

NEPHROS INC  
Form 424B3  
September 04, 2015

**PROSPECTUS Filed Pursuant to Rule 424(b)(3)  
Registration No. 333-206344**

**NEPHROS, INC.**

**5,150,000 Shares of Common Stock**

This prospectus relates to the offer and sale of up to 5,150,000 shares of common stock, par value \$0.001, of Nephros, Inc., a Delaware corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to a purchase agreement that we entered into with Lincoln Park on July 24, 2015. See “The Lincoln Park Transaction” for a description of that agreement and “Selling Stockholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares offered by this prospectus will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution”.

Shares of our common stock are quoted on the OTCQB operated by the OTC Markets Group, Inc. under the symbol “NEPH.” On September 3, 2015, the last reported sale price of our common stock on the OTCQB was \$0.50 per share.

**Investing in our common stock involves substantial risks. See “Risk Factors” beginning on page 7 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 September 4, 2015.

**TABLE OF CONTENTS**

<b><u>ABOUT THIS PROSPECTUS</u></b>	1
<b><u>PROSPECTUS SUMMARY</u></b>	1
<b><u>RISK FACTORS</u></b>	7
<b><u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	18
<b><u>THE LINCOLN PARK TRANSACTION</u></b>	19
<b><u>USE OF PROCEEDS</u></b>	22
<b><u>SELLING STOCKHOLDER</u></b>	22
<b><u>DIVIDEND POLICY</u></b>	23
<b><u>MARKET FOR OUR COMMON STOCK</u></b>	23
<b><u>PLAN OF DISTRIBUTION</u></b>	24
<b><u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	26
<b><u>BUSINESS</u></b>	38
<b><u>MANAGEMENT</u></b>	49
<b><u>EXECUTIVE COMPENSATION</u></b>	52
<b><u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u></b>	57
<b><u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u></b>	58
<b><u>DESCRIPTION OF CAPITAL STOCK</u></b>	60
<b><u>LEGAL MATTERS</u></b>	61
<b><u>EXPERTS</u></b>	61
<b><u>WHERE YOU CAN FIND MORE INFORMATION</u></b>	61
<b><u>DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS</u></b>	61

**FINANCIAL STATEMENTS**

F-1

## **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 three and six months ended June 30, 2015 and June 30, 2014 and for the years ended December 31, 2014 and 2013, and related notes appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the “Risk Factors” section beginning on page 7 and the “Special Note Regarding Forward-Looking Statements” section beginning on page 18. This prospectus contains important information that you should consider when making your investment decision.*

### **About the Company**

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water, bicarbonate concentrate and/or blood. 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 use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to optimize the three elements critical to filter performance:

Filtration - as low as 0.005 microns

Flow rate - minimal disruption

Filter life - up to 12 months

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, or 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 offer ultrafilters for sale to customers in five 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.

*Dialysis Centers - Blood:* Treatment of patients with chronic renal failure using the OLPūr H2H Hemodiafiltration, or HDF, Module in conjunction with a UF controlled hemodialysis machine and its accessories, the H2H Module accessories, appropriately prepared water and ultrapure dialysate for hemodialysis and the OLPūr MD 220 Hemodiafilter.

*Military and Outdoor Recreation:* Highly compact, individual water purification devices used by soldiers and backpackers to produce drinking water in the field.

*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 U.S. in 2013. The United States Centers for Disease Control and Prevention estimates that healthcare associated infections, or HAIs, 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 enacted in March 2010, establishes 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.

In June 2014, we submitted to the FDA, for 510(k) clearance, the DSU-H and SSU-H Ultrafilters to filter EPA quality drinking water to remove microbiological contaminants and waterborne pathogens. In October 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 sterile water.

In June 2015, the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. ("ASHRAE") approved Standard 188-2015, "Prevention of Legionellosis: Risk Management for Building Water Associated with 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 will be 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, 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 when needed.

In the first part of 2016, we plan to launch new products to expand on our hospital product line. The DSU-H and the SSU-H are both in-line filters designed to be installed between the wall water outlet and the point of delivery fixture, be it sink faucet, shower head or ice machine. The new products are designed to be attached to the end of a faucet or shower line. These products will compete directly with other end-of-faucet filters for short term use.

*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 United States. 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, or AAMI, the American National Standards Institute, or ANSI and the International Standards Organization, or 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, or ESAs, 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 is enhanced, consequently the overall need for ESAs is reduced.

We believe that our 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. Our in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine.

In March 2014, we signed a non-exclusive distributor agreement with Mar Cor Purification, a wholly-owned subsidiary of Cantel Medical Corp., to distribute our dialysis ultrafilters to U.S. and Canadian dialysis clinics. In July 2014, we received notification from Health Canada Therapeutic Products Directorate Medical Devices Bureau that we were successfully issued a license for our Single Stage Ultrafilter.

In the fall of 2015, we plan to launch a new marketing campaign focused on further expanding our products into dialysis clinics. We will be working with our distributors to leverage recent data generated by users of our dialysis products. We anticipate that one or more of those data sets will be presented at the America Society of Nephrology in November 2015.

*Dialysis Centers - Blood.* The current standard of care in the U.S. 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 U.S. is hemofiltration, or 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, or 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 U.S., HDF is much more prevalent in Europe and is performed in approximately 16% 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, 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 Module and OLpūr MD 220 Hemodiafilter. The OLpūr H2H HDF Module and OLpūr MD 220 Hemodiafilter are cleared by the FDA to market for use with a 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.

We completed preparation of our OLPūr H2H HDF Modules and have manufactured lots of our OLPūr MD220 Hemodiafilters, H2H Substitution filters and H2H water filters. We also finalized our service contract to support the commercialization of our system in the field. In May 2014, DaVita Healthcare Partners announced that it had commenced delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select 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. We and DaVita agreed upon a protocol for the additional validation work which was completed in March 2015. We have submitted the data report to DaVita, and have been informed that it is still under review. Upon confirmatory review of the additional validation work, we anticipate that DaVita will continue its evaluation. In March 2015, we announced that the Renal Research Institute, a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. We also anticipate evaluating our on-line mid-dilution HDF system at other clinics throughout the U.S. with the intent of developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of improving the quality of life for the patient, reducing overall expenditure compared to other dialysis modalities, minimizing the impact on nurse work flow at the clinic, and demonstrating the phamacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems.

*Military and Outdoor Recreation.* Water is a key requirement for the soldier to be fully mission-capable. The need for 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, resource intensive, and 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 levels specified by the Environmental Protection Agency, or EPA.

We developed our individual water treatment device, or IWTD, in both in-line (HydraGuard in-line) and point-of-use (HydraGuard Universal) 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.

In May 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC, or 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 HydraGuard individual water treatment devices. 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. Additionally, we have the right to terminate the sublicense with respect to a specific geographic area if CamelBak enters into an agreement or otherwise obtains or develops the rights to market or sell a product that competes with the HydraGuard individual water treatment devices in such geographic area. If we do not terminate the sublicense in such situation, and the sales of the competing product in such geographic area exceed the sales of the HydraGuard individual water treatment devices in the same area during any full calendar year, we may convert the exclusive sublicense to a non-exclusive sublicense solely with respect to such geographic area.

*Commercial Facilities.* In October 2013, we announced the voluntary recalls of our point of use, or POU, and DSU in-line ultrafilters used in hospital water treatment applications. As a result, we recalled all production lots of our POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, for the DSU in-line ultrafilter, we also requested that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect our dialysis products. In March, 2014, we requested termination of our product recall from the FDA. As of the date of this report, there has been no additional communication from the FDA regarding our request. We are also in the process of addressing certain issues raised by the FDA in a warning letter that we received in May 2015. In the letter, the FDA alleges deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter does not restrict our ability to manufacture, produce or ship any of our products, nor does it require the withdrawal of any product from the marketplace. We have responded in writing to the FDA's concerns and we intend to work diligently to address each concern to the FDA's satisfaction. On August 12, 2015, we received an additional letter from the FDA acknowledging our responses and noting that it will verify our implementation of corrective measures at its next inspection of our facility.

We have launched our new NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is 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 5nm in size and the water permeability (the ease at which water can pass through a membrane at a given pressure) of the membrane is higher than membranes with a similar pore size. This provides improved flow performance relative to the physical size of the filter. We anticipate that the filters will be used as a component of a facility water treatment system and also for filtering water to be used in ice machines and soda fountains.

We have been working with customers to test prototype filters in commercial settings, such as data centers, and other high-flow-rate applications where particle reduction can provide an advantage. In the first part of 2016, we intend to launch new products into the commercial market. Specifically, we will launch a 10” and 20” filter cartridges that insert into standard filter housings, such as Pentek, Cuno, Shelco and Graver. We will be working with existing distributors and their existing customers, and seeking new distributors to address customers not currently targeted by our existing distributors.

## **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).

## **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**

On July 24, 2015, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to \$10,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on July 24, 2015, we entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than 250,000 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 100,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also accelerate the amount of our common stock to be purchased under certain circumstances to up 200,000 shares or \$500,000 per purchase plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than \$0.35 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of June 30, 2015, there were 32,227,939 shares of our common stock outstanding, of which 15,745,474 shares were held by non-affiliates, excluding the 250,000 shares that we have already issued to Lincoln Park under the Purchase Agreement. The Purchase Agreement provides that we may sell up to \$10,000,000 of our common stock to Lincoln Park, and 5,150,000 shares of our common stock are being offered under this prospectus, which represents (i) 250,000 shares that we issued to Lincoln Park as a commitment fee and (ii) an additional 4,900,000 shares which may be issued to Lincoln Park in the future under the Purchase Agreement. If all of the 5,150,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 13.8% of the total number of shares of our common stock outstanding and 24.6% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. However, per the Purchase Agreement, we cannot issue or sell, and Lincoln Park cannot purchase or acquire, any shares of common stock pursuant to the Purchase Agreement which would result in Lincoln Park beneficially owning more than 9.99% of our outstanding common stock. If we elect to issue and sell more than the 5,150,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

## **Recent Developments**

On August 14, 2015, our Board of Directors appointed Moshe Pinto as a director of the Company. Mr. Pinto will receive the standard compensation and indemnification approved for non-employee directors. 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 currently serves on the Board of Directors of Spiracur Inc. 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.

## **Securities Offered**

Edgar Filing: NEPHROS INC - Form 424B3

5,150,000 shares of common stock, consisting of

Common stock to be offered by the selling stockholder	- 250,000 commitment shares issued to Lincoln Park and  - 4,900,000 shares we may sell to Lincoln Park under the Purchase Agreement
Common stock outstanding prior to this offering	32,227,939 shares of common stock, as of June 30, 2015
Common stock to be outstanding after giving effect to the issuance of 5,150,000 shares as offered under this prospectus	37,377,939 shares of common stock
Use of Proceeds	We will receive none of the proceeds from the sale of the shares by Lincoln Park in this offering. However, we may receive up to \$10,000,000 under the Purchase Agreement with Lincoln Park. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used for general corporate purposes. See "Use of Proceeds."
Risk Factors	The acquisition of our common stock involves substantial risks. See "Risk Factors" beginning on page 7 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 the Purchase Agreement with Lincoln Park**

*The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.*

On July 24, 2015, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$10,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement on July 24, 2015, we issued 250,000 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below \$0.35 per share, subject to adjustment as set forth in the Purchase Agreement. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. As such, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$10,000,000 of our common stock, exclusive of the 250,000 commitment shares issued to Lincoln Park as a commitment fee (which have already been issued to Lincoln Park and are part of this offering). Depending on the

price per share at which we sell our common stock to Lincoln Park, we may be authorized to issue and sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. Moreover, we may sell our common stock to Lincoln Park at prices that are less than the last reported sale price of our common stock on the day that we sell the shares to Lincoln Park. The purchase price at which we have the right to sell our shares to Lincoln Park is based on the lower of the average three lowest closing sale prices of our shares for the prior twelve days or the lowest sale price on the day we elect to sell shares. Accordingly, this price may be less than the last reported sale price of our common stock as reported on the OTCQB, and such sales to Lincoln Park may thereby have a dilutive effect on our stockholders depending on the tangible book value of our shares at the time of the sale.

Under the terms of the Purchase Agreement the price of our shares cannot trade below a minimum low price of \$0.35 per share on a day on which we choose to sell shares to Lincoln Park. However, if the minimum \$0.35 price is met on a sale date, sales to Lincoln Park may be made based on an average trailing average price formula. This formula specifies that the average of the three (3) lowest closing sale prices during the preceding consecutive twelve (12) trading day period immediately preceding the sale date would be used as the sale price on the sale date. The effect of this is that even if our shares have traded at a substantial discount to the \$0.35 minimum low price during the preceding twelve day period, we still have the right to sell shares to Lincoln Park, but the per share price for such sales would be based on the trailing average price formula.

If you invest in our common stock in this offering, your ownership will be diluted to the extent of the difference between the offering price per share and the pro forma net tangible book value per share as adjusted to give effect to this offering. Dilution results from the fact that the per share offering price the common stock in this offering is substantially in excess of the book value per share attributable to the shares of common stock held by existing shareholders.

***We may not be able to access sufficient funds under the Purchase Agreement with Lincoln Park when needed.***

Our ability to sell shares to Lincoln Park and obtain funds under the Purchase Agreement is limited by the terms and conditions in the Purchase Agreement, including restrictions on when we may sell shares to Lincoln Park, restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln Park to beneficially own more than 9.99% of our outstanding common stock. In addition, any amounts we sell under the Purchase Agreement may not satisfy all of our funding needs, even if we are able and choose to sell all \$10,000,000 under the Purchase Agreement. Assuming all 4,900,000 additional shares of our common stock being offered under this prospectus that may be purchased by Lincoln Park are sold at

\$0.35 per share (the floor price mentioned above), we would receive \$1,715,000. If we elect to issue and sell more than the 4,900,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act of 1933 any such additional shares.

We elected to enter into the Purchase Agreement with Lincoln Park as we expect that amount of capital over the next 12 months will be required for us to fully implement our business, operating and development plans. The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$10,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

## Risks Related to Our Company

*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 June 30, 2015, we had an accumulated deficit of approximately \$115,737,000, as a result of historical operating losses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures, including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. 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 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.

If we are unable to maintain proper and effective internal control over financial reporting, 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.

***Our independent registered public accounting firm, in its audit report related to our financial statements for the fiscal year ended December 31, 2014, expressed substantial doubt about our ability to continue as a going concern.***

Our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements included in this prospectus expressing 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 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, 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 would be materially adversely affected.

***If we violate any provisions of the FDC Act 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 FDC Act 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 October 30, 2013, we initiated a voluntary recall of our point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. We initiated the voluntary recall of these POU filters because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. In addition, we received reports from one customer of high bacterial counts that may be associated with the breakage of fiber in four filters. According to the reports received, one death and one infection may have occurred due to the failure mode associated with this voluntary recall. Investigation into these reports is ongoing. Prior to receiving the complaints mentioned previously, since we began marketing the products, we received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber. We have had no reports of adverse events associated with these 29 complaints. We have recalled all production lots of these POU filters, and are also requesting that customers remove and discard certain labeling/promotional materials for the products. We initiated the voluntary recall of the DSU in-line ultrafilter because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. We are requesting that customers remove and discard certain labeling/promotional materials for the product.

On May 28, 2015, we received a warning letter from the FDA resulting from an October 2014 inspection of our facility in River Edge, New Jersey. The warning letter alleges deficiencies relating to our compliance with the Quality System regulation and the Medical Device Reporting regulation. We take the matters identified in the warning letter seriously and are in the process of evaluating the corrective actions required to address the matters raised in the warning letter. We responded to the warning letter within 15 business days as requested by the FDA, and intend to work diligently and expeditiously to resolve the issues raised by the FDA. The warning letter does not restrict the manufacture, production or shipment of any of our products, nor require the withdrawal of any product from the marketplace. On August 12, 2015, we received an additional letter from the FDA acknowledging our responses and noting that it will verify our implementation of corrective measures at its next inspection of our facility.

If we violate the FDC Act 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 or we fail to promptly address the issues raised in the warning letter discussed above, 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.

In particular, the voluntary recalls of the POU and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues.

Under the FDC Act, we are required to submit medical device reports, or 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. In particular, the voluntary recalls of the POU and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances 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, or 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, or 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. 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 U.S.

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, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. 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 MDHDF 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. In particular, we are in the process of addressing certain issues raised by the FDA in the warning letter received in May 2015 and failure to promptly address these issues could result in regulatory action. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers or we fail to address issues raised by the FDA in these inspections, 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.

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

*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. As discussed elsewhere in this prospectus, we may issue up to \$10,000,000 of our Common Stock to Lincoln Park pursuant to the Purchase Agreement. 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.***

In the two years ended June 30, 2015, our Common Stock has traded at prices ranging from a high of \$1.71 to a low of \$0.30 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 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 June 30, 2015, our directors, executive officer and Lambda, our largest stockholder, owned approximately 51% of our outstanding Common Stock, representing approximately 66% on a fully-diluted basis. 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 Lincoln Park, 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 our intentions with regard to the sale of share to Lincoln Park and the anticipated use of proceeds from such sales, 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;

the voluntary recalls of point of use and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues;

we face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues;

there are 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 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 FDC Act 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, 2014, 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.

## THE LINCOLN PARK TRANSACTION

*The following description is qualified in its entirety by the terms and conditions of the Purchase Agreement and the Registration Rights Agreement, which are 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 Purchase Agreement and the Registration Rights Agreement that is important to you. We encourage you to read each of the Purchase Agreement and the Registration Rights Agreement in its entirety.*

On July 24, 2015, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$10,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement on July 24, 2015, we issued to Lincoln Park 250,000 shares of our common stock as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement. Other than the shares of our common stock that we have already issued to Lincoln Park as described above, we do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter and upon satisfaction of the other conditions set forth in the Purchase Agreement, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 100,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also accelerate the amount of our common stock to be purchased under certain circumstances to up to 200,000 shares or \$500,000 per purchase plus an additional "accelerated amount" under certain circumstances. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount. We issued 250,000 shares of our stock to Lincoln Park as a commitment fee for entering into the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

## Purchase of Shares Under the Purchase Agreement

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock on any such business day so long as one business day has passed since the last purchase. On any day that the closing sale price of our common stock is not below \$0.75 the purchase amount may be increased, at our sole discretion, to up to 150,000 shares of our common stock per purchase and on any day that the closing sale price of our common stock is not below \$1.00 the purchase amount may be increased, at our sole discretion, to up to 200,000 shares of our common stock per purchase. Such purchases are hereinafter referred to as “Regular Purchases”. The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or

- the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice, and provided that the closing price of our stock is not below \$0.75, to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, not to exceed the lesser of:

- 30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date; and

- two times the number of shares purchased pursuant to the corresponding Regular Purchase.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

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

the closing sale price of our common stock on the purchase date.

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

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

### **Minimum Purchase Price**

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

### **Events of Default**

Events of default under the Purchase Agreement include the following:

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

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

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

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

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

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

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

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

### **Our Termination Rights**

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

### **No Short-Selling or Hedging by Lincoln Park**

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

### **Effect of Performance of the Purchase Agreement on Our Stockholders**

All 5,150,000 shares registered in this offering which may be sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Except with respect to the 250,000 shares of common stock already issued to Lincoln Park pursuant to the Purchase Agreement, Lincoln Park may ultimately purchase all, some or none of the 5,150,000 shares of common stock registered in this offering. If we sell these shares to Lincoln Park, Lincoln Park may sell all, some or none of such shares. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

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

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$10,000,000 of our common stock, exclusive of the 250,000 shares issued to Lincoln Park as a commitment fee (which 250,000 shares are part of this offering). Depending on the price per share at which we sell

our common stock to Lincoln Park, we may be authorized to issue and sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

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

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase (1)(2)	Percentage of Outstanding	Proceeds from the Sale of
		Shares After Giving Effect to the Issuance to Lincoln Park (3)	Shares to Lincoln Park Under the \$10M Purchase Agreement (3)
\$ 0.35	(4) 4,900,000	13.1	% \$ 1,715,000
\$ 0.50	(5) 4,900,000	13.1	% \$ 2,450,000
\$ 0.75	4,900,000	13.1	% \$ 3,675,000
\$ 1.00	4,900,000	13.1	% \$ 4,900,000
\$ 1.50	4,900,000	13.1	% \$ 7,350,000

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

(2) The number of registered shares to be issued excludes the 250,000 commitment shares because no proceeds will be attributable to such commitment shares.

The denominator is based on 32,227,939 shares outstanding as of June 30, 2015, adjusted to include the 250,000 shares issued to Lincoln Park as commitment shares in connection with this offering and the number of shares set forth in the adjacent column which we would have sold to Lincoln Park at the applicable assumed average purchase price per share. The numerator does not include the 250,000 shares issued to Lincoln Park as commitment shares in connection with this offering, and is based on the number of shares registered in this offering to be issued under the Purchase Agreement at the applicable assumed purchase price per share set forth in the adjacent column. Per the Purchase Agreement, we cannot issue or sell, and Lincoln Park cannot purchase or acquire, any shares of common stock pursuant to the Purchase Agreement which would result in Lincoln Park beneficially owning more than 9.99% of our outstanding common stock.

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

(5) The closing sale price of our shares on August 10, 2015.

## **USE OF PROCEEDS**

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

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

## **SELLING STOCKHOLDER**

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



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

The following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder, and reflects its holdings as of July 24, 2015. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 32,227,939 shares of our common stock actually outstanding as of June 30, 2015.

	Shares	Percentage of		
		Outstanding	Shares to be Sold	Outstanding
Selling Stockholder	Beneficially Owned Before this Offering	Shares Beneficially Owned Before this Offering	Shares in this Offering	Shares Beneficially Owned After this Offering
Lincoln Park Capital Fund, LLC (1)	475,000	(2) 1.5	%(3) 5,150,000	(4) *

\* denotes less than 1%

---

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

Represents (i) 150,000 shares of our common stock held by Lincoln Park prior to July 24, 2015, (ii) warrants to purchase 75,000 shares of our common stock held by Lincoln Park prior to July 24, 2015; and (iii) 250,000 shares of our common stock issued to Lincoln Park on July 24, 2015 as a fee for its commitment to purchase additional (2) shares of our common stock under the Purchase Agreement. The registration statement that includes this prospectus does not cover the 150,000 shares of common stock otherwise held by Lincoln Park, nor does it cover the 75,000 shares of common stock that may be issued upon exercise of the warrant. See the description under the heading “The Lincoln Park Transaction” for more information about the Purchase Agreement.

Based on 32,227,939 outstanding shares of our common stock as of June 30, 2015, as adjusted to include 250,000 shares of our common stock issued to Lincoln Park on July 24, 2015 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement. Although we may at our discretion elect to (3) issue to Lincoln Park up to an aggregate amount of \$10,000,000 of our common stock under the Purchase Agreement, such shares are not included in determining the percentage of shares beneficially owned before this offering.

Represents (i) 250,000 shares of our common stock issued to Lincoln Park on July 24, 2015 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement, and (ii) 4,900,000 (4) additional shares that we may sell to Lincoln Park pursuant to the Purchase Agreement. If we elect to issue and sell more than the 5,150,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders.

## **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**

Edgar Filing: NEPHROS INC - Form 424B3

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, 2013	\$1.49	\$0.73
June 30, 2013	\$1.25	\$0.63
September 30, 2013	\$1.71	\$0.85
December 31, 2013	\$1.25	\$0.31
March 31, 2014	\$0.75	\$0.30
June 30, 2014	\$1.29	\$0.35
September 30, 2014	\$1.19	\$0.76
December 31, 2014	\$1.00	\$0.61
March 31, 2015	\$0.96	\$0.50
June 30, 2015	\$0.80	\$0.49
July 1, 2015 through September 3, 2015	\$0.77	\$0.45

As of June 30, 2015, there were approximately 61 holders of record and approximately 1,000 beneficial holders of our common stock.

On September 3, 2015, the last reported sale price of our common stock on the OTCQB was \$0.50 per share.

## PLAN OF DISTRIBUTION

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

· ordinary brokers' transactions;

· transactions involving cross or block trades;

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

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

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

· in privately negotiated transactions; or

· any combination of the foregoing.

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

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

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices

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

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

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

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

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

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

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

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

## **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, 2014. The following discussion should also be read in conjunction with the consolidated financial statements and notes included herein.*

### **Restatement**

In connection with the audit of our consolidated financial statements for the year ended December 31, 2014, our management further evaluated the warrants under Accounting Standards Codification ("ASC") Subtopic 815-40, "Contracts in Entity's Own Equity." ASC Subtopic 815-40-15 addresses equity versus liability treatment and classification of equity-linked financial instruments, including common stock purchase warrants, and states that a warrant may be classified as a component of equity only if, among other things, the warrant is indexed to the issuer's common stock. Under ASC Subtopic 815-40-15, a warrant is not indexed to the issuer's common stock if the terms of the warrant require an adjustment to the exercise price upon a specified event and that event is not an input to the fair value of the warrant. Based on management's evaluation, our audit committee, in consultation with management and after discussion with WithumSmith+Brown PC, our independent registered public accounting firm, concluded that our warrants are not indexed to our common stock in the manner contemplated by ASC Section 815-40-15 because the transactions that would trigger the Anti-Dilution Adjustment Provision are not inputs to the fair value of the warrants. As a result, we should have classified the warrants as derivative liabilities as of January 1, 2009, the date which ASC Section 815-40-15 was effective. Under this accounting treatment, we are required to measure the fair value of the warrants at the end of each reporting period beginning with the year ended December 31, 2009, with a cumulative effect presented as of January 1, 2009, and recognize changes in the fair value for all periods beginning with January 1, 2009 in our operating results for the current period.

The Company's financial statements as of January 1, 2009 and for the years ended December 31, 2009 to 2013 (the "Prior Financial Statements"), were audited by Rothstein Kass, an independent registered public accounting firm. Though it still exists, Rothstein Kass has ceased practicing public accounting and is therefore no longer able to re-audit the Prior Financial Statements. The report of WithumSmith+Brown PC regarding the audit of our financial statements as of and for the year ended December 31, 2014, included in this prospectus includes a statement that such

firm has only been engaged to audit the adjustments required by the restatement of the Prior Financial Statements, and not the Prior Financial Statements taken as a whole, as to which it expresses no opinion.

Our accounting for the warrants as components of equity instead of as derivative liabilities did not have any effect on our previously reported revenue, operating expenses, operating income, cash flows or cash.

We have not amended our previously filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for the periods affected by the restatement. The financial information that has been previously filed or otherwise reported for these periods is superseded by the information in our Annual Report on Form 10-K for the year ended December 31, 2014, and the financial statements and related financial information contained in such previously filed reports should no longer be relied upon.

The restatement is more fully described in Note 2 of the notes to the financial statements for the year ended December 31, 2014 included herein.

## **Business Overview**

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water, bicarbonate concentrate and/or blood. 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 use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to optimize the three elements critical to filter performance:

• Filtration - as low as 0.005 microns

• Flow rate - minimal disruption

• Filter life - up to 12 months

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, or 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.

## Recently Adopted 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 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. Early adoption is permitted, but not before the original effective date for public companies (annual reporting periods beginning after December 15, 2016). In July 2015, the FASB approved a one-year deferral of the effective date of the new standard, making it effective for annual and interim reporting periods beginning January 1, 2018. The Company has not yet determined the potential impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 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. Early adoption is permitted. The Company has not yet determined the impact, if any, of the adoption of ASU 2014-15 might have on its consolidated financial statements.

In April 2015, the FASB issued ASU No. 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 fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption of the amendments in ASU 2015-03 is permitted for financial statements that have not been previously issued. The Company does not believe that the adoption of ASU 2015-03 will have a significant impact on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory (Subtopic 2015-11).” ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value, and methods for valuing inventory that consider market value will be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. The Company has not yet determined the impact, if any, the adoption of ASU 2015-11 might have on its 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, 2014 consolidated balance sheet is approximately \$487,000 and is related to the Bellco license agreement. We have recognized approximately \$2,589,000 of revenue related to this license agreement to date and approximately \$834,000 for the year ended December 31, 2014, resulting in \$487,000 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 seven years.

### **Stock-Based Compensation**

We account for stock-based compensation in accordance with ASC 718 by recognizing the fair value of stock-based compensation in net income. 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 and elections 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 and elections 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 U.S. 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.

### **Three Months Ended June 30, 2015 Compared to the Three Months Ended June 30, 2014**

#### *Revenues*

Total net revenues for the three months ended June 30, 2015 were approximately \$567,000 compared to approximately \$441,000 for the three months ended June 30, 2014. Total net revenues increased approximately \$126,000 or 29%, arising from a 110% increase, or approximately \$273,000, in water filter sales on dialysis and commercial water as well as royalty revenue of approximately \$28,000 recognized in connection to the Bellco license agreement. These increases were partially offset by a 91% decrease, or approximately \$175,000, in licensing revenue related to the Bellco license agreement. The increase in water filter sales was primarily driven by an increase in sales in the hospital market resulting from the DSU-H and SSU-H product launch following the FDA 510k clearance in October 2014. Revenue recognized related to the Bellco license agreement in the three months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the Bellco license agreement were fully recognized as revenue as of December 31, 2014, accounting for the decrease in the higher recognition of licensing revenue in the six month period ended June 30, 2014.

#### *Cost of Goods Sold*

Cost of goods sold was approximately \$209,000 for the three months ended June 30, 2015 compared to approximately \$142,000 for the three months ended June 30, 2014. The increase of approximately \$67,000, or 47%, during the three months ended June 30, 2015 compared to the same period in 2014 is primarily due to an increase in sales volume and any cost of sales gains arising from favorable exchange rate impacts, offset by product mix changes in the three months ended June 30, 2015 compared to the three months ended June 30, 2014.

#### *Gross Margin*

Gross margin and gross margin as a percentage of product revenues was approximately \$312,000, or 60%, for the three months ended June 30, 2015 compared to approximately \$106,000, or 43%, for the six months ended June 30, 2014. The increase of approximately 17% was primarily related to both an increase in direct sales, which has higher margin than indirect sales, and a modification in the distributor pricing structure to focus on annual sales volume.

#### *Research and Development*

Research and development expenses were approximately \$164,000 and \$180,000 respectively, for the three months ended June 30, 2015 and June 30, 2014. This decrease of approximately \$16,000, or 9%, is primarily due to a decrease in research and development costs and other project costs related to our OLPur H2H Module, which is currently being used commercially to treat patients.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$53,000 for the three months ended June 30, 2015 compared to approximately \$55,000 for the three months ended June 30, 2014. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$53,000 for both the three months ended June 30, 2015 and the three months ended June 30, 2014. The remaining \$2,000 recognized in the three months ended June 30, 2014 was depreciation on equipment and tools.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$735,000 for the three months ended June 30, 2015 compared to approximately \$700,000 for the three months ended June 30, 2014, an increase of approximately \$35,000 or 5%. The increase is primarily due to an increase in travel expenses of approximately \$32,000 as a result of an increased sales effort and an increase in professional service and legal expenses of approximately \$21,000 partially offset by a decrease in personnel costs of approximately \$18,000. The decrease in personnel costs of approximately \$18,000 was primarily related to a decrease of in salaries and stock based compensation expense as a result of the departure of the former CEO. This decrease was partially offset by an increase of approximately \$23,000 in sales commission due to the increased sales effort in addition to an increase in directors' compensation expense of approximately \$13,000 due to an increase in the number of Board members.



*Interest Expense*

The table below summarizes interest expense for the three months ended June 30, 2015 and 2014:

	2015	2014
Interest – outstanding payables due to a vendor	\$9,000	\$16,000
Other	-	1,000
Total interest expense	\$9,000	\$17,000

*Change in Fair Value of Warrant Liability*

Certain warrants are classified as liabilities at their fair value and adjusted to their fair value at each reporting period. The fair value of such warrants issued have been estimated using a binomial options pricing model. For the three months ended June 30, 2015 and 2014, the change in fair value of the warrant liability was an increase of approximately \$1,196,000 and an increase of approximately \$4,685,000, respectively.

*Other Income (Expense)*

Other income (expense) relates to foreign currency gains and losses on invoices paid to an international supplier. A foreign currency loss of approximately \$16,000 was recognized for the three months ended June 30, 2015 compared to a foreign currency loss of approximately \$1,000 for the three months ended June 30, 2014.

**The Six Months Ended June 30, 2015 Compared to the Six Months Ended June 30, 2014***Revenues*

Total net revenues for the six months ended June 30, 2015 were approximately \$1,112,000 compared to approximately \$915,000 for the six months ended June 30, 2014. Total net revenues increased approximately \$197,000 or 22%, arising from a 197% increase, or approximately \$582,000, in water filter sales on dialysis and commercial water as well as royalty revenue of approximately \$28,000 recognized in connection to the Bellco license

agreement. These increases were partially offset by a \$413,000 decrease, or approximately 92%, in licensing revenue related to the Bellco license agreement. The increase in water filter sales was primarily driven by an increase in sales in the hospital market resulting from the DSU-H and SSU-H product launch following the FDA 510k clearance in October 2014. Revenue recognized related to the Bellco license agreement in the six months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the Bellco license agreement were fully recognized as revenue as of December 31, 2014, accounting for the decrease in the higher recognition of licensing revenue in the six month period ended June 30, 2014.

#### *Cost of Goods Sold*

Cost of goods sold was approximately \$471,000 for the six months ended June 30, 2015 compared to approximately \$248,000 for the six months ended June 30, 2014. The increase of approximately \$223,000, or 90%, during the three months ended June 30, 2015 compared to the same period in 2014 is primarily due to increase in sales volume and any cost of sales gains arising from favorable exchange rate impacts, offset by product mix changes in the six months ended June 30, 2015 compared to the six months ended June 30, 2014.

#### *Gross Margin*

Gross margin and gross margin as a percentage of product revenues was approximately \$578,000, or 55%, for the six months ended June 30, 2015 compared to approximately \$219,000, or 47%, for the six months ended June 30, 2014. This increase of approximately 8% was primarily related both an increase in direct sales, which has higher margin than indirect sales, and a modification in the distributor pricing structure to focus on annual sales volume.

#### *Research and Development*

Research and development expenses were approximately \$355,000 and \$343,000 respectively, for the six months ended June 30, 2015 and June 30, 2014. This increase of approximately \$12,000, or 3%, is primarily due to a slight increase in research and development costs and other project costs primarily related to our OLpür H2H Module as a result of timing of incurred expenses.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$106,000 for the six months ended June 30, 2015 compared to approximately \$110,000 for the six months ended June 30, 2014. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$105,000 for the six months ended June 30, 2015 compared to approximately \$106,000 for the six months ended June 30, 2014. The remaining \$1,000 and \$4,000, respectively, recognized in the six months ended June 30, 2015 and 2014 was depreciation on equipment and tools.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$1,578,000 for the six months ended June 30, 2015 compared to approximately \$1,412,000 for the six months ended June 30, 2014, an increase of approximately \$166,000, or 12%. The increase is primarily due to an increase in personnel costs of approximately \$65,000, an increase in travel related expense of approximately \$34,000 as a result of an increased sales effort and an increase in professional services expenses of approximately \$90,000 primarily related to the additional expenses incurred. These costs were partially offset by a decrease in legal expenses of approximately \$28,000. Legal expenses were higher for the six months ended June 30, 2014 as a result of fees incurred in relation to the October 2013 product recall. The increase in personnel costs of approximately \$65,000 was primarily related to an increase in salaries and commissions of approximately \$148,000 related to the hiring of a new CEO and an increase in the sales effort in addition to an increase in directors' compensation expense of approximately \$29,000 due to an increase in the number of Board members. Partially offsetting the increase in personnel costs was a decrease of approximately \$112,000 primarily related to the forfeiture of the former CEO's unvested stock options.

*Interest Expense*

The table below summarizes interest expense for the six months ended June 30, 2015 and 2014:

	2015	2014
Interest related to November 2013 senior secured note	\$-	\$37,000
Amortization of debt discount – November 2013 senior secured note	-	142,000
Interest – outstanding payables due to a vendor	21,000	32,000
Other	-	1,000
Total interest expense	\$21,000	\$212,000

*Change in Fair Value of Warrant Liability*

Certain warrants are classified as liabilities at their fair value and adjusted to their fair value at each reporting period. The fair value of such warrants issued have been estimated using a binomial options pricing model. For the six months ended June 30, 2015 and 2014, the change in fair value of the warrant liability was an increase of approximately \$188,000 and \$7,436,000, respectively.

*Other Income (Expense)*

Other income (expense) relates to foreign currency gains and losses on invoices paid to an international supplier. A foreign currency gain was recognized for the six months ended June 30, 2015 of approximately \$35,000 compared to a foreign currency loss of approximately \$4,000 for the six months ended June 30, 2014.

**The Fiscal Year Ended December 31, 2014 Compared to the Fiscal Year Ended December 31, 2013**

*Revenues*

Total revenues for the year ended December 31, 2014 were approximately \$1,748,000 compared to approximately \$1,740,000 for the year ended December 31, 2013. Total revenues increased approximately \$8,000, or 0.5%. An increase of approximately \$123,000 related to the Bellco license agreement was offset by a decrease in water filter sales of \$115,000. The decrease in water filter sales is primarily related to a decrease in water filter units sold partially offset by an increase in average selling price.

### *Cost of Goods Sold*

Cost of goods sold was approximately \$549,000 for the year ended December 31, 2014 compared to approximately \$898,000 for the year ended December 31, 2013. The decrease of approximately \$349,000, or 39%, in cost of goods sold was primarily related to an increase in inventory reserves related to the recall of our point of use and DSU ultrafilters that we announced in October 2013. Inventory reserves increased approximately \$210,000 during the year ended December 31, 2013, \$203,000 of which was a result of the October 2013 voluntary product recall. For the year ended December 31, 2014, inventory reserves increased approximately \$59,000, a decrease compared to 2013 of \$151,000. The cost of goods sold related to water filter sales decreased by approximately \$64,000 due to lower water filter sales. In addition, included in cost of goods sold for the year ended December 31, 2013 was approximately \$151,000 related to additional costs as a result of the product recall. Partially offsetting these decreases was an additional \$17,000 in costs of goods sold for the year ended December 31, 2014 related to the Medica royalty payments which began in the second quarter of fiscal year 2014.

### *Research and Development*

Research and development expenses were approximately \$781,000 and \$867,000, respectively, for the years ended December 31, 2014 and December 31, 2013. This decrease of approximately \$86,000, or 10%, is primarily due to lower stock compensation expense of approximately \$48,000. The decrease in stock compensation expense is related to restricted stock awards granted to employees during the year ended December 31, 2013. The remainder of the decrease in research and development expenses is due to a decrease of approximately \$38,000 in project costs primarily related to our OLpūr H2H Module.

### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$217,000 for the year ended December 31, 2014 compared to approximately \$223,000 for the year ended December 31, 2013, representing a decrease of 3%.

### *Selling, General and Administrative Expenses*

Selling, general and administrative, or SG&A, expenses were approximately \$2,870,000 for the year ended December 31, 2014 compared to approximately \$3,069,000 for the year ended December 31, 2013, representing a decrease of \$199,000 or 7%. The decrease is primarily due to a decrease in personnel costs of approximately \$205,000 related to

the absence of a chief financial officer in the year ended December 31, 2014, a decrease of approximately \$156,000 in legal and professional services and a decrease in stock compensation of approximately \$36,000, partly offset by an increase in SG&A expenses of approximately \$129,000 as a result of increased regulatory and quality system management resource costs due to the product recall and an increase in board of directors' fees of approximately \$89,000.

### *Interest Expense*

The table below summarizes interest expense for the years ended December 31, 2014 and 2013:

	2014	2013
Interest related to August 2014 senior secured note	\$63,000	\$-
Interest related to November 2013 senior secured note	37,000	24,000
Interest related to February 2013 senior secured note	-	47,000
Amortization of debt discount – August 2014 senior secured note	178,000	
Amortization of debt discount – November 2013 senior secured note	142,000	53,000
Amortization of debt discount – February 2013 senior secured note	-	204,000
Interest – outstanding payables due to a vendor	61,000	21,000
Other	2,000	2,000
Total interest expense	\$483,000	\$351,000

### *Change in Fair Value of Warrant Liability*

As a result of the restatement described in Note 2 of the notes to the financial statements included herein, we classify certain warrants as liabilities at their fair value and adjust the warrant liability to fair value at each reporting period. This liability is 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 have been estimated using a binomial options pricing model. For the years ended December 31, 2014 and 2013, the change in fair value of the warrant liability was an increase of approximately \$4,277,000 and a decrease of approximately \$5,020,000, respectively.

*Other Income/Expense*

Other income of approximately \$58,000 for the year ended December 31, 2014 is due to foreign currency gains.

Other expense, net, of approximately \$33,000 for the year ended December 31, 2013 is primarily due to other expenses of approximately \$36,000 related to foreign currency transaction losses and approximately \$14,000 of expenses related to the May 2013 rights offering warrant modification. These expenses were partially offset by other income of approximately \$17,000, which consisted primarily of a refund of \$15,000 received as a result of the Steris agreement termination.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of June 30, 2015 or December 31, 2014.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of June 30, 2015 and December 31, 2014 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	<b>June 30,</b>	December 31,
Liquidity and capital resources	<b>2015</b>	2014
Cash	\$ 1,037	\$ 1,284
Other current assets	775	400
Working capital (deficit)	(448 )	437
Stockholders' deficit	(5,929 )	(5,681 )

At June 30, 2015, we had an accumulated deficit of approximately \$115,737,000 and we expect to incur additional operating losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or license revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, license revenue, and rights offerings.

On July 24, 2015, we entered into a purchase agreement, together with a registration rights agreement, with Lincoln Park. 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 the date that the registration statement, of which this prospectus is a part, is declared effective by the SEC and a final prospectus in connection therewith is filed. 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.

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 warrants 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 (estimated at approximately \$1.95 using current exchange rates) per unit; thereafter, €1.25 (estimated at approximately \$1.40 using current exchange rates) per unit. As of June 30, 2015, the Company recorded a receivable of approximately \$28,000 related to the royalty payable by Bellco. 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.

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.

At June 30, 2015, we had cash totaling approximately \$1,037,000 and total assets of approximately \$1,812,000, excluding other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,579,000.

We expect that the approximately \$1.23 million of gross proceeds that we received upon the closing of the May 2015 private placement of 1,834,299 units of our securities, the \$10.0 million available to us pursuant to the purchase agreement with Lincoln Park, and the projected increase in product sales from the hospital market, will allow us to fund our operations through fiscal year 2016. If our sales are not sufficient to meet our cash needs, and our stock price goes below the floor set in the Lincoln Park purchase agreement of \$0.35, then we would not have access to the Lincoln Park funding mechanism and would need to raise additional financing using an alternative method. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must use additional financing available to us through the purchase agreement with Lincoln Park to fund our operations. We may need to raise additional financing in the future, and if we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we may be forced to curtail our planned activities and operations or cease operations entirely. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

*Cash Flows for the Six Months Ended June 30, 2015 Compared to the Six Months Ended June 30, 2014*

Net cash used in operating activities was approximately \$1,450,000 for the six months ended June 30, 2015 compared to approximately \$867,000 for the six months ended June 30, 2014. Although our net loss decreased by approximately \$7,278,000 during the six months ended June 30, 2015 compared to the six months ended June 30, 2014, the primary reason for the decrease was due to the noncash impact of the change in fair value of the warrant liability. The warrant liability increased by approximately \$188,000 in the six months ended June 30, 2015 compared to an increase of approximately \$7,436,000 in the six months ended June 30, 2014.

The most significant items contributing to the net increase of approximately \$584,000 in cash used in operating activities during the six months ended June 30, 2015 compared to the six months ended June 30, 2014 are highlighted below:

our deferred revenue decreased by approximately \$35,000 in the 2015 period compared to an increase of approximately \$170,000 in the 2014 period as a result of the upfront payment received from Bellco in February 2014;

our stock based compensation was approximately \$119,000 during the 2015 period compared to approximately \$227,000 during the 2014 period. The decrease was due to the forfeiture of unvested options as a result of the departure of the former CEO;

during the 2014 period, our inventory reserve increased by approximately \$31,000. There was no additional inventory reserve need during the 2015 period as a result of increased sales volume;

during the 2015 period, our amortization of debt discount decreased by approximately \$142,000 compared to the 2014 period. There was no outstanding debt during the 2015 period;

our accounts receivable increased by approximately \$184,000 during the 2015 period compared to a decrease of approximately \$9,000 during the 2014 period as a result of increased revenue; and

our inventory increased by approximately \$233,000 during the 2015 period compared to an increase of approximately \$32,000 during the 2014 period as a result of increased sales volume.

Offsetting the above changes are the following items:

our accounts payable increased by approximately \$152,000 in the 2015 period compared to a decrease of approximately \$46,000 in the 2014 period as a result of an increase in inventory;

and our accrued expenses decreased by approximately \$37,000 in the 2015 period compared to a decrease of approximately \$134,000 in the 2014 period.

Net cash provided by financing activities for the six months ended June 30, 2015 of \$1,206,000 resulted from net proceeds of approximately \$1,205,000 resulting from the issuance of common stock and approximately \$1,000 of proceeds resulting from the exercise of warrants.

Net cash provided by financing activities for the six months ended June 30, 2014 of \$515,000 resulted from proceeds of approximately \$2,013,000 resulting from the issuance of common stock in the 2014 rights offering and approximately \$2,000 of proceeds resulting from the exercise of warrants. These proceeds were offset by the payment of the November 2013 senior secured note of \$1,500,000.

*Cash Flows for the Year Ended December 31, 2014 Compared to the Year Ended December 31, 2013*

Net cash used in operating activities was approximately \$2,495,000 for the year ended December 31, 2014 compared to approximately \$3,583,000 for the year ended December 31, 2013. Although our net loss increased by approximately \$8,693,000 during the year ended December 31, 2014 compared to the year ended December 31, 2013, the primary reason for the decrease was due to the noncash impact of the change in fair value of the warrant liability. The warrant liability increase by approximately \$4,277,000 in the year ended December 31, 2014 compared to a decrease of approximately \$5,020,000 in the year ended December 31, 2013.

Excluding the impact of the change in the fair value of the warrant liability, the net decrease of approximately \$1,088,000 in cash used in operating activities during the year ended December 31, 2014 compared to the year ended December 31, 2013 are highlighted below:

during 2014, our deferred revenue decreased by approximately \$216,000 compared to a decrease of approximately \$711,000 during 2013 as a result of timing in recognition of revenue under the Bellco agreement; and

during 2013, license and supply fee payable decreased by \$1,318,000; and

during 2014, we recorded amortization of debt issuance costs of \$320,000, whereas amortization of debt issuance costs in 2013 was \$257,000.

Offsetting the above changes are the following items:

during 2014, our stock-based compensation expense, a non-cash expense, decreased by approximately \$146,000 compared to 2013;

during 2014, we recorded an inventory reserve of approximately \$59,000 compared to approximately \$210,000, primarily a result of the product recall, in 2013;

during 2014, our accounts receivable decreased by approximately \$11,000 compared to a decrease of approximately \$820,000, primarily reflecting the collection of amounts related to the Bellco agreement., during 2013;

during 2014, our accounts payable and accrued expenses decreased by approximately \$112,000 in the aggregate compared to an increase of approximately \$98,000 during 2013; and

as a result of changes in foreign currency rates, during 2014, we recognized a gain on foreign currency transactions of approximately \$48,000 compared to a loss of approximately \$26,000 during 2013.

Net cash provided by investing activities for the year ended December 31, 2013 was approximately \$3,000 related to the sale of fully depreciated manufacturing equipment. There were no investing transactions in 2014.

Net cash provided by financing activities for the year ended December 31, 2014 of \$3,203,000, net of equity issuance costs of approximately \$276,000, resulted primarily from gross proceeds of \$5.1 million related to the issuance of common stock related to the March 2014 rights offering and December 2014 rights offering, gross proceeds from the issuance of the August 2014 senior secured note of \$1.75 million and approximately \$15,000 of proceeds resulting from the exercise of warrants. Net cash provided by financing activities was partially offset by the repayment of the \$1.75 million August 2014 senior secured note, repayment of the \$1.5 million November 2013 senior secured note and payment of financing costs of approximately \$178,000.

Net cash provided by financing activities for the year ended December 31, 2013 of \$4,120,000, net of equity issuance costs of approximately \$229,000, resulted primarily from gross proceeds of \$3.0 million related to the issuance of common stock related to the May 2013 rights offering, gross proceeds from the issuance of the February 2013 senior secured note and the November 2013 senior secured note of \$2.8 million and approximately \$248,000 of proceeds resulting from the exercise of warrants. Net cash provided by financing activities was partially offset by the repayment of the \$1.3 million February 2013 senior secured note and the payment of financing costs of \$399,000.

### Contractual Obligations and Commercial Commitments

The following table summarizes our approximate minimum contractual obligations and commercial commitments as of December 31, 2014:

	Payments Due in Period				
	Total	Within 1 Year	Years 1-3	Years 4-5	More than 5 Years
Leases	\$106,000	\$104,000	\$2,000	\$ -	\$ -
Employment Contracts (1)	175,000	175,000	-	-	-
Total	\$281,000	\$279,000	\$2,000	\$ -	\$ -

Represents amount payable under severance agreement for John C. Houghton, effective January 4, 2015. See Note (1) 15, Subsequent Events, to the consolidated financial statements for the year ended December 31, 2014 for further discussion.

On April 15, 2015, the Company entered into a four-year employment agreement with Daron Evans, the President, CEO and Acting CFO, pursuant to which Mr. Evans will receive an annual base salary of \$240,000 per year.

## BUSINESS

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water, bicarbonate concentrate and/or blood. 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 use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to optimize the three elements critical to filter performance:

Filtration - as low as 0.005 microns

Flow rate - minimal disruption

Filter life - up to 12 months

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, or 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 offer ultrafilters for sale to customers in five 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.

*Dialysis Centers - Blood:* Treatment of patients with chronic renal failure using the OLPūr H2H Hemodiafiltration, or HDF, Module in conjunction with a UF controlled hemodialysis machine and its accessories, the H2H Module accessories, appropriately prepared water and ultrapure dialysate for hemodialysis and the OLPūr MD 220 Hemodiafilter.

*Military and Outdoor Recreation:* Highly compact, individual water purification devices used by soldiers and backpackers to produce drinking water in the field.

*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 U.S. in 2013. The United States Centers for Disease Control and Prevention estimates that healthcare associated infections, or HAIs, 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 enacted in March 2010, establishes 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.



In June 2014, we submitted to the FDA, for 510(k) clearance, the DSU-H and SSU-H Ultrafilters to filter EPA quality drinking water to remove microbiological contaminants and waterborne pathogens. In October 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 sterile water.

In June 2015, the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. ("ASHRAE") approved Standard 188-2015, "Prevention of Legionellosis: Risk Management for Building Water Associated with 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 will be 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, 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 when needed.

In the first part of 2016, we plan to launch new products to expand on our hospital product line. The DSU-H and the SSU-H are both in-line filters designed to be installed between the wall water outlet and the point of delivery fixture, be it sink faucet, shower head or ice machine. The new products are designed to be attached to the end of a faucet or shower line. These products will compete directly with other end-of-faucet filters for short term use.

*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 United States. 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, or AAMI, the American National Standards Institute, or ANSI and the International Standards Organization, or 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, or ESAs, 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 is enhanced, consequently the overall need for ESAs is reduced.

We believe that our 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. Our in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine.

In March 2014, we signed a non-exclusive distributor agreement with Mar Cor Purification, a wholly-owned subsidiary of Cantel Medical Corp., to distribute our dialysis ultrafilters to U.S. and Canadian dialysis clinics. In July 2014, we received notification from Health Canada Therapeutic Products Directorate Medical Devices Bureau that we were successfully issued a license for our Single Stage Ultrafilter.

In the fall of 2015, we plan to launch a new marketing campaign focused on further expanding our products into dialysis clinics. We will be working with our distributors to leverage recent data generated by users of our dialysis products. We anticipate that one or more of those data sets will be presented at the America Society of Nephrology in November 2015.

*Dialysis Centers - Blood.* The current standard of care in the U.S. 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 U.S. is hemofiltration, or 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, or 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 U.S., HDF is much more prevalent in Europe and is performed in approximately 16% 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, 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 Module and OLpūr MD 220 Hemodiafilter. The OLpūr H2H HDF Module and OLpūr MD 220 Hemodiafilter are cleared by the FDA to market for use with a 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.

We completed preparation of our OLpūr H2H HDF Modules and have manufactured lots of our OLpūr MD220 Hemodiafilters, H2H Substitution filters and H2H water filters. We also finalized our service contract to support the commercialization of our system in the field. In May 2014, DaVita Healthcare Partners announced that it had commenced delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select 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. We have submitted the data report to DaVita, and have been informed that it is still under review. Upon confirmatory review of the additional validation work, it is anticipated that DaVita will continue its evaluation. In March 2015, we announced that the Renal Research Institute, a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. We also anticipate evaluating our on-line mid-dilution HDF system at other clinics throughout the U.S. with the intent of developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of improving the quality of life for the patient, reducing overall expenditure compared to other dialysis modalities, minimizing the impact on nurse work flow at the clinic, and demonstrating the phamacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems.

*Military and Outdoor Recreation.* Water is a key requirement for the soldier to be fully mission-capable. The need for 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, resource intensive, and 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 levels specified by the Environmental Protection Agency, or EPA.

We developed our individual water treatment device, or IWTD, in both in-line (HydraGuard in-line) and point-of-use (HydraGuard Universal) 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.

In May 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC, or 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 HydraGuard individual water treatment devices. 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. Additionally, we have the right to terminate the sublicense with respect to a specific geographic area if CamelBak enters into an agreement or otherwise obtains or develops the rights to market or sell a product that competes with the HydraGuard individual water treatment devices in such geographic area. If we do not terminate the sublicense in such situation, and the sales of the competing product in such geographic area exceed the sales of the HydraGuard individual water treatment devices in the same area during any full calendar year, we may convert the exclusive sublicense to a non-exclusive sublicense solely with respect to such geographic area.

*Commercial Facilities.* In October 2013, we announced the voluntary recalls of our point of use, or POU, and DSU in-line ultrafilters used in hospital water treatment applications. As a result, we recalled all production lots of our POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, for the DSU in-line ultrafilter, we also requested that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect our dialysis products. In March, 2014, we requested termination of our product recall from the FDA. As of the date of this report, there has been no additional communication from the FDA regarding our request. We are also in the process of addressing certain issues raised by the FDA in a warning letter that we received in May 2015. In the letter, the FDA alleges deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter does not restrict our ability to manufacture, produce or ship any of our products, nor does it require the withdrawal of any product from the marketplace. We have responded in writing to the FDA's concerns and we intend to work diligently to address each concern to the FDA's satisfaction. On August 12, 2015, we received an additional letter from the FDA acknowledging our responses and noting that it will verify our implementation of corrective measures at its next inspection of our facility.

We have launched our new NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is 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 5nm in size and the water permeability (the ease at which water can pass through a membrane at a given pressure) of the membrane is higher than membranes

with a similar pore size. This provides improved flow performance relative to the physical size of the filter. We anticipate that the filters will be used as a component of a facility water treatment system and also for filtering water to be used in ice machines and soda fountains.

We have been working with customers to test prototype filters in commercial settings, such as data centers, and other high-flow-rate applications where particle reduction can provide an advantage. In the first part of 2016, we intend to launch new products into the commercial market. Specifically, we will launch a 10” and 20” filter cartridges that insert into standard filter housings, such as Pentek, Cuno, Shelco and Graver. We will be working with existing distributors and their existing customers, and seeking new distributors to address customers not currently targeted by our existing distributors

### **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 have not generated positive cash flow from operations for the three months ended June 30, 2015 or the year ended December 31, 2014. 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 July 24, 2015, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to \$10,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on July 24, 2015, we entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than 250,000 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase up 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. In no event shall Lincoln Park purchase more than \$500,000 worth of our common stock on any single business day, plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the up to 200,000 shares that may be sold to Lincoln Park under the Purchase Agreement on any business day will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than \$0.35 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate

the Purchase Agreement without fee, penalty or cost upon one business day's notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

## **Manufacturing and Suppliers**

We do not, and do not intend to in the near future, manufacture any of our products and components. With regard to the OLpūr MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, as amended by the first amendment dated February 19, 2014, with Bellco S.r.l., or 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), referred to herein as the Products. Under the agreement, as amended by the first amendment, we granted Bellco a license to manufacture, market and sell the 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 the Products as well as non-European countries, all such countries herein referred to as the Territory.

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 Products under its own name, label and CE mark in the Territory. In addition, if requested by us, Bellco will be required to sell the Products to our distributors in the Territory.

Our New Jersey office oversees global sales and marketing activity of our ultrafilter products. We are in discussions with several medical products and filtration products suppliers to act as non-exclusive distributors of our ultrafilter products to medical and non-medical institutions. In May 2012, we signed a non-exclusive U.S. distributor agreement with Vantage. In July 2012, we signed non-exclusive U.S. distributor agreements with TQM and Ameriwater. During 2013 we signed a non-exclusive North American distributor agreement with Chem-aqua and Garratt-Callahan. In February 2014 we signed a non-exclusive North American distributor agreement with Mar Cor Purification. For each prospective market for our ultrafilter products, we are pursuing alliance opportunities for joint product development and 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. We are also working on additional machine devices, next-generation user interface enhancements and other product enhancements.

We were awarded research contracts from the Office of Naval Research, or ONR, for development of a potable dual-stage military water purifying filter. The initial research contract was awarded in 2006 for approximately \$1 million and work was completed in August 2009. The second research contract was awarded in August 2009 and was an expansion of the 2006 ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes.

## **Major Customers**

For the years ended December 31, 2014 and 2013, three customers accounted for 78% and 86%, respectively, of our revenues.

As of December 31, 2014 three customers accounted for 83% of our accounts receivable. As of December 31, 2013, two customers accounted for 97% 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, which manufactures end-point water filtration systems, as well as 3M and Siemens. 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 needs of physicians and nephrologists, improve patient outcomes and remain cost-effective for payers.

We compete with other suppliers of End Stage Renal Disease, or ESRD, therapies, supplies and services. These suppliers include Fresenius Medical Care AG, and Baxter, currently two of the primary machine manufacturers in hemodialysis. At present, Fresenius Medical Care AG and Baxter also manufacture HDF machines.

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, 2014, we had eighteen 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, nine 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 2027. In addition, we have three pending U.S. patent applications, four pending patent applications in Canada, five pending patent applications in the European Patent Office, two pending patent applications in Brazil, one pending patent application in China, four pending patent applications in Israel, two pending patent applications in India and one pending patent application in South Korea. Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal.

On May 25, 2015, we received a Notice of Allowance for U.S. Patent Application No. 13/888,645, “Method and Apparatus of Flush Pump Feature for Portable Liquid Purifying Filter.” The Notice of Allowance covers claims relating to certain accessories used with our HydraGuard individual water purifier devices. The HydraGuard ultrafilter membrane provides a barrier to block sediment, bacteria, parasites, viruses & cysts from water filtered by the membrane. The flush pump apparatus, as described in the patent claims, provides a mechanism to provide real-time verification of filter integrity, to enable the user to clean the filter membrane while inside the filter casing, and to purge the filter for lighter storage or for protection against freeze-related damage in cold environments. The combination of our ultrafilter membrane and our flush pump apparatus enabled the HydraGuard to pass the NSF Protocol P248 for Military Operations Microbiological Water Purifiers.

Barring any unforeseen circumstances, we believe this patent should be valid until May 2033 given the patent filing occurred in May 2013. We licensed all intellectual property relating to the HydraGuard individual water purifier devices, including this patent, to Camelbak Products, LLC as part of a Sublicense Agreement on May 6, 2015. The Sublicense Agreement expires on December 31, 2022, unless terminated sooner in accordance with the terms of the agreement.

### *Trademarks*

As of December 31, 2014, we secured registrations of the trademarks CENTRAPUR, H2H,OLpūr and the Arrows Logo in the European Union. Applications for these trademarks are pending registration in the United States. We also have applications for registration of a number of other marks pending in the United States Patent and Trademark Office.

### **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 FDC Act. All of our ESRD therapy products are regulated in the United States as medical devices by the FDA under the FDC

Act. Under the FDC Act, 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 FDC Act or FDA clearance of a pre-market approval, or PMA, application under Section 515 of the FDC Act 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.

On July 1, 2009, we received FDA clearance of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

On August 11, 2011, we filed a 510(k) application with the FDA for clearance of our hemodiafiltration system for end-stage renal disease. On April 30, 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.

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 USP sterile water.

The FDC Act 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.

On May 28, 2015, we received a warning letter from the FDA resulting from an October 2014 inspection of our facility in River Edge, New Jersey. The warning letter alleges deficiencies relating to our compliance with the Quality System regulation and the Medical Device Reporting regulation. We take the matters identified in the warning letter seriously and are in the process of evaluating the corrective actions required to address the matters raised in the warning letter. We responded to the warning letter within 15 business days as requested by the FDA, and intend to work diligently and expeditiously to resolve the issues raised by the FDA. The warning letter does not restrict the manufacture, production or shipment of any of our products, nor require the withdrawal of any product from the marketplace. However, failure to promptly address the issues raised in the warning letter to the FDA's satisfaction or to comply with U.S. medical device regulatory requirements in general could result in regulatory action being initiated by the FDA. These actions could include, among other things, delays in approval of any FDA applications, product seizures, injunctions and civil monetary penalties. Any such actions could disrupt our ongoing business and operations and potentially have a material adverse impact on our financial condition and operating results. On August 12, 2015, we received an additional letter from the FDA acknowledging our responses and noting that it will verify our implementation of corrective measures at its next inspection of our facility.

In addition to the requirements described above, the FDC Act 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., or TÜV Rheinland, as the notified body to assist us in obtaining certification to the International Organization for Standardization, or 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 Products under its own name, label and CE mark in the Territory. In addition, if requested by us, Bellco will be required to sell the Products to our distributors in the 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 which 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 CE marking and Canadian approval of our OLPūr MD220 Hemodiafilter and DSU products, we have not obtained any regulatory approvals to sell any of our products 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, 2014, we employed a total of 8 employees, 7 of whom were full time and 1 who is employed on a part-time basis. We also have engaged 2 consultants on an ongoing basis. Of the 10 total employees and consultants, 3 are employed in a sales/marketing/customer support capacity, 3 in general and administrative and 4 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 term of the rental agreement is for one year commencing December 1, 2014 with a monthly cost of approximately \$8,800. We use these facilities to house our corporate headquarters and research facilities.

Our facilities in Europe are currently located at A5 Clonlara Avenue, Baldonnell Business Park, Dublin, Ireland, and consist of approximately 500 square feet of space. The lease agreement was entered into on July 1, 2010. The lease term is renewable for 6 month terms with a 2 month notice to discontinue, on a rolling basis. Our monthly cost is 500 Euro (approximately \$700).

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 is currently composed of six directors. Our Board of Directors 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 (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 of Directors at least once every three months. If we fail to do so, a Lambda Investors director will be empowered to convene such meeting.

### Class I Director — Term Expiring 2015

Name	Age (as of 7/31/15)	Director Since	Business Experience For Last Five Years
Arthur H. Amron	58	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 has also 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), since October 2010. 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.

Name	Age (as of 7/31/15)	Director Since	Business Experience For Last Five Years
Matthew Rosenberg	34	2014	<p>Dr. Rosenberg has served as a director of our company since May 2014. Dr. Rosenberg is an accomplished professional with extensive healthcare public policy experience. He is the Founder and President of Opaque as well as an active angel investor. Dr. Rosenberg was formerly at McKinsey &amp; Company, a global management consulting firm, where he focused on the Healthcare Systems and Services Practice. Dr. Rosenberg specializes in driving impact for payors and providers through strategic, organizational and operational improvements, including managed care contracting, alternative reimbursement designs, and clinical operations improvement. Dr. Rosenberg received his A.B. in Economics from Harvard University and his M.D. from Yale University School of Medicine. Among other experience, qualifications, attributes and skills, Dr. Rosenberg’s medical background and healthcare policy 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>

**Class II Directors — Term Expiring 2016**

<b>Name</b>	<b>Age (as of 7/31/15)</b>	<b>Director Since</b>	<b>Business Experience For Last Five Years</b>
Paul A. Mieyal	44	2007	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 until April 15, 2015. Dr. Mieyal also previously served as our Acting Chief Executive Officer from April 6, 2010 until April 20, 2012. Dr. Mieyal has been a Vice President of Wexford Capital LP since October 2006. From January 2000 through September 2006, he was Vice President in charge of healthcare investments for Wechsler & Co., Inc., a private investment firm and registered broker-dealer. Dr. Mieyal was a director of Nile Therapeutics, Inc., a publicly traded company, from September 2007 through November 2013. Dr. Mieyal received his Ph.D. in Pharmacology from New York Medical College, a B.A. in Chemistry and Psychology from Case Western Reserve University, and is a Chartered Financial Analyst. Among other experience, qualifications, attributes and skills, Dr. Mieyal's pharmacology and chemistry education, his experience in investment banking in the healthcare industry, as well as his experience serving on boards of directors of other public companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

<b>Name</b>	<b>Age (as of 7/31/15)</b>	<b>Director Since</b>	<b>Business Experience For Last Five Years</b>
Malcolm Persen	61	2015	Mr. Persen has served as a director of our Company since May 2015 and is currently the President of Resolute Performance Contracting, a solar construction firm that he founded in 2011. Previously, from 2009 through 2011, he was the Executive Vice President at Ironco Enterprises, a renewable energy contracting organization. From 2004 through 2008, Mr. Persen served as the Chief Financial Officer for Radyne Corporation, a NASDAQ-traded manufacturer and distributor of satellite and telecommunications equipment. While at Radyne, he was part of the management team that tripled revenues and sold the firm, resulting in a 100% return for shareholders. Earlier, Mr. Persen was employed as Group Financial Officer for Avnet, Inc., a global distributor of electronic components and computer systems. Other experience included assignments with consultancies Arthur D. Little and Mercer Management Consulting. In addition, Mr. Persen lectured in finance at the University of Arizona from 2010 to 2013 and at Boston College from 1988 to 1999. Mr. Persen currently serves on the Board of Valutek, a supplier of cleanroom supplies through direct and distribution channels. Mr. Persen holds a BA in Political Economics from The Colorado College, and an MBA from The Amos Tuck School of Business at Dartmouth College. Among other experience, qualifications, attributes and skills, Mr. Persen's extensive financial background led to the conclusion of our Board that he should serve as a director of our



company in light of our business and structure.

## Class III Directors — Term Expiring 2017

Name	Age (as of 7/31/15)	Director Since	Business Experience For Last Five Years
Daron Evans	41	2013	<p>Mr. Evans is currently our President, Chief Executive Officer and Acting Chief Financial 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 2006 to 2007, he was Director of Business Assessment for Vistakon, a division of Johnson &amp; Johnson Corp. From 2004 to 2006, he was Associate Director of Portfolio Management &amp; Business Analytics at Scios, Inc. after its acquisition by 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>

Name	Age (as of 7/31/15)	Director Since	Business Experience For Last Five Years
Lawrence J. Centella	74	2001	<p>Mr. Centella has served as a director of our company since January 2001 and currently serves as the Chairman of our Board of Directors. Mr. Centella serves as President of Renal Patient Services, LLC, a company that owns and operates dialysis centers, and has served in such capacity since June 1998. From 1997 to 1998, Mr. Centella served as Executive Vice President and Chief Operating Officer of Gambro Healthcare, Inc., an integrated dialysis company that manufactured dialysis equipment, supplied dialysis equipment and operated dialysis clinics. From 1993 to 1997, Mr. Centella served as President and Chief Executive Officer of Gambro Healthcare Patient Services, Inc. (formerly REN Corporation). Prior to that, Mr. Centella served as President of COBE Renal Care, Inc., Gambro Hospital, Inc., LADA International, Inc. and Gambro, Inc. Mr. Centella is also the founder of LADA International, Inc. Mr. Centella received a B.S. from DePaul University. Among other experience, qualifications, attributes and skills,</p>

Mr. Centella’s extensive experience in managing companies engaged in the business of dialysis centers and equipment, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Name	Age (as of 7/31/15)	Director Since	Business Experience For Last Five Years
Moshe Pinto	41	2015	<p>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 &amp; Neeman, a law firm based in Israel. He currently serves on the Board of Directors of Spiracur Inc. 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, Mr. Pinto’s hands-on expertise in dialysis equipment development and dialysis economics 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>

**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, CEO and Acting CFO, 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**

We currently have no executive officers other than Daron Evans, who serves as our President, Chief Executive Officer and Acting Chief Financial Officer.

On January 4, 2015, John C. Houghton separated from service with the Company as President, Chief Executive Officer and Acting Chief Financial Officer of the Company. Mr. Houghton also resigned as a member of the Board effective January 4, 2015. From January 4, 2015 through April 15, 2015, Paul A. Mieyal, a member of the Board of Directors, served as the Acting President, Chief Executive Officer and Chief Financial Officer.

## **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 2014, all of our officers, directors and 10% stockholders complied with applicable Section 16(a) filing requirements except as follows: (i) each of Messrs. Amron, Mieyal, and Centella did not timely file one Form 4 reporting a grant of stock options and restricted stock by the Board and (ii) Mr. Evans did not timely file one Form 4 related to shares issued to Mr. Evans upon exercise of nontransferable subscription rights in the March 2014 rights offering.

## **Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no disagreements with our accountants during 2014 or 2013 reportable pursuant to this requirement.

## **EXECUTIVE COMPENSATION**

The following table sets forth all compensation earned in the fiscal years ended December 31, 2014 and 2013 by our Named Executive Officers.

**Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$) <sup>(1)</sup>	Stock Awards (\$) <sup>(2)</sup>	Option Awards (\$) <sup>(2)</sup>	All Other Compensation (\$) <sup>(3)</sup>	Total
John C. Houghton <sup>(4)</sup> President, Chief Executive Officer and Acting Chief Financial Officer	2014	\$350,000	-	-	\$10,500	\$37,784	\$398,284
	2013	\$350,000	-	\$47,040	\$23,625	\$31,652	\$452,317

(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 2014 and 2013.

(2) The amount reported is the aggregate grant date fair value of the options 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."

(4) Mr. Houghton was appointed President and Chief Executive Officer effective April 20, 2012. On August 9, 2013, the Board of Directors of the Company appointed Mr. Houghton to also serve as the Company's Acting Chief Financial Officer and Principal Financial and Accounting Officer. Mr. Houghton separated from service with the Company effective January 4, 2015.

**All Other Compensation**

Name	Year	Matching 401K Plan Contribution	Health Insurance Paid by Company	Life Insurance Paid by the Company	Total Other Compensation
John C. Houghton	2014	\$14,000	\$20,520	\$3,264	\$37,784
	2013	\$14,000	\$15,732	\$1,920	\$31,652

**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, 2014 for our named executive officers.

**Outstanding Equity Awards at Fiscal Year-End 2014**

Name	Grant Date <sup>(1)</sup>	Option Awards <sup>(2)</sup>		Option Exercise Price (\$)	Option Expiration Date <sup>(3)</sup>
		Number of Securities Underlying Unexercised Options (#) Exercisable <sup>(2)</sup>	Number of Securities Underlying Unexercised Options (#) Unexercisable <sup>(2)</sup>		
John C. Houghton	April 20, 2012	464,063	210,938	\$ 0.95	4/20/22
John C. Houghton	July 3, 2012	227,941	331,550	\$ 1.89	7/3/22
John C. Houghton	May 23, 2013	9,375	28,125	\$ 0.71	5/23/23
John C. Houghton	February 5, 2014	-	35,000	\$ 0.71	5/23/23

(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, 2014, stock options became exercisable in accordance with the vesting schedule below:

Grantee	Grant Date	Vesting
John C. Houghton	April 20, 2012	14,063 vest monthly until March 20, 2016
John C. Houghton	July 3, 2012	6,907 vest monthly until March 20, 2016
John C. Houghton	May 23, 2013	9,375 vest annually until May 23, 2017
John C. Houghton	February 5, 2014	8,750 vest annually until February 5, 2018

Effective January 4, 2015, in connection with the separation from service of John C. Houghton from all of his positions with the Company, all unvested options were forfeited. The total unvested and forfeited options equaled 605,613.

- (3) Effective January 4, 2015, in connection with the separation from service of John C. Houghton from all of his positions with the Company, the expiration date for all options was accelerated to April 4, 2015.

### **Advisory Vote on Executive Compensation**

Our Board of Directors recognizes the fundamental interest our stockholders have in the compensation of our executive officers. At the Company's 2014 Annual Meeting, our stockholders approved with approximately 98% of the votes cast, on an advisory basis, in favor of the compensation of the Company's 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 the long term goals of the Company. 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 the Company's NEOs, the Company's stockholders indicated their approval of the Board's recommendation to hold a non-binding advisory vote on the Company's 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, or 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).

#### **Agreement with Mr. John C. Houghton**

Mr. Houghton's employment with the Company ended January 4, 2015. In connection with his separation from employment with the Company, Mr. Houghton entered into a Separation Agreement and General Release. Pursuant to this agreement, Mr. Houghton is entitled to six months severance (equal to six months of his then-current base salary, or a total of \$175,000 and is permitted to exercise his vested unexpired stock options for ninety days following January 4, 2015. During the severance term, Mr. Houghton will be subject to customary non-competition, non-solicitation and confidentiality restrictions.

On April 20, 2012, we entered into an Employment Agreement, or the Houghton Employment Agreement, effective as of April 20, 2012, with Mr. Houghton. The Houghton Employment Agreement had a term of four years, ending on April 20, 2016. The Employment Agreement provided that Mr. Houghton's annual base salary would be \$350,000. Mr. Houghton was eligible to receive a target discretionary bonus of 30% of annual base salary, as determined by us. The targets with respect to the bonus for the year ending December 31, 2012 were mutually agreed upon between Mr. Houghton and the Compensation Committee of the Board within 60 days following April 20, 2012 and such bonus was appropriately prorated for such annual period. The targets for each subsequent annual period were to be mutually agreed upon at the beginning of each calendar year between Mr. Houghton and the Compensation Committee.

Upon execution of the Houghton Employment Agreement, we granted Mr. Houghton options to purchase 675,000 shares of our common stock pursuant to our 2004 Stock Incentive Plan. In addition, we were required to grant Mr. Houghton options to purchase an additional 331,550 shares of our common stock. The Employment Agreement further provided that, subject to Mr. Houghton meeting and maintaining the director eligibility requirements of the Board, Mr. Houghton would be nominated for election as a director at each stockholders meeting during his employment at which his term as a director would otherwise expire.

The Houghton Employment Agreement provides that upon the occurrence of a change in control (as defined in the Houghton Employment Agreement), all of Mr. Houghton's unvested stock options would vest and become exercisable immediately and, unless all such options were cashed-out in the change in control transaction, would remain exercisable for a period of not less than 360 days (or the expiration of the stock option term, if sooner), regardless of whether Mr. Houghton's employment was terminated in connection with such change in control transaction.

In the event that Mr. Houghton's employment was terminated by us for "cause" (as defined in the Houghton Employment Agreement), then we would pay the earned but unpaid base salary for services rendered through the date of termination and any and all unvested stock options would automatically be cancelled and forfeited by Mr. Houghton as of the date of termination.

In the event that Mr. Houghton's employment was terminated by reason of Mr. Houghton's death, or by reason of Mr. Houghton's resignation or retirement (as to which at least two weeks notice is required), then we would pay to Mr. Houghton only the earned but unpaid base salary for services rendered through the date of termination. Any and all unvested stock options will automatically be cancelled and forfeited as of the date of Mr. Houghton's death, resignation or retirement.

If, as a result of Mr. Houghton's incapacity due to physical or mental illness, we determined that Mr. Houghton had failed to perform his duties on a full time basis for either ninety (90) days within any three hundred sixty-five (365) day period or sixty (60) consecutive days, we could terminate his employment hereunder for "disability". In that event, we would pay the earned but unpaid base salary for services rendered through such date of termination. Any and all unvested stock options would be cancelled as of the date of termination. During any period that Mr. Houghton failed to perform his duties as a result of incapacity due to physical or mental illness, he would continue to receive compensation and benefits provided by the Employment Agreement until his employment was terminated; provided, however, that the amount of compensation and benefits received during such period would be reduced by the aggregate amounts, if any, payable under our disability benefit plans and programs or under the Social Security disability insurance program. Additionally, the vesting of stock options would be tolled during such period and in the event of a termination of the Employment Agreement as a result of disability, any and all unvested stock options would automatically be cancelled and forfeited as of the date of termination.

In the event that Mr. Houghton's employment was terminated by us prior to the expiration of the term of the Employment Agreement for any reason other than as described above or by Mr. Houghton for "good reason" (as defined in the Employment Agreement) any and all unvested stock options would automatically be cancelled and forfeited by Mr. Houghton as of the date of such termination (except as provided in a change in control), vested stock options would remain exercisable for ninety (90) days after the date of such termination or the expiration of the stock option term, if sooner (except as otherwise provided in the event of a change in control), and we would pay to Mr. Houghton any earned but unpaid base salary for services rendered through the date of termination and continuing payments of severance pay (less applicable withholding taxes) at a rate equal to his base salary rate, as then in effect, for a period equal to three (3) months (or, when Mr. Houghton has been employed for at least one (1) year, a period equal to six (6) months), to be paid periodically in accordance with our normal payroll policies; provided that if Mr. Houghton continued to be employed in any capacity by a successor entity following a change in control, the severance pay that would otherwise be payable would be reduced by the amount of base compensation and guaranteed bonus (if any) Mr. Houghton received in such capacity during or attributable to the severance term. Payment of any severance benefits would be subject to the execution by Mr. Houghton of a general release and an agreement to continue to be bound by certain provisions of the Employment Agreement relating to, among others, non-competition, non-solicitation and confidentiality.

Mr. Houghton was also subject to non-competition, non-solicitation and confidentiality covenants during the term of his employment.

#### **2004 Stock Incentive Plan**

The 2004 Stock Incentive Plan provides that if there is a change in control, unless the agreement granting an award provides otherwise, all awards under the 2004 Stock Incentive Plan will become vested and exercisable as of the effective date of the change in control. As defined in the 2004 Plan, a change in control means the occurrence of any of the following events: (i) any "person," including a "group," as such terms are defined in sections 13(d) and 14(d) of the Exchange Act and the rules promulgated thereunder, becomes the beneficial owner, directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of more than 50% of the outstanding shares of our common stock; (ii) our complete liquidation; (iii) the sale of all or substantially all of our assets; or (iv) a majority of the members of our Board of Directors are elected to the Board without having previously been nominated and approved by a majority of the members of the Board incumbent on the day immediately preceding such election.

#### **401(k) Plan**

We have established a 401(k) deferred contribution retirement plan, which covers all employees. This 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 \$43,000 and \$46,000 in 2014 and 2013, respectively.

#### **Director Compensation**

For fiscal year 2014, 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 the Board received an annual retainer of \$30,000 and \$1,800 per meeting for each quarterly Board meeting attended. The chairperson 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.

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 our common stock 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, 2014. Mr. Persen was not a director during fiscal year 2014 and is not included in the table below.

#### **Non-Employee Director Compensation in Fiscal Year 2014**

Edgar Filing: NEPHROS INC - Form 424B3

Name	Fees Earned or Paid in Cash	<b>Restricted Stock Awards<sup>(1)</sup></b>	<b>Option Awards<sup>(2)</sup></b>	Total
Arthur H. Amron <sup>(8)</sup>	\$ -0-	\$ 21,840	\$ 10,905	(3) \$32,745
Paul A. Mieyal <sup>(8)</sup>	\$ -0-	\$ 21,840	\$ 10,905	(4) \$32,745
Lawrence J. Centella	\$ -0-	\$ 21,840	\$ 10,905	(5) \$32,745
Daron Evans	\$ -0-	\$ 37,147	\$ 30,898	(6) \$68,045
Matthew Rosenberg	\$ -0-	\$ 10,920	\$ 34,151	(7) \$45,071

(1) Director fees owed as of September 30, 2014 were paid in restricted stock awards in lieu of a cash payment.

The amount reported is the aggregate grant date fair value of the options granted, computed in accordance with (2)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.

(3) Options granted for services rendered by Mr. Amron totaled 80,348 options at December 31, 2014.

(4) Options granted for services rendered by Dr. Mieyal totaled 80,348 options at December 31, 2014.

- (5) Options granted for services rendered by Mr. Centella totaled 109,098 options at December 31, 2014.
- (6) Options granted for services rendered by Mr. Evans totaled 75,361 options at December 31, 2014.
- (7) Options granted for services rendered by Mr. Rosenberg totaled 48,864 options at December 31, 2014.
- (8) At the request of Messrs. Amron and Mieyal, their respective options and director fees were directed to Wexford Capital LP.

## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

On February 4, 2013, the Company issued a senior secured note to Lambda Investors LLC in the principal amount of \$1.3 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on August 4, 2013, at which time all principal and accrued interest was due. However, the Company paid amounts due under the note, including all accrued interest thereon of \$46,800, on May 22, 2013 with the cash proceeds from the May 2013 rights offering. In connection with the note, the Company paid Lambda Investors an 8%, or \$104,000, sourcing/transaction fee. In addition, the Company paid Lambda Investors' legal fees and other expenses incurred in connection with the note in the amount of \$50,000 as well as Lambda Investors' legal fees and other expenses incurred in connection with the May 2013 rights offering in the amount of \$50,000. Those payments totaling \$204,000 are reflected as amortization of debt discount.

On November 12, 2013, the Company issued a senior secured note to Lambda Investors LLC in the principal amount of \$1.5 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on May 12, 2014, at which time all principal and accrued interest was due. However, the Company paid amounts due under the note, including all accrued interest thereon of \$61,000, on March 18, 2014 with the cash proceeds from the March 2014 rights offering. In connection with the note, the Company paid Lambda Investors an 8%, or \$120,000, sourcing/transaction fee. In addition, the Company paid Lambda Investors' legal fees and other expenses incurred in connection with the note in the amount of \$75,000. Those payments totaling \$195,000 were made on November 12, 2013 and are reflected as a debt discount which is being amortized over the term of the senior secured note. Approximately \$142,000 and \$53,000, respectively, are included in interest expense on the consolidated statements of operations and comprehensive loss for the years ended December 31, 2014 and 2013.

On August 29, 2014, the Company issued a senior secured note to Lambda, in the principal amount of \$1.75 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on February 28, 2015, at which time all principal and accrued interest was due. However, the Company paid all amounts due under the note on December 18, 2014 with the cash proceeds from the rights offering that closed in December 2014. In connection with the note, the Company incurred an 8%, or \$140,000, sourcing/transaction fee with Lambda. In addition, the Company incurred

additional legal fees and other expenses in connection with the note in the amount of \$38,000 with Lambda. Those payments totaling \$178,000 were initially reflected as a debt discount and amortized over the term of the note. For the year ended December 31, 2014, \$178,000 is included in interest expense on the consolidated statements of operations and comprehensive loss.

As of May 31, 2015, Lambda Investors is our largest stockholder and beneficially owns approximately 48% of our outstanding common stock and, on a fully-diluted basis, owns approximately 56% of our outstanding common stock. The warrants held by Lambda Investors have an exercise price of \$0.30 or \$0.40 per share and certain warrants have full ratchet anti-dilution protection. In connection with the August 2014 senior note, we agreed to extend the expiration date of the existing warrants held by Lambda Investors to March 21, 2019.

In connection with the February 2013 loan, the November 2013 loan and the August 2014 loan from Lambda Investors, we entered into registration rights agreements with Lambda Investors pursuant to which we will file a registration statement on Form S-1 covering the resale by Lambda Investors of the common stock underlying shares sold to Lambda Investors. Under these registration rights agreements, we will pay all of the expenses, including reasonable legal fees, of Lambda Investors in connection with such registration statement and resale of shares by Lambda Investors under such registration statement, which may be in an underwritten public offering. We will be obligated to use our reasonable best efforts to keep such registration statement continuously effective until such time as all the securities registered on such registration statement have been sold or are eligible for sale without restriction under the applicable securities laws.

The shares beneficially owned by Lambda Investors 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 2014 and 2013, at the request of Messrs. Amron and Mieyal, fees and options in the aggregate amount of approximately \$65,490 and \$45,752, respectively, earned in respect of services they rendered to the company were directed to Wexford Capital LP.

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 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.

## **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, 2014 about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors upon exercise of options or warrants. Our equity compensation plans as of December 31, 2014 consisted of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (the "Prior Plans"). All of our employees and directors were eligible to participate in the Prior Plans. 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 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan is not reflected in the table below.



Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by our stockholders	2,140,684	\$ 0.91	2,054,799
Equity compensation plans not approved by our stockholders <sup>(1)</sup>	331,550	\$ 1.69	-
Total	2,472,184		2,054,799

On July 3, 2012, the Company granted Mr. Houghton an option to purchase 331,550 shares of common stock of the company, under a Non-qualified Stock Option Agreement, dated July 3, 2012, between Mr. Houghton and the Company, in connection with his appointment as the President and Chief Executive Officer. The terms of this Non-qualified Stock Option Agreement are substantially similar to the terms of the 2004 Stock Incentive Plan. The options granted to Mr. Houghton pursuant to this agreement vest in equal monthly installments over four years commencing on April 20, 2012, the date Mr. Houghton was appointed; provided that Mr. Houghton remains employed by the company at such time. In connection with the separation from service of John C. Houghton from all of his positions with the Company, all unvested options were forfeited on January 4, 2015.

**Security Ownership of Certain Beneficial Owners**

The following table sets forth the beneficial ownership of our common stock as of June 30, 2015, by (i) each person known to us to own beneficially more than five percent (5%) of our common stock, based on such persons' or entities' filings with the SEC as of that date; (ii) each director and named executive officer; and (iii) all directors and executive officers as a group:

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class (1)	
Lambda Investors LLC <sup>(2)</sup>	29,990,870	64.1	%
Arthur H. Amron <sup>(3)</sup>	145,373	*	
Lawrence J. Centella <sup>(4)</sup>	221,564	*	
John C. Houghton <sup>(5)</sup>	74,139	*	
Daron Evans <sup>(6)</sup>	172,104	*	
Paul A. Mieyal <sup>(7)</sup>	145,373	*	
Matthew Rosenberg <sup>(8)</sup>	922,271	2.8	%
Malcolm Persen <sup>(9)</sup>	65,734	*	
All executive officers and directors as a group <sup>(3)-(4), (6)-(9)</sup>	1,672,419	5.1	%

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

(1) Applicable percentage ownership is based on 32,227,939 shares of common stock outstanding as of June 30, 2015, 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 shares. Common stock subject to options and warrants exercisable on or within 60 days after June 30, 2015 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.

(2) Based in part on information provided in a Form 4 filed on December 22, 2014. The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors, Wexford GP LLC, which is the General Partner of Wexford Capital LP, by Charles E. Davidson in his capacity as Chairman and managing member of Wexford Capital LP and by Joseph M. Jacobs in his capacity as President and managing member of Wexford Capital LP. The address of each of Lambda Investors LLC, Wexford Capital LP, Mr. Davidson and Mr. Jacobs is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. Each of Wexford Capital LP, Wexford GP LLC, Mr. Davidson and Mr. Jacobs disclaims beneficial ownership of the shares of Common Stock owned by Lambda Investors except, in the case of Mr. Davidson and Mr. Jacobs, to the extent of their respective interests in each member of Lambda Investors. Includes 11,742,100 shares issuable upon exercise of warrants held by Lambda Investors having an exercise price of \$0.30 per share and 2,782,576 shares issuable upon exercise of warrants held by Lambda Investors having an exercise

price of \$0.40 per share. 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 former Acting President, Acting Chief Executive Officer, and Acting Chief Financial Officer until April 15, 2015, is a Vice President of Wexford Capital LP.

Mr. Amron's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Amron consist of: (i) 73,891 shares of restricted stock granted under (3) the 2004 Stock Incentive Plan; and (ii) 71,482 shares issuable upon exercise of options granted under the 2004 Stock Incentive Plan. Does not include 8,866 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

Mr. Centella's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Centella consist of: (i) 47,441 shares of common stock; (ii) 73,891 (4) shares of restricted stock granted under the 2004 Stock Incentive Plan; and (iii) 100,232 shares issuable upon exercise of options granted under the 2004 Stock Incentive Plan. Does not include 8,866 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

Mr. Houghton's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares (5) identified as being beneficially owned by Mr. Houghton consist of: (i) 66,254 shares of restricted stock granted under the 2004 Stock Incentive Plan; and (i) 7,885 shares purchased in a rights offering in December 2014.

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) 74,084 shares of common stock; and (ii) 98,020 (6) shares issuable upon exercise of options granted under the 2004 Stock Incentive Plan. Does not include 2,161,534 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

Dr. Mioyal's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Dr. Mioyal consist of: (i) 73,891 shares of restricted stock granted under (7) the 2004 Stock Incentive Plan; and (ii) 71,482 shares issuable upon exercise of options granted under the 2004 Stock Incentive Plan. Does not include 8,866 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

Mr. Rosenberg's address is the company address: 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Rosenberg consist of: (i) 776,997 shares of common stock; (ii) 12,698 shares of restricted stock granted under the 2004 Stock Incentive Plan; (iii) 32,576 shares issuable upon (8) exercise of options granted under the 2004 Stock Incentive Plan; and (iv) 100,000 shares issuable upon the exercise of warrants having an exercise price of \$0.85 per share. Does not include 16,288 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

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. Person consist of: (i) 31,160 shares of common stock held by Mr. (9) Persen's spouse; (ii) 18,993 shares of common stock issuance upon exercise of options granted under the 2015 Equity Incentive Plan; and (iii) 15,580 shares of common stock issuable upon the exercise of warrants having an exercise price of \$0.85 per share. Does not include 37,988 shares issuable upon the exercise of options which have been granted under our Stock Incentive Plans but will not vest within 60 days of June 30, 2015.

## **DESCRIPTION OF CAPITAL STOCK**

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

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

As of June 30, 2015, we had issued and outstanding approximately:

32,227,939 shares of common stock;

Options to purchase 3,634,502 shares of our common stock at exercise prices ranging from \$0.33 to \$51.40, with a weighted average price of \$0.70; and

Warrants to purchase 17,664,937 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, warrants to purchase 2,226,112 shares at an exercise price of \$0.40 per share with expiration dates in 2016, warrants to purchase 2,782,577 at an exercise price of \$0.40 per share with expiration dates in 2019, and warrants to purchase 11,742,100 shares at an exercise price of \$0.30 per share with expiration dates in 2019.

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.

As noted above under "Certain Relationships and Related Transactions", we have entered into several registration rights agreements with Lambda Investors. In connection with the February 2013 loan, the November 2013 loan and the August 2014 loan from Lambda Investors and in connection with our March 2011 rights offering, we entered into registration rights agreements with Lambda Investors pursuant to which we will file a registration statement on Form S-1 covering the resale by Lambda Investors of the common stock sold to Lambda Investors. Under these registration rights agreements, we will pay all of the expenses, including reasonable legal fees, of Lambda Investors in connection with such registration statement and resale of shares by Lambda Investors under such registration statement, which may be in an underwritten public offering. We will be obligated to use our reasonable best efforts to keep such registration statement continuously effective until such time as all the securities registered on such registration statement have been sold or are eligible for sale without restriction under the applicable securities laws.

## **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 year ended December 31, 2014 included in this prospectus have been audited by WithumSmith+Brown PC, 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. Our financial statements as of and for the year ended December 31, 2013 included in this prospectus have been audited by Rothstein Kass, 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**

Page

**Annual Financial Statements**

<u>Reports of Independent Registered Public Accounting Firms</u>	F-2
<u>Consolidated Balance Sheets — December 31, 2014 and 2013</u>	F-4
<u>Consolidated Statements of Operations and Comprehensive Loss — Years ended December 31, 2014 and 2013</u>	F-5
<u>Consolidated Statements of Changes in Stockholders' Deficit — Years ended December 31, 2014 and 2013</u>	F-6
<u>Consolidated Statements of Cash Flows — Years ended December 31, 2014 and 2013</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

**Quarterly Financial Statements**

<u>Condensed Consolidated Balance Sheets — June 30, 2015 (unaudited) and December 31, 2014 (audited)</u>	F-30
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss — Three and six months ended June 30, 2015 and June 30, 2014 (unaudited)</u>	F-31
<u>Condensed Consolidated Statements of Changes in Stockholders' Deficit — Six months ended June 30, 2015 and June 30, 2014 (unaudited)</u>	F-32
<u>Condensed Consolidated Statements of Cash Flows — Six months ended June 30, 2015 and June 30, 2014 (unaudited)</u>	F-33
<u>Notes to Condensed Consolidated Interim Financial Statements</u>	F-34

F-1



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Nephros, Inc.

We have audited the accompanying consolidated balance sheet of Nephros, Inc. and Subsidiary (collectively, the “Company”), as of December 31, 2014, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ deficit and cash flows for the year 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 audit.

We conducted our audit 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes 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 audit provides 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, 2014, and the results of their operations and their cash flows for the year then ended in accordance 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 3 to the consolidated financial statements, the Company has incurred negative cash flow from operations and recurring net losses since inception. 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 3. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited the adjustments described in Note 2 that were applied to restate the consolidated financial statements as of and for the year ended December 31, 2013, and the adjustments described in Note 2 that were applied to restate selected amounts as of January 1, 2009, and as of and for each of the years ended December 31, 2009 to 2012 as indicated in Note 2 (collectively, the "Restatement Adjustments"), to correct an error. In our opinion, the Restatement Adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the consolidated financial statements as of January 1, 2009, or the consolidated financial statements as of and for each of the years ended December 31, 2009 to 2013, of the Company other than with respect to the Restatement Adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2009 through 2013 consolidated financial statements, taken as a whole. Those consolidated financial statements were audited by other auditors, Rothstein Kass.

/s/ Withum Smith+Brown PC

Morristown, New Jersey

April 15, 2015

F-2

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Nephros, Inc.

We have audited, before the effects of the adjustments for the correction of the error described in Note 2, the accompanying consolidated balance sheet of Nephros, Inc. and Subsidiary (collectively, “the Company”) as of December 31, 2013, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ deficit and cash flows for the year ended December 31, 2013 (the 2013 financial statements before the effects of the adjustments discussed in Note 2 are not presented herein). 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 audit.

We conducted our audit 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 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 audit provide a reasonable basis for our opinion.

In our opinion, except for the error in Note 2, 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, 2013, and the results of their operations and their cash flows for the year ended December 31, 2013, 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 3 to the consolidated financial statements, the Company has incurred negative cash flow from operations and net losses since inception. 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 3. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We were not engaged to audit, review, or apply any procedures to the adjustments for the correction of an error described in Note 2 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by WithumSmith+Brown, PC.

/s/ Rothstein Kass

Roseland, New Jersey

March 27, 2014

F-3

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2014	December 31, 2013 (restated)
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,284	\$ 579
Accounts receivable, net	110	122
Inventory, net	186	162
Prepaid expenses and other current assets	104	125
Total current assets	1,684	988
Property and equipment, net	1	7
Other assets, net of accumulated amortization	1,684	1,894
Total assets	\$ 3,369	\$ 2,889
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Senior secured note payable, net of debt discount of \$142 at December 31, 2013	\$ -	\$ 1,358
Accounts payable	835	1,073
Accrued expenses	342	365
Deferred revenue, current portion	70	703
Total current liabilities	1,247	3,499
Warrant liability	7,386	3,109
Long-term portion of deferred revenue	417	-
Total liabilities	9,050	6,608
Commitments and Contingencies		
Stockholders' deficit:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2014 and 2013; no shares issued and outstanding at December 31, 2014 and 2013.	-	-
Common stock, \$.001 par value; 90,000,000 shares authorized at December 31, 2014 and 2013; 30,391,513 and 18,082,043 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively.	30	18
Additional paid-in capital	108,382	102,983

Edgar Filing: NEPHROS INC - Form 424B3

Accumulated other comprehensive income	72		74	
Accumulated deficit	(114,165	)	(106,794	)
Total stockholders' deficit	(5,681	)	(3,719	)
Total liabilities and stockholders' deficit	\$ 3,369		\$ 2,889	

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

F-4

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In Thousands, Except Share and Per Share Amounts)

	Years Ended December 31,	
	2014	2013 (restated)
Net revenue:		
Product revenues	\$914	\$1,029
Licensing revenues	834	711
Total net revenues	1,748	1,740
Cost of goods sold	549	898
Gross margin	1,199	842
Operating expenses:		
Research and development	781	867
Depreciation and amortization	217	223
Selling, general and administrative	2,870	3,069
Total operating expenses	3,868	4,159
Loss from operations	(2,669 )	(3,317 )
Change in fair value of warrant liability	(4,277 )	5,020
Interest expense	(483 )	(351 )
Gain on sale of equipment	-	3
Other income (expense), net	58	(33 )
Net income (loss)	(7,371 )	1,322
Other comprehensive loss, foreign currency translation adjustments	(2 )	(2 )
Total comprehensive income (loss)	\$(7,373 )	\$1,320
Net income (loss) per common share, basic	\$(0.31 )	\$0.08
Weighted average common shares outstanding, basic	23,817,184	15,624,999
Net loss per common share, diluted	\$(0.31 )	(0.18 )
Weighted average common shares outstanding, diluted	23,817,184	20,760,410

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

(In Thousands, Except Share Amounts)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Equity (Deficit) Total
Balance, December 31, 2012 (restated)	11,949,824	\$ 12	\$ 99,304	\$ 76	\$(108,116 )	\$(8,724 )
Net income, as restated					1,322	1,322
Net unrealized losses on foreign currency translation, net of tax				(2 )		(2 )
Shareholder rights offering, net	5,000,000	5	2,766			2,771
Issuance of restricted stock	340,220					-
Exercise of warrants	791,999	1	247			248
Noncash stock-based compensation			652			652
Warrant modification			14			14
Balance, December 31, 2013 (restated)	18,082,043	\$ 18	\$ 102,983	\$ 74	\$(106,794 )	\$(3,719 )
Net loss					(7,371 )	(7,371 )
Net unrealized losses on foreign currency translation, net of tax				(2 )		(2 )
Shareholder rights offerings, net	12,140,823	12	4,854			4,866
Issuance of restricted stock	132,077					-
Exercise of warrants	36,570		15			15
Noncash stock-based compensation			530			530
Balance, December 31, 2014	30,391,513	\$ 30	\$ 108,382	\$ 72	\$(114,165 )	\$(5,681 )

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 December 31,	
	2014	2013 (restated)
Operating activities		
Net income (loss)	\$ (7,371 )	\$ 1,322
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation of property and equipment	6	9
Amortization of other assets	210	214
Non-cash stock-based compensation, including stock options and restricted stock	429	575
Change in fair value of warrant liability	4,277	(5,020 )
Warrant inducement	-	14
Inventory reserve	59	210
Amortization of debt discount	320	257
Gain on disposal of property and equipment	-	(3 )
(Gain)/loss on foreign currency transactions	(48 )	26
(Increase) decrease in operating assets:		
Accounts receivable	12	820
Inventory	(82 )	(60 )
Prepaid expenses and other current assets	21	(16 )
Increase (decrease) in operating liabilities:		
Accounts payable	(190 )	(23 )
Accrued expenses	78	121
License and supply agreement fee payable	-	(1,318 )
Deferred revenue	(216 )	(711 )
Net cash used in operating activities	(2,495 )	(3,583 )
Investing activities		
Proceeds from sales of property and equipment	-	3
Net cash provided by investing activities	-	3
Financing activities		
Proceeds from issuance of common stock, net of equity issuance costs of \$276 and \$229, respectively	4,866	2,771
Proceeds from issuance of senior secured notes	1,572	2,800
Payment of financing costs	-	(399 )
Proceeds from exercise of warrants	15	248
Payment of senior secured notes	(3,250 )	(1,300 )
Net cash provided by financing activities	3,203	4,120

Edgar Filing: NEPHROS INC - Form 424B3

Effect of exchange rates on cash	(3	)	(8	)
Net increase in cash	705		532	
Cash, beginning of year	579		47	
Cash, end of year	\$ 1,284		\$ 579	
Supplemental disclosure of cash flow information				
Cash paid for interest	\$ 188		\$ 54	
Cash paid for taxes	\$ 6		\$ 2	
Restricted stock issued to settle liability	\$ 101		\$ 77	

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

F-7

**NEPHROS, INC.**

**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, or 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 – Restatement of Previously Issued Financial Statements**

In preparation of the Annual Report, the Company concluded it should correct its accounting related to the Company’s outstanding warrants that were originally issued in 2007 (the “2007 Warrants”). The Company had initially accounted for the warrants as a component of equity but upon further evaluation of the terms of these warrants, concluded that the 2007 Warrants should be accounted for as a derivative liability. The Company’s 2007 Warrants are not indexed to the Company’s common stock because the transactions that would trigger the Anti-Dilution Adjustment Provision are not inputs to the fair value of the warrants. As a result, we should have classified the 2007 Warrants as derivative liabilities as of January 1, 2009, the date which ASC Section 815-40-15 was effective. Under this accounting treatment, we are required to measure the fair value of the 2007 Warrants at the end of each reporting period

beginning in the year ended December 31, 2009, with a cumulative effect presented as of January 1, 2009, and recognize changes in the fair value for all periods beginning with January 1, 2009 in our operating results for the current period.

The following table summarizes the effect of the restatement to the Company's financial statements for (i) its 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) its 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:

	(Amounts in 000s, except share and per share data)		
	As		As
	Previously	Adjustments	Restated
	Reported		
Balance sheet as of September 30, 2014 (unaudited)			
Warrant Liability	\$ -	\$ 7,116	\$ 7,116
Additional Paid-in Capital	102,864	2,458	105,322
Accumulated Deficit	(103,348 )	(9,573 )	(112,921 )
Three months ended September 30, 2014 (unaudited)			
Change in fair value of warrant liability	-	3,428	3,428
Net income (loss)	(706 )	3,428	2,723
Net income (loss) per share, basic	(0.03 )	0.14	0.11
Net income (loss) per share, diluted	(0.03 )	0.01	(0.02 )
Weighted average common shares outstanding, diluted	25,238,412	8,252,777	33,491,189
Comprehensive income (loss)	(705 )	3,429	2,724

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 2 – Restatement of Previously Issued Financial Statements (continued)

	(Amounts in 000s, except share and per share data)		
	As		As
	Previously	Adjustments	Restated
	Reported		
Nine months ended September 30, 2014 (unaudited)			
Change in fair value of warrant liability	-	(4,007 )	(4,007 )
Net loss	(2,120 )	(4,007 )	(6,127 )
Net income (loss) per share, basic and diluted	(0.09 )	(0.18 )	(0.27 )
Comprehensive loss	(2,121 )	(4,007 )	(6,128 )
Balance sheet as of June 30, 2014 (unaudited)			
Warrant Liability	-	10,544	10,544
Additional Paid-in Capital	102,761	2,458	105,219
Accumulated Deficit	(102,642 )	(13,002 )	(115,644 )
Three months ended June 30, 2014 (unaudited)			
Change in fair value of warrant liability	-	(4,685 )	(4,685 )
Net loss	(654 )	(4,685 )	(5,339 )
Net loss per share, basic and diluted	(0.03 )	(0.18 )	(0.21 )
Comprehensive loss	(655 )	(4,685 )	(5,340 )
Six months ended June 30, 2014 (unaudited)			
Change in fair value of warrant liability	-	(7,436 )	(7,436 )
Net loss	(1,414 )	(7,436 )	(8,850 )
Net loss per share, basic and diluted	(0.06 )	(0.34 )	(0.40 )
Comprehensive loss	(1,416 )	(7,436 )	(8,852 )
Balance sheet as of March 31, 2014 (unaudited)			
Warrant Liability	-	5,859	5,859
Additional Paid-in Capital	102,656	2,458	105,114
Accumulated Deficit	(101,988 )	(8,317 )	(110,305 )
Three months ended March 31, 2014 (unaudited)			
Change in fair value of warrant liability	-	(2,751 )	(2,751 )

Edgar Filing: NEPHROS INC - Form 424B3

Net loss	(760	)	(2,751	)	(3,511	)
Net loss per share, basic and diluted	(0.04	)	(0.15	)	(0.19	)
Comprehensive loss	(761	)	(2,751	)	(3,512	)

Balance sheet as of December 31, 2013 (audited)

Warrant Liability	-		3,109		3,109	
Additional Paid-in Capital	100,526		2,457		102,983	
Accumulated Deficit	(101,228	)	(5,566	)	(106,794	)

F-9

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 2 – Restatement of Previously Issued Financial Statements (continued)

	(Amounts in 000s, except share and per share data)		
	As Previously Reported	Adjustments	As Restated
Year ended December 31, 2013 (audited)			
Change in fair value of warrant liability	-	5,020	5,020
Net income (loss)	(3,698	) 5,020	1,322
Net income (loss) per share, basic	(0.24	) 0.32	0.08
Net income (loss) per share, diluted	(0.24	) 0.06	(0.18
Weighted average common shares outstanding, diluted	15,624,999	5,135,411	20,760,410
Comprehensive income (loss)	(3,700	) 5,020	1,320
Balance sheet as of September 30, 2013 (unaudited)			
Warrant Liability	-	7,776	7,776
Additional Paid-in Capital	100,391	2,457	102,848
Accumulated Deficit	(100,053	) (10,234	) (110,287
Three months ended September 30, 2013 (unaudited)			
Change in fair value of warrant liability	-	(1,797	) (1,797
Net loss	(611	) (1,797	) (2,408
Net loss per share, basic and diluted	(0.03	) (0.11	) (0.14
Comprehensive loss	(611	) (1,797	) (2,408
Nine months ended September 30, 2013 (unaudited)			
Change in fair value of warrant liability	-	352	352
Net income (loss)	(2,523	) 352	(2,171
Net income (loss) per share, basic and diluted	(0.17	) 0.02	(0.15
Comprehensive loss	(2,525	) 352	(2,173
Balance sheet as of June 30, 2013 (unaudited)			
Warrant Liability	-	5,980	5,980
Additional Paid-in Capital	100,191	2,457	102,648
Accumulated Deficit	(99,442	) (8,437	) (107,879

Edgar Filing: NEPHROS INC - Form 424B3

Three months ended June 30, 2013 (unaudited)

Change in fair value of warrant liability	-	(608	)	(608	)	
Net loss	(671	)	(608	)	(1,279	)
Net loss per share, basic and diluted	(0.05	)	(0.05	)	(0.10	)
Comprehensive loss	(673	)	(608	)	(1,281	)

Six months ended June 30, 2013 (unaudited)

Change in fair value of warrant liability	-	2,149	2,149		
Net income (loss)	(1,912	)	2,149	237	
Net income (loss) per share, basic	(0.14	)	0.16	0.02	
Net income (loss) per share, diluted	(0.14	)	0.04	(0.10	)
Weighted average common shares outstanding, diluted	14,556,050	5,150,160	19,706,210		
Comprehensive income (loss)	(1,914	)	2,149	235	

F-10



## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 2 – Restatement of Previously Issued Financial Statements (continued)

	(Amounts in 000s, except share and per share data)		
	As Previously Reported	Adjustments	As Restated
Balance sheet as of March 31, 2013 (unaudited)			
Warrant Liability	-	5,372	5,372
Additional Paid-in Capital	96,988	2,457	99,445
Accumulated Deficit	(98,772)	) (7,830	) (106,602)
Three months ended March 31, 2013 (unaudited)			
Change in fair value of warrant liability	-	2,756	2,756
Net income (loss)	(1,242)	) 2,756	1,514
Net income (loss) per share, basic	(0.10)	) 0.23	0.13
Net income (loss) per share, diluted	(0.10)	) 0.03	(0.07)
Weighted average common shares outstanding, diluted	12,009,285	5,624,075	17,633,360
Comprehensive income (loss)	(1,242)	) 2,756	1,514
Balance sheet as of December 31, 2012 (audited)			
Warrant Liability	-	8,129	8,129
Additional Paid-in Capital	96,847	2,457	99,304
Accumulated Deficit	(97,530)	) (10,586	) (108,116)
Year ended December 31, 2012 (audited)			
Change in fair value of warrant liability	-	(3,361)	) (3,361)
Net loss	(3,262)	) (3,361)	) (6,623)
Net loss per share, basic and diluted	(0.29)	) (0.30)	) (0.59)
Comprehensive loss	(3,262)	) (3,361)	) (6,596)
Balance sheet as of December 31, 2011 (audited)			
Warrant Liability	-	5,096	5,096
Additional Paid-in Capital	95,630	2,129	97,759
Accumulated Deficit	(94,268)	) (7,225)	) (101,493)
Year ended December 31, 2011 (audited)			

Edgar Filing: NEPHROS INC - Form 424B3

Change in fair value of warrant liability	-	(4,638	)	(4,638	)	
Net loss	(2,360	)	(4,638	)	(6,998	)
Net loss per share, basic and diluted	(0.27	)	(0.54	)	(0.81	)
Comprehensive loss	(2,333	)	(4,638	)	(6,971	)
Balance sheet as of December 31, 2010 (audited)						
Warrant Liability	-	458		458		
Additional Paid-in Capital	91,979	2,129		94,108		
Accumulated Deficit	(91,908	)	(2,587	)	(94,495	)

F-11

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 2 – Restatement of Previously Issued Financial Statements (continued)

	(Amounts in 000s, except share and per share data)		
	As Previously Reported	Adjustments	As Restated
Year ended December 31, 2010 (audited)			
Change in fair value of warrant liability	-	5,813	5,813
Net income (loss)	(1,933 )	5,813	3,880
Net income (loss) per share, basic and diluted	(0.93 )	2.79	1.86
Balance sheet as of December 31, 2009 (audited)			
Warrant Liability	-	6,272	6,272
Additional Paid-in Capital	91,815	2,129	93,944
Accumulated Deficit	(89,975 )	(8,400 )	(98,375 )
Year ended December 31, 2009 (audited)			
Change in fair value of warrant liability	-	(10,056 )	(10,056 )
Net loss	(2,026 )	(10,056 )	(12,082 )
Net loss per share, basic and diluted	(1.06 )	(5.26 )	(6.32 )
Balance sheet as of January 1, 2009 (audited)			
Warrant Liability	-	2,107	2,107
Additional Paid-in Capital	90,375	(3,763 )	86,612
Accumulated Deficit	(87,949 )	1,656	(86,293 )

Historically, the Company had generated net losses thus its basic and diluted earnings per share calculations were based upon the same weighted average shares due to the anti-dilution effect. Certain periods above were restated to reflect net income. As such, the diluted earnings per share calculation for those periods are calculated based upon the treasury stock method as follows:

(restated)	(restated)	(restated)
	For the year	

Edgar Filing: NEPHROS INC - Form 424B3

(amounts in 000s, except share and per share data)	For the three months ended September 30, 2014	ended December 31, 2013	For the six months ended June 30, 2013
Loss per share – Basic:			
Numerator for basic income (loss) per share	\$ 2,723	\$ 1,322	\$ 237
Denominator for basic income (loss) per share	25,238,412	15,624,999	14,556,050
Basic income (loss) per common share	\$ 0.11	\$ 0.08	\$ 0.02
Loss per share – Diluted:			
Numerator for diluted income (loss) per share	\$ 2,723	\$ 1,322	237
Adjust: Fair value of dilutive warrants outstanding	(3,429	) (5,020	) (2,149 )
Numerator for diluted income (loss) per share	\$ (706	) (3,698	) (1,912 )
Denominator for basic income (loss) per share	25,238,412	15,624,999	14,556,050
Plus: Incremental shares underlying warrants outstanding	8,252,777	5,135,411	5,150,160
Denominator for diluted income (loss) per share	33,491,189	20,760,410	19,706,210
Diluted income (loss) per common share	\$ (0.02	) \$ (0.18	) \$ (0.10 )

F-12

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 2 – Restatement of Previously Issued Financial Statements (continued)**

(amounts in 000s, except share and per share data)	(restated) For the three months ended March 31, 2013	(restated) For the year ended December 31, 2010	
Loss per share – Basic:			
Numerator for basic income (loss) per share	\$ 1,514	\$ 3,880	
Denominator for basic income (loss) per share	12,009,285	2,087,068	
Basic income (loss) per common share	\$ 0.13	\$ 1.86	
Loss per share – Diluted:			
Numerator for diluted income (loss) per share	\$ 1,514	\$ 3,880	
Adjust: Fair value of dilutive warrants outstanding	(2,756	) -	
Numerator for diluted income (loss) per share	\$ (1,242	) \$ 3,880	
Denominator for basic income (loss) per share	12,009,285	2,087,068	
Plus: Incremental shares underlying warrants outstanding	5,624,075	-	
Denominator for diluted income (loss) per share	17,633,360	2,087,068	
Diluted income (loss) per common share	\$ (0.07	) \$ 1.86	(1)

<sup>(1)</sup>The impact of assumed exercise of warrants is not included because all of the warrants outstanding were “out of the money” during this period.

**Note 3 - 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, and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate. Certain prior year amounts have been reclassified to conform to the current year presentation.

### **Going Concern and Management's Response**

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, 2014 and 2013. To become profitable, the

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 - Summary of Significant Accounting Policies (continued)**

Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

On December 18, 2014, the Company completed a rights offering which resulted in gross proceeds of \$3.0 million. See Note 12, Stockholders' Deficit, for a more detailed discussion of the rights offering. The Company repaid the August 29, 2014 senior secured note issued to Lambda Investors LLC ("Lambda") in the principal amount of \$1.75 million with a portion of the proceeds from the rights offering. For a more detailed discussion of the terms of the August 2014 senior secured note, see Note 8, Senior Secured Notes.

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.

**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 years ended December 31, 2014 and 2013, three customers accounted for 78% and 86%, respectively, of the Company's revenues. As of December 31, 2014 three customers accounted for 83% of the Company's accounts receivable. As of December 31, 2013, two customers accounted for 97% 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. There was an allowance for doubtful accounts of approximately \$1,000 at December 31, 2014. There was no allowance for doubtful accounts at December 31, 2013. There was no allowance for sales returns at December 31, 2014 or 2013. There were no write offs of accounts receivable to bad debt expense during 2014 or 2013.

### **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.

In March 2014, the Company requested the closeout of its October 2013 voluntary product recall. The Company destroyed the respective product in April 2014.



**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 - Summary of Significant Accounting Policies (continued)**

**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.

**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. An estimate of the asset’s fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, 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 estimated net realizable market value. There were no impairment losses for long-lived assets recorded for the years ended December 31, 2014 and December 31, 2013.

### **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 4 for information on the fair value of derivative liabilities.

### **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 \$487,000 and \$703,000 on the accompanying consolidated balance sheets as of December 31, 2014 and 2013, respectively, and is related to the License Agreement with Bellco. The Company has recognized approximately \$2,589,000 of revenue related to this license agreement to date, including approximately \$834,000 for the year ended December 31, 2014, resulting in \$487,000 being deferred over the remainder of the expected obligation period (see Note 14). The Company recognized approximately \$711,000 of revenue related to this license agreement for the year ended December 31, 2013.

### **Shipping and Handling Costs**

Shipping and handling costs charged to customers are recorded as cost of goods sold and were approximately \$4,000 and \$5,000 for the years ended December 31, 2014 and 2013, respectively.

### **Research and Development Costs**

Research and development costs are expensed as incurred.



**NEPHROS, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

### **Note 3 - Summary of Significant Accounting Policies (continued)**

#### **Stock-Based Compensation**

The Company accounts for stock-based compensation in accordance with ASC Topic 718 by recognizing the fair value of stock-based compensation in the consolidated statement of operations and comprehensive loss. 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 ASC 835, which allows that costs paid directly to the issuer of the notes be reported in the balance sheet as a debt discount and amortized over the term of the associated

debt. Debt issuance costs associated with the senior secured note issued to Lambda on August 29, 2014 were \$178,000. All of these costs, in addition to the remaining unamortized debt issuance costs related to the senior secured note issued to Lambda on November 12, 2013 of \$142,000, were amortized as of December 31, 2014 and are included in interest expense on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2014.

Total debt issuance costs recorded during the year ended December 31, 2013 were approximately \$399,000. Approximately \$195,000 and \$204,000, respectively, were associated with the senior secured notes issued to Lambda on February 4, 2013 and November 12, 2013. Of the total debt issuance costs amortized as of December 31, 2013, approximately \$53,000 and \$204,000, respectively, were related to the senior secured notes issued to Lambda on February 4, 2013 and November 12, 2013 and are included in interest expense on the consolidated statements of operations and comprehensive loss.

### **Other Income (Expense), net**

Other income of approximately \$58,000 for the year ended December 31, 2014 is due to foreign currency transaction gains.

Other expense, net, of approximately \$33,000 for the year ended December 31, 2013 is primarily due to other expenses of approximately \$36,000 related to foreign currency transaction losses and approximately \$14,000 related to the May 2013 rights offering warrant modification. These expenses were partially offset by other income of approximately \$17,000, which consisted primarily of a refund of \$15,000 received as a result of the Steris agreement termination.

### **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, 2014 and 2013.



**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 3 - Summary of Significant Accounting Policies (continued)**

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 2011. During the years ended December 31, 2014 and 2013, 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,	
	2014	2013
Shares underlying options outstanding	2,472,234	2,410,134

## Edgar Filing: NEPHROS INC - Form 424B3

Shares underlying warrants outstanding	16,752,915	5,081,023
Unvested restricted stock	132,077	75,450

### **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.

### **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 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 it is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated financial statements.



**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 - Summary of Significant Accounting Policies (continued)**

In August 2014, the FASB issued ASU No. 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. Early adoption is permitted. The Company is currently evaluating any impact the adoption of ASU 2014-15 might have on its consolidated financial statements.

In April 2015, the FASB issued ASU No. 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 fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption of the amendments in ASU 2015-03 is permitted for financial statements that have not been previously issued. The Company does not believe that the adoption of ASU 2015-03 will have a significant impact on its consolidated financial statements.

**Note 4 – Financial Instruments**

The Company's 2007 Warrants are 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 utilizes a binomial options pricing model to value the 2007 Warrants.

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 estimated fair value of the 2007 Warrants is 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 4 – Financial Instruments (continued)

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liability measured at fair value on a recurring basis as of December 31, 2014 and 2013 (in thousands).

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2014:				
Warrant liability	\$-	\$ -	\$ 7,386	\$7,386

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2013:				
Warrant liability	\$-	\$ -	\$ 3,109	\$3,109

The Company has issued warrants to purchase common stock that are measured at fair value on a recurring basis using unobservable inputs or available market data in a binomial options pricing model to support the fair value (Level 3). A reconciliation of the warrant liability is as follows (in thousands):

	2007 Warrants
Balance at January 1, 2013	\$ 8,129
Decrease in fair value of warrant liability	(5,020 )
Balance at December 31, 2013	\$ 3,109
Increase in fair value of warrant liability	4,277
Balance at December 31, 2014	\$ 7,386

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

	2014	2013
Calculated aggregate value	\$7,386	\$3,109
Weighted average exercise price	\$0.30	\$0.40
Closing price per share of common stock	\$0.79	\$0.42
Volatility	165.6%	103.5%
Weighted average remaining expected life (years)	5.2	5.0
Risk-free interest rate	1.8 %	1.6 %
Dividend yield	-	-

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 5 - Inventory**

The Company's inventory components as of December 31, 2014 and 2013 were as follows:

	December 31,	
	2014	2013
Total gross inventory, finished goods	\$297,000	\$527,000
Less: inventory reserve	(111,000)	(365,000)
Total inventory	\$186,000	\$162,000

**Note 6 - Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets as of December 31, 2014 and 2013 were as follows:

	December 31,	
	2014	2013
Prepaid insurance premiums	\$70,000	\$70,000
Security deposit	21,000	21,000
Other	13,000	34,000
Prepaid expenses and other current assets	\$104,000	\$125,000

**Note 7 - Property and Equipment, Net**

Property and equipment as of December 31, 2014 and 2013 was as follows:

		December 31,	
	Life	2014	2013
Manufacturing equipment	3-5 years	\$599,000	\$599,000
Research equipment	5 years	37,000	37,000
Computer equipment	3-4 years	59,000	59,000
Furniture and fixtures	7 years	39,000	39,000
Property and equipment, gross		734,000	734,000
Less: accumulated depreciation		733,000	727,000
Property and equipment, net		\$1,000	\$7,000

Depreciation expense for each of the years ended December 31, 2014 and 2013 was approximately \$6,000 and \$9,000, respectively.

During 2013, the Company sold fully depreciated equipment totaling approximately \$3,000 which is reflected as gain on sale of equipment on the consolidated statements of operations and comprehensive loss.

#### Note 8 – Senior Secured Notes

On August 29, 2014, the Company issued a senior secured note to Lambda, in the principal amount of \$1.75 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on February 28, 2015, at which time all principal and accrued interest was due. However, the Company paid all amounts due under the note on December 18, 2014 with the cash proceeds from the rights offering that closed in December 2014. In connection with the note, the Company incurred an 8%, or \$140,000, sourcing/transaction fee with Lambda. In addition, the Company incurred additional legal fees and other expenses in connection with the note in the amount of \$38,000 with Lambda. Those payments totaling \$178,000 were initially reflected as a debt discount and amortized over the term of the note. For the year ended December 31, 2014, \$178,000 is included in interest expense on the consolidated statements of operations and comprehensive loss.

On November 12, 2013, the Company issued a senior secured note to Lambda in the principal amount of \$1.5 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on May 12, 2014, at which time all principal and accrued interest was due. However, the Company paid amounts due under the note on March 18, 2014 with the cash proceeds from the rights offering that closed in March 2014. In connection with the note, the Company incurred an 8%, or \$120,000, sourcing/transaction fee with Lambda. In addition, the Company incurred additional legal fees and other expenses in connection with the note in the amount of \$75,000 with Lambda. Those payments totaling \$195,000 were made on November 12, 2013 and are reflected as a debt discount which was amortized over the term of the senior secured note. Approximately \$142,000 and \$53,000, respectively, are included in interest expense on the consolidated statements of operations and comprehensive loss for the years ended December 31, 2014 and 2013.

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Lambda is an affiliate of Wexford Capital LP, which is the managing member of Lambda. Arthur H. Amron, a director of the Company, is a partner and general counsel of Wexford Capital LP. Paul A. Mieyal, a director of the Company and currently its acting President, CEO and CFO, is also a Vice President of Wexford Capital LP.

**Note 9 - Accrued Expenses**

Accrued expenses as of December 31, 2014 and 2013 were as follows:

	December 31,	
	2014	2013
Accrued legal	\$145,000	\$149,000
Accrued management bonus	50,000	81,000
Accrued directors' compensation	36,000	-
Accrued stock transfer agent fees	27,000	-
Accrued accounting	23,000	-
Accrued interest	14,000	39,000
Accrued product recall	-	60,000
Accrued other	47,000	36,000
	\$342,000	\$365,000

**Note 10 - 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:

	2014	2013
U.S. federal statutory rate	35.00 %	35.00 %
Warrant liability	(23.70)%	(155.10)%

Edgar Filing: NEPHROS INC - Form 424B3

State & local taxes	5.02	%	6.40	%
Tax on foreign operations	0.20	%	2.00	%
State research and development credits	0.55	%	(3.10)	)%
Other	(3.10)	)%	6.50	%
Valuation allowance	(13.97)	%	108.30	%
Effective tax rate	-		-	

Significant components of the Company's deferred tax assets as of December 31, 2014 and 2013 are as follows:

	2014	2013
Deferred tax assets:		
Net operating loss carry forwards	\$27,935,165	\$27,029,000
Research and development credits	1,118,389	1,096,000
Nonqualified stock option compensation expense	1,913,673	1,801,000
Other temporary book - tax differences	436,178	408,000
Total deferred tax assets	31,403,405	30,334,000
Valuation allowance for deferred tax assets	(31,403,405)	(30,334,000)
Net deferred tax assets	\$-	\$-

F-21



**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 - 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.

At December 31, 2014, the Company had Federal and New Jersey income tax net operating loss carryforwards of \$92,928,000 and foreign income tax net operating loss carryforwards of \$8,070,000. The Company also had Federal research tax credit carryforwards of \$1,118,389 at December 31, 2014 and \$1,096,000 at December 31, 2013. The Federal and New Jersey net operating loss carryforwards and Federal tax credit carryforwards will expire at various times between 2014 and 2026 unless utilized.

It is the Company's policy to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

**Note 11 - Stock Plans, Share-Based Payments and Warrants**

**Stock Plans**

In 2000, the Company adopted the Nephros 2000 Equity Incentive Plan. In January 2003, the Board of Directors adopted an amendment and restatement of the plan and renamed it the Amended and Restated Nephros 2000 Equity Incentive Plan (the "2000 Plan"), under which 106,538 shares of common stock had been authorized for issuance upon exercise of options granted.

As of December 31, 2014 there were no outstanding options under the 2000 Plan. On March 15, 2014, the 2,834 options outstanding as of December 31, 2013 expired.

The Board retired the 2000 Plan in June 2004, and thereafter no additional awards may be granted under the 2000 Plan.

In 2004, the Board of Directors adopted and the Company's stockholders approved the Nephros, Inc. 2004 Stock Incentive Plan. During the year ended December 31, 2013, the Company's stockholders approved an amendment to such plan (as amended, the "2004 Plan"), that increased the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan to 4,500,000.

As of December 31, 2014, 1,236,975 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between April 27, 2015 and February 5, 2024, and have vested or will vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2014, there were 2,054,799 shares available for future grants under the 2004 Plan. As of December 31, 2014, 903,709 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between April 26, 2015 and November 17, 2024, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

As of December 31, 2013, 1,028,509 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between April 27, 2015 and March 24, 2021, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2013, there were 2,407,318 shares available for future grants under the 2004 Plan. As of December 31, 2013, 715,692 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 11, 2014 and November 18, 2021, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

In addition, 331,550 options were issued in 2012 to the Company's CEO per terms of his employment agreement and were outstanding as of December 31, 2014 and 2013.

### **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, 2014 and 2013 was approximately \$421,000 and approximately \$418,000, respectively.

Gerald J. Kochanski, Chief Financial Officer, Treasurer and Corporate Secretary of Nephros, Inc., resigned effective June 15, 2013. The Company agreed, in consideration of Mr. Kochanski providing certain consulting services to the Company, to extend the exercise period of his outstanding vested stock options from September 15, 2013 to March 14, 2014. The change in the terms under this modification did not result in any additional compensation expense. All of Mr. Kochanski's vested stock options expired on March 14, 2014.

F-22

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 11 - Stock Plans, Share-Based Payments and Warrants (continued)**

The following table summarizes the option activity for the years ended December 31, 2014 and 2013:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2012	2,294,714	\$ 2.14
Options granted	237,315	0.64
Options forfeited or expired	(121,895 )	3.27
Outstanding at December 31, 2013	2,410,134	1.28
Options granted	352,519	0.50
Options forfeited or expired	(290,419 )	2.45
Outstanding at December 31, 2014	2,472,234	\$ 0.96

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2014 and 2013:

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2013	1,385,199	\$ 1.46
Vested and expected to vest at December 31, 2013	2,350,688	\$ 1.29
Exercisable at December 31, 2014	1,679,392	\$ 1.11
Vested and expected to vest at December 31, 2014	2,426,249	\$ 1.04

The following table summarizes information about stock options outstanding and exercisable at December 31, 2014:

Edgar Filing: NEPHROS INC - Form 424B3

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding of December 31, 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable of December 31, 2014	Weighted Average Exercise Price
\$0.33 - \$2.60	2,460,284	8.57	\$ 0.91	1,667,441	\$ 0.92
\$15.40 - \$29.80	10,450	4.51	\$ 21.89	10,450	\$ 21.89
\$51.40-\$96.00	1,500	1.58	\$ 64.47	1,500	\$ 64.47
Total Outstanding	2,472,234		\$ 0.96	1,679,392	\$ 1.11

F-23

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 11 - 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			
	2014		2013	
Stock Price Volatility	129.8	%	129.8	%
Risk-Free Interest Rates	1.86	%	1.36	%
Expected Life (in years)	5.84		5.91	
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 total fair value of options vested during the fiscal year ended December 31, 2014 was approximately \$507,000. The total fair value of options vested during the fiscal year ended December 31, 2013 was approximately \$519,000.

The weighted-average fair value of options granted in 2014 and 2013 is \$0.45 and \$0.56, respectively. The aggregate intrinsic value of stock options outstanding at December 31, 2014 is \$241,000 and of stock options vested or expected to vest is approximately \$235,000. 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 7.5 years.

The aggregate intrinsic value of stock options outstanding at December 31, 2013 is \$0 and of stock options vested or expected to vest is approximately \$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 8.1 years.

As of December 31, 2014, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$504,000 and will be amortized over the weighted-average remaining requisite service period of 1.9 years.

### Restricted Stock

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, 2014 and 2013:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2012	-	\$ -
Granted	398,227	0.73
Vested	(264,770)	0.71
Forfeited	(58,007 )	0.88
Nonvested at December 31, 2013	75,450	0.66
Granted	132,077	0.86
Vested	(75,450 )	0.66
Nonvested at December 31, 2014	132,077	\$ 0.86

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 11 - Stock Plans, Share-Based Payments and Warrants (continued)**

Total stock-based compensation expense for the restricted stock was approximately \$109,000 for the year ended December 31, 2014 and is included in Selling, General and Administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. Any additional stock-based compensation related to non-employee directors will be recorded to stock-based compensation expense. As of December 31, 2014, there was approximately \$8,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next four months.

**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.

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2014 and 2013:

## Total Outstanding Warrants

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable as of	
				December 31, 2014	December 31, 2013
Liability-classified warrants					
2007 Warrants - Lambda	11/14/2007	3/21/2019	\$ 0.30	11,742,100	8,806,575
				11,742,100	8,806,575



Equity-classified warrants					
July 2009 Warrants	7/24/2009	7/24/2014	\$ 22.40	-	33,629
Shareholder Rights Offering Warrants	3/10/2011	3/10/2016	\$ 0.40	2,228,238	2,264,817
March 2011 Lambda Warrants	3/10/2011	3/21/2019	\$ 0.40	2,782,577	2,782,577
				5,010,815	5,081,023
Total				16,752,915	13,887,598

The weighted average exercise price of the outstanding warrants was \$0.33 for December 31, 2014 and \$0.45 for December 2013.

Following the issuance of the August 2014 senior secured note, Lambda's existing warrants to purchase 11,742,100 shares that remain outstanding were amended to expire on March 21, 2019.

As a result of the March 2014 rights offering, the full ratchet anti-dilution protection for Class D warrants held by Lambda was triggered. The respective warrants are now exercisable for 11,742,100 shares of common stock at an exercise price of \$0.30 per share compared to the 8,806,575 shares of common stock and \$0.40 exercise price prior to the rights offering.

### Warrants exercised during 2014 and 2013

During the twelve months ended December 31, 2014, 791,278 warrants were exercised, resulting in proceeds of approximately \$15,000 and the issuance of 36,570 shares of the Company's common stock.

In connection with the May 2013 rights offering, the Company temporarily reduced the exercise price for its warrants issued in March 2011 from \$0.40 per share to \$0.30 per share. The Company determined that this inducement was a modification of equity instruments and, therefore, an incremental fair value of the inducement was determined using the Black-Scholes option pricing model.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 11 - Stock Plans, Share-Based Payments and Warrants (continued)**

During the period that the May 2013 rights offering was open, warrant holders exercised 14,879,708 warrants, issued in March 2011, for 687,793 shares of common stock, resulting in gross proceeds of approximately \$206,000 to the Company. The incremental fair value of the inducement recorded in the year ended December 31, 2013 was approximately \$14,000.

Additionally, during the twelve months ended December 31, 2013, 2,254,500 warrants were exercised outside the period that the May 2013 rights offering was open, resulting in proceeds of approximately \$42,000 and the issuance of 104,206 shares of the Company's common stock.

In addition, 9 and 374 common shares, respectively, were not issued as a result of warrant exercises for the years ended December 31, 2014 and 2013 due to rounding.

**Note 12 – Stockholders' Deficit**

**December 2014 Rights Offering**

On October 20, 2014, the Company filed a Registration Statement on Form S-1 in connection with a \$3 million rights offering. On November 4, 2014, the Company's Registration Statement on Form S-1 related to the Rights Offering was declared effective by the SEC.

The December 2014 rights offering commenced on November 10, 2014 and expired on December 15, 2014. All of the Company's stockholders and warrant holders were eligible to participate in the rights offering on a pro rata basis based upon their proportionate ownership of the Company's common stock on a fully-diluted basis. Pursuant to the

rights offering, the Company distributed to holders of its common stock and/or warrants one non-transferable subscription right for each share of common stock, and each share of common stock underlying a warrant, held as of November 5, 2014. Each right entitled the holder to purchase 0.11901 of a share of the Company's common stock at a subscription price of \$0.60 per share. The Company rounded up any fractional shares to the nearest whole share.

On December 18, 2014, the Company completed a rights offering which resulted in the issuance of 5,000,000 shares for gross proceeds of \$3.0 million. The aggregate net proceeds were approximately \$1.1 million, after deducting the repayment of the \$1.75 million August 2014 senior secured note, plus \$64,000 of accrued interest thereon, issued to Lambda, and an aggregate of \$75,000 for reimbursement of Lambda's legal fees incurred in connection with the August 2014 senior secured note and the rights offering.

### **March 2014 Rights Offering**

On January 7, 2014, the Company filed a Registration Statement on Form S-1 in connection with a \$2.8 million rights offering. On February 12, 2014, the Company's Registration Statement on Form S-1 related to the March 2014 rights offering was declared effective by the SEC. The March 2014 rights offering commenced on February 14, 2014 and expired on March 14, 2014. All of the Company's stockholders and warrant holders were eligible to participate in the March 2014 rights offering on a pro rata basis based upon their proportionate ownership of the Company's common stock on a fully-diluted basis. Pursuant to the March 2014 rights offering, the Company distributed to holders of its common stock and/or warrants one non-transferable subscription right for each share of common stock, and each share of common stock underlying a warrant, held as of January 30, 2014. Each right entitled the holder to purchase 0.28673 of a share of the Company's common stock at a subscription price of \$0.30 per share. The Company rounded up any fractional shares to the nearest whole share.

On March 21, 2014, the Company completed the March 2014 rights offering that resulted in gross proceeds of \$2.1 million. The aggregate net proceeds were approximately \$581,000, after deducting the repayment of the November 2013 \$1.5 million senior secured note and the \$61,000 of accrued interest thereon.

The Company issued a total of 7,140,823 shares of common stock to the holders of subscription rights who validly exercised their subscription rights, which represents 77% of the total shares offered in the March 2014 rights offering. Fees of approximately \$128,000 were also incurred related to the March 2014 rights offering and were recorded as reduction to equity.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 12 – Stockholders’ Deficit (continued)**

**May 2013 Rights Offering**

On March 4, 2013, the Company filed a Registration Statement on Form S-1 in connection with a \$3 million rights offering. On April 17, 2013, the Company’s Registration Statement on Form S-1 related to the May 2013 rights offering was declared effective by the SEC.

The May 2013 rights offering commenced on April 17, 2013 and expired on May 17, 2013. All of the Company’s stockholders and warrant holders were eligible to participate in the Rights Offering on a pro rata basis based upon their proportionate ownership of the Company’s common stock on a fully-diluted basis. Pursuant to the May 2013 rights offering, the Company distributed to holders of its common stock and/or warrants one non-transferable subscription right for each share of common stock, and each share of common stock underlying a warrant, held as of April 4, 2013. Each right entitled the holder to purchase 0.18776 of a share of the Company’s common stock at a subscription price of \$0.60 per share. The Company rounded up any fractional shares to the nearest whole share.

On May 22, 2013, the Company completed its May 2013 rights offering which resulted in the issuance of 5,000,000 shares for gross proceeds of \$3.0 million. The aggregate net proceeds were approximately \$1.4 million, after deducting the repayment of the \$1.3 million February 2013 senior secured note, plus \$46,800 of accrued interest thereon, issued to Lambda, the payment of an 8% sourcing transaction fee of \$104,000 with respect to the February 2013 senior secured note and an aggregate of \$100,000 for reimbursement of Lambda’s legal fees incurred in connection with the February 2013 senior secured note and the May 2013 rights offering. Those payments totaling \$204,000 are reflected as amortization of debt discount.

**Note 13 - 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 contributions to the 401(k) Plan. The Company contributed and expensed \$43,000 and \$46,000 in 2014 and 2013, respectively.

#### **Note 14 - 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 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 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 \$2.40) per unit; thereafter, €1.25 (approximately \$1.71) 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.

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 14 - Commitments and Contingencies (continued)****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 \$880,000) for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2014, the Company’s aggregate purchase commitments totaled approximately €766,000 (approximately \$900,000). For calendar years 2015 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. The annual minimum amount for calendar 2015 has not been finalized. 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 has been capitalized as a long-term intangible asset along with the total installment payments described. Other long-term assets on the consolidated balance sheet is approximately \$1,684,000, net of \$566,000 accumulated amortization, and is related to the License and Supply Agreement. The asset is being amortized as an expense over the life of the agreement. Approximately \$210,000 and \$214,000 have been charged to amortization expense for the years ended December 31, 2014 and 2013, respectively, 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, 2015 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. 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.

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.

### **Contractual Obligations**

The Company had an operating lease that expired on November 30, 2014 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately \$8,000. On August 27, 2014, the Company signed a one year lease extension for the same office space which will expire on November 30, 2015 with a monthly cost of approximately \$8,800 beginning December 1, 2014.

The lease agreement for the facilities in Europe was entered into on July 1, 2010. The lease term is renewable for 6 month terms with a 2 month notice to discontinue, on a rolling basis. The monthly cost is 500 Euro (approximately \$600).

Rent expense for the years ended December 31, 2014 and 2013 totaled \$117,000 and \$116,000, respectively.

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 14 - 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, 2014:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 - 3	Years 4 - 5	More than 5 Years
Leases	\$106,000	\$104,000	\$2,000	\$ -	\$ -
Employment Contracts (1)	175,000	175,000	-	-	-
Total	\$281,000	\$279,000	\$2,000	\$ -	\$ -

(1) Represents amount payable under severance agreement for John C. Houghton, effective January 4, 2015. See Note 15, Subsequent Events, for further discussion.

**Product Recall**

On October 30, 2013, the Company filed a Current Report on Form 8-K announcing the voluntary recalls of its point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. As a result, the Company recalled all production lots of its POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, the Company also requested, for the DSU in-line ultrafilter, that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect the Company's dialysis products. The consolidated financial statements for the year ended December 31, 2013 included product revenues and cost of goods sold adjustments of approximately \$216,000 and \$110,000, respectively, reflecting estimates of the financial impact of product recalled to the Company. The recall



and the related circumstances could subject the Company to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact the Company's sales and revenues. The Company destroyed the respective product in April 2014.

#### **Note 15 - Subsequent Events**

On January 4, 2015, the Board of Directors appointed Daron Evans, a member of the Board, to serve as Chairman of the Board. Also on January 4, 2015, the Board of Directors appointed Paul A. Mieyal, a member of the Board, to serve as the Acting President, Acting Chief Executive Officer, Acting Chief Financial Officer and Acting Secretary of the Company. Dr. Mieyal succeeded John C. Houghton, whose separation of employment as President, Chief Executive Officer and Acting Chief Financial Officer of the Company was effective on January 4, 2015. In addition, Mr. Houghton resigned as a member of the Board, effective on January 4, 2015. The resignation as a member of the Board was not due to any disagreement by or with Mr. Houghton on any matter relating to the Company's operations, policies or practices. In connection with his separation from employment with the Company, Mr. Houghton entered into a Separation Agreement and General Release (the "Agreement"). Pursuant to the Agreement, Mr. Houghton is entitled to six months severance and is permitted to exercise his vested unexpired stock options for ninety days following January 4, 2015. During the severance term, Mr. Houghton will be subject to customary non-competition, non-solicitation and confidentiality restrictions.

## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	(Unaudited) June 30, 2015	(Audited) December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,037	\$ 1,284
Accounts receivable, net	295	110
Inventory, net	419	186
Prepaid expenses and other current assets	61	104
Total current assets	1,812	1,684
Property and equipment, net	-	1
Other assets, net of accumulated amortization	1,579	1,684
Total assets	\$ 3,391	\$ 3,369
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 988	\$ 835
Accrued expenses	306	342
Deferred revenue, current portion	70	70
Total current liabilities	1,364	1,247
Warrant liability	7,574	7,386
Long-term portion of deferred revenue	382	417
Total liabilities	9,320	9,050
Commitments and Contingencies		
Stockholders' deficit:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding at June 30, 2015 and December 31, 2014	-	-
Common stock, \$.001 par value; 90,000,000 shares authorized at June 30, 2015 and December 31, 2014; 32,227,939 and 30,391,513 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	32	30
Additional paid-in capital	109,705	108,382
Accumulated other comprehensive income	71	72
Accumulated deficit	(115,737 )	(114,165 )
Total stockholders' deficit	(5,929 )	(5,681 )

Total liabilities and stockholders' deficit	\$ 3,391	\$ 3,369
---	----------	----------

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

F-30

## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net revenues:				
Product revenues	\$521	\$248	\$1,049	\$467
License and royalty revenues	46	193	63	448
Total net revenues	567	441	1,112	915
Cost of goods sold	209	142	471	248
Gross margin	358	299	641	667
Operating expenses:				
Research and development	164	180	355	343
Depreciation and amortization	53	55	106	110
Selling, general and administrative	735	700	1,578	1,412
Total operating expenses	952	935	2,039	1,865
Loss from operations	(594)	(636)	(1,398)	(1,198)
Change in fair value of warrant liability	(1,196)	(4,685)	(188)	(7,436)
Interest expense	(9)	(17)	(21)	(212)
Other income (expense)	(16)	(1)	35	(4)
Net loss	(1,815)	(5,339)	(1,572)	(8,850)
Other comprehensive loss, foreign currency translation adjustments	(1)	(1)	(1)	(2)
Total comprehensive loss	(1,816)	(5,340)	(1,573)	(8,852)
Net loss per common share, basic and diluted	\$(0.06)	\$(0.21)	\$(0.05)	\$(0.40)
Weighted average common shares outstanding, basic and diluted	31,190,714	25,166,752	30,727,840	22,004,712

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount		Income	Deficit	
Balance, December 31, 2014 (audited)	30,391,513	\$ 30	\$ 108,382	\$ 72	\$ (114,165 )	\$(5,681)
Net loss					(1,572 )	(1,572)
Net unrealized losses on foreign currency translation, net of tax				(1 )		(1 )
Issuance of common stock, net of equity issuance costs of \$24	1,834,299	2	1,203			1,205
Exercise of warrants	2,127	-	1			1
Noncash stock-based compensation			119			119
Balance, June 30, 2015	32,227,939	\$ 32	\$ 109,705	\$ 71	\$ (115,737 )	\$(5,929)

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

## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30, 2015	2014
Operating activities:		
Net loss	\$ (1,572 )	\$ (8,850 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	1	5
Amortization of other assets	105	105
Noncash stock-based compensation, including stock options and restricted stock	119	227
Change in fair value of warrant liability	188	7,436
Amortization of debt discount	-	142
Inventory reserve	-	31
Loss on foreign currency transactions	1	4
(Increase) decrease in operating assets:		
Accounts receivable	(185 )	9
Inventory	(233 )	(32 )
Prepaid expenses and other current assets	43	66
Increase (decrease) in operating liabilities:		

## Edgar Filing: NEPHROS INC - Form 424B3

Accounts payable	153		(46	)
Accrued expenses	(36	)	(134	)
Deferred revenue	(35	)	170	
Net cash used in operating activities	(1,451	)	(867	)
Financing activities:				
Proceeds from issuance of common stock	1,205		2,013	
Proceeds from exercise of warrants	1		2	
Payment of senior secured note	-		(1,500	)
Net cash provided by financing activities	1,206		515	
Effect of exchange rates on cash and cash equivalents	(2	)	(2	)
Net decrease in cash	(247	)	(354	)
Cash, beginning of period	1,284		579	
Cash, end of period	\$ 1,037		\$ 225	
Supplemental disclosure of cash flow information				
Cash paid for income taxes	\$ 2		\$ 4	
Cash paid for interest	\$ 25		\$ 54	

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

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM 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, or 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.

**Note 2 - Basis of Presentation and Going Concern**

**Interim Financial Information**

The accompanying unaudited condensed consolidated interim financial statements of Nephros, Inc. and its wholly owned subsidiary, Nephros International Limited (collectively, the “Company” or “Nephros”) should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2014 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on April 15, 2015. In the Company’s Annual Report on Form 10-K for the year ended December 31, 2014, the Company restated (i) its 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) its 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. The restatement results from the Company’s prior accounting for certain outstanding common stock



purchase warrants originally issued in November 2007 as components of equity instead of as derivative liabilities. Accordingly, certain amounts as of and for the three and six months ended June 30, 2014 presented herein reflect these previously restated amounts. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying condensed consolidated interim financial statements do not include all of the information and notes required by GAAP for a complete financial statement presentation. The condensed consolidated balance sheet as of December 31, 2014 was derived from the Company's audited consolidated financial statements but does not include all disclosures required by GAAP. In the opinion of management, the condensed consolidated interim financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. Certain reclassifications were made to the prior year's amounts to conform to the 2015 presentation. All intercompany transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

The preparation of financial statements in conformity with GAAP 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 lives of fixed assets and intangible assets, and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 2 - Basis of Presentation and Going Concern (continued)**

**Going Concern and Management's Response**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring operating 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 condensed consolidated interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has incurred significant losses in operations in each quarter since inception. To become profitable, the Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

On May 18, 2015, the Company raised gross proceeds of \$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 warrants are exercisable at a price of \$0.85 per share.

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.

**Note 3 - Concentration of Credit Risk**

For the six months ended June 30, 2015 and 2014, the following customers accounted for the following percentages of the Company's revenues, respectively.

Customer	2015	2014
A	26 %	25 %
B	25 %	- %
C	16 %	5 %
D	3 %	49 %

As of June 30, 2015 and December 31, 2014, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2015	2014
A	52 %	22 %
B	10 %	25 %
C	3 %	35 %

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 4 - 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.

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 the Company. Shipments for all products are currently received directly by the Company's customers.

Deferred revenue on the accompanying June 30, 2015 condensed consolidated balance sheet is approximately \$452,000 and is related to the Company's License Agreement with Bellco (see Note 11), which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,624,000 of revenue related to the Bellco License Agreement to date and approximately \$35,000 for the six months ended June 30, 2015. The Company recognized approximately \$448,000 of revenue related to this License Agreement for the six months ended June 30, 2014. Revenue recognized in the six months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the License Agreement were fully recognized as revenue as of December 31, 2014. Approximately \$35,000 of revenue will be recognized in the remaining six months of fiscal year 2015 and approximately \$70,000 of revenue will be recognized in each of the years ended December 31, 2016 through 2021. See Note 11, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

**Note 5 - 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.

The Company's outstanding warrants that were originally issued in 2007 (the "2007 Warrants") are accounted for as a derivative liability because the transactions that would trigger the anti-dilution adjustment provision in the 2007 Warrants are not inputs to the fair value of the warrants. The 2007 Warrants are 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 utilizes a binomial options pricing model to value the 2007 Warrants at each reporting period.

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 estimated fair value of the 2007 Warrants is 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.

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

## Note 5 - Fair Value of Financial Instruments (continued)

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014 (in thousands):

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At June 30, 2015:				
Warrant liability	\$ -	\$ -	\$ 7,574	\$ 7,574

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2014:				
Warrant liability	\$ -	\$ -	\$ 7,386	\$ 7,386

On the condensed consolidated statement of operations for the three month periods ended June 30, 2015 and 2014, the Company recorded expense of \$1,196,000 and \$4,685,000, respectively, as a result of the change in fair value of the warrant liability. On the condensed consolidated statement of operations for the six month periods ended June 30,

Edgar Filing: NEPHROS INC - Form 424B3

2015 and 2014, the Company recorded expense of \$188,000 and \$7,436,000, respectively, as a result of the change in fair value of the warrant liability.

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

	June 30, 2015	December 31, 2014		
Calculated aggregate value	\$ 7,574	\$ 7,386		
Weighted average exercise price	\$ 0.30	\$ 0.30		
Closing price per share of common stock	\$ 0.71	\$ 0.79		
Volatility	135.0 %	136.9 %		
Weighted average remaining expected life (years)	4.5	5.0		
Risk-free interest rate	1.6 %	1.6 %		
Dividend yield	-	-		

F-37

**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 6 - Stock-Based Compensation****Stock Options**

The Company accounts for stock option grants to employees and non-employee directors under the provisions of ASC 718, Stock Compensation. ASC 718 requires the recognition of the fair value of stock-based compensation in the statement of operations. In addition, the Company accounts for stock option grants to consultants under the provisions of ASC 505-50, Equity-Based Payments to Non-Employees, and as such, these stock options are revalued at each reporting period through the vesting period.

The fair value of stock option awards is estimated using a Black-Scholes option pricing model. The fair value of stock-based awards that vest upon service conditions is amortized over the vesting period of the award using the straight-line method. 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.

The Company granted 2,242,693 stock options during the six months ended June 30, 2015 to employees. These stock options will be expensed over their respective applicable vesting periods, which are based on service and performance conditions. The fair value of all stock-based awards granted during the six months ended June 30, 2015 was approximately \$1,191,000.

The following assumptions were used for options granted for the six months ended June 30, 2015:

Assumptions for Option Grants	Six Months Ended June 30, 2015	
Stock Price Volatility	122.9	%
Risk-Free Interest Rates	1.53	%



Edgar Filing: NEPHROS INC - Form 424B3

Expected Life (in years)	6.15	
Expected Dividend Yield	0	%

The Company calculates expected volatility for a stock-based grant based on historic monthly common stock price observations during the period immediately preceding the grant that is equal in length to the expected term of the grant. The Company also estimates future forfeitures, using historical employee behaviors related to forfeitures, as a part of the estimate of expense as of the grant date. With respect to grants of options, the risk free rate of interest is based on the U.S. Treasury rates appropriate for the expected term of the grant.

Stock-based compensation expense was approximately \$110,000 and \$224,000 for the six months ended June 30, 2015 and 2014, respectively. For the six months ended June 30, 2015, approximately \$100,000 and approximately \$10,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. For the six months ended June 30, 2014, approximately \$212,000 and approximately \$12,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statements of operations.

There was no tax benefit related to expense recognized in the six months ended June 30, 2015 and 2014, as the Company is in a net operating loss position. As of June 30, 2015, there was approximately \$1,157,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Included in the \$1,157,000 of total unrecognized compensation, approximately \$167,000 will be recognized at the time that certain performance conditions are met. The remaining approximately \$990,000 will be amortized over the weighted average remaining requisite service period of 3.8 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$990,000 of unrecognized compensation cost, the Company expects to recognize approximately 17% in the remaining interim periods of 2015, approximately 30% in 2016, approximately 21% in 2017, approximately 21% in 2018, approximately 7% in 2019 and approximately 4% in 2020.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 6 - Stock-Based Compensation (continued)**

**Restricted Stock**

Total stock-based compensation expense for the restricted stock grants was approximately \$9,000 and \$3,000, respectively, for the six months ended June 30, 2015 and 2014 and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations. All compensation expense related to the restricted stock awards has been recognized as of June 30, 2015.

**Note 7 - Warrants**

For the six months ended June 30, 2015, 2,127 shares of common stock were issued as a result of warrants exercised, resulting in proceeds of \$851.

**Note 8 - 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, adjusted for the change in the fair value of the warrant liability 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.

Edgar Filing: NEPHROS INC - Form 424B3

	For the three months		For the six months	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Loss per share - Basic:				
Numerator for basic loss per share	\$(1,815,000 )	\$(5,339,000 )	\$(1,572,000 )	\$(8,850,000 )
Denominator for basic loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Basic loss per common share	\$(0.06 )	\$(0.21 )	\$(0.05 )	\$(0.40 )
Loss per share - Diluted:				
Numerator for diluted loss per share	\$(1,815,000 )	\$(5,339,000 )	\$(1,572,000 )	\$(8,850,000 )
Adjust: Change in fair value of dilutive warrants outstanding	1,196,000	4,685,000	188,000	7,436,000
Numerator for diluted loss per share	\$(619,000 )	\$(654,000 )	\$(1,384,000 )	\$(1,414,000 )
Denominator for basic loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Plus: Incremental shares underlying warrants outstanding	-	-	-	-
Denominator for diluted loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Diluted loss per common share	\$(0.06 )	\$(0.21 )	\$(0.05 )	\$(0.40 )

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive:

	June 30,	
	2015	2014
Shares underlying warrants outstanding	17,667,937	16,819,881
Shares underlying options outstanding	3,634,502	2,424,612

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 9 - 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 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. Early adoption is permitted, but not before the original effective date for public companies (annual reporting periods beginning after December 15, 2016). In July 2015, the FASB approved a one-year deferral of the effective date of the new standard, making it effective for annual and interim reporting periods beginning January 1, 2018. The Company has not yet determined the potential impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 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. Early adoption is permitted. The Company has not yet determined the impact, if any, of the adoption of ASU 2014-15 might have on its consolidated financial statements.

In April 2015, the FASB issued ASU No. 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 fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption of the amendments in ASU 2015-03 is permitted for financial statements that have not been previously issued. The Company does not believe that the adoption of ASU 2015-03 will have a significant impact on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory (Subtopic 2015-11)." ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value, and methods for valuing inventory that consider market value will be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. The Company has not yet determined the impact, if any, the adoption of ASU 2015-11 might have on its consolidated financial statements.

#### **Note 10 - Inventory, net**

Inventory is stated at the lower of cost or market using the first-in first-out method and consists entirely of finished goods. The Company's inventory as of June 30, 2015 and December 31, 2014 was as follows:

	June 30, 2015 (Unaudited)	December 31, 2014 (Audited)
Total Gross Inventory, Finished Goods	\$ 478,000	\$ 297,000
Less: Inventory reserve	(59,000 )	(111,000 )
Total Inventory	\$ 419,000	\$ 186,000

#### **Note 11 - 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").

**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 11 - Commitments and Contingencies (continued)**

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. 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 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 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 (estimated at approximately \$1.95 using current exchange rates) per unit; thereafter, €1.25 (estimated at approximately \$1.40 using current exchange rates) per unit. As of June 30, 2015, the Company recognized approximately \$28,000 related to the royalty payable by Bellco. 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 \$880,000) for the years 2012, 2013 and 2014, respectively. In the six months ended June 30, 2015, the Company's aggregate purchase commitments totaled approximately €567,000 (approximately \$630,000). For calendar years 2015 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. The annual minimum amount for calendar 2015 is €1,000,000 (estimated at approximately \$1,110,000 using current exchange rates). 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 6 under Stock-Based Compensation. The fair market value of the options has been capitalized as a long-term intangible asset along with the total installment payments described. Other long-term assets on the consolidated balance sheet is approximately \$1,579,000, net of \$672,000 accumulated amortization, and is related to the License and Supply Agreement. The asset is being amortized as an expense over the life of the agreement. Approximately \$105,000 has been charged to amortization expense in each of the six month periods ended June 30, 2015 and 2014 on the consolidated statements of operations and comprehensive loss. Approximately \$105,000 of amortization expense will be recognized in the remaining six months of fiscal year 2015 and approximately \$210,000 of amortization expense will be recognized in each of the years ended December 31, 2016 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. 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.

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.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 12 - Subsequent Events**

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”), 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 the date that a registration statement, which the Company agreed to file with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. 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. Lincoln Park represented to the Company, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the “Securities Act”)), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities issued may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.



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 it 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.

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Purchase Agreement will be used for general corporate purposes and working capital requirements.