer service departments.

We believe our current facilities will be adequate to meet our needs. We do not own any real property for use in our operations or otherwise.

Legal Proceedings

There are no currently pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject.

Available Information

We make available free of charge on our website (http://www.nephros.com) our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. We provide electronic or paper copies of filings free of charge upon request. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street N.E. Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC at http://www.sec.gov.

MANAGEMENT

Director Classes

Our Board of Directors (the "Board") is currently composed of five directors. Our Board is divided into three classes. Each year, one class is elected to serve for three years. The business address for each director for matters regarding our company is 41 Grand Avenue, River Edge, New Jersey 07661.

In connection with our September 2007 financing, we entered into an investor rights agreement with the 2007 investors pursuant to which we agreed to take such corporate actions as may be required, among other things, to entitle Lambda Investors, LLC ("Lambda") (i) to nominate two individuals having reasonably appropriate experience and background to our Board to serve as directors until their respective successor(s) are elected and qualified, (ii) to nominate each successor to the Lambda Investors nominees, provided that any successor shall have reasonably appropriate experience and background, and (iii) to direct the removal from the Board of any director nominated under the foregoing clauses (i) or (ii). Under the investor rights agreement, we are required to convene meetings of the Board at least once every three months. If we fail to do so, a Lambda director will be empowered to convene such meeting. Arthur Amron and Paul Mieyal are the current Lambda directors.

Name	Age (as of 3/31/17)	Director Since	Business Experience For The Last Five Years
Class I Directors			
Arthur H. Amron	60	2007	Mr. Amron has served as a director of our company since September 2007. Mr. Amron is a Partner of Wexford Capital LP, an SEC-registered investment advisor and serves as its General Counsel. Mr. Amron also actively participates in various private equity transactions, particularly in the bankruptcy and restructuring areas, and has served on the boards and creditors' committees of a number of public and private companies in which Wexford has held investments. Mr. Amron served as a director of Rhino GP LLC, which is the general partner of Rhino Resource Partners LP, a publicly traded master limited partnership (NYSE - RNO), from October 2010 to March 2016. From 1991 to 1994, Mr. Amron was an Associate at Schulte Roth & Zabel LLP, specializing in corporate and bankruptcy law, and from 1984 to 1991, Mr. Amron was an Associate at Debevoise & Plimpton LLP specializing in corporate litigation and bankruptcy law. Mr. Amron holds a J.D. from Harvard University, a B.A. in Political Theory from Colgate University and is a member of the New York

E	dgar Filing: ORASURE TECHNOLOGIES INC - Form S-3
	Bar. Among other experience, qualifications, attributes and skills, Mr. Amron's legal training and experience in the capital markets, as well as his experience serving on boards of directors of other public companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.
Class II Directors	
Paul A. 47 2007 Mieyal	Dr. Mieyal has served as a director of our company since September 2007 and served as our Acting President, Acting Chief Executive Officer, Acting Chief Financial Officer and Acting Secretary from January 4, 2015 to April 15, 2015. Dr. Mieyal also previously served as our Acting Chief Executive Officer from April 6, 2010 until April 20, 2012.Dr. Mieyal has been a Vice President of Wexford Capital LP since October 2006. From January 2000 through September 2006, he was Vice President in charge of healthcare investments for Wechsler & Co., Inc., a private investment firm and registered broker-dealer. Dr. Mieyal was a director of Nile Therapeutics, Inc., a publicly traded company, from September 2007 through November 2013. Dr. Mieyal received his Ph.D. in Pharmacology from New York Medical College, a B.A. in Chemistry and Psychology from Case Western Reserve University, and is a Chartered Financial Analyst. Among other experience, qualifications, attributes and skills, Dr. Mieyal's pharmacology and chemistry education, his experience in investment banking in the healthcare industry, as well as his experience serving on boards of directors of other public companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Malcolm Persen	63 2015	Mr. Persen has served as a director of our Company since May 2015 and is currently the President of Resolute Performance Contracting, a solar construction firm that he founded in 2011. Previously, from 2009 through 2011, he was the Executive Vice President at Ironco Enterprises, a renewable energy contracting organization. From 2004 through 2008, Mr. Persen served as the Chief Financial Officer for Radyne Corporation, a NASDAQ-traded manufacturer and distributor of satellite and telecommunications equipment. While at Radyne, he was part of the management team that tripled revenues and sold the firm, resulting in a 100% return for shareholders. Earlier, Mr. Persen was employed as Group Financial Officer for Avnet, Inc., a global distributor of electronic components and computer systems. Other experience included assignments with consultancies Arthur D. Little and Mercer Management Consulting. In addition, Mr. Persen lectured in finance at the University of Arizona from 2010 to 2013 and at Boston College from 1988 to 1999. Mr. Persen currently serves on the Board of Valutek, a supplier of cleanroom supplies through direct and distribution channels. Mr. Persen holds a BA in Political Economics from The Colorado College, and an MBA from The Amos Tuck School of Business at Dartmouth College. Among other experience, qualifications, attributes and skills, Mr. Persen's extensive financial background led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.
Class III Directors		
Daron Evans	42 2013	Mr. Evans is currently our President and Chief Executive Officer. He previously served as the Chairman of our Board of Directors from January 4, 2015 through April 15, 2015. Mr. Evans is a life sciences executive with over 20 years of financial leadership and operational experience. Mr. Evans is currently Managing Director of PoC Capital, LLC, and a Director of Zumbro Discovery, an early stage company developing a novel therapy for resistant hypertension. Mr. Evans was most recently Chief Financial Officer of Nile Therapeutics, Inc., from 2007 until its merger with Capricor, Inc. in November 2013. From 2004 to 2007, he held various positions at Scios, Inc. and Vistakon, Inc., both divisions of Johnson & Johnson Corp. Mr. Evans was a co-founder of Applied Neuronal Network Dynamics, Inc. and served as its President from 2002 to 2004. From 1995 to 2002, Mr. Evans served in various roles at consulting firms Arthur D. Little and Booz Allen & Hamilton. Mr. Evans is the author of four U.S. patents. Mr. Evans received his Bachelor of Science in Chemical Engineering from Rice University, his Master of Science in Biomedical Engineering from a joint program at the University of Texas at Arlington and Southwestern Medical School and his MBA from the Fuqua School of Business at Duke University. Among other experience, qualifications, attributes and skills, Mr. Evans's extensive operational and business development experience led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Mr. Pinto has served as a director of our Company since August 2015. Mr. Pinto was recently the CEO of Home Dialysis Plus, now Outset Medical, Inc., a Warburg Pincus backed company dedicated to the development and commercialization of a new hemodialysis system, providing an improved experience for patients. Previously, from 2007 through 2010, he was CEO of Spiracur Inc., a developer of innovative wound healing technologies that Mr. Pinto co-founded out of the Stanford University Biodesign Innovation Program. Mr. Pinto also worked for Herzog, Fox & Neeman, a law firm based in Israel. He served on the Board of Directors of Spiracur Inc. from 2010 to 2015. Mr. Pinto received an MBA from Stanford University, an LLM from Universita di Bologna, an EMLE from the University of Hamburg, and an LLB in Law from Tel Aviv University. Among other experience, qualifications, attributes and skills, the Board concluded that Mr. Pinto should serve as a director of our Company due to his historical experience with businesses in the medical industry and in light of our business and structure.

Director Independence

Our Board of Directors has determined that all of the current directors are "independent" within the meaning of the Nasdaq independence standard, other than Mr. Evans, who currently serves as the Company's President and CEO, and Mr. Mieyal, who served as the Company's Acting President, Acting Chief Executive Officer, Acting Chief Financial Officer and Acting Secretary from January 4, 2015 until April 15, 2015.

Executive Officer

Our current executive officers are Daron Evans, who serves as our President and Chief Executive Officer, and Andy Astor, who serves as our Chief Financial Officer. Mr. Astor joined as our Chief Financial Officer on February 13, 2017, and his biography is set forth below:

Andrew Astor, age 60, is a technology and business executive with 30 years of financial and operating experience. From June 2015 to January 2017, Mr. Astor was President and Chief Financial Officer at Open Source Consulting Group, a growth stage services firm. Previously, he was a Managing Director at Synechron, a global consulting organization, from 2013 to 2015. From 2009 to 2013, he served as Vice President at Asurion, a large, privately-held insurance company. Mr. Astor was co-founder of the software company EnterpriseDB, and served as its CEO from 2004 to 2008. Mr. Astor was Vice President, Strategic Solutions at webMethods, a software firm, from 2002 to 2004 and Vice President of Transactional Products at Dun & Bradstreet from 1998 to 2001. Prior to 1998, Mr. Astor held various roles at American Management Systems, SHL/MCI Systemhouse, and Ernst & Young. Mr. Astor received his Bachelor of Arts in Mathematics from Clark University, and his MBA from The Wharton School at the University of Pennsylvania.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership on Form 3 and changes in ownership on Form 4 or Form 5 with the SEC. Officers, directors and 10% stockholders are also required by SEC rules to furnish us with copies of all such forms that they file. Based solely on a review of the copies of such forms received by us, or written representations from reporting persons, we believe that during fiscal year 2016, all of our officers, directors and 10% stockholders complied with applicable Section 16(a) filing requirements.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no disagreements with our accountants during 2016 or 2015 reportable pursuant to this requirement.

EXECUTIVE COMPENSATION

The following table sets forth all compensation earned in the fiscal years ended December 31, 2016 and 2015 by our named executive officers.

Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$) ⁽¹⁾	Stock Awards (\$) ⁽²⁾	Option Awards (\$) ⁽²⁾	All Other Compensation (\$) ⁽³⁾	Total
Daron Evans	2016	\$240,000	\$ -	\$68,182	\$-	\$ 17,880	\$326,062
President and Chief Executive Officer ⁽⁴⁾	2015	\$170,000	\$11,475	\$12,852	\$1,150,087	\$ 7,000	\$1,351,414

(1) The amounts in this column reflect decisions approved by our Compensation Committee and are based on an analysis of the executive's contribution to our company during fiscal years 2016 and 2015.

(2) The amount reported is the aggregate grant date fair value of the options and restricted stock awards granted, computed in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the option awards are set forth in Note 2 of the consolidated financial statements set forth elsewhere in

this Annual Report.

(3) See table below for details on "All Other Compensation."

Mr. Evans has served as President, Chief Executive Officer and Acting Chief Financial Officer since April 15, (4)2015. He no longer serves as Acting Chief Financial Officer as of February 13, 2017, in connection with the appointment of Andrew Astor as Chief Financial Officer.

All Other Compensation

		Matahina	Heal	lth	Life						
Name	Year	Matching 401(k) Plan Contribution							Total Other Compensation		
		(\$)	Company		Company		(\$)		(\$)		
		(φ)	(\$)		(\$)						
Daron Evans	2016	\$ 17,880	\$	-	\$	-	\$	-	\$	17,880	
	2015	\$ 7,000	\$	-	\$	-	\$	-	\$	7,000	

Option and Restricted Stock Holdings and Fiscal Year-End Option and Restricted Stock Values

The following table shows information concerning unexercised options and unvested restricted stock awards outstanding as of December 31, 2016 for our named executive officers.

Outstanding Equity Awards at Fiscal Year-End 2016

Name Gran	N o S t Date ⁽¹⁾ U C E	f Securities Jnderlying Jnexercise Intions	Number of Securities Underlying Unexercised Options	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date ⁽³⁾	Stock Aw Number of Shares or Units of Stock that Have Not Vested (#)	ards Market Value of Shares or Units That Have Not Vested (\$)
Daron Evans 3/26/	14 7	75,361	-	-	0.46	3/26/24	-	-
Daron Evans 3/15/	15 3	334,454	430,014	1,419,725	0.60	4/15/25	-	-
Daron Evans 12/14	/16 -	-	-	-	-	-	9,165	3,391
Daron Evans 12/22	./16 -	-	-	-	-	-	213,068	78,835

(1) For better understanding of this table, we have included an additional column showing the grant date of stock options.

(2) As of December 31, 2016, stock options became exercisable in accordance with the vesting schedule below:

Name	Grant Date	Vesting
Daron Evans	3/26/14	Fully exercisable
Daron Evans	3/15/15	35% of the shares subject to the option vest in 16 equal quarterly installments over 4 years, commencing June 30, 2015
Daron Evans	3/15/15	15% of the shares subject to the option will vest upon approval of listing of the Company's common stock on the NASDAQ Stock Market, New York Stock Exchange or such other national securities exchange approved by the Board

Daron Evans	3/15/15	10% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$3,000,000
Daron Evans	3/15/15	20% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$6,000,000
Daron Evans	3/15/15	20% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$10,000,000

Advisory Vote on Executive Compensation

Our Board of Directors recognizes the fundamental interest our stockholders have in the compensation of our executive officers. At our 2014 Annual Meeting, our stockholders approved with approximately 98% of the votes cast, on an advisory basis, in favor of the compensation of our named executive officers as disclosed in the compensation tables and related narrative disclosure in the proxy statement for the 2014 Annual Meeting. Based on the results of such advisory vote and our review of our compensation policies and decisions, we believe that our existing compensation policies and decisions are consistent with our compensation philosophy and objectives disclosed in the compensation tables and related narrative disclosure and adequately align the interests of our named executive officers with our long term goals. In addition, based on a separate advisory vote of our stockholders at the Company's 2014 Annual Meeting relating to the frequency of the advisory vote on the compensation of our named executive officers, our stockholders indicated their approval of the Board's recommendation to hold a non-binding advisory vote on our executive compensation once every two years.

Employment and Change in Control Agreements

We have used employment agreements as a means to attract and retain executive officers. These are more fully discussed below. We believe that these agreements provide our executive officers with the assurance that their employment is a long-term arrangement and provide us with the assurance that the officers' services will be available to us for the foreseeable future.

Agreement with Mr. Daron Evans

The terms of Mr. Evans' employment with the Company are set forth in an Employment Agreement dated as of April 15, 2015 (the "Evans Employment Agreement"). The Evans Employment Agreement provides for a four-year term expiring on April 14, 2019, unless sooner terminated by either party. Pursuant to the Evans Employment Agreement, Mr. Evans will receive an initial annualized base salary of \$240,000 and will be eligible to receive an annual performance bonus of up to 30% of his annualized base salary. At such time that the Company's common stock is approved for listing on the NASDAQ Stock Market, New York Stock Exchange or such other national securities exchange approved by the Board and begins trading on such exchange, the Board may review and adjust Executive's base salary to a market competitive level. In addition, Mr. Evans was granted a 10-year stock option to purchase an aggregate of 2,184,193 shares of the Company's common stock pursuant to the Company's 2015 Equity Incentive Plan. The option is exercisable at a price of \$0.60 per share, which represents the closing sale price of the Company's common stock on the Effective Date. Mr. Evans right to purchase the shares vests, subject to his continued employment, as follows:

35% of the shares subject to the option vest in 16 equal quarterly installments over 4 years, commencing June 30, 2015;

15% of the shares subject to the option will vest upon approval of listing of the Company's common stock on the NASDAQ Stock Market, New York Stock Exchange or such other national securities exchange approved by the Board;

10% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$3,000,000;

20% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$6,000,000; and

20% of the shares subject to the option will vest, if ever, on the February 1st following the Company's first completed fiscal year in which annual revenue exceeds \$10,000,000.

The Evans Employment Agreement provides that if the Company terminates Mr. Evans without "Cause," or if he resigns for "Good Reason" (each as defined in the Evans Employment Agreement), then he shall be entitled to: (i) continuation of his base salary for a period of three months if such termination occurs prior to the first anniversary of April 15, 2015, or if such termination occurs following the first anniversary of April 15, 2015, continuation of his base salary for a period of the expiration of the term of the Evans Employment Agreement, if sooner).

2004 Stock Incentive Plan

The 2004 Stock Incentive Plan (the "2004 Plan") provides that if there is a change in control, as such term is defined in the 2004 Plan, unless the agreement granting an award provides otherwise, all awards under the 2004 Plan will become vested and exercisable as of the effective date of the change in control.

2015 Stock Incentive Plan

The 2015 Equity Incentive Plan (the "2015 Plan") provides that upon a change of control, as such term is defined in the 2015 Plan, unless the agreement granting an award provides otherwise, the administrator of the 2015 Plan may provide for one or more of the following: (i) the acceleration of the exercisability, vesting, or lapse of the risks of forfeiture of any or all awards (or portions thereof); (ii) the complete termination of the 2015 Plan and the cancellation of any or all awards (or portions thereof) that have not been exercised, have not vested, or remain subject to risks of forfeiture, as applicable in each case as of the effective date of the change of control; (iii) that the entity succeeding the Company by reason of such change of control, or the parent of such entity, must assume or continue any or all awards (or portions thereof) outstanding immediately prior to the change of control or substitute for any or all such awards (or portions thereof) a substantially equivalent award with respect to the securities of such successor entity, as determined in accordance with applicable laws and regulations; or (iv) that participants holding outstanding awards will become entitled to receive, with respect to each share of common stock subject to such award (whether vested or unvested, as determined by the administrator pursuant to the 2015 Plan) as of the effective date of any such change of control, cash in an amount equal to (1) for participants holding options or stock appreciation rights, the excess of the fair market value of such common stock on the date immediately preceding the effective date of such change of control over the exercise price per share of options or stock appreciation rights, or (2) for participants holding awards other than options or stock appreciation rights, the fair market value of such common stock on the date immediately preceding the effective date of such change of control. The administrator need not take the same action with respect to all awards (or portions thereof) or with respect to all participants.

401(k) Plan

We have established a 401(k) deferred contribution retirement plan (the "401(k) Plan") which covers all employees. The 401(k) Plan provides for voluntary employee contributions of up to 15% of annual earnings, as defined. As of January 1, 2004, we began matching 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. We contributed and expensed \$42,000 and \$44,000 in 2016 and 2015, respectively.

Director Compensation

For fiscal year 2016, our directors received a \$20,000 annual retainer, \$1,500 per meeting for each quarterly Board meeting attended and reimbursement for expenses incurred in connection with serving on our Board of Directors. The Chairman of our Audit Committee was paid a \$10,000 annual retainer and \$1,000 per meeting for meetings of the Audit Committee, with a maximum of eight meetings per year. There was no named Chairman of the Board during fiscal year 2016.

We grant each non-employee director who first joins our Board, immediately upon such director joining our Board, the number of options equal to the product of 0.0011 multiplied by the total number of outstanding shares of common stock of the Company on a fully-diluted basis. The exercise price per share will be equal to the fair market value price per share of our common stock on the date of grant. We will also grant annually to each non-employee director the number of options equal to the product of 0.0006 multiplied by the total number of outstanding shares of common stock of the company on a fully-diluted basis. The exercise price per share will be equal to the fair market value price per share of our common stock on the date of grant. These non-employee director options vest in three equal installments on each of the date of grant and the first and second anniversaries thereof.

Our executive officers do not receive additional compensation for service as directors if any of them so serve.

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2016.

Non-Employee Director Compensation in Fiscal Year 2016

Name	Fees Earned or Paid in Cash	Restricted Stock Awards ⁽¹⁾⁽²⁾	Option Awards ⁽³⁾⁽⁴⁾	Total
Arthur H. Amron ⁽⁵⁾	\$6,500	\$ 29,545	\$ 10,994	\$47,039
Paul A. Mieyal ⁽⁵⁾	\$6,500	\$ 29,545	\$ 10,994	\$47,039
Malcolm Persen	\$10,000	\$ 35,455	\$ 10,994	\$66,449
Moshe Pinto	\$6,500	\$ 29,545	\$ 10,994	\$47,039
Matthew Rosenberg ⁽⁶⁾	\$-	\$ 15,659	\$ -	\$22,159

(1)Director fees owed as of September 30, 2016 were paid in restricted stock in lieu of a cash payment.

(2) As of December 31, 2016, Mr. Persen had 113,636 shares of restricted stock, Mr. Pinto had 73,864 shares of restricted stock, and Mr. Rosenberg had 55,398 shares of restricted stock.

The amount reported is the aggregate grant date fair value of the options granted, computed in accordance with (3)FASB ASC Topic 718. The assumptions used in determining the grant date fair values of these awards are set forth in Note 2 of the consolidated financial statements set forth elsewhere in this Annual Report.

As of December 31, 2016, Mr. Persen had 49,281 shares of common stock issuance upon exercise of vested (4) options and 41,580 shares issuable upon the exercise of unvested options; Mr. Pinto had 50,731 shares of common stock issuance upon exercise of vested options and 42,304 shares issuable upon the exercise of unvested options; and Mr. Rosenberg had 48,864 shares issuable upon the exercise of vested options.

(5) At the request of Messrs. Amron and Mieyal, their respective options and director fees were directed to Wexford Capital LP.

(6)Mr. Rosenberg's service as a director ended on June 30, 2016.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In connection with the May 2015 private placement of shares, Matthew Rosenberg and Janet Persen, the spouse of Malcolm Persen, purchased shares of common stock and warrants from us for an aggregate purchase price of \$134,000 and \$20,877, respectively. These purchase prices are the equivalent of 200,000 shares and warrants to purchase 100,000 shares for Mr. Rosenberg and 31,160 shares and warrants to purchase 15,580 shares for Ms. Persen. Additionally, the following immediate family members, or entities controlled by immediate family members, of Mr. Rosenberg purchased shares of common stock and warrants from us in the May 2015 private placement: Best Six, LLC purchased 149,254 shares and warrants to purchase 74,627 shares for an aggregate purchase price of \$100,000; Franklin Associates, LLC purchased 74,630 shares and warrants to purchase 37,315 shares for an aggregate purchase price of \$147,400; and Seligman Rosenberg purchased 74,626 shares and warrants to purchase 37,313 shares for an aggregate purchase price of \$50,000. The exercise price for the warrants is \$0.85 per share and the warrants are exercisable for five-years from the date of issuance.

On September 29, 2015, we entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda. Pursuant to the Amendment, we agreed to reduce the current exercise price of the Class D Warrant issued to Lambda Investors on November 14, 2007 (together with all amendments thereto entered into prior to the Amendment, the "Lambda Warrant") representing the right to purchase 11,742,100 shares of our common stock by 50%, from \$0.30 to \$0.15 per share, in exchange for Lambda's agreement to exercise such Lambda Warrant in its entirety. Upon exercise of the Lambda Warrant, we issued 11,742,100 shares of common stock to Lambda and received approximately \$1.76 million in cash proceeds from Lambda. In addition, pursuant to the Amendment, we will offer such holders the right to exercise their respective warrants at a 50% discount to their current exercise prices, which

range from \$0.40 to \$0.85 per share.

On December 18, 2015, we completed our offer to exercise certain warrants to purchase an aggregate of 5,008,689 shares of our common stock, including outstanding warrants to purchase an aggregate of 2,782,577 shares of our common stock at an exercise price of \$0.40 per share, issued on March 10, 2011 to Lambda in connection with a private placement financing transaction. These warrants were exercisable at a temporarily reduced cash exercise price of \$0.20 per share of common stock for the period beginning on November 20, 2015 and ending on December 18, 2015, and upon exercise of the warrants, we received gross proceeds of approximately \$556,000.

On June 3, 2016, we entered into a note and warrant purchase agreement with certain accredited investors pursuant to which we sold an aggregate principal amount of \$807,000 of 11% unsecured promissory notes and five-year warrants to purchase an aggregate of 1,614,000 shares of our common stock at an exercise price of \$0.30 per share. Purchasers included PoC Capital, LLC, an entity owned by Daron Evans, our President and Chief Executive Officer, as well as two of Mr. Evans minor children for whom he acts as custodian. Collectively, such purchasers related to Mr. Evans purchased \$30,000 principal amount of notes and warrants to purchase 60,000 shares of common stock. Lambda also purchased notes in the principal amount of \$300,000 and received warrants to purchase 600,000 shares of common stock. Lambda is controlled by Wexford Capital LP. Arthur H. Amron, one of our directors, is a Partner and General Counsel of Wexford Capital LP. Paul A. Mieyal, one of our directors and our former Acting President, Acting Chief Executive Officer, and Acting Chief Financial Officer until April 15, 2015, is a Vice President of Wexford Capital LP.

On March 17, 2017, we entered into a securities purchase agreement with certain purchasers identified therein pursuant to which we agreed to sell, and the purchasers agreed to purchase 4,059,994 units of our securities, each unit consisting of one share of our common stock, par value \$0.001 per share, and a warrant to purchase one share of common stock, at a cash purchase price equal to \$0.30 per unit. Purchasers included two minor children of Daron Evans, the Company's President and Chief Executive Officer, who collectively purchased 83,332 units of the our securities under the securities purchase agreement, and Andy Astor, our Chief Financial Officer, who purchased 166,666 units.

The shares beneficially owned by Lambda may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors. Arthur H. Amron, a director of Nephros, is a partner and general counsel of Wexford Capital. Paul A. Mieyal, a director of Nephros and the former Acting President, Acting Chief Executive Officer and Acting Chief Financial Officer until April 15, 2015, is a vice president of Wexford Capital. During 2016 and 2015, at the request of Messrs. Amron and Mieyal, fees and options in the aggregate amount of approximately \$94,078 and \$71,240, respectively, earned in respect of services they rendered to the company were directed to Wexford Capital LP.

As of March 31, 2017, Lambda Investors is our largest stockholder and beneficially owns approximately 56% of our outstanding common stock.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2016 about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors. Our equity compensation plans as of December 31, 2015 consisted of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (together, the "Prior Plans") and our 2015 Equity Incentive Plan (the "2015 Plan"). All of our employees and directors were eligible to participate in the Prior Plans and are eligible to participate in the 2015 Plan. The Prior Plans are both expired and no further equity is granted under the Prior Plans. Our Prior Plans were approved by our stockholders.

On March 26, 2015, our Board approved the 2015 Plan.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	exe out opt	eighted-average ercise price of tstanding tions, warrants d rights	(c) Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a) and restricted stock granted under the 2015 Plan)
Equity compensation plans approved by our stockholders	1,268,123	\$	0.50	-
Equity compensation plans not approved by our stockholders	3,324,224	\$	0.54	1,865,610
Total	4,592,347			1,865,610

Security Ownership of Certain Beneficial Owners

The following table sets forth the beneficial ownership of our common stock as of March 31, 2017, by (i) each person known to us to own beneficially more than five percent (5%) of our common stock, based on such persons' or entities' filings with the SEC as of that date; (ii) each director and named executive officer; and (iii) all directors and executive officers as a group:

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentag of Class (1)	ge
Lambda Investors LLC ⁽²⁾	30,921,882	56.3	%
Arthur H. Amron ⁽³⁾	-	*	
Andrew Astor ⁽⁴⁾	333,332	*	
Daron Evans ⁽⁵⁾	1,263,676	2.3	%
Paul A. Mieyal ⁽⁶⁾	-	*	
Malcolm Persen ⁽⁷⁾	266,620	*	
Moshe Pinto ⁽⁸⁾	133,312	*	
All executive officers and directors as a group $^{(3)-(8)}$	1,996,940	3.6	%

* Represents less than 1% of the outstanding shares of our common stock.

Applicable percentage ownership is based on 54,160,548 shares of common stock outstanding as of March 31, 2017, together with applicable options and warrants for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors including voting and investment power with respect to

(1) accordance with the futes of the SEC, based on factors including voting and investment power with respect to shares. Common stock subject to options and warrants exercisable on or within 60 days after March 31, 2017 are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options or warrants, but not for computing the percentage ownership of any other person.

Based on information provided in a Form 4 dated June 3, 2016 and updated by information provided to us. The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors, Wexford GP LLC, which is the General Partner of Wexford Capital LP, by Charles E. Davidson in his capacity as Chairman and managing member of Wexford Capital LP and by Joseph M. Jacobs in his capacity as President and managing member of Wexford Capital LP. The address of each of Lambda Investors LLC, Wexford Capital LP, Mr. Davidson and Mr. Jacobs is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. Each of Wexford Capital LP, Wexford GP LLC, Mr. Davidson and Mr. Jacobs disclaims beneficial ownership of the shares of Common Stock owned by Lambda Investors except, in the case of Mr. Davidson and Mr. Jacobs, to the extent of their respective interests in each member of Lambda Investors. Includes 183,284 vested stock options and 600,000 shares issuable upon the exercise of

- Lambda Investors. Includes 183,284 vested stock options and 600,000 shares issuable upon the exercise of warrants. Lambda Investors is controlled by Wexford Capital LP. Arthur H. Amron, one of our directors, is a Partner and General Counsel of Wexford Capital LP. Paul A. Mieyal, one of our directors and our former Acting President, Acting Chief Executive Officer, and Acting Chief Financial Officer until April 15, 2015, is a Vice President of Wexford Capital LP.
- (3)Mr. Amron's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830.

Mr. Astor's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares (4) identified as being beneficially owned by Mr. Astor consist of: (i) 166,666 shares of common stock and (ii) 166,666 shares issuable upon the exercise of warrants. Does not include 579,571 shares issuable upon the exercise

of options which will not vest within 60 days of March 31, 2017.

Mr. Evans' address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Evans consist of: (i) 422,760 shares of common stock; (ii) 239,989
(5) shares of restricted stock; (iii) 457,595 shares issuable upon exercise of options and (iv) 143,332 shares of

common stock issuable upon the exercise of warrants. Does not include 1,801,959 shares issuable upon the exercise of options which will not vest within 60 days of March 31, 2017.

(6) Dr. Mieyal's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830.

Mr. Persen's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Persen consist of: (i) 151,605 shares of common stock; (ii) 31,160
 (7) shares of common stock held by Mr. Persen's spouse; (iii) 68,275 shares of common stock issuable upon exercise of options and (v) 15,580 shares of common stock issuable upon the exercise of warrants having an exercise price of \$0.85 per share. Does not include 22,586 shares issuable upon the exercise of options which will not vest within 60 days of March 31, 2017.

Mr. Pinto's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Pinto consist of: (i) 82,581 shares of common stock; (ii) 50,731 shares of common stock issuable upon exercise of options. Does not include 42,304 shares issuable upon the exercise of options which will not vest within 60 days of March 31, 2017.

DESCRIPTION OF CAPITAL STOCK

This prospectus relates to the shares of our common stock that have been issued to Lincoln Park and that may be issued to Lincoln Park in the future pursuant to the Purchase Agreement. For a further description of the Purchase Agreement, see "The Lincoln Park Transaction."

Our authorized capital stock consists of 90,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.

As of December 31, 2016, we had issued and outstanding approximately:

49,782,797 shares of common stock;

Options to purchase 4,592,347 shares of our common stock at exercise prices ranging from \$16.00 to \$0.30, with a weighted average exercise price of \$0.60; and

Warrants to purchase 3,291,149 shares of our common stock, including warrants to purchase 917,149 shares of our common stock at \$0.85 per share with expiration dates in 2020 and warrants to purchase 2,374,000 shares at an exercise price of \$0.30 per share with expiration dates in 2021.

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of our common stock entitled to vote in any election of directors may elect all of the directors standing for election. Apart from preferences that may be applicable to any holders of preferred stock outstanding at the time, holders of our common stock are entitled to receive dividends, if any, ratably as may be declared from time to time by the Board out of funds legally available therefor. Upon our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive ratably our net assets available after the payment of all liabilities and liquidation preferences on any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

LEGAL MATTERS

The legality of the securities offered hereby have been passed upon for us by Fredrikson & Byron P.A., Minneapolis, Minnesota.

EXPERTS

Our financial statements as of and for the years ended December 31, 2016 and 2015 included in this prospectus have been audited by Moody, Famiglietti & Andronico, LLP, an independent registered public accounting firm, as stated in their report, which report includes an explanatory paragraph related to the Company's ability to continue as a going concern.

Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings are also available to the public free of charge at the SEC's website at www.sec.gov and on our website at www.nephros.com.

DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides for indemnification of directors and officers of the Registrant to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. We have obtained liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of the registrant. Our Second Amended and Restated By-Laws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the DGCL. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

FINANCIAL STATEMENTS

	Page
Annual Financial Statements	
Report of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets — December 31, 2016 and 2015	F-3
Consolidated Statements of Operations — Years ended December 31, 2016 and 2015	F-4
Consolidated Statements of Changes in Stockholders' Equity — Years ended December 31, 2016 and 2016	F-5
Consolidated Statements of Cash Flows — Years ended December 31, 2016 and 2015	F-6
Notes to Consolidated Financial Statements	F-7

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Nephros, Inc.

River Edge, New Jersey

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and Subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit) and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nephros, Inc. and Subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred negative cash flow from operations and recurring net losses. These conditions, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Moody, Famiglietti & Andronico, LLP Tewksbury, MA March 20, 2017

CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2016	December 31, 2015
ASSETS	-)	- ,
Current assets:		
Cash	\$275	\$1,248
Accounts receivable, net	388	397
Investment in lease, net-current portion	27	-
Inventory, net	479	591
Prepaid expenses and other current assets	95	228
Total current assets	1,264	2,464
Property and equipment, net	70	12
Investment in lease, net-less current portion	61	-
License and supply agreement, net	1,262	1,473
Other asset	21	21
Total assets	\$2,678	\$3,970
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$585	\$652
Accrued expenses	240	237
Deferred revenue, current portion	70	70
Total current liabilities	895	959
Unsecured long-term note payable, net of debt issuance costs and debt discount of \$349	838	-
Long-term portion of deferred revenue	278	347
Total liabilities	2,011	1,306
Commitments and Contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2016 and 2015; no shares issued and outstanding at December 31, 2016 and 2015. Common stock, \$.001 par value; 90,000,000 shares authorized at December 31, 2016 and	-	-
2015; 49,782,797 and 48,580,355 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively.	50	49
Additional paid-in capital Accumulated other comprehensive income	120,835 67	119,797 71

Accumulated deficit	(120,285)) (117,253)
Total stockholders' equity	667	2,664
Total liabilities and stockholders' equity	\$2,678	\$3,970

The accompanying notes are an integral part of these consolidated financial statements.

F-3

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In Thousands, Except Share and Per Share Amounts)

	Years Ended December 31,			
	2016		2015	
Net revenue:				
Product revenues	\$2,093		\$1,790	
License, royalty and other revenues	227		154	
Total net revenues	2,320		1,944	
Cost of goods sold	1,026		884	
Gross margin	1,294		1,060	
Operating expenses:				
Research and development	1,079		826	
Depreciation and amortization	230		212	
Selling, general and administrative	2,854		3,443	
Total operating expenses	4,163		4,481	
Loss from operations	(2,869)	(3,421)
Change in fair value of warrant liability	-		2,099	
Warrant modification expense	-		(1,761)
Interest expense	(172)	(42)
Interest income	5		-	
Other income (expense), net	4		37	
Net loss	(3,032)	(3,088)
Other comprehensive loss, foreign currency translation adjustments	(4)	(1)
Total comprehensive loss	\$(3,036)	\$(3,089)
Net loss	\$(3,032)	\$(3,088)
Deemed dividend as a result of warrant modification	-		(73)
Net loss attributable to common stockholders	\$(3,032		\$(3,161)
Net loss per common share, basic and diluted	\$(0.06		\$(0.09)
Weighted average common shares outstanding, basic and diluted	48,583,16	5	34,780,50	06

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(In Thousands, Except Share Amounts)

Balance, December 31, 2014	Common Sto Shares 30,391,513		Additional Paid-in nt Capital \$ 108,382	Ot Co	ccumula ther omprehe come 72	ensiAœcumulat Deficit	ed E T	tockholde quity (De otal (5,681	
Net loss Net unrealized losses on foreign currency translation, net of tax					(1	(3,088))	(3,088 (1))
Issuance of common stock, net of equity issuance costs of \$24	1,834,299	2	1,203					1,205	
Issuance of common stock, net of commitment fee of \$163	550,000	1	135					136	
Issuance of restricted stock Issuance of restricted stock to a vendor Exercise of warrants Noncash stock-based compensation	501,182 116,613 15,186,748	1 15	174 68 9,484 351					175 68 9,499 351	
Balance, December 31, 2015	48,580,355	\$ 49	\$119,797	\$	71	\$ (117,253)\$	(2,664)
Net loss						(3,032)	(3,032)
Net unrealized losses on foreign currency translation, net of tax Issuance of restricted stock Restricted stock issued to settle liability Exercise of warrants Issuance of warrants Noncash stock-based compensation Balance, December 31, 2016	1,021,763 179,773 906 49,782,797	1 - \$ 50	51 1 389 597 \$120,835	\$	(4) \$ (120,285)\$	(4 1 51 1 389 597 667)

The accompanying notes are an integral part of these consolidated financial statements.

F-5

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In Thousands)

	Years Ended December 31,			
	2016	2015		
Operating activities				
Net loss	\$(3,032) \$(3,088)			
Adjustments to reconcile net loss to net cash used in operating activities:		(-))		
Depreciation of property and equipment	19	1		
Amortization of license and supply agreement	211	211		
Non-cash stock-based compensation, including stock options and restricted stock	551	489		
Non-employee stock-based compensation	46	68		
Change in fair value of warrant liability	-	(2,099)		
Warrant modification	-	1,761		
Inventory reserve	27	-		
Allowance for doubtful accounts reserve	35	15		
Amortization of debt discount	53	-		
Gain on foreign currency transactions	(4)	(7)		
(Increase) decrease in operating assets:				
Accounts receivable	(17)	(302)		
Inventory	103	(405)		
Prepaid expenses and other current assets	(10)	(144)		
Increase (decrease) in operating liabilities:				
Accounts payable	(76)	(176)		
Accrued expenses	51	(69)		
Deferred revenue	(69)	(70)		
Net cash used in operating activities	(2,112)	(3,815)		
Investing activities				
Purchases of property and equipment	(45)	(13)		
Net cash used in investing activities	(45)			
Financing activities				
Proceeds from issuance of unsecured note	1,187	-		
Proceeds from issuance of common stock	-	1,340		
Proceeds from exercise of warrants	1	2,451		
Payment of senior secured notes	-	-		

Net cash provided by financing activities Effect of exchange rates on cash Net decrease in cash Cash, beginning of year Cash, end of year	1,188 (4) (973) 1,248 \$275	3,791) 1) (36) 1,284 \$1,248
Supplemental disclosure of cash flow information		
Cash paid for interest expense	\$113	\$43
Cash paid for income taxes	\$11	\$5
Supplemental disclosure of noncash financing activities Fair value of warrants issued with unsecured note payable Investment in lease receivable, net Cost of equipment in sales-type lease Restricted stock issued to settle liability Deposit on inventory reclassified from prepaid expenses and other current assets to inventory Deposit on property and equipment reclassified from prepaid expenses and other current assets to	\$393 \$92 \$92 \$51 \$18 \$124	\$- \$- \$36 \$- \$-
property and equipment Deemed dividend as a result of warrant modification Issuance of common stock as commitment fee Extinguishment of warrant liability	\$- \$- \$-	\$73 \$163 \$5,287

The accompanying notes are an integral part of these consolidated financial statements.

F-6

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Organization and Nature of Operations

Nephros, Inc. ("Nephros" or the "Company") was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease ("ESRD") therapy technology and products. The Company has two products in the hemodiafiltration ("HDF") modality to deliver therapy for ESRD patients. These are the OLpūr mid-dilution HDF filter or "dialyzer," designed expressly for HDF therapy, and the OLpūr H2H HDF module, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy. In 2009, the Company introduced its Dual Stage Ultrafilter ("DSU") water filter, which represented a new and complementary product line to the Company's ESRD therapy business. The DSU incorporates the Company's unique and proprietary dual stage filter architecture.

On June 4, 2003, Nephros International Limited was incorporated under the laws of Ireland as a wholly-owned subsidiary of the Company. In August 2003, the Company established a European Customer Service and financial operations center in Dublin, Ireland.

The U.S. facilities, located at 41 Grand Avenue, River Edge, New Jersey, 07661, are used to house the Company's corporate headquarters and research facilities.

Note 2 - Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Nephros International Limited. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates in the Preparation of Financial Statements

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amount of revenues and expenses, during the reporting period. Actual results could differ materially from those estimates. Included in these estimates are assumptions about the valuation of the warrant liability, the collection of accounts receivable, value of inventories, useful life of fixed assets and intangible assets, assumptions used in determining stock compensation such as expected volatility and risk-free interest rate and the ability of the Company to continue as a going concern.

Reclassifications

Certain reclassifications were made to the prior year's amounts to conform to the 2016 presentation. Other assets, net, as presented as of December 31, 2015 is now presented as license and supply agreement, net and other asset, respectively.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has incurred significant losses from operations in each quarter since inception. In addition, the Company has not generated positive cash flow from operations for the years ended December 31, 2016 and 2015. To become profitable, the Company must increase revenue substantially and achieve and maintain income from operations. If the Company is not able to increase revenue and generate income from operations sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

F-7

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

On March 17, 2017, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers, including members of the Company's management, identified therein. Pursuant to the Purchase Agreement, the Company agreed to issue and sell, and the purchasers agreed to purchase, an aggregate of 4,059,994 shares at a price of \$0.30 per share for total gross proceeds of approximately \$1.2 million. In addition, the Company will issue to the purchasers warrants to purchase an aggregate of 4,059,994 shares of common stock. The warrants will have an exercise price of \$0.30 per share and will be exercisable for a five-year term. See Note 14 for further discussion.

On June 7, 2016, the Company received gross proceeds of approximately \$1,187,000 in connection with the issuance of unsecured promissory notes and warrants. The portion of the outstanding unsecured promissory notes held by related parties comprised of entities controlled by a member of management and by Lambda Investors LLC ("Lambda"), the majority shareholder, amounted to \$30,000 and \$300,000, respectively. The outstanding principal under the Notes accrues interest at a rate of 11% per annum. In addition to the Notes, the Company issued Warrants to purchase approximately 2.4 million shares of the Company's common stock to the investors in the Agreement. The Warrants have an exercise price of \$0.30 per share and are exercisable for 5 years from the issuance date. See Note 7 for further discussion.

On December 23, 2015, the Company received proceeds of approximately \$688,000 in connection with its offer to holders of certain warrants of the opportunity to exercise their warrants at a temporarily reduced cash exercise price. Warrant holders elected to exercise warrants to purchase an aggregate of 3,442,521 shares of the Company's common stock at the reduced cash exercise price of \$0.20 per share, providing a total of approximately \$688,000 in gross proceeds to the Company. Of the 3,442,521 shares issued, 2,782,577 are held by Lambda, the majority shareholder. The warrants that were not exercised pursuant to the offer to exercise will remain in effect, with an exercise price of \$0.40 per share of common stock.

On September 29, 2015, the Company issued 11,742,100 shares of common stock to Lambda, the majority shareholder, for warrants exercised and received approximately \$1,761,000 in cash proceeds. The exercise price for each warrant was \$0.15. See Note 3 for further discussion.

On July 24, 2015, the Company entered into a purchase agreement (the "Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company has the right to sell and Lincoln Park has the obligation to purchase up to \$10,000,000 of the Company's common stock. In connection with the Purchase Agreement, the Company issued to Lincoln Park 250,000 shares of common stock for no proceeds. Pursuant to the Purchase Agreement, in September 2015, the Company issued and sold 300,000 shares of common stock to Lincoln Park at a per share purchase price of \$0.45, resulting in gross proceeds of \$136,000. See Note 11 - Stockholders' Equity (Deficit).

On May 18, 2015, the Company raised gross proceeds of approximately \$1,230,000 through the private placement of 1,834,299 units of its securities. Each unit consisted of one share of its common stock and a five-year warrant to purchase one-half of one share of the Company's common stock. The purchase price for each unit was \$0.67. The 917,149 warrants issued are exercisable at a price of \$0.85 per share. See Note 11 - Stockholders' Equity (Deficit).

There can be no assurance that the Company's future cash flow will be sufficient to meet its obligations and commitments. If the Company is unable to generate sufficient cash flow from operations in the future to service its commitments, the Company will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing its planned activities or ceasing its operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable the Company to continue to satisfy its capital requirements.

Recently Adopted Accounting Pronouncement

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and sets rules for how this information should be disclosed in the financial statements. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods thereafter. The Company adopted ASU 2014-15 as of the fiscal year ended December 31, 2016.

In April 2015, the FASB issued ASU 2015-03, "Interest - Imputation of Interest (Subtopic 2015-03): Simplifying the Presentation of Debt Issuance Costs" related to the presentation requirements for debt issuance costs and debt discount and premium. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 is effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU 2015-03 upon entering into the Note and Warrant Agreement as discussed in Note 7.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

Concentration of Credit Risk

The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. To date, the Company has not experienced any impairment losses on its cash.

Major Customers

For the year ended December 31, 2016, four customers accounted for 55% of the Company's revenues. For the year ended December 31, 2015, four customers accounted for 67% of the Company's revenues. As of December 31, 2016, four customers accounted for 59% of the Company's accounts receivable. As of December 31, 2015, four customers accounted for 73% of the Company's accounts receivable.

Accounts Receivable

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was approximately \$50,000 and \$15,000 as of December 31, 2016 and 2015, respectively. There was no allowance for sales returns at December 31, 2016 or 2015. There were no write offs of accounts receivable to bad debt expense during 2016 or 2015.

Inventory

The Company engages third parties to manufacture and package inventory held for sale, takes title to certain inventory once manufactured, and warehouses such goods until packaged for final distribution and sale. Inventory consists of finished goods held at the manufacturers' facilities, and are valued at the lower of cost or market using the first-in, first-out method.

The Company's inventory reserve requirements are based on factors including the products' expiration date and estimates for the future sales of the product. If estimated sales levels do not materialize, the Company will make adjustments to its assumptions for inventory reserve requirements.

License and Supply Rights

The Company's rights under the License and Supply Agreement are capitalized and stated at cost, less accumulated amortization, and are amortized using the straight-line method over the term of the License and Supply Agreement. The License and Supply Agreement term is from April 23, 2012 through December 31, 2022. The Company determines amortization periods for licenses based on its assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms.

Patents

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. All costs and direct expenses incurred in connection with patent applications have been expensed as incurred and are included in Selling, General and Administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

Property and Equipment, net

Property and equipment, net is stated at cost less accumulated depreciation. These assets are depreciated over their estimated useful lives of three to seven years using the straight line method.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

Impairment for Long-Lived Assets

The Company adheres to Accounting Standards Codification ("ASC") Topic 360 and periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived assets, or the appropriate grouping of assets, is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. For long-lived assets, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its fair value less costs to sell. There were no impairment losses for long-lived assets recorded for the years ended December 31, 2016 and December 31, 2015.

Fair Value of Financial Instruments

The carrying amounts of cash, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments. See Note 3 for information on the fair value of derivative liabilities.

The carrying amounts of the investment in lease, net, and the unsecured long-term note payable approximate fair value as of December 31, 2016 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

Revenue Recognition

Revenue is recognized in accordance with ASC Topic 605. Four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured.

The Company recognizes revenue related to product sales when delivery is confirmed by its external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by the Company's customers.

Deferred revenue was approximately \$348,000 and \$417,000 on the accompanying consolidated balance sheets as of December 31, 2016 and 2015, respectively, and is related to the License Agreement with Bellco. The Company has recognized approximately \$2,728,000 of revenue related to this license agreement to date, including approximately \$69,000 for the year ended December 31, 2016, resulting in \$348,000 being deferred over the remainder of the expected obligation period (see Note 13). The Company recognized approximately \$70,000 of revenue related to this license agreement for the year ended December 31, 2015.

Beginning on January 1, 2015, Bellco began paying the Company a royalty based on the number of units of certain products sold per year (see Note 13). The Company recognized royalty income of approximately \$114,000 and \$84,000, respectively, for the years ended December 31, 2016 and 2015.

The Company also invoiced Biocon 1, LLC approximately \$24,000 related to consulting services provided during the fiscal year ended December 31, 2016, which is included in license, royalty and other revenue on the consolidated statement of operations and comprehensive loss. Approximately \$24,000 is also included in accounts receivable as of December 31, 2016.

On May 6, 2015, the Company entered into a Sublicense Agreement with CamelBak Products, LLC ("CamelBak"). The Company granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the HydraGuard individual water treatment devices. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay the Company a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay the Company a fixed per-unit fee for any other sales made. The Company recognized royalty revenue of \$10,000 during the fiscal year ended December 31, 2016.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

On October 17, 2016, the Company entered into a Sublicense Agreement with Roving Blue, Inc. ("Roving Blue"). The Company granted Roving Blue an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license. In exchange for the rights granted to Roving Blue, Roving Blue paid the Company an upfront fee of \$10,000, which was recognized as royalty revenue during the fiscal year ended December 31, 2016. The Sublicense Agreement with Roving Blue also includes an agreement for Roving Blue to pay the Company a fixed per-unit fee for sales made, subject to certain minimums.

Shipping and Handling Costs

Shipping and handling costs charged to customers are recorded as cost of goods sold and were approximately \$24,000 and \$12,000 for the years ended December 31, 2016 and 2015, respectively.

Research and Development Costs

Research and development costs are expensed as incurred.

Stock-Based Compensation

The fair value of stock options is recognized as stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. The Company calculates employee stock-based compensation expense in accordance with ASC 718. The Company accounts for stock option grants to consultants under the provisions of ASC 505-50, and as such, these stock options are revalued at each reporting period through the vesting period. The fair value of the Company's stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price

Table of Contents

volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that the Company estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award.

Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for anti-dilution of the warrant exercise price under certain conditions are accounted for as derivative liabilities. The Company classifies derivative warrant liabilities on the balance sheet as a liability, which is revalued using a binomial options pricing model at each balance sheet date subsequent to the initial issuance. A binomial options pricing model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. The changes in fair value of the derivative warrant liabilities are remeasured at each balance sheet date and the resulting changes in fair value are recorded in current period earnings.

Amortization of Debt Issuance Costs

The Company accounts for debt issuance costs in accordance with ASU 2015-03, which requires that costs paid directly to the issuer of a recognized debt liability be reported in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company amortizes the debt discount, including debt issuance costs, in accordance with ASC 835, Interest, over the term of the associated debt. See Note 7 for a discussion of the Company's unsecured long-term note payable.

Other Income (Expense), net

Other income of approximately \$4,000 and \$37,000, respectively, for the years ended December 31, 2016 and 2015 is primarily due to foreign currency transaction gains.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

Income Taxes

The Company accounts for income taxes in accordance with ASC Topic 740, which requires accounting for deferred income taxes under the asset and liability method. Deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable in future years to differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities.

For financial reporting purposes, the Company has incurred a loss in each period since its inception. Based on available objective evidence, including the Company's history of losses, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2016 and 2015.

ASC Topic 740 prescribes, among other things, a recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return. ASC 740 utilizes a two-step approach for evaluating uncertain tax positions. Step one, or recognition, requires a company to determine if the weight of available evidence indicates a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, or measurement, is based on the largest amount of benefit, which is more likely than not to be realized on settlement with the taxing authority. The Company is subject to income tax examinations by major taxing authorities for all tax years subsequent to 2012. During the years ended December 31, 2016 and 2015, the Company recognized no adjustments for uncertain tax positions. However, management's conclusions regarding this policy may be subject to review and adjustment at a later date based on factors including, but not limited to, on-going analyses of and changes to tax laws, regulation and interpretations, thereof.

Net Income (loss) per Common Share

Basic income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted earnings (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants, as applicable. The Company calculates dilutive potential common shares using the treasury stock method, which assumes the Company will use the proceeds from the exercise of stock options and warrants to repurchase shares of common stock to hold in its treasury stock reserves.

The following securities have been excluded from the dilutive per share computation as they are antidilutive:

	December 31,		
	2016	2015	
Shares underlying options outstanding	4,592,347	4,303,638	
Shares underlying warrants outstanding	3,291,149	2,482,563	
Unvested restricted stock	957,336	501,182	

Foreign Currency Translation

Foreign currency translation is recognized in accordance with ASC Topic 830. The functional currency of Nephros International Limited is the Euro and its translation gains and losses are included in accumulated other comprehensive income. The balance sheet is translated at the year-end rate. The statement of operations is translated at the weighted average rate for the year.

Comprehensive Income (Loss)

Comprehensive income (loss), as defined in ASC 220, is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)). The Company's other comprehensive income (loss) consists only of foreign currency translation adjustments.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and was effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. Early adoption was not permitted. In August, 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of the Effective Date". The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting periods within that fiscal year. Earlier application is permitted only as of fiscal years beginning after December 31, 2016, including interim reporting periods with that fiscal year. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. The Company does not believe that the adoption of ASU 2015-11 will have a significant impact on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, "Balance Sheet Classification of Deferred Taxes," that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard

may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. The Company does not believe that the adoption of ASU 2015-17 will have a significant impact on its consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

In January 2016, the FASB issued ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases", that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for the Company beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-08, "Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," which clarifies the implementation guidance on principal versus agent considerations. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting," which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2017. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, "Identifying Performance Obligations and Licensing," which clarifies the implementation guidance for performance obligations and licensing. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, "Narrow Scope Improvements and Practical Expedients," which clarifies the accounting for certain aspects of guidance issued in ASU 2014-09, including assessing collectability and noncash consideration. The clarifications in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments," which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Classification of Certain Cash Receipts and Cash Payments," which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-17, "Restricted Cash," which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, "Clarifying the Definition of a Business," which clarifies the definition of a business in a business combination. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company does not expect this ASU to have a significant impact on its consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (continued)

In January 2017, the FASB issued ASU 2017-04, "Simplifying the Test for Goodwill Impairment," which simplifies the test for goodwill impairment. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual goodwill impairments tests after January 1, 2017. The Company does not expect this ASU to have a significant impact on its consolidated financial statements.

Note 3 - Financial Instruments

The fair value guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The Company had outstanding warrants originally issued in 2007 (the "2007 Warrants") that were accounted for as a derivative liability until they were fully exercised on September 29, 2015. The 2007 Warrants were classified as a liability because the transactions that would trigger the anti-dilution adjustment provision in the 2007 Warrants were not inputs to the fair value of the warrants. The 2007 Warrants were recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in changes in fair value of warrant liability in the Company's consolidated statement of operations and comprehensive income (loss) in each subsequent period. The Company utilized a binomial options pricing model to value the 2007 Warrants at each reporting period.

The estimated fair value of the 2007 Warrants was determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 3 - Financial Instruments (continued)

On the consolidated statement of operations for the year ended December 31, 2015, the Company recorded income of approximately \$2,099,000 as a result of the change in fair value of the warrant liability. A reconciliation of the warrant liability is as follows (in thousands):

	2007
	Warrants
Balance at December 31, 2014	\$ 7,386
Decrease in fair value of warrant liability	(2,099)
Balance at September 29, 2015	\$ 5,287

The following table summarizes the calculated aggregate fair value of the warrants, along with the assumptions utilized in the calculation:

	Septembe	er
	29, 2015	
Calculated aggregate value	\$ 5,287	
Weighted average exercise price	\$ 0.30	
Closing price per share of common stock	\$ 0.40	
Volatility	137	%
Weighted average remaining expected life (years)	4.2	
Risk-free interest rate	1.4	%
Dividend yield	-	

On September 29, 2015, the Company entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda. Pursuant to the Amendment, the Company agreed to reduce the current exercise price of the 2007 Warrants by 50%, to \$0.15 per share, in exchange for Lambda's agreement to exercise the 2007 Warrants in their entirety immediately following the modification. Upon exercise of the 2007 Warrants, the Company issued 11,742,100 shares of common stock to Lambda and received approximately \$1,761,000 in cash proceeds from Lambda. Following such exercise, no 2007 Warrants remain outstanding. The value of the 2007 Warrants as of September 29, 2015, after the modification, was approximately \$7,048,000, calculated as intrinsic value with an

expected term of zero. As a result, approximately \$1,761,000 was recorded as warrant modification expense for the year ended December 31, 2015.

Note 4 - Inventory

The Company's inventory components as of December 31, 2016 and 2015 were as follows:

	December 31,		
	2016	2015	
Total gross inventory, finished goods	\$528,000	\$634,000	
Less: inventory reserve	(49,000)	(43,000)	
Total inventory	\$479,000	\$591,000	

Note 5 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2016 and 2015 were as follows:

	December 31,		
	2016	2015	
Prepaid insurance premiums	\$66,000	\$62,000	
Deposit on equipment	-	124,000	
Inventory in transit	-	18,000	
Other	29,000	24,000	
Prepaid expenses and other current assets	\$95,000	\$228,000	

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 6 - Property and Equipment, Net

Property and equipment as of December 31, 2016 and 2015 was as follows:

		December 31,		
	Life	2016	2015	
Manufacturing equipment	3-5 years	\$690,000	\$611,000	
Research equipment	5 years	37,000	37,000	
Computer equipment	3-4 years	43,000	43,000	
Furniture and fixtures	7 years	37,000	37,000	
Property and equipment, gross		807,000	728,000	
Less: accumulated depreciation		737,000	716,000	
Property and equipment, net		\$70,000	\$12,000	

Depreciation expense for each of the years ended December 31, 2016 and 2015 was approximately \$19,000 and \$1,000, respectively.

Note 7 - Unsecured Promissory Notes and Warrants

On June 7, 2016, the Company entered into a Note and Warrant Agreement (the "Agreement") with new creditors as well as existing shareholders under which the Company issued unsecured promissory notes ("Notes") and warrants ("Warrants") resulting in total gross proceeds to the Company during June 2016 of approximately \$1,187,000. As of December 31, 2016, the portion of the outstanding unsecured promissory notes held by related parties comprised of entities controlled by a member of management and by Lambda Investors LLC ("Lambda"), the majority shareholder, amounted to \$30,000 and \$300,000, respectively. The outstanding principal under the Notes accrues interest at a rate of 11% per annum. The Company is required to make interest only payments on a semi-annual basis, and all outstanding principal under the Notes is repayable in cash on June 7, 2019, the third anniversary of the date of issuance. In addition to the Notes, the Company issued Warrants to purchase approximately 2.4 million shares of the Company's common stock to the investors in the Agreement. The Warrants have an exercise price of \$0.30 per share and are exercisable for 5 years from the issuance date. The Warrants issued under the Agreement are indexed to the Company's common stock, therefore, the Company is accounting for the Warrants as a component of equity. In

Table of Contents

connection with the Agreement, the Company incurred approximately \$13,000 in legal fees.

The approximately \$1,187,000 in gross proceeds from the Agreement, along with the legal fees of approximately \$13,000, were allocated between the Notes and Warrants based on their relative fair values. The portion of the gross proceeds allocated to the Warrants of approximately \$393,000 was accounted for as additional paid-in capital. Approximately \$4,000 of the legal fees were allocated to the Warrants and recorded as a reduction to additional paid-in capital. The remainder of the gross proceeds of approximately \$794,000, net of the remainder of the fees of approximately \$9,000, was allocated to the Notes with the fair value of the Warrants resulting in a debt discount. The debt discount is being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the Agreement. Approximately \$53,000 was recognized as amortization of debt discount during the fiscal year ended December 31, 2016 and is included in interest expense on the consolidated statement of operations and comprehensive loss. Approximately \$77,000 was recognized as interest expense for the fiscal year ended December 31, 2016 for interest payable to noteholders. For the year ended December 31, 2016, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda Investors LLC ("Lambda"), the majority shareholder, was approximately \$2,000 and \$19,000, respectively. As of December 31, 2016, approximately \$65,000 of interest has been paid to noteholders and approximately \$12,000 of interest is included in accrued expenses on the consolidated balance sheet.

There were no unsecured long-term notes payable outstanding as of December 31, 2015.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 - Accrued Expenses

Accrued expenses as of December 31, 2016 and 2015 were as follows:

	December 31,		
	2016	2015	
Accrued legal	\$99,000	\$103,000	
Accrued directors' compensation	30,000	52,000	
Accrued royalty	18,000	14,000	
Accrued credits issued to customers	-	10,000	
Accrued management bonus	19,000	-	
Accrued accounting	6,000	1,000	
Accrued interest	17,000	12,000	
Accrued other	51,000	45,000	
	\$240,000	\$237,000	

Note 9 - Income Taxes

A reconciliation of the income tax provision computed at the statutory tax rate to the Company's effective tax rate is as follows:

	2016		2015	
U.S. federal statutory rate	35.00	%	34.00	%
Warrant liability	-	%	3.71	%
State & local taxes	(5.21)%	5.78	%
Tax on foreign operations	-	%	0.36	%
State research and development credits	1.87	%	1.47	%
Other	0.97	%	(3.11)%
Valuation allowance	(32.63	3)%	(42.21)%
Effective tax rate	-	%	-	%

Significant components of the Company's deferred tax assets as of December 31, 2016 and 2015 are as follows:

	2016	2015
Deferred tax assets:		
Net operating loss carry forwards	\$29,861,148	\$29,092,799
Research and development credits	1,220,115	1,163,616
Nonqualified stock option compensation expense	537,037	374,769
Other temporary book - tax differences	254,813	258,445
Total deferred tax assets	31,873,112	30,889,629
Valuation allowance for deferred tax assets	(31,873,112)	(30,889,629)
Net deferred tax assets	\$-	\$-

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 9 - Income Taxes (continued)

A valuation allowance has been recognized to offset the Company's net deferred tax asset as it is more likely than not that such net asset will not be realized. The Company primarily considered its historical loss and potential Internal Revenue Code Section 382 limitations to arrive at its conclusion that a valuation allowance was required. The Company's valuation allowance increased \$983,483 from December 31, 2015 to December 31, 2016.

At December 31, 2016, the Company had Federal income tax net operating loss carryforwards of \$79,458,888 and New Jersey income tax net operating loss carryforwards of \$19,233,370. Foreign income tax net operating loss carryforwards were \$7,403,077 as of December 31, 2016. The Company also had Federal research tax credit carryforwards of \$1,220,115 at December 31, 2016 and \$1,163,616 at December 31, 2015. The Company's net operating losses and research credits may ultimately be limited by Section 382 of the code and, as a result, it may be unable to offset future taxable income (if any) with losses, or its tax liability with credits, before such losses and credits expire. The Federal and New Jersey net operating loss carryforwards and Federal tax credit carryforwards will expire at various times between 2017 and 2035 unless utilized.

The Company has analyzed the tax positions taken or expected to be taken in its tax returns and concluded it has no liability related to uncertain tax positions. It is the Company's policy to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Note 10 - Stock Plans, Share-Based Payments and Warrants

Stock Plans

In 2015, the Board of Directors adopted the Nephros, Inc. 2015 Equity Incentive Plan ("2015 Plan"). Under the 2015 Plan, 7,000,000 shares are reserved and authorized for awards and the maximum contractual term is 10 years for stock options issued under the 2015 Plan.

The Company's previously adopted and approved plan, the 2004 Stock Incentive Plan ("2004 Plan"), expired in the year ended December 31, 2014.

As of December 31, 2016, 3,042,568 options had been issued to employees under the 2015 Plan and were outstanding. The options issued to employees expire on various dates between May 7, 2025 and December 14, 2026. As of December 31, 2016, 281,656 options had been issued to non-employees under the 2015 Plan, were outstanding and will expire on various dates between May 31, 2021 and May 7, 2025. Taking into account all options and restricted stock granted under the 2015 Plan, 1,865,610 shares are available for future grant under the 2015 Plan. Options currently outstanding are fully vested or will vest upon a combination of the following: immediate vesting, performance-based vesting or straight line vesting of two or four years. Of the 3,042,568 options granted to employees, 1,604,725 options will vest when the specified performance condition is met.

As of December 31, 2016, 475,263 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between January 6, 2019 and February 5, 2024. As of December 31, 2016, 792,861 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 30, 2017 and November 17, 2024. No shares are available for future grants under the 2004 Plan. Options currently outstanding are fully vested or are currently vesting over a period of four years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 - Stock Plans, Share-Based Payments and Warrants (continued)

Share-Based Payment

Expense is recognized, net of expected forfeitures, over the vesting period of the options. Stock based compensation expense recognized for the years ended December 31, 2016 and 2015 was approximately \$388,000 and approximately \$328,000, respectively. Approximately \$5,000 of total stock based compensation expense is the result of a modification of stock options awards issued to a non-employee director who is no longer serving as a director for the Company.

Approximately \$363,000 and \$306,000, respectively, has been recognized in Selling, General and Administrative expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2016 and 2015. Approximately \$25,000 and \$22,000, respectively, has been recognized in Research and Development expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2016 and 2015.

The following table summarizes the option activity for the years ended December 31, 2016 and 2015:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2014	2,472,234	\$ 0.96
Options granted	2,911,829	0.56
Options forfeited or expired	(1,080,425)	1.28
Outstanding at December 31, 2015	4,303,638	0.65
Options granted	510,520	0.37
Options forfeited or expired Outstanding at December 31, 2016	(221,811) 4,592,347	1.04 \$ 0.60

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2016 and 2015:

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2015	1,377,665	\$ 0.84
Vested and expected to vest at December 31, 2015	4,133,932	\$ 0.66
Exercisable at December 31, 2016	1,866,019	\$ 0.70
Vested and expected to vest at December 31, 2016	4,434,220	\$ 0.61

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 - Stock Plans, Share-Based Payments and Warrants (continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the below assumptions for the risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility.

	Option Pricing			
	Assumptions			
Grant Year	2016		2015	
Stock Price Volatility	114.6	3%	121.9	0%
Risk-Free Interest Rates	1.81	%	1.60	%
Expected Life (in years)	5.83		6.15	
Expected Dividend Yield	0	%	0	%

Expected volatility is based on historical volatility of the Company's common stock at the time of grant. The risk-free interest rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected life of the options. For the expected life, the Company is using the simplified method as described in the SEC Staff Accounting Bulletin 107. This method assumes that stock option grants will be exercised based on the average of the vesting periods and the option's life.

The weighted-average fair value of options granted in 2016 and 2015 is \$0.31 and \$0.49, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2016 are approximately \$25,000 and \$24,000, respectively. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest is 7.8 years.

The aggregate intrinsic values of stock options outstanding and of stock options vested or expected to vest as of December 31, 2015 are \$0. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest is 8.5 years.

As of December 31, 2016, there was approximately \$934,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately \$158,000 of the \$934,000 total unrecognized compensation will be recognized at the time if and when certain performance conditions are met. The remaining approximately \$776,000 will be amortized over the weighted average remaining requisite service period of 2.2 years.

Restricted Stock Issued to Employees and Directors

The Company has issued restricted stock as compensation for the services of certain employees and non-employee directors. The grant date fair value of restricted stock was based on the fair value of the common stock on the date of grant, and compensation expense is recognized based on the period in which the restrictions lapse.

The following table summarizes restricted stock activity for the year end December 31, 2016 and 2015:

		Weighted	
		Average	
	Shares	Grant	
	Shares	Date	
		Fair	
		Value	
Nonvested at December 31, 2014	132,077	\$ 0.86	
Granted	617,795	0.48	
Vested	(248,690)	0.73	
Nonvested at December 31, 2015	501,182	0.46	
Granted	957,336	0.35	
Vested	(501,182)	0.46	
Nonvested at December 31, 2016	957,336	\$ 0.35	

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 - Stock Plans, Share-Based Payments and Warrants (continued)

The total fair value of restricted stock which vested during the years ended December 31, 2016 and 2015 was approximately \$291,000 and \$181,000, respectively.

Total stock-based compensation expense for the restricted stock granted to employees and non-employee directors was approximately \$163,000 and \$161,000, respectively, for the years ended December 31, 2016 and December 31, 2015 and is included in Selling, General and Administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. Approximately \$51,000 and \$36,000 of restricted stock was granted to employees for the years ended December 31, 2016 and 2015, respectively, to settle liabilities for services incurred in the respective prior fiscal years. As of December 31, 2016, there was approximately \$178,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next six months.

Restricted Stock Issued to Nonemployees

In March 2016, 57,143 shares of restricted stock, with a fair value of approximately \$16,000, were issued as payment for consulting services to be provided through December 2016. The Company recorded approximately \$16,000 of selling, general and administrative expense during the year ended December 31, 2016. The restricted stock vested on June 15, 2016.

In March 2016, 38,461 shares of restricted stock, with a fair value of approximately \$10,000, were issued as payment for consulting services to be provided during the fiscal year ended December 31, 2016. The Company recorded approximately \$10,000 of selling, general and administrative expense during the year ended December 31, 2016. The restricted stock vested on September 30, 2016.

In January 2016, 58,823 shares of restricted stock, with a fair value of approximately \$20,000, were issued as payment for consulting services to be provided through December 2016. The Company recorded approximately \$20,000 of

selling, general and administrative expense during the year ended December 31, 2016. The restricted stock vested on April 12, 2016.

In September 2015, 47,382 shares of restricted stock, with a fair value of approximately \$23,000, were issued as payment for marketing services to be provided in fiscal year 2015. The Company recorded approximately \$23,000 of selling, general and administrative expense during the year ended December 31, 2015. The restricted stock vested on November 25, 2015.

In July 2015, 69,231 shares of restricted stock, with a fair value of approximately \$45,000, were issued as payment for marketing services to be provided through November 2015 under the Company's agreement with Proactive Capital Resources Group. The Company recorded approximately \$45,000 of selling, general and administrative expense during the year ended December 31, 2015. The restricted stock vested on August 7, 2015.

Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as derivative liabilities if the stock warrants allow for cash settlement or provide for modification of the warrant exercise price in the event that subsequent sales of common stock are at a lower price per share than the then-current warrant exercise price. The Company classifies derivative warrant liabilities on the balance sheet as a long-term liability, which is measured to fair value at each balance sheet date subsequent to the initial issuance of the stock warrant.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 - Stock Plans, Share-Based Payments and Warrants (continued)

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2016 and 2015:

Total Outstanding Warrants

				Total Common Shares Issuable as of	
			Exercise		
				December 31,	
Title of Warrant	Date Issued	Expiry Date	Price	2016	2015
Equity-classified warrants					
Shareholder Rights Offering Warrants	3/10/2011	3/10/2016	\$ 0.40	-	1,565,414
May 2015 - private placement warrants	3/18/2015	3/18/2020	\$ 0.85	917,149	917,149
June 2016 – Note and Warrant Agreement	6/7/2016	6/7/2021	\$ 0.30	2,374,000	-
				3,291,149	2,482,563
Total				3,291,149	2,482,563

The weighted average exercise price of the outstanding warrants was \$0.45 as of December 31, 2016 and \$0.57 as of December 31, 2015.

Warrants exercised during 2016 and 2015

During the twelve months ended December 31, 2016, 19,621 warrants were exercised, resulting in proceeds of approximately \$1,000 and the issuance of 906 shares of the Company's common stock.

On December 18, 2015, the Company completed its offer to exercise (the "Offer to Exercise") certain outstanding warrants to purchase an aggregate of 5,008,689 shares of the Company's common stock, consisting of outstanding warrants to purchase an aggregate of 2,226,112 shares of the Company's common stock at an exercise price of \$0.40 per share, issued on March 10, 2011 to investors participating in the Company's 2011 rights offering (the "Rights Offering Warrants") and outstanding warrants to purchase an aggregate of 2,782,577 shares of the Company's common stock at an exercise price of \$0.40 per share, issued on March 10, 2011 to Lambda in connection with a private placement financing transaction (the "Lambda Warrants" and, together with the Rights Offering Warrants, the "2011 Warrants"). Pursuant to the Offer to Exercise, 2011 Warrants to purchase an aggregate of 3,442,521 shares of the Company's common stock were tendered by their holders and were exercised in connection therewith. Gross proceeds of approximately \$688,000 were received by the Company on December 23, 2015.

The 2011 Warrants of holders who elected to participate in the Offer to Exercise were exercisable at a temporarily reduced cash exercise price of \$0.20 per share of common stock beginning on November 20, 2015 and expiring on December 18, 2015. The incremental value of the 2011 Warrants exercised pursuant to the Offer to Exercise on November 20, 2015, after the modification, was approximately \$106,000. As a result, approximately \$73,000 was recorded as a deemed dividend for the year ended December 31, 2015.

During the twelve months ended December 31, 2015, in addition to those warrants exercised during Offer to Exercise period above and those warrants exercised by Lambda on September 29, 2015 (see Note 3), 2,127 shares of common stock were issued as a result of additional warrants exercised, resulting in proceeds of \$851.

In addition, 30 common shares were not issued as a result of warrant exercises for the years ended December 31, 2015 due to rounding.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 11 - Stockholders' Equity (Deficit)

July 2015 Purchase Agreement and Registration Rights Agreement

On July 24, 2015, the Company entered into a Purchase Agreement, together with a Registration Rights Agreement, with Lincoln Park, an Illinois limited liability company.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to \$10.0 million in shares of the Company's common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 200,000 shares depending upon the closing sale price of the common stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than \$500,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price as set forth in the Purchase Agreement. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then-outstanding shares of the common stock.

In connection with the Purchase Agreement, the Company issued to Lincoln Park 250,000 shares of common stock for no proceeds. The fair value of the 250,000 shares of common stock issued was approximately \$163,000 and was recorded as a commitment fee. Pursuant to the Purchase Agreement, in September 2015, the Company issued and sold an additional 300,000 shares of common stock to Lincoln Park at a per share price of \$0.45, resulting in gross proceeds of \$135,000. The commitment fee of \$163,000 was fully amortized and recorded in additional paid-in capital as of December 31, 2015.

The Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. There are no trading volume requirements or restrictions under the Purchase Agreement. Lincoln Park has no right to require any sales by the Company, but is obligated to make purchases from the Company as the Company directs in accordance with the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of Company shares.

May 2015 Private Placement

On May 18, 2015, the Company raised gross proceeds of approximately \$1.23 million through the private placement of 1,834,299 units of its securities. Each unit consisted of one share of its common stock and a five-year warrant to purchase one-half of one share of the Company's common stock. The purchase price for each unit was \$0.67. The 917,149 warrants issued are equity-classified and are exercisable at a price of \$0.85 per share. Proceeds net of equity issuance costs of \$24,000 were recorded as a result of the private placement was approximately \$1,205,000.

Note 12 - 401(k) Plan

The Company has established a 401(k) deferred contribution retirement plan (the "401(k) Plan") which covers all employees. The 401(k) Plan provides for voluntary employee contributions of up to 15% of annual earnings, as defined. As of January 1, 2004, the Company matches 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. The Company contributed and expensed \$44,000 and \$42,000 in 2016 and 2015, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13 - Commitments and Contingencies

Manufacturing and Suppliers

The Company has not and does not intend in the near future, to manufacture any of its products and components. With regard to the OLpur MD190 and MD220, on June 27, 2011, the Company entered into a license agreement, effective July 1, 2011, with Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where the Company does not sell the Products as well as non-European countries (referred to as the "Territory").

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the "First Amendment"), by and between the Company and Bellco, which amends the License Agreement, entered into as of July 1, 2011 by and between the Company and Bellco. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include, on an exclusive basis, Sweden, Denmark, Norway and Finland and on a non-exclusive basis, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. The Company has agreed to reduce the fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (approximately \$1.91) per unit; thereafter, €1.25 (approximately \$1.36) per unit. In addition, the Company received a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that the Company pursues a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, the Company will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.

License and Supply Agreement

On April 23, 2012, the Company entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products (collectively, the "Filtration Products"), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, the Company granted to Medica an exclusive license under the Company's intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, the Company agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$1,000,000) for the years 2012, 2013 and 2014, respectively. The Company's aggregate purchase commitments totaled approximately €1,200,000 (approximately \$1,300,000) and €999,000 (approximately \$1,119,000) for the years ended December 31, 2016 and 2015, respectively. For calendar years 2017 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. The Company has not yet formalized an agreed upon minimum purchase level for 2017 with Medica. In exchange for the license, the Company paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013.

As further consideration for the license and other rights granted to the Company, the Company granted Medica options to purchase 300,000 shares of the Company's common stock. The fair market value of these stock options was approximately \$273,000 at the time of their issuance, calculated as described in Note 2 under Stock-Based Compensation. The fair market value of the options, along with the total installment payments, is approximately \$2,250,000 and has been capitalized as a long-term intangible asset on the consolidated balance sheet. As of December 31, 2016 and 2015, accumulated amortization related to the Medica long-term asset is approximately \$988,000 and \$777,000, respectively. The Medica long-term asset is being amortized as an expense over the life of the agreement. Approximately \$211,000 has been charged to amortization expense for the years ended December 31, 2016 and 2015 on the consolidated statement of operations and comprehensive loss. Approximately \$210,000 of amortization expense will be recognized in each of the years ended December 31, 2017 through 2022. In addition, for the period beginning April 23, 2014 through December 31, 2022, the Company will pay Medica a royalty rate of 3% of net sales of the Filtration Products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. Royalty expense of approximately \$18,000 and \$14,000, respectively was included in accrued expenses as of December 31, 2016 and 2015. The term of the License and Supply Agreement commenced on April 23, 2012 and continues in effect through December 31, 2022, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13 - Commitments and Contingencies (continued)

As of September 2013, the Company has an understanding with Medica whereby the Company has agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms. For each of the fiscal years ended December 31, 2016 and 2015, approximately \$41,000 was recognized as interest expense.

Contractual Obligations

The Company had an operating lease that expired on November 30, 2015 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately \$8,000. The rental agreement was renewed with a monthly cost of approximately \$9,000 and will expire in November 2018. Approximately \$21,000 related to a security deposit for the U.S. office facility is classified as an other asset on the consolidated balance sheet as of December 31, 2016 and 2015. We use these facilities to house our corporate headquarters and research facilities.

The lease agreement for the office space in Europe was entered into on August 1, 2016 and includes a twelve month term.

Rent expense for the years ended December 31, 2016 and 2015 totaled \$126,000 and \$125,000, respectively.

Investment in Lease, net

On October 8, 2015, the Company entered into an equipment lease agreement with Biocon 1, LLC. The lease commenced on January 1, 2016 with a term of 60 months and monthly rental payments of approximately \$1,800 will be paid to the Company. At the completion of the lease term, Biocon 1, LLC will own the equipment provided under the agreement. An investment in lease was established for the sales-type lease receivable at the present value of the

Table of Contents

future minimum lease payments. Interest income will be recognized monthly over the lease term using the effective-interest method. Cash received will be applied against the direct financing lease receivable and will be presented within changes in operating assets and liabilities in the operating section of the Company's consolidated statement of cash flows. At lease inception, an investment in the lease of approximately \$92,000 was recorded, net of unearned interest of approximately \$14,000. During the fiscal year ended December 31, 2016, approximately \$5,000 was recognized in interest income. As of December 31, 2016, investment in lease, current, is approximately \$27,000, net of unearned interest of \$4,000. As of December 31, 2016, investment in lease, noncurrent, is approximately \$61,000, net of unearned interest of \$5,000.

As of December 31, 2016, scheduled maturities of minimum lease payments receivable were as follows:

2016	\$13,000
2017	17,000
2018	18,000
2019	19,000
2020	21,000
	88,000
Less: Current portion	(27,000)
Investment in sales-type lease, noncurrent	\$61,000

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13 - Commitments and Contingencies (continued)

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2016:

	Payments Due in Period			
	Total	Within	Years	Years
		1 Year	2 - 3	4 - 5
Leases ¹	\$240,000	\$116,000	\$118,000	\$6,000
Employment Contract ²	550,000	240,000	310,000	-
Total	\$790,000	\$356,000	\$428,000	\$6,000

¹In addition to lease obligations for office space, obligations include a lease for various office equipment which expires in 2020.

²Relates to employment agreement with Daron Evans, the Company's President and Chief Executive Officer, entered into on April 15, 2015 for a term of four years.

Note 14 – Subsequent Event

On March 17, 2017, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers identified therein. Pursuant to the Purchase Agreement, the Company agreed to issue and sell, and the purchasers agreed to purchase, an aggregate of 4,059,994 shares at a price of \$0.30 per share for total gross proceeds of approximately \$1.2 million. In addition, the Company will issue to the purchasers warrants to purchase an

Table of Contents

aggregate of 4,059,994 shares of common stock. The warrants will have an exercise price of \$0.30 per share and will be exercisable for a five-year term. The purchase and sale of the shares and warrants is expected to close on or about March 22, 2017, subject to satisfying customary closing conditions. Additionally, the Company entered into a Registration Rights Agreement with such purchasers, pursuant to which the Company has agreed to file a registration statement with the SEC covering the resale of the shares of common stock and shares issuable upon the exercise of the warrants within thirty days of the closing date. Maxim Group LLC ("Maxim") is acting as the sole placement agent for the offering, and the Company has agreed to pay Maxim a cash fee equal to 7.5% of the aggregate gross proceeds of the offering, to reimburse Maxim for certain expenses, and to grant Maxim a warrant to purchase 81,199 shares of common stock, upon substantially the same terms as the warrants issued to the purchasers, except that the warrant issued to Maxim will have an exercise price of \$0.33 per share.