

NEPHROS INC
Form POS AM
March 07, 2013

As filed with the Securities and Exchange Commission on March 7, 2013

Registration No. 333-169728

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

POST-EFFECTIVE AMENDMENT NO. 4

TO

FORM S-1

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

NEPHROS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

3841

13-3971809

*(State or Other Jurisdiction of (Primary Standard Industrial (I. R. S. Employer
Incorporation or Organization) Classification Code Number) Identification No.)*

41 Grand Avenue

River Edge, New Jersey 07661

(201) 343-5202

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

John C. Houghton

President and Chief Executive Officer

Nephros, Inc.

41 Grand Avenue

River Edge, New Jersey 07661

(201) 343-5202

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

Copies to:

Michael T. Rave, Esq.

Day Pitney LLP

One Jefferson Road

Parsippany, New Jersey 07054

Telephone: (973) 966-6300

Facsimile: (973) 966 1015

Approximate date of commencement of proposed sale to the public: As promptly as practicable after this registration statement becomes effective and the satisfaction or waiver of certain other conditions described herein.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. x

Edgar Filing: NEPHROS INC - Form POS AM

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

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

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

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

Large accelerated filer "

Accelerated filer "

Non-accelerated filer " (Do not check if smaller reporting company) Smaller reporting company x

EXPLANATORY NOTE

This Post-Effective Amendment No. 4 to Form S-1 (this “Post-Effective Amendment”) is being filed pursuant to Section 10(a)(3) of the Securities Act of 1933, as amended, to update the Form S-1 Registration Statement (Registration No. 333-169728), which was previously declared effective by the Securities and Exchange Commission (“SEC”) on January 31, 2011, to include the audited consolidated financial statements and the notes thereto included in the Registrant’s Annual Report on Form 10-K for the fiscal year ended December 31, 2012 that have been filed with the SEC since the Post-Effective Amendment No. 3 to Form S-1 was declared effective by the SEC on April 5, 2012, and contains an updated prospectus relating to the offering and sale of the securities that were registered on Form S-1. As of the date of filing of this Post-Effective Amendment, no further offering will be made of the units registered on Form S-1. The rights offering was completed on March 10, 2011. Accordingly, this Post-Effective Amendment concerns only the exercise of the warrants underlying the units.

All applicable registration fees were paid at the time of the original filing of such Registration Statement on October 1, 2010.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Post-Effective Amendment No. 4 to the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION — DATED MARCH 7, 2013

NEPHROS, INC.

Issuance of up to 2,981,898 Shares of Common Stock upon Exercise of Warrants

We previously sold 4,964,854 units, each unit consisting of one share of our common stock and a warrant to purchase 4,590,171 shares of our common stock (the “Units”). The warrants are exercisable for a five-year term following the issue date of the warrants, which was March 10, 2011, and have an exercise price of \$0.40 per share. This prospectus relates to the issuance of shares of common stock pursuant to the exercise of the warrants to purchase an aggregate of 2,981,898 shares of common stock.

All costs associated with this registration statement will be borne by us. Shares of our common stock are quoted on the OTC Bulletin Board under the ticker symbol “NEPH.” On February 20, 2013, the closing sales price for our common stock was \$1.00 per share. The shares of common stock issued upon the exercise of warrants will also be quoted on the OTC Bulletin Board under the same ticker symbol. Neither the warrants nor the subscription rights will be listed for trading on any stock exchange or market or quoted on the OTC Bulletin Board.

On March 10, 2011, we completed our rights offering and a private placement that together resulted in gross proceeds of approximately \$3.2 million. The aggregate net proceeds were approximately \$2.3 million, after deducting the estimated aggregate expenses of these transactions which approximated \$200,000, the repayment of the \$500,000 note, plus \$26,650 of accrued interest thereon, issued to Lambda Investors, LLC, the payment of an 8% sourcing/transaction fee of \$40,000 in respect of the note and an aggregate of \$100,000 for reimbursement of Lambda Investors’ legal fees incurred in connection with the loan and the rights offering.

After giving effect to the 1:20 reverse stock split on March 11, 2011, our stockholders subscribed for 4,964,854 units in the rights offering and we accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of \$0.40. Gross proceeds to us from the sale of these units in the rights offering was approximately \$2.0 million. We issued an aggregate of 4,964,854 shares of our common stock and warrants to purchase an aggregate of approximately 4,590,171 shares of our common stock to stockholders who subscribed.

Simultaneously with the closing of the rights offering, Lambda Investors, LLC purchased in a private placement 3,009,711 units at the same per unit purchase price of \$0.40, pursuant to a purchase agreement between us and Lambda Investors. We issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,579 shares of common stock. Of the \$3.2 million in gross proceeds from the rights offering and the private placement, we received approximately \$1.2 million in gross proceeds from the sale of units to Lambda Investors.

We effected a reverse stock split, in which every 20 shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:00 p.m. on March 11, 2011, were converted into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to \$0.04 per pre-split share for such fractional interests. The number of shares of common stock issued and outstanding was reduced from approximately 201,300,000 pre-split to approximately 10,100,000 post-split. The reverse stock split was effected in connection with the rights offering and private placement.

The reverse stock split was approved by our stockholders at the annual meeting held on January 10, 2011. The number of shares of common stock subject to outstanding stock warrants and options, and the exercise prices and conversion ratios of those securities, were automatically proportionately adjusted for the 1-for-20 ratio provided for by the reverse stock split.

All of the share and per share amounts discussed in this Post-Effective Amendment have been adjusted to reflect the effect of this reverse split.

Investing in our common stock involves substantial risks. See “Risk Factors” beginning on page 6 of this prospectus to read about important factors you should consider before purchasing our common stock.

We do not intend to sell any more Units.

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

The date of this prospectus is _____, 2013.

NEPHROS, INC.

TABLE OF CONTENTS

About this Prospectus	1
Prospectus Summary	1
Risk Factors	6
Special Note Regarding Forward-Looking Statements	17
Use of Proceeds	18
Determination of Offering Price	18
Dilution	18
Dividend Policy	18
Market for Our Common Stock	19
Plan of Distribution	19
Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Business	26
Management	36
Executive Compensation	43
Certain Relationships and Related Transactions	48
Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	50
Description of Common Stock	52
Description of Warrants	53
Legal Matters	54
Experts	54
Where You Can Find More Information	54

Edgar Filing: NEPHROS INC - Form POS AM

Disclosure of SEC Position on Indemnification for Securities Law Violations	54
Financial Statements	55
Report of Independent Registered Public Accounting Firm	F-1

ABOUT THIS PROSPECTUS

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

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

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. For a more complete understanding of our business, you should read this summary together with the more detailed information and financial statements for the years ended December 31, 2012 and 2011, and related notes appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the “Risk Factors” section beginning on page 6 and the “Special Note Regarding Forward-Looking Statements” section beginning on page 17. This prospectus contains important information that you should consider when making your investment decision.

About the Company

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers and healthcare facilities for the production of ultrapure water and bicarbonate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they eliminate a wide variety of bacteria, viruses, fungi, parasites, and endotoxins harmful to humans.

All of our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to be the only commercially available filters for healthcare applications that 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

By comparison, competitive filters on the market today are typically effective only to the 0.2 micron level and are prone to clog more quickly, thus reducing their useful lives.

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). In 2009, we began to extend our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Our Products

Presently, we offer seven types of ultrafilters for sale to customers in four markets:

Dialysis Centers – Water/Bicarbonate: Treatment of both water and bicarbonate for the production of ultrapure dialysate

Hospitals and Other Healthcare Facilities: Removal of infectious agents in drinking and bathing water, particularly in high risk patient areas

Military: Highly compact, individual water treatment devices used by soldiers to produce safe drinking water in the field

Dialysis Centers – Blood: Clearance of toxins from blood using an alternative method to HD in patients with chronic renal failure

We have designed our ultrafilters as either in-line products, filters that are incorporated into the existing plumbing of healthcare facilities, or point-of-use products, filters that can be easily installed onto a faucet or as a replacement shower head or can be used stand-alone to purify small quantities of water immediately prior to use.

Our Target Markets

Dialysis Centers – Water/Bicarbonate. To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce pure water and bicarbonate. Water and bicarbonate 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 payor for dialysis treatment in the U.S. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate 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/bicarbonate purity, assist in achieving those standards and 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 just prior to entering each dialysis machine.

Hospitals and Other Healthcare Facilities. According to the United States Centers for Disease Control and Prevention (CDC), healthcare acquired infections (HAIs) annually account for 1.7 million infections, 99,000 deaths, and \$4.5 - \$6.5 billion in extra costs in U.S. hospitals. At the root of many HAIs are waterborne pathogens such as *Legionella* and *Pseudomonas* which can thrive in aging or complex plumbing systems often found in healthcare facilities. According to the CDC, 23% of *Legionella* infections originate in healthcare facilities and *Pseudomonas* infections account for 10% of all water-related HAIs. These pathogens are most harmful to patients in intensive care, neonatal, burn, cancer, and transplant units.

The Affordable Care Act (ACA) which was passed in March 2010 puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. The ACA encompasses HAIs and shifts the costs associated with their treatment back onto the healthcare provider. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce the potential for HAIs.

Our ultrafilters are designed to reduce the risk of HAIs in the hospital/healthcare setting by treating water just prior to use. Our products can be used for reactive infection control. For example, during acute disease outbreaks (such as Legionnaires' disease), our ultrafilters have been used at hospitals and other healthcare facilities to quickly and efficiently assist in the control of such outbreaks. Our ultrafilters are also being used as a preventative measure in healthcare facilities, particularly in areas where high risk patients are being treated. Our point-of-use filters can be easily installed onto the end of faucets or as replacement shower heads.

The plastic casing of our hospital ultrafilters contains BACTiglas™. BACTiglas™ releases silver ions at the surface of the plastic casing such that they are imparted to anything that touches it. Silver ions (through chemical bonding with amino acids) result in the killing of the bacteria that remains on the surface of the plastic. This enables our hospital ultrafilters to be bacteriocidal to any touch contamination or any growth on the surface of the plastic in addition to their water treatment effect.

Military. 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; thereby reducing the effects of acute debilitating illnesses to soldiers.

We offer our individual water treatment device (IWTD), which allows a soldier in the field to derive biologically safe water from any fresh water source. Our IWTD is available in both in-line and point-of-use configurations. Our IWTD is one of the few portable filters that have 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 IWTDs from individual units of the U.S. armed forces and could become more widely used by soldiers in the future.

In January 2013, the U.S. Army issued a request for proposal (RFP) relating to an IWTD, Nephros submitted its response to this RFP on February 25th. 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. The RFP evaluation period may take up to 6 months before an award is made, if at all.

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 on-line mid-dilution hemodiafiltration (mid-HDF) system and it consists of our OLpūr H2H Module and OLpūr MD220 Hemodiafilter. On April 30, 2012, we announced that we received clearance from the U.S. Food and Drug Administration to market the OLpūr H2H Module and OLpūr MD220 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. Like HD, on-line mid-HDF treatment is given to patients at least 3 times weekly for 3-4 hours per treatment. Our mid-HDF system is the only HDF system of its kind to be cleared by the FDA to date.

We are currently preparing our OLpūr H2H Modules and manufacturing our OLpūr MD220 Hemodiafilters in readiness for market release. We expect to place a mid-HDF system in a U.S. dialysis clinic in Q2. We have not begun to broadly market our mid-HDF system and plan to seek a commercialization partner in the U.S.

Corporate Information

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

Where You Can Find More Information

We make available on our website, www.nephros.com, our annual reports, quarterly reports, proxy statements and other filings made with the SEC. The registration statement on Form S-1, of which this prospectus is a part, and its exhibits, as well as our other reports filed with the SEC, can be inspected and copied at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information about the operation of the public reference room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a web site at www.sec.gov which contains our registration statement on Form S-1 and any amendments thereto and other reports, proxy and information statements and information regarding us that we file electronically with the SEC.

The Offering

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

Securities Offered	2,981,898 shares of common stock issuable upon exercise of the warrants issued in connection with the Units sold on March 10, 2011.
Exercise Price and Term of Warrants	The warrants have an exercise price of \$0.40 per share and are exercisable at any time prior to March 10, 2016. For a more complete description of the terms of the warrants, see “Description of Warrants.”
Use of Proceeds	The proceeds of this offering consist solely of the payment by warrant holders of the exercise price. We plan to use the net proceeds of this offering to further develop our products and for general working capital purposes. For a more complete description of our intended use of proceeds from this offering, see “Use of Proceeds.”
Risk Factors	The exercise of the warrants and the acquisition of our common stock involve substantial risks. See “Risk Factors” beginning on page 6 of this prospectus.
State Securities Law Matters	The issuance and exercise of warrants is subject to compliance with state securities laws and regulations. We reserve the right in some states to require stockholders, if they wish to participate, to state and agree upon exercise of their warrants that they are acquiring the shares for investment purposes only, and that they have no present intention to resell or transfer any shares acquired. This offering is not being made and our securities are not being offered in any jurisdiction where the offer is not permitted under applicable local laws. We have the right, in our sole discretion, to not effect registration or qualification of the shares underlying the warrants in any state or other jurisdiction, or take any other action required by any state or other jurisdiction to allow the offer to take place in that state or jurisdiction. If you reside in a state or other jurisdiction in which registration, qualification or other action is necessary with which we choose not to comply, you will not be eligible to participate in the offering.
Listing	The shares of our common stock issuable upon exercise of the warrants will be listed on the OTC Bulletin Board under the ticker symbol “NEPH.”

Unless otherwise indicated, the information in this prospectus reflects a 1-for-20 reverse split of our common stock, which was effective on March 11, 2011.

RISK FACTORS

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

Risks Related to Our Company

Our independent registered public accounting firm, in its audit report related to our financial statements for the fiscal year ended December 31, 2012, 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 our Annual Report on Form 10-K for the year ended December 31, 2012 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.

If we do not receive capital from the rights offering or from another source, we may be forced to cease operations.

We are in immediate need of capital. We expect that the \$1.3 million in proceeds from the senior secured note issued to Lambda Investors LLC will allow us to fund our operations through May 2013. If we do not successfully complete a rights offering by May 2013, we expect that we will not have sufficient resources to fund our operations and may be required to cease and wind down operations unless we can find another source of financing at such time, which we believe would be difficult and may not be possible on acceptable terms or at all.

Our secured note with Lambda Investors LLC affects our business operations and contains provisions which restrict our ability to execute certain strategic transactions

On February 4, 2013, we issued a senior secured note to Lambda Investors LLC in the principal amount of \$1.3 million. We expect that the proceeds from the note will allow us to fund our operations through May 2013. The note bears interest at the rate of 12% per annum and matures on August 4, 2013, at which time all principal and accrued interest will be due. If we do not pay principal and interest under the note when due, the interest rate increases to 16% per annum. The note is secured by a first priority lien on all of our property, including our intellectual property. In the event of a default, our outstanding indebtedness could become immediately due and payable and, if outstanding indebtedness is not immediately satisfied from cash resources, Lambda could realize on the collateral to secure such indebtedness. Currently, we do not have sufficient cash to satisfy the indebtedness.

As long as indebtedness remains outstanding under the senior secured note with Lambda Investors LLC, we will be subject to certain covenants which, among other items, restrict our ability to merge with another company, sell a material amount of our assets, incur any additional indebtedness, repay any existing indebtedness, or declare or pay any dividends in cash, property or securities. These restrictions significantly impact our future alternatives to enter into strategic transactions and limit our ability to obtain additional or other financing because our assets have been pledged as collateral for repayment of our indebtedness. We have agreed to prepay amounts due under the note with the cash proceeds from (a) a rights offering and an offering of a discounted exercise price to public warrant holders, each as further described in the note, (b) any other equity or debt financing, or (c) the issuance or incurrence of any other indebtedness or the sale of any assets outside the ordinary course of business, in each case prior to the maturity date. In addition, the net proceeds of any offering, financing, asset disposition or other external liquidity generating transaction would need to be first applied to our existing indebtedness which, while reducing our level of indebtedness, cannot be assured to be sufficient for our continuing cash requirements and cash needs.

In the event that we default under the senior secured note or we are unable to repay the indebtedness when it becomes due, Lambda could foreclose on all of our property and assets. If this were to occur, our stockholders could lose all or a portion of their investment in the Company.

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, 2012, we had an accumulated deficit of approximately \$97,530,000, 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.

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 OLpur 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. Recently, we received clearance from the FDA to market our OLpūr MD220 Hemodiafilter and OLpūr H2H Module for use with a hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of chronic renal failure patients. We have not yet begun to market these products 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.

We cannot assure you that our medically approved products will be safe and we are required under applicable law to report any product-related deaths or serious injuries or product malfunctions that could result in deaths or serious injuries, and such reports 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 medically approved products will be safe. Under the Food, Drug and Cosmetic Act (FDCA), we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and product malfunctions 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 gain market acceptance of our medically approved 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 medically approved 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. 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.

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. If we violate the FDC Act or other regulatory requirements 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.

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 16 granted U.S. patents will expire at various times from 2018 to 2026, 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 Our Common Stock and Warrants

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 OTC Bulletin Board. Trading in our Common Stock on the OTC Bulletin Board 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 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.

As previously disclosed, we expect to commence a rights offering in March 2013. Holders of our common stock and public warrants that choose not to fully exercise their basic subscription privilege will be diluted as a result of the rights offering if other shareholders and/or warrant holders fully exercise their basic subscription privilege, and such affected holders' voting and other rights will likewise be diluted.

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, 2012, our Common Stock has traded at prices ranging from a high of \$3.19 to a low of \$0.40 per share, after giving effect to the 1:20 reverse stock split effected on March 11, 2011. 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 December 31, 2012, our directors, executive officers and Lambda Investors LLC, our largest stockholder, beneficially owned approximately 31% of our outstanding Common Stock, representing approximately 55% on a fully-diluted basis. As previously disclosed, we expect to commence a rights offering in March 2013. Holders of our common stock and public warrants that choose not to fully exercise their basic subscription privilege will be diluted as a result of the rights offering if Lambda fully exercises its subscription privilege, and, consequently, such affected holders' voting and other rights will likewise be diluted. If our stockholders and/or warrant holders do not exercise their subscription privilege in full, and Lambda elects to purchase such shares in the rights offering by exercising an oversubscription right, Lambda would increase its ownership percentage and obtain greater voting power.

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.

The market price of our common stock may fall below the exercise price of the warrants issued in connection with the rights offering.

The warrants are currently exercisable and will expire on March 10, 2016. The market price of our common stock may fall below the exercise price for these warrants prior to their expiration. Any warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the holders of warrants.

If an effective registration is not in place and a current prospectus is not available when an investor desires to exercise warrants, such investor may be unable to exercise his, her or its warrants, causing such warrants to expire worthless.

We will not be obligated to issue shares of common stock upon exercise of warrants unless, at the time such holder seeks to exercise such warrant, we have a registration statement under the Securities Act in effect covering the shares of common stock issuable upon the exercise of the warrants and a current prospectus relating to the common stock. We intend to use our best efforts to keep a registration statement in effect covering shares of common stock issuable upon exercise of the warrants and to maintain a current prospectus relating to the common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so, and if we do not maintain a current prospectus related to the common stock issuable upon exercise of the warrants, holders will be unable to exercise their warrants and we will not be required to settle any such warrant exercise. If the prospectus relating to the common stock issuable upon the exercise of the warrants is not current, the warrants held by public stockholders may have no value, we will have no obligation to settle the warrants for cash, the market for such warrants may be limited, such warrants may expire worthless and, as a result, an investor may have paid the full price solely for the shares of common stock included in the Units.

An investor will only be able to exercise a warrant if the issuance of common stock upon such exercise has been registered or qualified or is deemed exempt under the securities laws of the state of residence of the holder of the warrants.

No warrants will be exercisable and we will not be obligated to issue shares of common stock unless the shares of common stock issuable upon such exercise have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Because the exemptions from qualification in certain states for resales of warrants and for issuances of common stock by the issuer upon exercise of a warrant may be different, a warrant may be held by a holder in a state where an exemption is not available for issuance of common stock upon an exercise and the holder will be precluded from exercise of the warrant. As a result, the warrants may be deprived of any value, the market for the warrants may be limited, the holders of the warrants may not be able to exercise their warrants and they may expire worthless if the common stock issuable upon such exercise is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended (the “PSLRA”). 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” or similar words. For such statements, we claim the protection of the PSLRA. Forward-looking statements are not guarantees of future performance are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

· we may not be able to continue as a going concern;

· we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;

· a default under the terms of the secured note with Lambda Investors LLC would result in the lender foreclosing upon substantially all of our assets and could result in our inability to continue business operations;

· we may not be able to complete the contemplated rights offering which could result in our inability to continue business operations;

· even if we are able to complete the rights offering, we may not have sufficient capital to successfully implement our business plan;

· restrictions in the secured note and related security agreement which require the prior consent of the lender may restrict our ability to operate our business, sell the company or sell our assets;

· 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 and manufacturers;

· we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;

· we may not obtain appropriate or necessary regulatory approvals to achieve our business plan;

· products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;

- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and
- we may not be able to achieve sales growth in key geographic markets.

More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2012, 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. 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.

Any information contained in this prospectus relating to the contemplated rights offering previously disclosed on a Form 8-K filed on February 5, 2013 is preliminary in nature. The securities that are to be offered in the rights offering described therein may not be sold, nor may offers to buy be accepted, prior to the time the registration statement relating to the rights offering becomes effective. This communication shall not constitute an offer to sell or the solicitation of an offer to buy in the rights offering, nor shall there be any sale of the securities in the rights offering, in any state in which such offer, solicitation or sale would be unlawful prior to their registration or qualification under the securities laws of any such state.

USE OF PROCEEDS

We received proceeds from the offer and sale of the Units, net of discounts, commissions and expense, of approximately \$2,300,000. In the event of full exercise of all of the warrants, we will receive additional net proceeds of approximately \$1,836,068. The actual exercise of any of the warrants, however, is beyond our control and depends on a number of factors, including the market price of our common stock. There can be no assurance that any of the warrants will be exercised.

While we have no specific plan for the proceeds, we expect to use the net proceeds of this offering, if any, to further develop our products and for general working capital purposes. The principal reason for this offering is to provide shares of common stock issuable upon conversion of our outstanding warrants issued in connection with the offer and sale of the Units.

DETERMINATION OF OFFERING PRICE

The exercise price of \$0.40 was not based on any discount to the market price of our common stock. The exercise price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the warrants. We did not consult with any financial or other advisor in determining the exercise price. After the date of this prospectus, our common stock may trade at prices above or below the exercise price. You should not consider the exercise price as an indication of value of our company or our common stock. You should not assume or expect that our shares of common stock will trade at or above the exercise price in any given time period. The market price of our common stock may decline during or after this offering, and you may not be able to exercise or sell the shares of our common stock. You should obtain a current quote for our common stock before exercising and make your own assessment of our business and financial condition, our prospects for the future, and the terms of the warrants. On February 20, 2013, the closing sale price of our common stock on the OTC Bulletin Board was \$1.00 per share.

DILUTION

Our net tangible book value as of December 31, 2012 was approximately (\$595,000) or approximately (\$0.05) per share. Net tangible book value per share represents the amount of our total tangible assets, less our total liabilities divided by the number of outstanding shares of common stock. Dilution in net tangible book value per share represents the difference between the amount per share paid by the purchaser of shares of common stock upon the exercise of warrants and the net tangible book value per share of common stock immediately after the exercise of warrants.

After giving effect to the exercise of 3,306,399 warrants that remained outstanding at December 31, 2012 at an exercise price of \$0.40, which would have resulted in 3,057,190 common shares being issued, our pro forma net tangible book value as of December 31, 2012 would have been \$627,876 or \$0.04 per share. This represents an immediate increase in net tangible book value of \$0.09 per share to existing stockholders and an immediate dilution in net tangible book value of \$0.36 per share to warrants exercised from this offering.

The shares outstanding as of December 31, 2012 used to calculate the information in this section exclude:

- 2,294,714 shares issuable upon the exercise of stock options outstanding on December 31, 2012; and
- 14,679,971 shares issuable upon the exercise of warrants outstanding on December 31, 2012.

Unless otherwise indicated, the information in this prospectus reflects a 1-for-20 reverse split of our common stock, which was effective on March 11, 2011.

DIVIDEND POLICY

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

MARKET FOR OUR COMMON STOCK

Our common stock is quoted on the Over the Counter (OTC) Bulletin Board 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 OTC Bulletin Board 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, 2011	\$.53	\$.40
June 30, 2011	\$.98	\$.30
September 30, 2011	\$2.19	\$.70
December 31, 2011	\$1.90	\$.41
March 31, 2012	\$1.09	\$.44
June 30, 2012	\$3.19	\$.80
September 30, 2012	\$1.98	\$1.15
December 31, 2012	\$1.40	\$1.02

As of February 20, 2013, there were approximately 20 holders of record and approximately 1,000 beneficial holders of our common stock.

On February 20, 2013, the last reported sale price of our common stock on the OTC Bulletin Board was \$1.00 per share.

PLAN OF DISTRIBUTION

Pursuant to the terms of the warrants, the shares of common stock will be distributed to those warrant holders who surrender their warrant certificate with their subscription form, together with the payment of the exercise price, to our warrant agent, Continental Stock Transfer & Trust Company.

MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS

The following discussion includes forward-looking statements about our business, financial condition, and results of operations, including discussions about management's expectations for our business. These statements represent projections, beliefs and expectations based on current circumstances and conditions and in light of recent events and trends, and you should not construe these statements either as assurances of performances or as promises of a given course of action. Instead, various known and unknown factors are likely to cause our actual performance and management's actions to vary, and the results of these variances may be both material and adverse. A list of the known material factors that may cause our results to vary, or may cause management to deviate from its current plans and expectations, is included herein under "Risk Factors" and Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2012. 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 and healthcare facilities for the production of ultrapure water and bicarbonate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they eliminate a wide variety of bacteria, viruses, fungi, parasites, and endotoxins harmful to humans.

All of our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to be the only commercially available filters for healthcare applications that 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

By comparison, competitive filters on the market today are typically effective only to the 0.2 micron level and are prone to clog more quickly, thus reducing their useful lives.

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). In 2009, we began to extend our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

We have not begun to broadly market our mid-HDF system and plan to seek a commercialization partner in the U.S.

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

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

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

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

the consolidation of dialysis clinics into larger clinical groups; and

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

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

Recently Adopted Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income," ("ASU 2011-05") which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after Dec. 15, 2011 with early adoption permitted. We adopted this guidance as of January 1, 2012 and since this relates to presentation only, the adoption of this guidance did not have any other effect on our consolidated financial statements.

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 our Annual Report on Form 10-K for the year ended December 31, 2012, 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, 2012 consolidated balance sheet is approximately \$1,414,000 and is related to the Bellco license agreement. We have recognized approximately \$1,045,000 of revenue related to this license agreement to date and approximately \$680,000 for the twelve months ended December 31, 2012, resulting in \$1,414,000 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 \$707,000 in each of the years ended December 31, 2013 and 2014.

The final guaranteed fixed payment of approximately \$791,000 is due in January 2013 and is included in current trade receivables on the accompanying December 31, 2012 consolidated balance sheet.

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 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, 2012 Compared to the Fiscal Year Ended December 31, 2011

Revenues

Total revenues for the year ended December 31, 2012 were approximately \$1,807,000 compared to approximately \$2,214,000 for the year ended December 31, 2011. Total revenues decreased approximately \$407,000, or 18% as a

result of decreases of approximately \$733,000 related to our MD filters in Europe, \$346,000 related to the Office of Naval Research, whose contract ended as of March 2012, and approximately \$33,000 related to the STERIS project. These decreases were partially offset by an increase of approximately \$315,000 related to the Bellco license agreement as well as a 63% increase in water filter sales, which increased from \$620,000 in 2011 to \$1,010,000 in 2012.

Revenues were not significantly impacted by inflation or changing prices for the years ended December 31, 2012 or 2011.

Cost of Goods Sold

Cost of goods sold was approximately \$737,000 for the year ended December 31, 2012 compared to approximately \$1,346,000 for the year ended December 31, 2011. The decrease of approximately \$609,000 or 45%, in cost of goods sold is primarily related to a \$583,000 reduction in cost of goods sold of our MD filters in Europe. Additional decreases include approximately \$208,000 related to the Office of Naval Research, approximately \$15,000 related to DSU sales for the year ended December 31, 2012 compared to the same period in 2011 and a decrease of approximately \$29,000 related to the STERIS project. These decreases were partially offset by an increase in cost of goods sold of approximately \$226,000 related to filters sold to the military during the year ended December 31, 2012, a 100% increase compared to the same period in 2011. Cost of goods sold includes increases in inventory reserves of approximately \$82,000 and \$218,000 for the years ended December 31, 2012 and 2011, respectively.

Research and Development

Research and development expenses were approximately \$632,000 and \$451,000 respectively, for the years ended December 31, 2012 and December 31, 2011. This increase of approximately \$181,000 or 40% is primarily due to an increase in research and development personnel related costs of approximately \$136,000 during the year ended December 31, 2012 compared to the year ended December 31, 2011.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$151,000 for the year ended December 31, 2012 compared to approximately \$91,000 for the year ended December 31, 2011, an increase of 66%. The increase of approximately \$60,000 is primarily due to amortization of approximately \$142,000 related to the asset recognized in conjunction with the License and Supply Agreement offset partially by several assets having been fully depreciated as of year-end 2011 resulting in no depreciation expense for those assets during the year ended December 31, 2012.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$3,620,000 for the year ended December 31, 2012 compared to approximately \$2,636,000 for the year ended December 31, 2011, an increase of \$984,000 or 37%. The increase is primarily due to \$489,000 of salary expense, an increase in legal expenses of approximately \$330,000, an increase in stock compensation expense of \$159,000, and \$171,000 of travel related expenses during the year ended December 31, 2012 compared to the year ended December 30, 2011. These increases were partially offset by a reduction in bonus expense of approximately \$165,000 for the year ended December 31, 2012 compared to the year ended December 31, 2011.

Interest Income

Interest income was approximately \$2,000 for the year ended December 31, 2012 compared to approximately \$4,000 for the year ended December 31, 2011. The decrease of \$2,000 reflects the impact of having less cash on hand in 2012 compared to 2011.

Interest Expense

Interest expense for the year ended December 31, 2012 was \$0 compared to \$12,000 for the year ended December 31, 2011. Interest expense for the year ended December 31, 2011 relates to interest accrued on the \$500,000 senior secured note issued to Lambda Investors LLC, which was paid in March 2011.

Amortization of Debt Issuance Costs

We account for debt issuance costs in accordance with ASC 835, which requires that these costs be reported in the balance sheet as deferred charges and amortized over the term of the associated debt. Amortization of debt issuance costs of \$0 and \$40,000 for the years ended December 31, 2012 and 2011, respectively, were associated with the senior secured note issued to Lambda Investors LLC. The note was paid in March 2011 and these capitalized costs were fully amortized by the first quarter of 2011.

Other Income/Expense

Other income in the amount of approximately \$69,000 for the year ended December 31, 2012 was primarily due to approximately \$55,000 arising from the sale of fully depreciated manufacturing equipment sold to Medica in October 2012. In addition, approximately \$18,000 was related to the write-offs of vendor invoices which are no longer due. Other income was partially offset by \$4,000 related to foreign currency losses on invoices paid to an international supplier.

Other expense in the amount of approximately \$2,000 for the year ended December 31, 2011 was due to foreign currency loss on invoices paid to an international supplier.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the periods ended December 31, 2012 and December 31, 2011.

Liquidity and Capital Resources

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

- receipt of scheduled payments per the Bellco S.r.l. license agreement;
- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;
- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and

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

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

- for the marketing and sales of our water-filtration products;
- to pursue business development opportunities with respect to our chronic renal treatment system; and