

NEPHROS INC  
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PROSPECTUS  
Registration No. 335-205169

**NEPHROS, INC.**

**2,751,448 Shares of Common Stock**

The selling stockholders identified beginning on page 21 of this prospectus are offering on a resale basis a total of 2,751,448 shares of our common stock, of which 917,149 are issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Shares of our common stock are quoted on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, under the ticker symbol "NEPH." On April 19, 2017, the closing sales price for our common stock was \$0.34 per share. The shares of common stock issued upon the exercise of warrants will also be quoted on the OTCQB under the same ticker symbol. The warrants are not listed for trading on any stock exchange or market or quoted on the OTCQB.

**Investing in our common stock involves substantial risks. See "Risk Factors" beginning on page 8 of this prospectus to read about important factors you should consider before purchasing our common stock.**

**We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is April 20, 2017.



NEPHROS, INC.

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## **ABOUT THIS PROSPECTUS**

We refer to Nephros, Inc. and its consolidated subsidiary as “Nephros”, the “Company”, “we”, “our”, and “us”. This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, which we refer to as the SEC or the Commission, utilizing a registration process. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus before making a decision whether to invest in the common stock. You should also read and consider the information contained in the exhibits filed with our registration statement, of which this prospectus is a part, as described in “Where You Can Find More Information” in this prospectus.

You should rely only on the information contained in this prospectus and any applicable prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. We are not offering to sell or soliciting offers to buy, and will not sell, any securities in any jurisdiction where it is unlawful. You should assume that the information contained in this prospectus or any prospectus supplement, as well as information contained in a document that we have previously filed or in the future will file with the SEC is accurate only as of the date of this prospectus, the applicable prospectus supplement or the document containing that information, as the case may be.

## **PROSPECTUS SUMMARY**

*This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. For a more complete understanding of our business, you should read this summary together with the more detailed information and financial statements for the years ended December 31, 2016 and 2015, and related notes appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the “Risk Factors” section beginning on page 8 and the “Special Note Regarding Forward-Looking Statements” section beginning on page 19. This prospectus contains important information that you should consider when making your investment decision.*

### **About the Company**

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.

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 had 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 HydraGuard™ 10” Ultrafilter. We expect to begin shipping HydraGuard™ 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 <http://www.nephros.com/infection-control/>. 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 EndoPur™ 10” Endotoxin filter, which is designed to fit in the existing cartridge housing of a dialysis clinic’s large RO water system. We expect to begin shipping the EndoPur™ 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'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 EndoPur™ 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 [www.nephros.com](http://www.nephros.com).

## **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.



## Recent Developments

On March 17, 2017, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement, referred to as the 2017 Private Placement, a total of 4,059,994 units of our securities, each unit consisting of one share of our common stock and a five-year warrant to purchase one share of our common stock, referred to as the 2017 Warrants. The closing of the 2017 Private Placement occurred on March 22, 2017. The purchase price for each unit was \$0.30. The 2017 Warrants are exercisable at a price of \$0.30 per warrant share and will be exercisable for a five-year term. The sale of the shares and 2017 Warrants resulted in aggregate gross proceeds of approximately \$1.218 million, before deducting expenses. Additionally, we entered into a registration rights agreement with such purchasers, pursuant to which we 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 2017 Warrants within thirty days of the closing date. Maxim Group LLC acted as the sole placement agent for the offering, and we paid Maxim a cash fee equal to 7.5% of the aggregate gross proceeds of the offering, to reimburse Maxim for certain expenses, and granted Maxim a warrant to purchase 81,199 shares of common stock, upon substantially the same terms as the 2017 Warrants, except that the warrant issued to Maxim has an exercise price of \$0.33 per share.

## Where You Can Find More 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>.

## The Offering

*The following summary describes the principal terms of the offering, but is not intended to be complete.*

|                    |  |
|--------------------|--|
| Securities Offered | 2,751,448 shares of common stock, including 917,149 shares of common stock issuable upon exercise of certain outstanding warrants. |
|--------------------|--|

Use of Proceeds We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which we expect to use to further develop our products and for general working capital purposes.

Risk Factors The acquisition of our common stock involves substantial risks. See “Risk Factors” beginning on page 8 of this prospectus.

OTCQB Symbol NEPH

## **RISK FACTORS**

*An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus, before you decide whether to buy our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition and results of operations.*

### **Risks Related to Our Company**

*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.*

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 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. Based on our current cash flow projections and the approximately \$1.2 million raised in a private placement offering in March 2017 and projected increase in product sales from the launch of new products we may be able to fund our operations at least into 2018, if not longer, depending on the timing and market acceptance of our new products. If we are unable to generate cash flow from our operating activities by such time, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we may be required to cease operations.

*We have a history of operating losses and a significant accumulated deficit, and we may not achieve or maintain profitability in the future.*

As of December 31, 2016, we had an accumulated deficit of approximately \$120,285,000, as a result of historical operating losses. While we believe that the revenues following the launch of our new products will help us achieve profitability, there can be no guarantee. We may continue to incur additional losses in the future depending on the timing and marketplace acceptance of our new products and as a result of operating expenses being higher than our gross margin from product sales. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

the market acceptance 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; and  
our ability to continue to develop products and maintain a competitive advantage in our industry.

***If we violate any provisions of the FDCA or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.***

We face a significant compliance burden under the U.S. Food, Drug and Cosmetic Act, or the FDCA, and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our medically approved products.

On May 28, 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. On August 12, 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 had 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.

If we violate the FDCA or other regulatory requirements (either with respect to our POU or DSU ultrafilters or otherwise) at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including:

- fines;
- injunctions;
- civil penalties;
- recalls or seizures of products;
- total or partial suspension of the production of our products;
- withdrawal of any existing approvals or pre-market clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations that we not be allowed to enter into government contracts; and
- criminal prosecution.

Any of the above could have a material adverse effect on our business, financial condition and results of operations.

***We cannot assure you that our products will be safe or that there will not be product-related deaths, serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.***

We cannot assure you that our products will prove to be safe or that there will not be product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm.

Under the FDCA, we are required to submit medical device reports (“MDRs”) to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;
- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions;
- and

if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products.

***Product liability associated with the production, marketing and sale of our products, and/or the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our reputation.***

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Voluntary recalls could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance for our products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and adversely affect the demand for our products, our ability to generate sales and our profitability.

Some of the agreements that we may enter into with manufacturers of our products and components of our products may require us:

to obtain product liability insurance; or  
to indemnify manufacturers against liabilities resulting from the sale of our products.

For example, the agreement with our contract manufacturer (“CM”) requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, provided they do not arise out of our CM’s breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, then we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. 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.

***We face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues.***

We do not yet have an established market or customer base for our products. Acceptance of our products in the marketplace by both potential users, including chronic renal failure patients, and potential purchasers, including nephrologists, dialysis clinics and other health care providers, is uncertain, and our failure to achieve sufficient market

acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform dialysis patients and nephrologists, dialysis clinics and other health care providers of the benefits of using our products. We may encounter significant clinical and market resistance to our products and our products may never achieve market acceptance. We may not be able to build key relationships with physicians, clinical groups and government agencies, pursue or increase sales opportunities in Europe or elsewhere, or be the first to introduce hemodiafiltration therapy in the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Factors that may affect our ability to achieve acceptance of our chronic renal failure therapy products in the marketplace include whether:

- such products will be safe for use;
- such products will be effective;
- such products will be cost-effective;
- we will be able to demonstrate product safety, efficacy and cost-effectiveness;
- there are unexpected side effects, complications or other safety issues associated with such products; and
- government or third party reimbursement for the cost of such products is available at reasonable rates, if at all.

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance and endurance standards. Our water filtration products and technology may not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial, military, industrial or retail applications.



Many of the same factors that may affect our ability to achieve acceptance of our chronic renal failure therapy products in the marketplace will also apply to our water filtration products, except for those related to side effects, clinical trials and third party reimbursement.

***If we are not able to successfully scale-up production of our products, then our sales and revenues will suffer.***

In order to commercialize our products, we need to be able to produce them in a cost-effective way on a large scale to meet commercial demand, while maintaining extremely high standards for quality and reliability. The extent to which we fail to successfully commercialize our products will limit our ability to be profitable.

We expect to rely on a limited number of independent manufacturers to produce our products. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, if any, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

***If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute our products effectively and/or customers may decide not to order our products. In either case, our sales and revenues will suffer.***

Our strategy requires us to distribute our products and provide a significant amount of customer service and maintenance and other technical service. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost-effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products and our sales and revenues will suffer.

***We have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.***

Our business strategy depends in part on our ability to sell our products to hospitals and other healthcare facilities that include dialysis clinics. We have limited experience with respect to sales and marketing. If we are unsuccessful at manufacturing, marketing and selling our products, our operations and potential revenues will be materially adversely affected.

***We cannot sell our products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. If we fail to receive, or experience a significant delay in receiving, such approvals and clearances, then we may not be able to get our products to market and enhance our revenues.***

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We have obtained a Conformité Européene (“CE”) mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpūr mid dilution hemodiafilter series product and our Dual Stage Ultrafilter (“DSU”). We have not yet obtained the CE mark for any of our other products. On April 30, 2012, we announced that we received clearance from the FDA to market our OLpūr MD220 Hemodiafilter and OLpūr H2H Module for use with a hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of chronic renal failure patients. We have not begun to broadly market these products and are actively seeking a commercialization partner in the United States.

There is no assurance that any existing products that have not yet been approved, or any new products developed by us in the future, will be approved for marketing. The clearance and/or approval processes can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or regulatory approval for any of our existing or new products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals would prevent us from selling our affected products in the applicable regions. If we cannot sell some of our products in such regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

We intend to market our products globally. Requirements pertaining to the sale of our products vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our products in many countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our products in a particular region, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

***Clinical studies that may be required for our products are costly and time-consuming, and their outcome is uncertain.***

Before obtaining regulatory approvals for the commercial sale of any of our products, other than those for which we have already received marketing approval in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our products are safe and effective, we will not obtain marketing approvals from the applicable regulatory authorities. In particular, one or more of our products may not exhibit the expected medical benefits, may cause harmful side effects, may not be effective in treating dialysis patients or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

- slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;
- lower than expected retention rates of subjects in a clinical trial;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's review board, or other required approvals;
- longer treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product;  
adverse medical events or side effects in treated subjects; and  
lack of effectiveness of the product being tested.

Even if we obtain positive results from clinical studies for our products, we may not achieve the same success in future studies of such products. Data obtained from clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in regulatory policy for device approval during the period of product development and regulatory review of each submitted new device application. Moreover, regulatory approval may entail limitations on the indicated uses of the device. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products. Additionally, we may be unable to complete our clinical trials if we are unable to obtain additional capital.

***We may be required to design and conduct additional clinical trials.***

We may be required to design and conduct additional clinical trials to further demonstrate the safety and efficacy of our products, which may result in significant expense and delay. Regulatory agencies may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials, a possible failure to conduct clinical trials in complete adherence to certain regulatory standards, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our products. It is possible that regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

***Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales and revenues.***

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. Any future laws, regulations, interpretations, applications or enforcements could delay or prevent regulatory approval or clearance of our products and our ability to market our products. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

***Protecting our intellectual property in our technology through patents may be costly and ineffective. If we are not able to adequately secure or enforce protection of our intellectual property, then we may not be able to compete effectively and we may not be profitable.***

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 18 granted U.S. patents will expire at various times from 2018 to 2027, assuming they are properly maintained.

The protection provided by our patents, and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. Numerous publications may have been disclosed by, and numerous patents may have been issued to, our competitors and others relating to methods and devices for dialysis of which we are not aware and additional patents relating to methods and devices for dialysis may be issued to our competitors and others in the future. If any of those publications or patents conflict with our patent rights, or cover our products, then any or all of our patent applications could be rejected and any or all of our granted patents could be invalidated, either of which could materially adversely affect our competitive position.

Litigation and other proceedings relating to patent matters, whether initiated by us or a third party, can be expensive and time-consuming, regardless of whether the outcome is favorable to us, and may require the diversion of substantial financial, managerial and other resources. An adverse outcome could subject us to significant liabilities to third parties or require us to cease any related development, product sales or commercialization activities. In addition, if patents that contain dominating or conflicting claims have been or are subsequently issued to others and the claims of these patents are ultimately determined to be valid, then we may be required to obtain licenses under patents of others in order to develop, manufacture, use, import and/or sell our products. We may not be able to obtain licenses under any of these patents on terms acceptable to us, if at all. If we do not obtain these licenses, we could encounter delays in, or be prevented entirely from using, importing, developing, manufacturing, offering or selling any products or practicing any methods, or delivering any services requiring such licenses.

If we file patent applications or obtain patents in foreign countries, we will be subject to laws and procedures that differ from those in the United States. Such differences could create additional uncertainty about the level and extent of our patent protection. Moreover, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be as favorable to us. Many non-U.S. jurisdictions, for example, prohibit patent claims covering methods of medical treatment of humans, although this prohibition may not include devices used for such treatment.

***If we are not able to secure and enforce protection of our trade secrets through enforcement of our confidentiality and non-competition agreements, then our competitors may gain access to our trade secrets, we may not be able to compete effectively and we may not be profitable. Such protection may be costly and ineffective.***

We attempt to protect our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. If these employees or other parties breach our confidentiality agreements and non-competition agreements, or if these agreements are not sufficient to protect our technology or are found to be unenforceable, then our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Policing unauthorized use of our trade secrets is difficult and expensive, particularly because of the global nature of our operations. The laws of other countries may not adequately protect our trade secrets.

***If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales and revenues will suffer.***

Approval or clearance of our products could be withdrawn, delayed or denied by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective

manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our products in the European Community. The FDA also imposes requirements through quality system requirements regulations, which include requirements for good manufacturing practices. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MD HDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.



***We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.***

We expect to manufacture and to market our products globally. Our international operations are subject to a number of risks, including the following:

fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;  
we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;  
local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;  
political instability could disrupt our operations;  
some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow;  
and  
some countries could impose additional taxes or restrict the import of our products.

Any one or more of these factors could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition and results of operations.

***If we are unable to maintain effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and the market price of our securities may be negatively affected.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to maintain internal control over financial reporting and to report any material weaknesses in such internal control. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We also are required to furnish a report by management on the effectiveness of our internal control over financial reporting. We perform system and process evaluation and testing of our internal controls over financial reporting to allow management to prepare and furnish such a report.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2014, we discovered that we had improperly accounted for our warrants as components of equity instead of as derivative liabilities, and our management and auditors determined that this resulted from a material weakness in internal control over financial reporting. This material weakness led to the need for the restatement of (i) our audited consolidated financial statements as of and for the years ended December 31, 2013, 2012, 2011, 2010 and 2009, including the cumulative effect as of January 1, 2009, and (ii) our unaudited condensed consolidated interim financial statements as

of, and for each of the quarterly periods ended, March 31, June 30, and September 30, in the years 2014 and 2013.

While the above material weakness has been remediated, if we are unable to maintain proper and effective internal control over financial reporting in the future, we may not be able to produce timely and accurate financial statements. If that were to happen, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

## **Risks Related to Our Common Stock and Warrants**

*There currently is a limited trading market for our Common Stock and stockholders may have difficulty in selling our Common Stock.*

We do not currently meet all of the requirements for initial listing of our Common Stock on a registered stock exchange. Our Common Stock is quoted on the OTCQB. Trading in our Common Stock on the OTCQB has been very limited. As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our Common Stock, and our Common Stock may be less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes. There is no guarantee that we will ever become listed on the Nasdaq Capital Market, or any other exchange, or that a liquid trading market for our Common Stock will develop. If an active public market for our common stock does not develop, stockholders may not be able to re-sell the common stock that they own and affect the value of their common stock.

*Our Common Stock could be further diluted as a result of the issuance of additional shares of Common Stock, warrants or options.*

In the past we have issued Common Stock and warrants in order to raise money. We have also issued stock options and restricted stock as compensation for services and incentive compensation for our employees, directors and consultants. We have shares of Common Stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional Common Stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our Common Stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our Common Stock), or could obligate us to issue additional shares of Common Stock.

Market sales of large amounts of our Common Stock, or the potential for those sales even if they do not actually occur, may have the effect of depressing the market price of our Common Stock, the supply of Common Stock available for resale could be increased which could stimulate trading activity and cause the market price of our Common Stock to drop, even if our business is doing well. Furthermore, the issuance of any additional shares of our Common Stock or securities convertible into our Common Stock could be substantially dilutive to holders of our Common Stock if they do not invest in future offerings.

*The prices at which shares of the Common Stock trade have been and will likely continue to be volatile.*

During the two years ended December 31, 2016, our Common Stock has traded at prices ranging from a high of \$0.96 to a low of \$0.20 per share. Due to the lack of an active trading market for our Common Stock, you should expect the prices at which our Common Stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our Common Stock. These include, but are not limited to:

- achievement or rejection of regulatory approvals by our competitors or us;
- publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;
- delays or failures in initiating, completing or analyzing clinical trials or the unsatisfactory design or results of these trials;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our results of operations;
- threatened or actual litigation;
- changes in financial estimates by securities analysts; and
- sales of our Common Stock.

We are not able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for medical technology companies in particular, has experienced extreme price and volume fluctuations in recent years that might have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors might seriously harm the market price of our Common Stock, regardless of our operating performance. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

***We have never paid dividends and do not intend to pay cash dividends.***

We have never paid dividends on our Common Stock and currently do not anticipate paying cash dividends on our Common Stock for the foreseeable future. Consequently, any returns on an investment in our Common Stock in the foreseeable future will have to come from an increase in the value of the stock itself. As noted above, the lack of an active trading market for our Common Stock will make it difficult to value and sell our Common Stock. While our dividend policy will be based on the operating results and capital needs of our business, it is anticipated that all earnings, if any, will be retained to finance our future operations.

***Because we are subject to the "penny stock" rules, you may have difficulty in selling our Common Stock.***

Our Common Stock is subject to regulations of the SEC relating to the market for penny stocks. Penny stock, as defined by the Penny Stock Reform Act, is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The penny stock regulations generally require that a disclosure schedule explaining the penny stock market and the risks associated therewith be delivered to purchasers of penny stocks and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. The broker-dealer must make a suitability determination for each purchaser and receive the purchaser's written agreement prior to the sale. In addition, the broker-dealer must make certain mandated disclosures, including the actual sale or purchase price and actual bid offer quotations, as well as the compensation to be received by the broker-dealer and certain associated persons. The regulations applicable to penny stocks may severely affect the market liquidity for your Common Stock and could limit your ability to sell your securities in the secondary market.

***Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our Common Stock.***

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our Common Stock could be reduced as a result. These provisions include:

- authorizing our board of directors to issue “blank check” preferred stock without stockholder approval;
- providing for a classified board of directors with staggered, three-year terms;
- prohibiting us from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

***As a smaller reporting company with little or no name recognition and with several risks and uncertainties that could impair our business operations, we are not likely to generate widespread interest in our Common Stock. Without widespread interest in our Common Stock, our Common Stock price may be highly volatile and an investment in our Common Stock could decline in value.***

Unlike many companies with publicly traded securities, we have little or no name recognition in the investment community. We are a relatively new company and very few investors are familiar with either our company or our products. We do not have an active trading market in our Common Stock, and one might never develop, or if it does develop, might not continue.

Additionally, the market price of our Common Stock may fluctuate significantly in response to many factors, many of which are beyond our control. Risks and uncertainties, including those described elsewhere in this “Risk Factors” section could impair our business operations or otherwise cause our operating results or prospects to be below expectations of investors and market analysts, which could adversely affect the market price of our Common Stock. As a result, investors in our Common Stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company’s securities. We may become subject to this type of litigation in the future. Litigation of this type could be extremely expensive and divert management’s attention and resources from running our company.

***Our directors, executive officers and Lambda Investors LLC control a significant portion of our stock and, if they choose to vote together, could have sufficient voting power to control the vote on substantially all corporate matters.***

As of March 31, 2017, Lambda Investors LLC, our largest stockholder, beneficially owned approximately 56% of our outstanding Common Stock. As a result of this ownership, Lambda has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda, whether acting alone or acting with other stockholders, could have the power to elect all of our directors and to control the vote on substantially all other corporate matters without the approval of other stockholders. Furthermore, such concentration of voting power could enable Lambda, whether acting alone or acting with other stockholders, to delay or prevent another party from taking control of our company even where such change of control transaction might be desirable to other stockholders. The interests of Lambda in any matter put before the stockholders may differ from those of any other stockholder.

***Future sales of our Common Stock could cause the market price of our Common Stock to decline.***

The market price of our Common Stock could decline due to sales of a large number of shares in the market, including sales of shares by Lambda or any other large stockholder, or the perception that such sales could occur. These sales could also make it more difficult or impossible for us to sell equity securities in the future at a time and price that we deem appropriate to raise funds through future offerings of Common Stock. Future sales of our Common Stock by stockholders could depress the market price of our Common Stock.

*Shares eligible for future sale may adversely affect the market.*

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of Common Stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after holding their shares for six months and affiliates may sell freely after holding their shares for one year, in each case, subject to current public information, notice and other requirements. Any substantial sales of our Common Stock pursuant to Rule 144 may have a material adverse effect on the market price of our Common Stock.



## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus constitute “forward-looking statements”. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the availability of funding sources for continued development of such products, and our ability to continue as a going concern and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

- we may not be able to continue as a going concern;
- we face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues;
- product-related deaths or serious injuries or product malfunctions could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products;
- we face potential liability associated with the production, marketing and sale of our products and the expense of defending against claims of product liability could materially deplete our assets and generate negative publicity which could impair our reputation;
- to the extent our products or marketing materials are found to violate any provisions of the FDCA or any other statutes or regulations then we could be subject to enforcement actions by the FDA or other governmental agencies;
- we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;
- we may not have sufficient capital to successfully implement our business plan;
- we may not be able to effectively market our products;
- we may not be able to sell our water filtration products or chronic renal failure therapy products at competitive prices or profitably;
- we may encounter problems with our suppliers, manufacturers and distributors;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and
- we may not be able to achieve sales growth in key geographic markets.

More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2016, is set forth in our filings with the SEC, including our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC’s web site at [www.sec.gov](http://www.sec.gov). We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.



## **DESCRIPTION OF 2015 PRIVATE PLACEMENT**

*The following description is qualified in its entirety by the terms and conditions of the Securities Purchase Agreement, which is incorporated by reference into the registration statement of which this prospectus forms a part, and the 2015 Warrants, the form of which is incorporated by reference into the registration statement of which this prospectus forms a part. The following description may not contain all the information with respect to the Securities Purchase Agreement and the 2015 Warrants that is important to you. We encourage you to read each of the Securities Purchase Agreement and the form of 2015 Warrant in its entirety.*

On May 12, 2015, we entered into a securities purchase agreement, referred to as the Securities Purchase Agreement, with various accredited investors pursuant to which we agreed to sell in a private placement, referred to as the 2015 Private Placement, a total of 1,834,299 units of our securities, each unit consisting of one share of our common stock and a five-year warrant to purchase one-half of one share of our common stock, referred to as the 2015 Warrants. The closing of the 2015 Private Placement occurred on May 19, 2015. The purchase price for each unit was \$0.67. The 2015 Warrants are exercisable at a price of \$0.85 per warrant share. The sale of the shares and 2015 Warrants resulted in aggregate gross proceeds of approximately \$1.23 million, before deducting expenses.

### **The 2015 Warrants**

The 2015 Warrants have a five-year term and are exercisable at a price of \$0.85 per share, subject to adjustment for stock splits, combinations and recapitalization events. The 2015 Warrants are required to be exercised for cash, provided that if during the term of the 2015 Warrants there is not an effective registration statement under the Securities Act covering the resale of the shares issuable upon exercise of the 2015 Warrants, then the 2015 Warrants may be exercised on a cashless (net exercise) basis.

If we effect any merger or consolidation, or any sale of all or substantially all of our assets or the majority of our shares are acquired by a third party, or any tender offer or exchange offer is completed, or we effect any reclassification or compulsory share exchange, the holder of the 2015 Warrant will have the right to receive on the exercise of the 2015 Warrant the kind and amount of securities, cash or other property which the holder would have owned or have been entitled to receive immediately after such reorganization, reclassification, consolidation, merger or reorganization had the 2015 Warrant been exercised immediately prior to the effective date of such transaction. Our consummation of any such transaction in which we are not the surviving entity will be contingent upon the assumption of the 2015 Warrants by the surviving party to such transaction.

### **Registration Rights**

Pursuant to the terms of the Securities Purchase Agreement, we agreed to file a registration statement with the SEC in order to register the resale of the shares of common stock issued in the 2015 Private Placement and the shares of common stock issuable upon exercise of the 2015 Warrants. In the event we did not file the registration statement by July 18, 2015, we would have been required to pay liquidated damages to the investors in the amount of 1% of such investor's aggregate investment amount each month until the registration statement was filed. The registration statement of which this prospectus forms a part covers the resale of the shares of common stock issued in the 2015 Private Placement, including the shares issued upon the exercise of the 2015 Warrants. We are required to maintain the effectiveness of the registration statement until all of the shares covered thereby are sold or may be sold pursuant to Rule 144 under the Securities Act without volume restrictions.

#### **USE OF PROCEEDS**

We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the 2015 Warrants, which would be used to further develop our products and for general working capital purposes.

**SELLING STOCKHOLDERS**

This prospectus covers the resale by the selling stockholders identified below of 2,751,448 shares of our common stock, of which 917,149 shares are issuable upon the exercise of certain outstanding warrants.

The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of March 31, 2017, and after giving effect to this offering, except as otherwise referenced below.

| Selling Stockholder                           | Shares beneficially owned before offering (1) | Number of shares outstanding offered by selling stockholder | Number of shares offered by stockholder upon exercise of warrants | Beneficial ownership after offering (1)<br>Number of shares | Percent |
|---|---|---|---|---|---------|
| Best Six, LLC (2)                             | 223,881                                       | 149,254   | 74,627  | -   | *       |
| Bumack LLC (3)                                | 55,971  | 37,314  | 18,657  | -   | *       |
| Crockett-Boragno Trust (4)                    | 55,971  | 37,314  | 18,657  | -   | *       |
| Patricia M. and Preston W. Evans, JTWROS      | 22,500  | 15,000  | 7,500   | -   | *       |
| Franklin Associates, LLC (5)                  | 111,945                                       | 74,630  | 37,315  | -   | *       |
| Allan Gordon                                  | 22,500  | 15,000  | 7,500   | -   | *       |
| Arlene R. and David Henick (6)                | 30,889  | 14,926  | 7,463   | 8,500   | *       |
| Karen Weil Revocable Trust u/a dtd 7/2/10 (7) | 270,000                                       | 100,000   | 50,000  | 120,000   | *       |
| Leon J. Laviolette (8)                        | 91,850  | 40,000  | 20,000  | 31,850  | *       |
| Stephen Todd Leis                             | 55,969  | 37,313  | 18,656  | -   | *       |
| Hsiao Dee Lieu                                | 22,500  | 15,000  | 7,500   | -   | *       |
| Lincoln Park Capital Fund, LLC (9)            | 2,675,000                                     | 150,000   | 75,000  | 2,450,000   | 4.5 %   |
| Theodore James Mallinson (10)                 | 142,403                                       | 94,030  | 47,015  | 1,358   | *       |
| Richard Molinski (11)                         | 222,637                                       | 37,314  | 18,657  | 166,666   | *       |
| Janet C. Persen (12)                          | 122,696                                       | 31,160  | 15,580  | 75,956  | *       |
| Fredric R. Rosenberg                          | 330,000                                       | 220,000   | 110,000   | -   | *       |
| Matthew Rosenberg (13)                        | 1,052,197                                     | 200,000   | 100,000   | 752,197   | 1.4 %   |
| Michael Rosenberg                             | 55,971  | 37,314  | 18,657  | -   | *       |
| Seligman Rosenberg (14)                       | 132,939                                       | 74,626  | 37,313  | 21,000  | *       |
| Lewis Schneider (15)                          | 1,495,332                                     | 100,000   | 50,000  | 1,345,332   | 2.4 %   |
| Robert W. Schubert (16)                       | 55,875  | 29,850  | 14,925  | 11,100  | *       |
| Joseph Schueller (17)                         | 704,893                                       | 100,000   | 50,000  | 554,893   | 1.0 %   |
| Peter Vasconcelos                             | 55,971  | 37,314  | 18,657  | -   | *       |
| James Waldron                                 | 112,500                                       | 75,000  | 37,500  | -   | *       |

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|                       |         |           |         |     |   |
|-----------------------|---------|-----------|---------|-----|---|
| Norman M. Whitton     | 67,164  | 44,776    | 22,388  | -   | * |
| L.E. Luke Wilson (18) | 101,306 | 67,164    | 33,582  | 560 | * |
| TOTALS                |         | 1,834,299 | 917,149 |     |   |

\* denotes less than 1%

Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein (1) that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares. Percentage of shares beneficially owned after the resale of all the shares offered by this prospectus assumes there are outstanding 55,077,697 shares of common stock, including all shares offered hereby that are issuable upon exercise of warrants.

- (2) Phyllis Rosenberg holds voting and/or dispositive power over the shares held by the selling stockholder.
- (3) Josh Lebewohl and Jeremy Lebewohl hold voting and/or dispositive power over the shares held by the selling stockholder.
- (4) Michael Crockett, trustee, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (5) Harrison Rosenberg holds voting and/or dispositive power over the shares held by the selling stockholder.
- (6) In addition to the shares offered hereby, beneficial ownership also includes 3,800 shares of our common stock held by Arlene Henick and 4,700 shares of our common stock held by David Henick.  
  
Karen Weil, trustee, holds voting and/or dispositive power over the shares held by the selling stockholder. In  
(7) addition to the shares offered hereby, beneficial ownership also includes 60,000 shares of our common stock and warrants to purchase 60,000 shares of our common stock.
- (8) In addition to the shares offered hereby, beneficial ownership also includes 31,850 shares of our common stock.  
  
Joshua Scheinfeld and Jonathan Cope, the principals of Lincoln Park are deemed to be beneficial owners of all of  
shares of common stock owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and dispositive  
(9) power over the shares being offered under this prospectus. In addition to the shares offered hereby, beneficial ownership also includes 1,650,000 shares of common stock and warrants to purchase 800,000 shares of our common stock.
- (10) In addition to the shares offered hereby, beneficial ownership also includes 1,358 shares of our common stock.
- (11) In addition to the shares offered hereby, beneficial ownership also includes 83,333 shares of our common stock and warrants to purchase 83,333 shares of our common stock.  
  
Ms. Persen is the spouse of Malcolm Persen, a director of the Company. In addition to the shares offered hereby,  
(12) beneficial ownership also includes 37,969 shares of restricted stock and 37,987 shares issuable upon the exercise of options to purchase common stock held by Malcolm Persen.
- (13) In addition to the shares offered hereby, beneficial ownership also includes 703,333 shares of our common stock and 48,864 shares issuable upon the exercise of options to purchase common stock.
- (14) In addition to the shares offered hereby, beneficial ownership also includes 21,000 shares of our common stock.
- (15) In addition to the shares offered hereby, beneficial ownership also includes 1,078,666 shares of our common stock and warrants to purchase 266,666 shares of our common stock.
- (16) In addition to the shares offered hereby, beneficial ownership also includes 11,100 shares of our common stock.
- (17) In addition to the shares offered hereby, beneficial ownership also includes 354,893 shares of our common stock and warrants to purchase 200,000 shares of our common stock.
- (18) In addition to the shares offered hereby, beneficial ownership also includes 560 shares of our common stock.





## PLAN OF DISTRIBUTION

We are registering the shares offered by this prospectus on behalf of the selling stockholders. The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders might be, and any broker-dealers that act in connection with the sale of securities will be, deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals will be deemed to be underwriting discounts or commissions under the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement that includes this prospectus effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement that contains this prospectus or (2) the date on which the shares may be sold without registration or restriction pursuant to Rule 144 of the Securities Act.



**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 2019. We are evaluating the impact of adopting this guidance on 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 incurred by such service providers. The majority of our service providers invoice us monthly in arrears for 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**

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

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. 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, €1.75 (approximately \$1.91) per unit; thereafter, €1.25 (approximately \$1.36) per unit. In addition, we 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 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 a 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 |                  |                |                | More<br>than<br>5<br>Years |
|-----------------------------------|------------------------|------------------|----------------|----------------|----------------------------|
|                                   | Total                  | Within<br>1 Year | Years<br>2 - 3 | Years<br>4 - 5 |                            |
| Leases <sup>1</sup>               | \$240,000              | \$116,000        | \$118,000      | \$6,000        | \$ -                       |
| Employment Contracts <sup>2</sup> | 550,000                | 240,000          | 310,000        | -              | -                          |
| Total                             | \$790,000              | \$356,000        | \$428,000      | \$6,000        | \$ -                       |

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

<sup>2</sup>Relates 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 had 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 HydraGuard™ 10” Ultrafilter. We expect to begin shipping HydraGuard™ 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 <http://www.nephros.com/infection-control/>. 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 EndoPur™ 10” Endotoxin filter, which is designed to fit in the existing cartridge housing of a dialysis clinic’s large RO water system. We expect to begin shipping the EndoPur™ 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 EndoPur™ 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 [www.nephros.com](http://www.nephros.com).

## **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 OLP<sub>ur</sub> 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<sup>®</sup> 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*



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 HydraGuard™ 10” Ultrafilter; and in March 2017, we announced that we received 510(k) clearance from the FDA to market our EndoPur™ 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<br>(as of<br>3/31/17) | Director<br>Since | Business Experience For The Last Five Years   |
|------------------------------|---------------------------|-------------------|---|
| <i>Class I<br/>Directors</i> |                           |                   |   |
| 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 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.<br>Mieyal | 47 | 2007 | <p>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 &amp; 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.</p> |
|-------------------|----|------|--|

| Name           | Age | Director Since | Business Experience For The Last Five Years  |
|----------------|-----|----------------|--|
| Malcolm Persen | 63  | 2015           | <p>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.</p> |

*Class III  
Directors*

|             |    |      |   |
|-------------|----|------|---|
| Daron Evans | 42 | 2013 | <p>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 &amp; 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 &amp; 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.</p> |
|-------------|----|------|---|

| <b>Age</b> | <b>Name</b> | <b>Director Since</b>  | <b>Business Experience For The Last Five Years</b>  |
|------------|-------------|------------------------|---|
|            |             | <b>(as of 3/31/17)</b> |   |
|            | Moshe Pinto | 42 2015                | 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 Synchron, 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.

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**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**

| <b>Name and Principal Position</b>           | <b>Year</b> | <b>Salary<br/>(\$)</b> | <b>Bonus<br/>(\$)<sup>(1)</sup></b> | <b>Stock<br/>Awards<br/>(\$)<sup>(2)</sup></b> | <b>Option<br/>Awards<br/>(\$)<sup>(2)</sup></b> | <b>All Other<br/>Compensation<br/>(\$)<sup>(3)</sup></b> | <b>Total</b> |
|--|-------------|------------------------|-------------------------------------|--|---|--|--------------|
| Daron Evans                                  | 2016        | \$240,000              | \$-                                 | \$68,182                                       | \$-   | \$17,880   | \$326,062    |
| President and Chief Executive Officer<br>(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

| Name        | Year | Matching<br>401(k) Plan<br>Contribution<br>(\$) | Health<br>Insurance<br>Paid by<br>Company<br>(\$) | Life<br>Insurance<br>Paid by<br>Company<br>(\$) | Severance<br>Payments<br>(\$) | Total Other<br>Compensation<br>(\$) |
|-------------|------|---|---|---|-------------------------------|-------------------------------------|
| 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        | Grant Date <sup>(1)</sup> | Option Awards  |  |   | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price (\$) | Option Expiration Date <sup>(3)</sup> | Stock Awards  |  |
|-------------|---------------------------|--|--|---|--|----------------------------|---------------------------------------|---|--|
|             |                           | Number of Securities Underlying Unexercised Options Exercisable (#) <sup>(2)</sup> | Number of Securities Underlying Unexercised Options Unexercisable (#) <sup>(2)</sup> | Number of Shares or Units of Stock that Have Not Vested (#) |  |                            |                                       | Market Value of Shares or Units That Have Not Vested (\$) |  |
| Daron Evans | 3/26/14                   | 75,361   | -  | -   | 0.46   | 3/26/24                    | -                                     | -   |  |
| Daron Evans | 5/15/15                   | 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 | 5/15/15    | 35% of the shares subject to the option vest in 16 equal quarterly installments over 4 years, commencing June 30, 2015  |
| Daron Evans | 5/15/15    | 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<br>Evans | 5/15/15 | 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<br>Evans | 5/15/15 | 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<br>Evans | 5/15/15 | 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 six months (or 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<br>Earned<br>or Paid<br>in Cash | Restricted<br>Stock<br>Awards <sup>(1)(2)</sup> | Option<br>Awards <sup>(3)(4)</sup> | Total    |
|----------------------------------|--------------------------------------|---|------------------------------------|----------|
| Arthur H. Amron <sup>(5)</sup>   | \$6,500                              | \$ 29,545                                       | \$ 10,994                          | \$47,039 |
| Paul A. Mieyal <sup>(5)</sup>    | \$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 <sup>(6)</sup> | \$-                                  | \$ 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.

- (4) As of December 31, 2016, Mr. Persen had 49,281 shares of common stock issuance upon exercise of vested 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 \$50,002; Fredric R. Rosenberg purchased 220,000 shares and warrants to purchase 110,000 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 committed to initiating a tender offer to the holders of all of our remaining outstanding warrants pursuant to which 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.

| <b>Plan Category</b>                                       | <b>(a)<br/>Number of<br/>securities to<br/>be issued<br/>upon<br/>exercise of<br/>outstanding<br/>options,<br/>warrants<br/>and rights</b> | <b>(b)<br/>Weighted-<br/>average<br/>exercise<br/>price of<br/>outstanding<br/>options,<br/>warrants<br/>and rights</b> | <b>(c)<br/>Number of<br/>securities<br/>remaining<br/>available for<br/>issuance<br/>under equity<br/>compensation<br/>plans<br/>(excluding<br/>securities<br/>reflected in<br/>column (a)<br/>and restricted<br/>stock granted<br/>under the<br/>2015 Plan)</b> |
|--|--|---|--|
| 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:

| <b>Name and Address of Beneficial Owner</b>                        | <b>Amount<br/>and Nature<br/>of<br/>Beneficial<br/>Ownership</b> | <b>Percentage<br/>of Class<br/>(1)</b> |   |
|--|--|--|---|
| Lambda Investors LLC <sup>(2)</sup>                                | 30,921,882   | 56.3                                   | % |
| Arthur H. Amron <sup>(3)</sup>                                     | -  | *                                      |   |
| Andrew Astor <sup>(4)</sup>  | 333,332  | *                                      |   |
| Daron Evans <sup>(5)</sup>   | 1,263,676  | 2.3                                    | % |
| Paul A. Mieyal <sup>(6)</sup>                                      | -  | *                                      |   |
| Malcolm Persen <sup>(7)</sup>                                      | 266,620  | *                                      |   |
| Moshe Pinto <sup>(8)</sup>   | 133,312  | *                                      |   |
| All executive officers and directors as a group <sup>(3)-(8)</sup> | 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) 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
- (2) 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 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 identified as being beneficially owned by Mr. Astor consist of: (i) 166,666 shares of common stock and (ii)
- (4) 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.

- (8) 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 issued to the investors in the 2015 Private Placement and to the shares of our common stock issuable upon the exercise of the 2015 Warrants. For a further description of the 2015 Warrants, see “Description of 2015 Private Placement – The 2015 Warrants.”*

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](http://www.sec.gov) and on our website at [www.nephros.com](http://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**

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**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



## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share and Per Share Amounts)

|   | December<br>31, 2016 | December<br>31, 2015 |
|---|----------------------|----------------------|
| <b>ASSETS</b>   |                      |                      |
| 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              |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                      |                      |
| 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  | 120,835              | 119,797              |
| Accumulated other comprehensive income  | 67                   | 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.*

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## NEPHROS, INC. AND SUBSIDIARY

## 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      | 48,583,165               | 34,780,506 |

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(In Thousands, Except Share Amounts)

|  | Common Stock<br>Shares | Common Stock<br>Amount | Additional<br>Paid-in<br>Capital | Other<br>Comprehensive<br>Income | Accumulated<br>Other<br>Comprehensive<br>Income<br>Deficit | Accumulated<br>Deficit | Stockholders'<br>Equity (Deficit)<br>Total |
|--|------------------------|------------------------|----------------------------------|----------------------------------|--|------------------------|--|
| Balance, December 31, 2014   | 30,391,513             | \$ 30                  | \$ 108,382                       | \$ 72                            |  | \$(114,165 )           | \$( 5,681 )                                |
| Net loss   |                        |                        |                                  |                                  |  | (3,088 )               | (3,088 )                                   |
| Net unrealized losses on foreign<br>currency translation, net of tax |                        |                        |                                  | (1 )                             |  |                        | (1 )                                       |
| Issuance of common stock, net of equity<br>issuance costs of \$24    | 1,834,299              | 2                      | 1,203                            |                                  |  |                        | 1,205                                      |
| Issuance of common stock, net of<br>commitment fee of \$163          | 550,000                | 1                      | 135                              |                                  |  |                        | 136  |
| Issuance of restricted stock   | 501,182                | 1                      | 174                              |                                  |  |                        | 175  |
| Issuance of restricted stock to a vendor                             | 116,613                |                        | 68                               |                                  |  |                        | 68   |
| Exercise of warrants   | 15,186,748             | 15                     | 9,484                            |                                  |  |                        | 9,499                                      |
| Noncash stock-based compensation                                     |                        |                        | 351                              |                                  |  |                        | 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<br>currency translation, net of tax |                        |                        |                                  | (4 )                             |  |                        | (4 )                                       |
| Issuance of restricted stock   | 1,021,763              | 1                      |                                  |                                  |  |                        | 1  |
| Restricted stock issued to settle liability                          | 179,773                |                        | 51                               |                                  |  |                        | 51   |
| Exercise of warrants   | 906                    | -                      | 1                                |                                  |  |                        | 1  |
| Issuance of warrants   |                        |                        | 389                              |                                  |  |                        | 389  |
| Noncash stock-based compensation                                     |                        |                        | 597                              |                                  |  |                        | 597  |
| Balance, December 31, 2016   | 49,782,797             | \$ 50                  | \$ 120,835                       | \$ 67                            |  | \$(120,285 )           | \$ 667                                     |

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In Thousands)

|   | Years Ended<br>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 )                       | (13 )     |
| 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   | -                           | -         |



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|   |        |         |
|---|--------|---------|
| Net cash provided by financing activities   | 1,188  | 3,791   |
| Effect of exchange rates on cash  | (4 )   | 1       |
| Net decrease in cash  | (973 ) | (36 )   |
| Cash, beginning of year   | 1,248  | 1,284   |
| Cash, end of year   | \$275  | \$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   | \$393  | \$-     |
| Investment in lease receivable, net   | \$92   | \$-     |
| Cost of equipment in sales-type lease   | \$92   | \$-     |
| Restricted stock issued to settle liability   | \$51   | \$36    |
| Deposit on inventory reclassified from prepaid expenses and other current assets to inventory                           | \$18   | \$-     |
| Deposit on property and equipment reclassified from prepaid expenses and other current assets to property and equipment | \$124  | \$-     |
| Deemed dividend as a result of warrant modification   | \$-    | \$73    |
| Issuance of common stock as commitment fee  | \$-    | \$163   |
| Extinguishment of warrant liability   | \$-    | \$5,287 |

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

## **NEPHROS, INC. AND SUBSIDIARY**

### **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.

## NEPHROS, INC. AND SUBSIDIARY

### 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.

## **NEPHROS, INC. AND SUBSIDIARY**

### **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.

**NEPHROS, INC. AND SUBSIDIARY**

**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.

## NEPHROS, INC. AND SUBSIDIARY

### 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

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.

**NEPHROS, INC. AND SUBSIDIARY**

**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.

## NEPHROS, INC. AND SUBSIDIARY

### 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.

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## NEPHROS, INC. AND SUBSIDIARY

### 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.

## NEPHROS, INC. AND SUBSIDIARY

### 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 expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

## NEPHROS, INC. AND SUBSIDIARY

## 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<br>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:

|  | September<br>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 |

**NEPHROS, INC. AND SUBSIDIARY****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

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.

**NEPHROS, INC. AND SUBSIDIARY****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)% | (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                        | \$-          | \$-          |

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**NEPHROS, INC. AND SUBSIDIARY**

**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.

**NEPHROS, INC. AND SUBSIDIARY****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<br>Average<br>Exercise<br>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     | (221,811 )  | 1.04                                     |
| Outstanding at December 31, 2016 | 4,592,347   | \$ 0.60                                  |

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

|  | Shares    | Weighted<br>Average<br>Exercise<br>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                                  |

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## NEPHROS, INC. AND SUBSIDIARY

## 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.

| Grant Year               | Option Pricing Assumptions |   |         |   |
|--------------------------|----------------------------|---|---------|---|
|                          | 2016                       |   | 2015    |   |
| Stock Price Volatility   | 114.63%                    |   | 121.90% |   |
| 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:

|                                | Shares    | Weighted<br>Average<br>Grant<br>Date<br>Fair<br>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   |

**NEPHROS, INC. AND SUBSIDIARY**

**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.

**NEPHROS, INC. AND SUBSIDIARY****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

| Title of Warrant                       | Date Issued | Expiry Date | Exercise Price | Total Common Shares Issuable as of December 31, |           |
|--|-------------|-------------|----------------|---|-----------|
|  |             |             |                | 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.

**NEPHROS, INC. AND SUBSIDIARY**

**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 is not below the threshold price as set forth in the Purchase Agreement. The Company's 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, 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.

## NEPHROS, INC. AND SUBSIDIARY

### 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.

**NEPHROS, INC. AND SUBSIDIARY**

**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



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 |

**NEPHROS, INC. AND SUBSIDIARY****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<br>1 Year | Years<br>2 - 3 | Years<br>4 - 5 |
| Leases <sup>1</sup>              | \$240,000              | \$116,000        | \$118,000      | \$6,000        |
| Employment Contract <sup>2</sup> | 550,000                | 240,000          | 310,000        | -              |
| Total                            | \$790,000              | \$356,000        | \$428,000      | \$6,000        |

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

<sup>2</sup>Relates 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

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.

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