

NEPHROS INC  
Form 10-K  
March 28, 2014

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Transition Period from** \_\_\_\_\_ **to** \_\_\_\_\_

**Commission File Number 001-32288**

**NEPHROS, INC.**

(Exact name of registrant specified in its charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**13-3971809**

(I.R.S. Employer  
Identification No.)

**41 Grand Avenue**

**River Edge, NJ 07661**

(Address of Principal Executive Offices)

**(201) 343-5202**

(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

(Title of Class)

Common Stock, \$.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 28, 2013, was approximately \$10,181,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, on June 28, 2013. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 28, 2013.

As of March 25, 2014 there were 25,225,704 shares of the registrant's common stock, \$0.001 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's Proxy Statement (the "2014 Proxy Statement"), which will be filed with the SEC in connection with the 2014 Annual Meeting of Stockholders, are incorporated by reference into Part III of this Form 10-K. The 2014 Proxy Statement will be filed within 120 days of December 31, 2013.

**NEPHROS, INC. AND SUBSIDIARY**

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## FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K constitute “forward-looking statements”. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for continued development of such products 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,” “aims,” “believes,” “hopes,” “potential” 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 (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;

· 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/or 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 Annual Report on Form 10-K, 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.

## PART I

### Item 1. 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 (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 four markets:

- o *Dialysis Centers - Water/Bicarbonate:* Filtration of water or bicarbonate concentrate used in hemodialysis devices
- o *Dialysis Centers - Blood:* Clearance of toxins from blood using an alternative method to HD in patients with chronic renal failure
- o *Military and Outdoor Recreation:* Highly compact, individual water purification devices used by soldiers to produce drinking water in the field
- o *Hospitals and Other Commercial Facilities:* Filtration of water for drinking and washing

#### Our Target Markets

*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. Within the U.S., there are approximately 5,700 clinics with 100,000 dialysis machines providing over 50 million dialysis treatments to 370,000 patients annually.

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

in 2009 will be adopted by Medicare in the near future.

Published studies have shown that the use of ultrapure dialysate can make patients healthier and reduce their dependence on erythropoietin (EPO), an expensive drug 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, cytokine levels within a patient stay low, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient's responsiveness to EPO is enhanced, consequently the overall need for the drug 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 EPO 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.

*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 (HF), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD. However, HF treatment is performed on a daily basis, and typically takes 12-24 hours.

Hemodiafiltration (HDF) is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the U.S., HDF is much more prevalent in Europe and is performed in approximately 16% of patients. Clinical experience and literature show the following multiple 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 which 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-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 is cleared by the U.S. Food and Drug Administration (FDA) to market 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. 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 have completed preparation of our OLpūr H2H HDF Modules and have manufactured initial lots of our OLpūr MD220 Hemodiafilters, H2H Substitution filters and H2H water filters. We have finalized our service contract and are in the process of finalizing site selection in anticipation of market release. We have experienced delays with the approval process at our initial placement site in the U.S. but expect to place our on-line mid-dilution HDF system in a U.S. dialysis clinic in the second quarter of 2014. We have not begun to broadly market our on-line mid-dilution HDF system and are actively seeking a commercialization partner in the U.S.

*Military and Outdoor Recreation.* 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 Environmental Protection Agency specified levels.

We offer our individual water purification device (IWPD), which allows a soldier in the field to derive biologically safe water from any fresh water source. Our IWPD is available in both in-line and point-of-use configurations. Our IWPD 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 (USAPHC) and U.S. Army Test and



Evaluation Command (ATEC) for deployment. To date, we have received purchase orders for approximately 2,000 IWPDs from individual units of the U.S. armed forces.

In response to a Special Notice Announcement from the U.S. Army, Nephros submitted its (IWPD) containing the Nephros proprietary ultrafilter technology for consideration as part of a standard issue personal hydration pack for soldiers in the field. Nephros has been informed by the Military Government Review Agency that its IWPD has been validated to meet the military's NSF P248 standard as a microbiological water treatment device for military operations. In February 2013, Nephros submitted its response to a U.S. Army request for proposal (RFP) relating to IWPDs. In March 2013, we received notification from the U.S. Army that the Government has completed the initial evaluation of our proposal and found Nephros to be within the competitive range to commence negotiations. We also received a request for 180 of our IWPDs to be used as test assets during the Limited User Evaluation (LUE) phase of the source selection. As of March 2014, we have confirmed with the U.S. Army that the RFP LUE period was still ongoing. The U.S. Army may award several, one or no contracts as a result of this solicitation. The maximum quantity of all contracts combined is not to exceed 450,000 units or \$45,000,000 over a 3 year period.

In addition to the RFP, we continue to make our IWPD available to the U.S. military. During 2013, we signed distributor agreements with W.S. Darley & Company, Source One Distribution Inc. and Atlantic Diving Supply, Inc. The UF40L and 30L recently were listed on the Darley website.

In September 2013, we were awarded the contract for 30 UF-40L units in response to RFI Solicitation Number: M67854-13-I-7310 from the U.S. Marine Corp Warfighting Laboratory. We are currently waiting for final feedback from this testing.

*Hospitals and Other Commercial Facilities.* In October 2013, We announced the voluntary recalls of our point of use (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, we 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 our dialysis products. We are working towards a resolution of the issues raised by the FDA and we are unable to predict at this time what additional effect this recall might have on our business, financial condition, future prospects or reputation or whether we may be subject to future actions from the FDA.

We have launched our new NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is to be used for drinking and washing. 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.

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 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. For the years ended December 31, 2013 and 2012, we incurred net losses of \$3,698,000 and \$3,262,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2013 and 2012. 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 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 us to continue to satisfy its capital requirements.



## Recent Developments

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 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 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, 2016, Bellco will pay us a royalty based on the number of units of our patented mid-dilution dialysis filters (MD190, MD220) sold per year in the Territory as follows: for the first 125,000 units sold, €1.75 per unit; thereafter, €1.25 per unit. In addition, the Company will receive a total of €450,000 in upfront fees in connection with the First Amendment, half of which were paid on February 19, 2014, and the other half of which are payable on March 31, 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.

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, we received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber, since we began marketing the products. We have had no reports of adverse events associated with these 29 complaints. We are recalling 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. In March 2014, the Company requested the closeout of its October 2013 voluntary product recall. The Company has fully reserved the recalled product and will destroy the respective product by April 20, 2014.

## 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, 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 (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.

## 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. In February 2013 we signed a non-exclusive North American distributor agreement with Chem-aqua. 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 (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 (ATD) 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.

Approximately \$317,000 was billed to the projects during the year ended December 31, 2012. Approximately \$2,700,000 of revenue has been recognized on both research contracts. The second research contract project ended in March 2012.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement of \$40,000 and were eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and further milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of \$100,000 during 2010, of which approximately \$67,000 was recognized in 2010 and approximately \$33,000 was recognized in 2011. In the fourth quarter of 2013, this development agreement was terminated and, in exchange, STERIS paid us \$15,000.

## Major Customers

For the years ended December 31, 2013 and 2012, three customers accounted for 86% and 68%, respectively, of the Company's sales. In addition, as of December 31, 2013 and 2012, those three customers accounted for 97% and 88%, respectively, of the Company's 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 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, 2013, we have 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 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.

### *Trademarks*



As of December 31, 2013, we secured registrations of the trademarks CENTRAPUR, H2H, OLpur 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 June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. On August 11, 2011, Nephros filed a new 510(k) application with the FDA for clearance of the Company’s hemodiafiltration (HDF) system for end-stage renal disease. On April 30, 2012, the Company announced that it received 510(k) clearance 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.

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.

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. ("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 OLpur MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the CE marking and Canadian approval of our OLpur 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, 2013, 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.

## **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>.

## Item 1A. Risk Factors

### Risks Related to Our Company

***Our independent registered public accounting firm, in its audit report related to our financial statements for the fiscal year ended December 31, 2013, 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 financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2013 expressing doubt as to our ability to continue as a going concern. The accompanying 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.

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

We have not been profitable since our inception in 1997. As of December 31, 2013, we had an accumulated deficit of approximately \$101,228,000, primarily 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 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, we received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber, since we began marketing the products. We have had no reports of adverse events associated with these 29 complaints. We are recalling 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.



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, 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 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 Food, Drug and Cosmetic Act (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.***

Our products are new to the market, and 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. If we fail to successfully commercialize our products, then we will not 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 and, 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 OLp<sub>ur</sub> mid dilution hemodiafilter series product and our Dual Stage Ultrafilter ("DSU"). We have not yet obtained the CE mark for any of our other products. On April 30, 2012, we announced that we received clearance from the FDA to market our OLp<sub>ur</sub> MD220 Hemodiafilter and OLp<sub>ur</sub> 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. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.

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

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

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

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

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

***There currently is a limited trading market for our Common Stock.***

Our Common Stock currently does not meet all of the requirements for initial listing 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.

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

In the past we have issued Common Stock and warrants in order to raise money. We have also issued stock options and restricted stock as compensation for services and incentive compensation for our employees, directors and consultants. We have shares of Common Stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional Common Stock,

convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our Common Stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our Common Stock), or could obligate us to issue additional shares of Common Stock.

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

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

In the two years ended December 31, 2013, our Common Stock has traded at prices ranging from a high of \$3.19 to a low of \$0.31 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 biotechnology 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.

***If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results, which could have a material adverse effect on our business, financial condition and the market value of our securities.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our reputation and operating results may be harmed.

If management is unable to express a favorable opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

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

As of March 21, 2014, our directors, executive officers and Lambda Investors LLC, our largest stockholder, beneficially owned approximately 48% of our outstanding Common Stock, representing approximately 60% on a fully-diluted basis. As a result of this ownership, Lambda Investors has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda Investors, 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 Investors, 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 Investors in any matter put before the stockholders may differ from those of any other stockholder.

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

The market price of our Common Stock could decline due to sales of a large number of shares in the market, including sales of shares by Lambda Investors 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.



## **Item 2. 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, 2013 with a monthly cost of approximately \$8,400. We use our 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 our facilities to house our accounting, operations and customer service departments. We believe this space will be adequate to meet our needs. We do not own any real property for use in our operations or otherwise.

## **Item 3. 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.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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. All prices have been adjusted to reflect the effect of the reverse split effective March 11, 2011. 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, 2012	\$ 1.09	\$ 0.44
June 30, 2012	\$ 3.19	\$ 0.80
September 30, 2012	\$ 1.98	\$ 1.15
December 31, 2012	\$ 1.40	\$ 1.02
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

As of March 20, 2014, there were approximately 20 holders of record and approximately 1,000 beneficial holders of our common stock.

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.

#### *Recent Sales of Unregistered Securities*

Except as previously reported in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, we have not sold any equity security during the three years ended December 31, 2013 which was not registered under the Securities Act of 1933, as amended.

#### *Issuer Repurchases of Equity Securities*

There were no repurchases of our common stock during the fourth quarter of 2013.

### Item 6. Selected Financial Data

Not required.

### Item 7. 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 in Item 1A "Risk Factors." The following discussion should also be read in conjunction with the consolidated financial statements and notes included herein.*

## Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this Form 10-K which expressed doubt as to our ability to continue as a going concern. The accompanying 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.

## 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 (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

There are no recent accounting pronouncements that are expected to have an effect on our consolidated financial statements set forth in Item 8 of this Annual Report on Form 10-K.



## **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 Annual Report on Form 10-K for the year ended December 31, 2013, 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 recognize the fixed license revenue under the Bellco license agreement on a straight line basis over the forty-two month expected obligation period which ends on December 31, 2014. Any difference between payments received and recognized revenue is reported as deferred revenue.

Deferred revenue on the accompanying December 31, 2013 consolidated balance sheet is approximately \$703,000 and is related to the Bellco license agreement. We have recognized approximately \$1,756,000 of revenue related to this license agreement to date and approximately \$711,000 for the twelve months ended December 31, 2013, resulting in \$703,000 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, 2014. This will result in expected recognized revenue of approximately \$703,000 in the year ended December 31, 2014.

### **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.

### **Accounts Receivable**

We provide credit terms to our customers in connection with purchases of our products. We periodically review customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit

worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect our best estimate of potential losses.

### **Inventory Reserves**

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

## **Accrued Expenses**

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

## **Results of Operations**

### **Fluctuations in Operating Results**

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

### **The Fiscal Year Ended December 31, 2013 Compared to the Fiscal Year Ended December 31, 2012**

#### **Revenues**

Total revenues for the year ended December 31, 2013 were approximately \$1,740,000 compared to approximately \$1,807,000 for the year ended December 31, 2012. Total revenues decreased approximately \$67,000, or 4%, as a result of decreases of approximately \$117,000 related to the Office of Naval Research, whose contract ended as of March 2012, and approximately \$216,000 related to the sales credits recorded to reflect the impact of a voluntary product recall of point of use filters (POU) announced on October 30, 2013. These decreases were partially offset by an increase of approximately \$31,000 related to the Bellco license agreement as well as underlying increases in total water filter sales. Total water filter sales increased by 23% from \$1,005,000 in 2012 to \$1,240,000 in 2013 reflecting growth in key business segments of dialysis water and hospital water. Dialysis water and hospital water sales increased by approximately 66% and 25%, respectively. These increases were partially offset by decreases in military water sales of approximately 83%.

Revenues were not significantly impacted by inflation or changing prices for the years ended December 31, 2013 or 2012.

#### **Cost of Goods Sold**

Cost of goods sold was approximately \$898,000 for the year ended December 31, 2013 compared to approximately \$737,000 for the year ended December 31, 2012. The increase of approximately \$161,000, or 22%, in cost of goods



sold was related to the increase in inventory reserves of approximately \$210,000, \$203,000 of which is a result of the October 2013 voluntary product recall and an increase in cost of goods sold of approximately \$119,000 related to increased sales of water filters in key business segments during the year ended December 31, 2013. The increases were partially offset by a decrease in sales related to the Office of Naval Research combined with the impact of a voluntary product recall of point of use filters (POU) of approximately \$168,000.

#### Research and Development

Research and development expenses were approximately \$826,000 and \$632,000, respectively, for the years ended December 31, 2013 and December 31, 2012. This increase of approximately \$194,000, or 31%, is primarily due to an increase in research and development material and other project costs primarily related to our OLPur H2H Module of approximately \$104,000 and an increase in personnel related costs of approximately \$88,000 during the year ended December 31, 2013 compared to the year ended December 31, 2012.

#### Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$223,000 for the year ended December 31, 2013 compared to approximately \$151,000 for the year ended December 31, 2012, representing an increase of 48%. The increase of approximately \$72,000 is due to amortization related to the asset recognized in conjunction with the License and Supply Agreement that began in the second quarter of the year ended December 31, 2012.

### Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$3,110,000 for the year ended December 31, 2013 compared to approximately \$3,620,000 for the year ended December 31, 2012, representing a decrease of \$510,000 or 14%. The decrease is primarily due to a decrease in legal and professional services expenses. In the twelve months ended December 31, 2013, approximately \$229,000 of legal and professional services expenses were recorded in equity as a result of the May 2013 rights offering and approximately \$204,000 were recorded as amortization of debt discount as they were fees paid in relation to the February 2013 Senior Secured Note. In addition, travel and other expenses decreased approximately \$130,000 during the year ended December 31, 2013 compared to the year ended December 30, 2012. These decreases were partially offset by an increase in personnel related expenses of approximately \$53,000, primarily a result of increased expenses related to bonus and stock-based compensation expense.

### Interest Income

There was no interest income recognized for the year ended December 31, 2013 compared to approximately \$2,000 for the year ended December 31, 2012. The decrease reflects the impact of having less cash on hand during the year ended December 31, 2013 compared to the year ended December 31, 2012.

### Interest Expense

Interest expense for the year ended December 31, 2013 was \$94,000. There was no interest expense recognized for the year ended December 31, 2012. Interest expense for the year ended December 31, 2013 primarily relates to interest on the February 2013 Senior Secured Note and November 2013 Senior Secured Note each issued to Lambda Investors LLC of approximately \$71,000 and interest of approximately \$21,000 related to outstanding payables due to a vendor.

### Amortization of Debt Discount

The Company accounts for debt issuance costs in accordance with ASC 835, which requires 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. Amortization of debt discounts of approximately \$257,000 for the year ended December 31, 2013, was due to fees paid to Lambda Investors LLC of approximately \$204,000 and approximately \$53,000 as a result of the issuance of the February 2013 Senior Secured Note and the November 2013 Senior Secured Note, respectively.

### Other Income/Expense

Other income (expense), net, of approximately \$33,000 includes approximately \$50,000 of other expense for the year ended December 31, 2013, primarily due to approximately \$36,000 related to foreign currency losses and approximately \$14,000 related to the May 2013 rights offering warrant modification. Other expense was partially offset by other income of approximately \$17,000, which consisted primarily of a refund of approximately \$15,000 received as a result of the Steris agreement termination.

Other expense in the amount of approximately \$14,000 for the year ended December 31, 2012 was primarily the result of approximately \$18,000 related to the write-offs of vendor invoices which are no longer due. Other expense was partially offset by \$4,000 related to foreign currency losses on invoices paid to an international supplier.

### Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the years ended December 31, 2013 and 2012.

## **Liquidity and Capital Resources**

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 costs involved in connection with the voluntary recalls of our point of use and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances;
- 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.

In response to liquidity issues experienced with our auction rate securities, and in order to facilitate greater liquidity in our short-term investments, on March 27, 2008, our board of directors adopted an Investment, Risk Management and Accounting Policy. Such policy limits the types of instruments or securities in which we may invest our excess funds in the future to: U.S. Treasury Securities; Certificates of Deposit issued by money center banks; Money Funds by money center banks; Repurchase Agreements; and Eurodollar Certificates of Deposit issued by money center banks. This policy provides that our primary objectives for investments shall be the preservation of principal and achieving sufficient liquidity to meet our forecasted cash requirements. In addition, provided that such primary objectives are met, we may seek to achieve the maximum yield available under such constraints.

At December 31, 2013, we had an accumulated deficit of approximately \$101,228,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue.

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 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 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, 2016, 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, €1.75 per unit; thereafter, €1.25 per unit. In addition, the Company will receive a total of €450,000 in upfront fees in connection with the First Amendment, half of which were paid on February 19, 2014, and the other half of which are payable on March 31, 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. Anticipated payments from this License Agreement will be a positive source of cash flow to us.

On April 23, 2012, we entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica, an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products (collectively, the "Filtration Products"), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to us an exclusive license, with right of

sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, we have agreed to make minimum annual aggregate purchases from Medica of €300,000, €500,000 and €750,000 for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2013, our aggregate purchase commitments totaled approximately €532,000. For calendar years thereafter, annual minimum amounts will be mutually agreed upon between Medica and us. In exchange for the license, we paid Medica €1,500,000 in three installments: €500,000 on April 23, 2012, €600,000 on February 4, 2013, and €400,000 on May 23, 2013. As part of the agreement, we have granted to Medica 300,000 options to purchase our common stock which will vest over the first three years of the agreement. As of September 2013, we have an understanding with Medica whereby we have agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

As of the date of this Annual Report, we expect that the proceeds from the March 2014 rights offering and the First Amendment with Bellco will allow us to fund our operations into the third quarter of fiscal year 2014. This assumption excludes the impact of future cash receipts from operations. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in our Company. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$3,583,000 for the year ended December 31, 2013 compared to approximately \$1,547,000 for the year ended December 31, 2012. The most significant items contributing to this net increase of approximately \$2,036,000 in cash used in operating activities during the year ended December 31, 2013 compared to the year ended December 31, 2012 are highlighted below:

- during 2013, our net loss increased by approximately \$436,000 compared to 2012;

- during 2013, our accounts receivable decreased by approximately \$820,000 compared to a decrease of approximately \$1,006,000 during 2012;

- during 2013, our deferred revenue decreased by approximately \$711,000 compared to an increase of approximately \$680,000 during 2012; and

- during 2013, our accounts payable and accrued expenses increased by approximately \$59,000 in the aggregate compared to an increase of approximately \$904,000 during 2012;

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

Offsetting the above changes are the following items:

- during 2013, depreciation and amortization expense increased by approximately \$72,000 compared to 2012;

- during 2013, we recorded amortization of debt issuance costs of \$257,000, whereas amortization of debt issuance costs in 2012 were \$0;

- during 2013, we recorded noncash interest expense of approximately \$39,000, whereas noncash interest expense in 2012 was \$0;

- during 2013, our stock-based compensation expense, a non-cash expense, increased by approximately \$132,000 compared to 2012;

- during 2013, we recorded an inventory reserve of approximately \$210,000 compared to \$82,000 in 2012;

- during 2013, we recognized a gain on the sale of property and equipment of approximately \$3,000 compared to a gain of approximately \$55,000 in 2012 ;

- during 2013, our inventory increased by approximately \$60,000 compared to an increase of approximately \$147,000 during 2012;

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. Net cash used in investing activities for the year ended December 31, 2012 was \$612,000 related to approximately \$659,000 for the purchase of intangible assets associated with the Medica License and Supply Agreement and approximately \$8,000 used for the purchase of equipment. Cash used in investing activities for the year ended December 31, 2012 was partially offset by proceeds received of approximately \$55,000 related to the sale of property and equipment.

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, 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 payment of financing costs of \$399,000. Net cash provided by financing activities was approximately \$503,000 for the year ended December 31, 2012 as a result of the exercise of warrants.

**Contractual Obligations and Commercial Commitments**

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2013:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 - 3	Years 4 - 5	More than 5 Years
Leases	\$ 108,000	\$ 100,000	\$ 8,000	\$ -	\$ -
Employment Contracts	788,000	350,000	438,000	-	-
Total	\$ 896,000	\$ 450,000	\$ 446,000	\$ -	\$ -

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not required.



**Item 8. Financial Statements**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Nephros, Inc.

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and Subsidiary (collectively, “the Company”) as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders’ equity (deficit) and cash flows in the two year period ended December 31, 2013. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform audits 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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nephros, Inc. and Subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows in the two year period 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 2 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 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Rothstein Kass

Roseland, New Jersey  
March 27, 2014

**NEPHROS, INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEETS**

**(In Thousands, Except Share Amounts)**

	December 31, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 579	\$ 47
Accounts receivable	122	935
Inventory, less allowances of \$365 at December 31, 2013 and \$269 at December 31, 2012	162	312
Prepaid expenses and other current assets	125	109
Total current assets	988	1,403
Property and equipment, net	7	16
Other assets, net of accumulated amortization	1,894	2,109
Total assets	\$ 2,889	\$ 3,528
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Senior secured note payable, net of debt discount of \$142	\$ 1,358	\$ -
Accounts payable	1,073	1,070
License and supply agreement fee payable	-	1,318
Accrued expenses	365	321
Deferred revenue, current portion	703	707
Total current liabilities	3,499	3,416
Long-term portion of deferred revenue	-	707
Total liabilities	3,499	4,123
Commitments and Contingencies (Note 12)		
Stockholders' deficit:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012.	-	-
Common stock, \$.001 par value; 90,000,000 shares authorized at December 31, 2013 and 2012; 18,082,043 and 11,949,824 shares issued and outstanding at December 31, 2013 and December 31, 2012, respectively.	18	12
Additional paid-in capital	100,526	96,847
Accumulated other comprehensive income	74	76
Accumulated deficit	(101,228)	(97,530)
Total stockholders' deficit	(610)	(595)
Total liabilities and stockholders' deficit	\$ 2,889	\$ 3,528

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



## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In Thousands, Except Share and Per Share Amounts)

	Years Ended December 31,	
	2013	2012
Net revenue:		
Product revenues	\$ 1,029	\$ 1,127
Licensing revenues	711	680
Total net revenues	1,740	1,807
Cost of goods sold	898	737
Gross margin	842	1,070
Operating expenses:		
Research and development	826	632
Depreciation and amortization	223	151
Selling, general and administrative	3,110	3,620
Total operating expenses	4,159	4,403
Loss from operations	(3,317)	(3,333)
Interest income	-	2
Interest expense	(94)	-
Gain on sale of equipment	3	55
Amortization of debt discount	(257)	-
Other income (expense)	(33)	14
Net loss	(3,698)	(3,262)
Other comprehensive income, foreign currency translation adjustments	(2)	27
Total comprehensive loss	(3,700)	(3,235)
Net loss per common share, basic and diluted	\$ (0.24)	\$ (0.29)
Weighted average common shares outstanding, basic and diluted	15,624,999	11,223,878

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

## NEPHROS, INC. AND SUBSIDIARY

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

(In Thousands, Except Share Amounts)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in Capital	Other Comprehensive Income	Deficit	
Balance, December 31, 2011	10,501,477	\$ 10	\$ 95,630	\$ 49	\$ (94,268)	\$ 1,421
Comprehensive income:						
Net loss					(3,262)	(3,262)
Net unrealized gains on foreign currency translation				27		27
Comprehensive loss						(3,235)
Exercise of warrants	1,448,347	2	501			503
Noncash stock-based compensation			443			443
Issuance of stock options related to licensing agreement			273			273
Balance, December 31, 2012	11,949,824	\$ 12	\$ 96,847	\$ 76	\$ (97,530)	\$ (595)
Comprehensive income:						
Net loss					(3,698)	(3,698)
Net unrealized losses on foreign currency translation				(2)		(2)
Comprehensive loss						(3,700)
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	18,082,043	\$ 18	\$ 100,526	\$ 74	\$ (101,228)	\$ (610)

*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,	
	2013	2012
Operating activities		
Net loss	\$ (3,698)	\$ (3,262)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	9	9
Amortization of other assets	214	142
Non-cash stock-based compensation, including stock options and restricted stock	575	443
Warrant inducement	14	-
Inventory reserve	210	82
Amortization of debt discount	257	-
Noncash interest	39	-
Gain on disposal of property and equipment	(3)	(55)
Loss on foreign currency transactions	26	7
(Increase) decrease in operating assets:		
Accounts receivable	820	1,006
Inventory	(60)	(147)
Prepaid expenses and other current assets	(16)	4
Long-term receivable		-
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	59	904
License and supply agreement fee payable	(1,318)	-
Deferred revenue	(711)	(680)
Net cash used in operating activities	(3,583)	(1,547)
Investing activities		
Purchase of property and equipment	-	(8)
Purchase of intangible assets	-	(659)
Proceeds from sales of property and equipment	3	55
Net cash provided by (used in) investing activities	3	(612)
Financing activities		
Proceeds from issuance of common stock, net of equity issuance costs of \$229	2,771	-
Proceeds from issuance of Senior Secured Notes	2,800	-
Payment of financing costs	(399)	-
Proceeds from exercise of warrants	248	503
Payment of Senior Secured Note	(1,300)	-
Net cash provided by financing activities	4,120	503
Effect of exchange rates on cash and cash equivalents	(8)	34
Net increase (decrease) in cash and cash equivalents	532	(1,622)
Cash and cash equivalents, beginning of year	47	1,669
Cash and cash equivalents, end of year	\$ 579	\$ 47

Supplemental disclosure of cash flow information			
Cash paid for taxes	\$	2	\$ 18
Restricted stock issued to settle liability	\$	77	\$ -
Payable related to license and supply agreement	\$	-	\$ 1,318
Receivable related to license agreement	\$	-	\$ 791
Fair value of stock options granted to Medica	\$	-	\$ 273

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



**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 various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy for ESRD patients. These are the OLpur MDHDF filter series or “dialyzers,” designed expressly for HDF therapy, the OLpur H2H, 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 system, which represents a new and complementary product line to the Company’s existing 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 - 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.

These consolidated financial statements were approved by management and the Board of Directors and are available for issuance as of the date of the audit opinion. Subsequent events have been evaluated through this date.

**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. 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 in operations in each quarter since inception. For the years ended December 31, 2013 and 2012, the Company has incurred net losses of \$3,698,000 and \$3,262,000, respectively. In

addition, the Company has not generated positive cash flow from operations for the years ended December 31, 2013 and 2012. 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.

The voluntary recalls of point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 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.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 - Summary of Significant Accounting Policies (continued)**

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee (“Bellco”), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros’ patented mid-dilution dialysis filters. This Agreement provided the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. 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. As a result of the amendment, the Company will receive a total of €450,000 in upfront fees in connection with the First Amendment, half of which were paid on February 19, 2014, and the other half of which are payable on March 31, 2014. See Note 12, Commitments and Contingencies for further discussion.

On February 4, 2013 and November 12, 2013, the Company issued senior secured notes to Lambda Investors LLC in the principal amount of \$1.3 million and \$1.5 million, respectively. As of December 31, 2013, the \$1.5 million note is outstanding. The \$1.3 million note was repaid on May 22, 2013. For a more detailed discussion of the terms of the senior secured notes, see Note 6, Senior Secured Notes.

On March 21, 2014 the Company completed a rights offering which resulted in gross proceeds of \$2.1 million. See Note 14, Subsequent Events, for further discussion.

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.

**Cash and Cash Equivalents**

The Company invests its excess cash in bank deposits and money market accounts. The Company considers all highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximate cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

**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 were no allowances for doubtful accounts at December 31, 2013 or 2012. There was no allowance for sales returns at December 31, 2013 or 2012. There were no write offs of accounts receivable to bad debt expense during 2013 or 2012.

**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 and raw materials (fiber) 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.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 - Summary of Significant Accounting Policies (continued)**

In March 2014, the Company requested the closeout of its October 2013 voluntary product recall. The Company has fully reserved the recalled product and will destroy the respective product by April 20, 2014.

**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.

**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 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, 2013 and December 31, 2012.

**Fair Value of Financial Instruments**

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments.

**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 \$703,000 and \$1,414,000 on the accompanying consolidated balance sheets as of December 31, 2013 and 2012, respectively, and is related to the License Agreement with Bellco. The Company has recognized approximately \$1,756,000 of revenue related to this license agreement to date, including approximately \$711,000 for the year ended December 31, 2013, resulting in \$703,000 being deferred over the remainder of the expected obligation period. The Company amortizes the deferred revenue monthly over the expected obligation period which ends on December 31, 2014. This will result in expected recognized revenue of approximately \$703,000 for each of the year ending December 31, 2014. Total payments of approximately \$2,459,000, including the final payment of approximately \$791,000 received in January 2013, were related to the License Agreement with Bellco.

#### **Shipping and Handling Costs**

Shipping and handling costs are recorded as cost of goods sold and are approximately \$30,000 and \$33,000 for the years ended December 31, 2013 and 2012, respectively.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 - Summary of Significant Accounting Policies (continued)**

**Research and Development Costs**

Research and development costs are expensed as incurred.

**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. For stock-based 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.

**Amortization of Debt Issuance Costs**

The Company accounts for debt issuance costs in accordance with ASC 835, which requires 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 of \$399,000 for the year ended December 31, 2013 are associated with the senior secured notes issued to Lambda Investors LLC on February 4, 2013 and November 12, 2013. Approximately \$257,000 of these costs were amortized as of December 31, 2013 and are included in amortization of debt discount on the consolidated statements of operations and comprehensive loss. There were no debt issuance costs for the year ended December 31, 2012.

**Other Income (Expense), net**

Other income (expense), net, of approximately \$33,000 includes approximately \$50,000 of other expense for the year ended December 31, 2013, primarily due to approximately \$36,000 related to foreign currency losses and approximately \$14,000 related to the May 2013 rights offering warrant modification. Other expense was partially offset by other income of approximately \$17,000, which consisted primarily of a refund of approximately \$15,000 received as a result of the Steris agreement termination. Other income (expense), net, in the amount of approximately \$14,000 for the year ended December 31, 2012 is due primarily to approximately \$18,000 in write-offs of old vendor invoices which are no longer due, offset partially by approximately \$4,000 of net foreign currency losses on invoices paid to and due to an international supplier.

**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, 2013 and 2012.

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 2010. The adoption of the provisions of ASC 740 did not have a material impact on the Company's consolidated financial statements. During the years ended December 31, 2013 and 2012, 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.



**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 2 - Summary of Significant Accounting Policies (continued)****Loss per Common Share**

In accordance with ASC 260-10, net loss per common share amounts (“basic EPS”) are computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution (“diluted EPS”) is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. The following securities have been excluded from the dilutive per share computation as they are antidilutive:

	2013	2012
Stock options	2,410,134	2,294,714
Warrants	13,887,598	14,679,971
Unvested restricted stock	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)) such as foreign currency translation adjustments. For the years ended December 31, 2013 and 2012, the comprehensive loss was approximately \$3,700,000 and \$3,235,000, respectively.

**Recently Adopted Accounting Pronouncements**

There were no recent accounting pronouncements that are expected to have an effect on the Company’s consolidated financial statements.

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 3 - Inventory**

The Company's inventory components as of December 31, 2013 and 2012 were as follows:

	December 31, 2013	2012
Total Gross Inventory, Finished Goods	\$ 527,000	\$ 581,000
Less: Inventory reserve	(365,000)	(269,000)
Total Inventory	\$ 162,000	\$ 312,000

**Note 4 - Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets as of December 31, 2013 and 2012 were as follows:

	December 31, 2013	2012
Prepaid insurance premiums	\$ 70,000	\$ 78,000
Security deposit	21,000	21,000
Other	34,000	10,000
Prepaid expenses and other current assets	\$ 125,000	\$ 109,000

**Note 5 - Property and Equipment, Net**

Property and equipment as of December 31, 2013 and 2012 was as follows:

	Life	December 31, 2013	2012
Manufacturing equipment	3-5 years	\$ 599,000	\$ 602,000
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	737,000
Less: accumulated depreciation		727,000	721,000
Property and equipment, net		\$ 7,000	\$ 16,000

Depreciation expense for each of the years ended December 31, 2013 and 2012 was \$9,000, including amortization expense relating to research and development assets.

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. During 2012, the Company agreed to sell its manufacturing equipment to Medica for approximately €42,500, or \$55,000. All assets at the manufacturing plant were fully depreciated as of the date of the sale. Approximately €42,500, or \$55,000, is recognized as gain on sale of equipment on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2012.



**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 6 Senior Secured Notes**

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 on May 22, 2013 with the cash proceeds from the rights offering that closed in May 2013. 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 on March 18, 2014 with the cash proceeds from the rights offering that closed in March 2014. 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 \$53,000 is reflected as amortization of debt discount on the consolidated statements of operations and comprehensive loss for the year the ended December 31, 2013.

On March 21, 2014 the Company completed a rights offering which resulted in gross proceeds of \$2.1 million. A portion of the proceeds was used for the repayment of a \$1.5 million note, plus all accrued interest thereon of \$61,000. See Note 13, Subsequent Events, for further discussion.

**Note 7 - Accrued Expenses**

Accrued expenses as of December 31, 2013 and 2012 were as follows:

	December 31, 2013	2012
Accrued Legal	\$ 149,000	\$ 90,000
Accrued Product Recall	60,000	
Accrued Directors' Compensation	-	77,000
Accrued Management Bonus	81,000	-
Accrued Interest	39,000	-
Accrued Travel	-	84,000
Accrued Other	36,000	70,000
Accrued Expenses	\$ 365,000	\$ 321,000

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 8 - 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:

	2013		2012	
U.S. federal statutory rate	35.00	%	35.00	%
State & local taxes	5.22	%	5.36	%
Tax on foreign operations	0.40	%	(0.78)	%
State research and development credits	1.09	%	1.06	%
Other	(3.00)	%	(2.29)	%
Valuation allowance	(38.71)	%	(38.35)	%
Effective tax rate	-		-	

Significant components of the Company's deferred tax assets as of December 31, 2013 and 2012 are as follows:

	2013		2012
Deferred tax assets:			
Net operating loss carry forwards	\$ 27,029,000		\$ 25,721,000
Research and development credits	1,096,000		1,054,000
Nonqualified stock option compensation expense	1,801,000		1,701,000
Other temporary book - tax differences	408,000		441,000
Total deferred tax assets	30,334,000		28,917,000
Valuation allowance for deferred tax assets	(30,334,000)		(28,917,000)
Net deferred tax assets	\$ -		\$ -

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, 2013, the Company had Federal and New Jersey income tax net operating loss carryforwards of \$87,292,000 and foreign income tax net operating loss carryforwards of \$8,305,000. The Company also had Federal research tax credit carryforwards of \$1,096,000 at December 31, 2013 and \$1,054,000 at December 31, 2012. The Federal net operating loss and 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.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 - 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, 2013 and 2012, 831 and 2,053 options, respectively, had been issued to non-employees under the 2000 Plan and were outstanding. During the twelve months ended December 31, 2013, 1,222 non-employee options expired. The remaining outstanding options, all of which are fully vested, will expire on March 15, 2014. As of December 31, 2013 and 2012, 2,003 and 7,230 options, respectively, had been issued to employees under the 2000 Plan and were outstanding. During the twelve months ended December 31, 2013, 5,227 employee options expired. The remaining employee options, all of which are fully vested, will expire on March 15, 2014.

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, 2013, 1,360,059 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 are outstanding as of December 31, 2013.

As of December 31, 2012, 1,316,628 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between April 27, 2015 and May 23, 2023, and vest upon a combination of the following: immediate vesting or straight line vesting of two to four years. At December 31, 2012, there were 19,904 shares available for future grants under the 2004 Plan. As of December 31, 2012, 637,253 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 December 31, 2023, and vest upon a combination of the following: immediate vesting or straight line vesting of two to four years.

**Share-Based Payment**

Prior to the Company’s initial public offering, options were granted to employees, non-employees and non-employee directors at exercise prices which were lower than the fair market value of the Company’s stock on the date of grant. After the date of the Company’s initial public offering, stock options are granted to employees, non-employees and

non-employee directors at exercise prices equal to the fair market value of the Company's stock on the date of grant. Stock options granted have a life of 10 years.

Expense is recognized, net of expected forfeitures, over the vesting period of the options. For options that vest upon the achievement of certain milestones, expense is recognized when it is probable that the condition will be met. Stock based compensation expense recognized for the years ended December 31, 2013 and 2012 was approximately \$418,000 or less than \$0.03 per share and approximately \$443,000 or less than \$0.04 per share, respectively.

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 9 - Stock Plans, Share-Based Payments and Warrants (continued)

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. This modification did not result in any additional compensation expense. In addition, as a result of Mr. Kochanski's resignation, 90,945 stock options that were granted to him were forfeited on June 15, 2013. Of these 90,945 stock options, 25,000 were granted during the twelve month period ended December 31, 2013.

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 related to risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility.

Grant Year	Option Pricing Assumptions		
	2013		2012
Stock Price Volatility	127.46-135.98	%	123.48 128.54 %
Risk-Free Interest Rates	1.09-1.75	%	..093-1.32 %
Expected Life (in years)	5.00-6.25		5.75-62.5
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, 2013 was approximately \$519,000. The total fair value of options vested during the fiscal year ended December 31, 2012 was approximately \$506,000.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2013:

Range of Exercise Price	Options Outstanding			Options Exercisable		
	Number Outstanding as of December 31, 2013	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable as of December 31, 2013	Weighted Average Exercise Price	
\$0.41 - \$2.60	2,374,514	8.16	\$ 0.93	1,349,579	\$ 0.83	
\$15.00 - \$29.80	27,909	4.58	\$ 17.82	27,909	\$ 17.82	
\$34.20-\$96.00	7,711	1.38	\$ 51.49	7,711	\$ 51.49	
Total Outstanding	2,410,134		\$ 1.28	1,385,199	\$ 1.46	



The number of new options granted in 2013 and 2012 is 237,315 and 1,547,550, respectively. The weighted-average fair value of options granted in 2013 and 2012 is \$0.56 and \$1.03, respectively.

## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 9 - Stock Plans, Share-Based Payments and Warrants (continued)**

The following table summarizes the option activity for the year ended December 31, 2013:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2012	2,294,714	\$ 2.14
Options granted	237,315	0.64
Options exercised	-	-
Options forfeited or expired	(121,895)	3.27
Outstanding at December 31, 2013	2,410,134	\$ 1.28
Exercisable at December 31, 2013	1,385,199	\$ 1.46
Vested and expected to vest at December 31, 2013	2,350,688	\$ 1.29

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.

The aggregate intrinsic value of stock options outstanding at December 31, 2012 is \$793,000 and of stock options vested or expected to vest is approximately \$768,000. 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 8.9 years.

As of December 31, 2013, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$727,000 and will be amortized over the weighted-average remaining requisite service period of 2.3 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, 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
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## NEPHROS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 9 - Stock Plans, Share-Based Payments and Warrants (continued)

Total stock-based compensation expense for the restricted stock was approximately \$157,000 for the year ended December 31, 2013. For the year ended December 31, 2012, approximately \$109,000 and approximately \$48,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. The remaining expense related to the restricted stock awards issued to non-employee directors of approximately \$77,000 was recorded to offset accrued director's fees that were incurred prior to December 31, 2012. Any additional stock-based compensation related to non-employee directors will be recorded to stock-based compensation expense. As of December 31, 2013, there was approximately \$4,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next six months.

## Warrants

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2013 and 2012:

## Total Outstanding Warrants at December 31, 2013

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable	
				2013	2012
Class D Warrants - Lambda	11/14/2007	3/10/2017	\$ 0.40	8,806,575	8,806,575
July 2009 Warrants	7/24/2009	7/24/2014	\$ 22.40	33,629	33,629
Shareholder Rights Offering Warrants	3/10/2011	3/10/2016	\$ 0.40	2,264,817	3,057,190
March 2011 Lambda Warrants	3/10/2011	3/10/2017	\$ 0.40	2,782,577	2,782,577
				13,887,598	14,679,971

The weighted average exercise price of the outstanding warrants was \$0.45 for December 31, 2013 and 2012.

Following the closing of the rights offering in 2013, Lambda Investors' existing warrants to purchase 8,806,575 shares that remain outstanding were amended to expire on March 10, 2017.

The following table summarizes the Class D outstanding warrants at December 31, 2013 and 2012:

	Lambda Investors	Other Investors	Total Shares to be issued
As of December 31, 2011	8,806,575	447,197	9,253,772
Exercised in 2012	-	(352,034)	(352,034)
Expired in 2012	-	(95,163)	(95,163)
As of December 31, 2012	8,806,575	-	8,806,575
Exercised in 2013	-	-	-
Expired in 2013	-	-	-
As of December 31, 2013	8,806,575	-	8,806,575

Class D warrant holders elected to exercise 352,034 of the outstanding Class D Warrants in 2012. As a result, 190,326 were exercised pursuant to the cashless exercise provision of the warrant. In addition, 161,708 warrants were exercised resulting in proceeds of approximately \$65,000.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 - Stock Plans, Share-Based Payments and Warrants (continued)**

**Warrants exercised during 2013 and 2012**

In connection with the 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.

During the period that the 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 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.

An additional 374 common shares were not issued as a result of warrant exercises for the year ended December 31, 2013 due to rounding.

Shareholders exercised 23,720,667 warrants, resulting in proceeds of approximately \$438,000 and the issuance of 1,096,313 shares of the Company's common stock for the year ended December 31, 2012.

**Note 10 Stockholders' Equity**

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

The 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 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 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 Investors, LLC, 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 Investors' legal fees incurred in connection with the February 2013 senior secured note and the Rights Offering. Those payments totaling \$204,000 are reflected as amortization of debt discount.

**Note 11 - 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 began matching 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. The Company contributed and expensed \$46,000 and \$49,000 in 2013 and 2012, respectively.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 12 - 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 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 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, 2016, 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, €1.75 per unit; thereafter, €1.25 per unit. In addition, the Company will receive a total of €450,000 in upfront fees in connection with the First Amendment, half of which were paid on February 19, 2014, and the other half of which are payable on March 31, 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 has agreed to make minimum annual aggregate purchases from Medica of €300,000, €500,000 and €750,000 for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2013 the Company’s aggregate purchase commitments totaled approximately €532,000. For calendar years thereafter, annual minimum amounts will be mutually agreed upon between Medica and the Company.



In exchange for the license, the Company paid Medica €1,500,000 in three installments: €500,000 on April 23, 2012, €600,000 on February 4, 2013, and €400,000 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 \$1,894,000, net of \$356,000 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 \$214,000 and \$142,000 have been charged to amortization expense for the years ended December 31, 2013 and 2012, respectively, on the consolidated statement of operations and comprehensive loss. Approximately \$208,000 of amortization expense will be recognized in the years ended December 31, 2014 and 2015, respectively. 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.

**NEPHROS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 12 - Commitments and Contingencies (continued)**

As of September 2013, we have an understanding with Medica whereby we have agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

**Employment Agreement**

On April 20, 2012, the Company entered into an Employment Agreement, effective as of April 20, 2012, with John C. Houghton (“Employment Agreement”). The Employment Agreement has a term of four years, ending on April 20, 2016. The Employment Agreement provides that Mr. Houghton’s annual base salary will be \$350,000. Mr. Houghton will be eligible to receive a target discretionary bonus of 30% of annual base salary, as determined by the Company.

**Contractual Obligations**

The Company had an operating lease that expired on November 30, 2013 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately \$8,000. On July 25, 2013, the Company signed a one year lease extension for the same office space which will expire on November 30, 2014 with a monthly cost of approximately \$8,000 beginning December 1, 2013.

Rent expense for the years ended December 31, 2013 and 2012 totaled \$108,000 and \$109,000, respectively.

**Contractual Obligations and Commercial Commitments**

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2013:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 - 3	Years 4 - 5	More than 5 Years
Leases	\$ 108,000	\$ 100,000	\$ 8,000	\$ -	\$ -
Employment Contracts	788,000	350,000	438,000	-	-
Total	\$ 896,000	\$ 450,000	\$ 446,000	\$ -	\$ -

**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 has 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 do not affect the Company’s dialysis products. The consolidated financial statements for the year ended December 31, 2013 include product revenues and cost of goods sold adjustments of approximately \$216,00 and \$110,000, respectively, reflecting estimates of the financial impact of product recalled to the Company. This 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 has fully reserved the recalled product and will destroy the respective product by April 20, 2014.

**NEPHROS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 13 - Concentration of Credit Risk**

Cash and cash equivalents are financial instruments which potentially subject the Company to concentrations 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 and cash equivalents.

**Major Customers**

For the years ended December 31, 2013 and 2012, three customers accounted for 86% and 68%, respectively, of the Company's sales. In addition, as of December 31, 2013 and 2012, those three customers accounted for 97% and 88%, respectively, of the Company's accounts receivable.

**Note 14 - Subsequent Events**

On March 24, 2014, the Company announced the completion of a rights offering that resulted in gross proceeds of \$2.1 million and the issuance of 7,140,822 shares of common stock. A portion of the proceeds was used for the repayment of the \$1.5 million note issued to Lambda Investors LLC in November 2013 in connection with its loan to the Company, plus \$61,000 of accrued interest thereon. The Company issued a total of 7,140,822 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 rights offering.

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 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 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. The Company will receive a total of €450,000 in upfront fees in connection with the First Amendment, half of which were paid on February 19, 2014, and the other half of which are payable on March 31, 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.

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no changes in or disagreements with our accountants during 2013 or 2012.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

We carried out an evaluation under the supervision and with the participation of our management, including our President, Chief Executive Officer and Acting Chief Financial Officer (CEO and Acting CFO effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 (the “Exchange Act”), as amended for financial reporting as of December 31, 2013. Based on that evaluation, our CEO and Acting CFO concluded that these controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported as specified in Securities and Exchange Commission rules and forms. There were significant changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during 2013 based on the resignation of the former CFO and the CEO expansion of duties to include acting CFO. These changes were considered in the review of the internal control structure.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our CEO and Acting CFO, as appropriate to allow timely decisions regarding required disclosure.

#### **Management’s Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the CEO and effected by the board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and board of directors;
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (1992) in Internal Control-Integrated Framework.

Based on our assessment, our management believes that, as of December 31, 2013, our internal control over financial reporting is effective.

**Item 9B. Other Information**

Not applicable.

### **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file the 2014 Proxy Statement within one hundred twenty (120) days after the end of the fiscal year pursuant to Regulation 14A for our Annual Meeting of Stockholders currently being planned to occur in May 2014, and the information included in the 2014 Proxy Statement is incorporated herein by reference.

#### **Item 10. Directors, Executive Officers and Corporate Governance**

The information set forth under the captions “Proposal No. 1 Election of Directors”, “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2014 Proxy Statement is incorporated herein by reference.

#### **Item 11. Executive Compensation**

The information set forth under the caption “Compensation Matters” in the 2014 Proxy Statement is incorporated herein by reference.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information set forth under the captions “Stock Ownership of Management and Principal Shareholders” and “Compensation Matters” in the 2014 Proxy Statement is incorporated herein by reference.

#### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information set forth under the captions “Corporate Governance” and “Certain Relationships and Related Transactions” in the 2014 Proxy Statement is incorporated herein by reference.

#### **Item 14. Principal Accounting Fees and Services**

The information set forth under the caption “Proposal No. 2 Ratification of Selection of Independent Registered Public Accounting Firm” in the 2014 Proxy Statement is incorporated herein by reference.

**Item 15. Exhibits**

**(a) Documents filed as part of this report:**

**(1) Consolidated Financial Statements of Nephros, Inc.**

Report of independent registered public accounting firm.

Consolidated balance sheets as of December 31, 2013 and 2012.

Consolidated statements of operations for the years ended December 31, 2013 and 2012.

Consolidated statement of changes in stockholders' equity for the years ended December 31, 2013, 2012, and 2011.

Consolidated statements of cash flows for the years ended December 31, 2013 and 2012.

Notes to consolidated financial statements.



**(b) Exhibits:****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (Reg. No. 333-127264), filed with the Securities and Exchange Commission on August 5, 2005.
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 13, 2007 (SEC File No. 001-32288).
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 13, 2007 (SEC File No. 001-32288).
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on November 13, 2007, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the Securities and Exchange Commission on November 13, 2007 (SEC File No. 001-32288).
3.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on October 26, 2009, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-162781), filed with the Securities and Exchange Commission on October 30, 2009.
3.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 10, 2011, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 16, 2011.
3.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 11, 2011, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 16, 2011.
3.8	Second Amended and Restated By-Laws of the Registrant, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 3, 2007 (SEC File No. 001-32288).
4.1	Specimen of Common Stock Certificate of the Registrant, incorporated by reference to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on July 20, 2004.
4.2	Form of Underwriter's Warrant, incorporated by reference to Nephros, Inc.'s Amendment No. 2 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on August 26, 2004.
4.3	Warrant for the purchase of shares of common stock dated January 18, 2006, issued to Marty Steinberg, Esq., as Court-appointed Receiver for Lancer Offshore, Inc, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008 (SEC File No. 001-32288).
4.4	Form of Class D Warrant, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 25, 2007 (SEC File No. 001-32288).
4.5	

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- Form of Placement Agent Warrant, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 25, 2007 (SEC File No. 001-32288).
- 4.6 Form of Investor Warrant issued on July 24, 2009, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 14, 2009.
- 4.7 Form of Warrant Certificate, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-169728), filed with the Securities and Exchange Commission on October 1, 2010.
- 4.8 Form of Warrant Agreement between Nephros, Inc. and Continental Stock Transfer & Trust Company, incorporated by reference to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-169728), filed with the Securities and Exchange Commission on November 8, 2010.
- 4.9 Form of Subscription Rights Certificate, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-169728), filed with the Securities and Exchange Commission on October 1, 2010.
- 10.1 Amended and Restated 2000 Nephros Equity Incentive Plan, incorporated by reference to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on July 20, 2004.

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- 10.2 2004 Nephros Stock Incentive Plan, incorporated by reference to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on July 20, 2004.
- 10.3 Amendment No. 1 to 2004 Nephros Stock Incentive Plan, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (Reg. No. 333-127264), filed with the Securities and Exchange Commission on August 5, 2005.
- 10.4 Amendment No. 2 to the Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the Securities and Exchange Commission on November 13, 2007 (SEC File No. 001-32288).
- 10.5 Supply Agreement between Nephros, Inc. and Membrana GmbH, dated as of December 17, 2003, incorporated by reference to Nephros, Inc.'s Amendment No. 2 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on August 26, 2004.
- 10.6 Amended Supply Agreement between Nephros, Inc. and Membrana GmbH dated as of June 16, 2005, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on August 15, 2005 (SEC File No. 001-32288).
- 10.7 Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of May 12, 2003, incorporated by reference to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the Securities and Exchange Commission on July 20, 2004.
- 10.8 Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of March 22, 2005. Supersedes prior Agreement dated May 12, 2003, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB, filed with the Securities and Exchange Commission on April 20, 2006 (SEC File No. 001-32288).
- 10.9 Form of Common Stock Purchase Warrant, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 2, 2006 (SEC File No. 32288).
- 10.10 Form of Registration Rights Agreement, dated as of June 1, 2006, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 2, 2006 (SEC File No. 32288).
- 10.11 Addendum to Commercial Contract between Nephros, Inc. and Bellco S.p.A, effective as of January 1, 2007, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2006, filed with the Securities and Exchange Commission on April 10, 2007 (SEC File No. 001-32288).
- 10.12 Registration Rights Agreement, dated as of September 19, 2007, among Nephros and the Holders, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 25, 2007 (SEC File No. 001-32288).
- 10.13 License Agreement, dated October 1, 2007, between the Trustees of Columbia University in the City of New York, and Nephros, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008 (SEC File No. 001-32288).
- 10.14 Lease Agreement between Nephros, Inc. and 41 Grand Avenue, LLC dated as of November 20, 2008, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 20, 2008 (SEC File No. 001-32288).
- 10.15 Lease Agreement between Nephros International LTD and Coldwell Banker Penrose & O'Sullivan dated November 30, 2008, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 31, 2009 (SEC File No. 001-32288).
- 10.16 Amendment No. 3 to the Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 31, 2009 (SEC File No. 001-32288).
- 10.17

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- Senior Secured Note dated October 1, 2010 issued to Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-169728), filed with the Securities and Exchange Commission on October 1, 2010.
- 10.18 Form of Registration Rights Agreement, dated as of September 30, 2010, by and between the Registrant and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-169728), filed with the Securities and Exchange Commission on October 1, 2010.
- 10.19 Amendment No. 4 to the Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Nephros, Inc.'s 2011 Proxy Statement (Exhibit A), filed with the Securities and Exchange Commission on December 2, 2010.
- 10.20 Employment Agreement between Nephros, Inc. and Gerald J. Kochanski dated April 1, 2011, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 31, 2011.
- 10.21 License Agreement, entered into as of July 1, 2011 by and between Nephros, Inc. and Belco S.r.l., incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 27, 2011.
- 10.22 License and Supply Agreement dated as of April 23, 2012 between Nephros, Inc. and Medica S.p.A., incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 26, 2012.

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- 10.23 Employment Agreement dated as of April 20, 2012 between Nephros, Inc. and John C. Houghton, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 26, 2012.
- 10.24 Non-qualified Stock Option Agreement made as of July 3, 2012 by Nephros, Inc. and John C. Houghton, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, filed with the Securities and Exchange Commission on November 9, 2012.
- 10.25 Senior Secured Note, dated February 4, 2013, issued to Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-187036), filed with the Securities and Exchange Commission on March 4, 2013.
- 10.26 Registration Rights Agreement, dated February 4, 2013, by and between Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-187036), filed with the Securities and Exchange Commission on March 4, 2013.
- 10.27 Security Agreement, dated as of February 4, 2013, by and between Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-187036), filed with the Securities and Exchange Commission on March 4, 2013.
- 10.28 Intellectual Property Security Agreement, dated as of February 4, 2013, made by Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-187036), filed with the Securities and Exchange Commission on March 4, 2013.
- 10.29 First Amendment to Registration Rights Agreement, dated as of May 23, 2013, by and between Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 13, 2013.
- 10.30 Amendment No. 6 to Nephros, Inc. 2004 Stock Incentive Plan dated June 14, 2013, incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 13, 2013.
- 10.31 Senior Secured Note, dated November 12, 2013, issued to Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 14, 2013.
- 10.32 Registration Rights Agreement, dated November 12, 2013, by and between Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 14, 2013.
- 10.33 Security Agreement, dated as of November 12, 2013, by and between Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 14, 2013.
- 10.34 Intellectual Property Security Agreement, dated as of November 12, 2013, made by Nephros, Inc. and Lambda Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 14, 2013.
- 10.35 First Amendment to License Agreement, dated as of February 19, 2014, by and between Nephros, Inc. and Bellco S.r.l., incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 25, 2014.
- 14.1 Code of Ethics and Business Conduct, as amended on April 2, 2007, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 6, 2007 (SEC File No. 001-32288).
- 21.1 Subsidiaries of Registrant, incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2006, filed with the Securities and Exchange Commission on April 10, 2007 (SEC File No. 001-32288).
- 23.1 Consent of Rothstein Kass, Independent Registered Public Accounting Firm. \*
- 24.1 Power of Attorney. (included on the signature page)
- 31.1 Certification by the Chief Executive Officer and Acting Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. \*
- 32.1

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Certification by the Chief Executive Officer and Acting Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*

101 Interactive Data File. \*

\* Filed herewith.  
Management contract or compensatory plan arrangement.

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**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NEPHROS, INC.**

Date: March 28, 2014

By: /s/ John C. Houghton

Name: John C. Houghton  
 Title: President, Chief Executive Officer and Acting Chief Financial Officer, and Director (Principal Executive Officer and Principal Financial and Accounting Officer)

**POWER OF ATTORNEY**

We, the undersigned directors and officers of Nephros, Inc., hereby severally constitute and lawfully appoint John C. Houghton, our true and lawful attorney-in-fact with full power to him to sign for us, in our names in the capacities indicated below, the Annual Report on Form 10-K for the fiscal year ended December 31, 2013 of Nephros, Inc. and any and all amendments thereto, and to file the same with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ John C. Houghton	President, Chief Executive Officer and Acting Chief Financial Officer, and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 28, 2014
John C. Houghton		
/s/ Arthur H. Amron	Director	March 28, 2014
Arthur H. Amron		
/s/ Lawrence J. Centella	Director	March 28, 2014
Lawrence J. Centella		
/s/ Paul A. Mieyal	Director	March 28, 2014
Paul A. Mieyal		
/s/ Daron Evans	Director	March 28, 2014
Daron Evans		

