

NEPHROS INC  
Form S-1/A  
April 08, 2013

As filed with the Securities and Exchange Commission on April 8, 2013

**Registration No. 333-187036**

**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549**

**Amendment No.1 to  
FORM S-1  
REGISTRATION STATEMENT**

**UNDER THE SECURITIES ACT OF 1933**

**NEPHROS, INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

3841  
*(Primary Standard Industrial  
Classification Code Number)*

13-3971809  
*(I. R. S. Employer  
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 & 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, NJ 07054**  
**Telephone: (973) 966-8123**  
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**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

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.  o

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.  o

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.  o

Michael T. Rave, Esq. Day Pitney LLP One Jefferson Road Parsippany, NJ 07054 Telephone: (973) 966-8223 Facs

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

## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered <sup>(1)(2)</sup>	Amount to be registered	Proposed maximum aggregate offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Subscription rights to purchase Common Stock <sup>(3)</sup> Common stock, \$0.001 par value per share <sup>(4)</sup>	5,000,000	\$ 0.60	\$ 3,000,000	\$ 409.20 <sup>(4)(5)</sup>

Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate (1) number of shares of common stock as may be issuable with respect to securities being registered hereunder as a result of stock splits, stock dividends, recapitalizations or similar transactions.

(2) This registration statement relates to (a) subscription rights to purchase our common stock and (b) shares of our common stock deliverable upon exercise of the subscription rights.

The subscription rights are being issued without consideration. Pursuant to Rule 457(g), no separate registration fee (3) is payable with respect to the rights being offered hereby since the rights are being registered on the same registration statement as the securities offered pursuant thereto.

(4) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum offering price of our common stock of \$0.60.

(5) Previously paid.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities 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 APRIL 8, 2013

## NEPHROS, INC.

# Up to 5,000,000 Shares of Common Stock Issuable Upon Exercise of Non-Transferable Rights to Subscribe for such Shares

We are distributing, at no charge, to holders of our common stock and/or warrants non-transferable subscription rights to purchase up to 5,000,000 shares of our common stock. We refer to this offering as the rights offering. In this rights offering, you will receive one non-transferable subscription right for each share of common stock and/or each share of common stock underlying a warrant owned by you at 5:00 p.m., Eastern Time, on April 4, 2013, which we refer to as the record date. Each non-transferable subscription right will entitle you to purchase 0.18776 of a share of our common stock at a subscription price of \$0.60 per share, which we refer to as the basic subscription privilege.

There is no minimum number of shares you must purchase. All exercises of subscription rights are irrevocable. We will not issue any fractional shares. Instead we will round up any fractional shares to the nearest whole share.

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional shares not subscribed for by other rights holders in the offering at the same subscription price of \$0.60 per share, subject to certain limitations. If an insufficient number of shares is available to fully satisfy all over-subscription privilege requests, the available shares will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of shares each such holder subscribed for under the basic subscription privilege. To the extent you properly exercise your over-subscription privilege for an amount of shares that exceeds the number of unsubscribed shares available to you, any excess subscription payment received by the subscription agent will be promptly returned to you, without interest or deduction.

Subject to the satisfaction of certain conditions including compliance with all obligations under a \$1.3 million note, related security agreement and the other transaction documents between Lambda Investors and us and no material adverse change having occurred with respect to our business, assets, and financial condition, Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders and warrant holders in the rights offering, if any. Therefore, subject to these conditions, unless we terminate the rights offering, we anticipate that the 5,000,000 shares that we are offering in the rights offering will be purchased regardless of whether any shares are subscribed for by our stockholders and warrant holders other than Lambda Investors pursuant to the exercise of the basic subscription privilege and over-subscription privilege.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on May 17, 2013, unless we

extend the subscription period in our sole discretion, but in no event by more than 60 days from the date of this prospectus. However, our board of directors reserves the right to cancel the rights offering at any time, for any reason. If the rights offering is cancelled, all subscription payments received by the subscription agent will be returned promptly.

Shares of our common stock are quoted on the OTC Bulletin Board under the ticker symbol NEPH. On April 4, 2013, the closing sales price for our common stock was \$0.85 per share. The shares of common stock issued in the rights offering will also be quoted on the OTC Bulletin Board under the same ticker symbol. The subscription rights will not be listed for trading on any stock exchange or market or quoted on the OTC Bulletin Board.

This is not an underwritten offering. The shares are being offered directly by us without the services of an underwriter or selling agent.

**The purchase of shares involves substantial risks. See Risk Factors beginning on page 16 of this prospectus to read about important factors you should consider before subscribing for shares.**

**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.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is April , 2013.

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**ABOUT THIS PROSPECTUS**

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

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

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## 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 and the rights offering, you should read this summary together with the more detailed information and financial statements appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the Risk Factors and Special Note Regarding Forward-Looking Statements sections. 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.

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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

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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 25<sup>th</sup>. 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 OLpur H2H Module and OLpur MD220 Hemodiafilter. On April 30, 2012, we announced that we received clearance from the U.S. Food and Drug Administration to market the OLpur H2H Module and OLpur 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 OLpur H2H Modules and manufacturing our OLpur 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.

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## **Immediate Need for Capital and Recent Loan from Lambda Investors LLC**

As of December 31, 2012, we had cash and cash equivalents totaling approximately \$47,000 and tangible assets of approximately \$1,419,000.

Due to our dwindling cash position, on February 4, 2013, we issued a senior secured note to Lambda Investors LLC in the principal amount of \$1,300,000. We expect that the proceeds from the note will allow us to fund our operations only through May 2013. The terms of the Lambda Investors note are discussed in more detail under the heading **The Rights Offering** **Background of the Rights Offering** **Loan from Lambda Investors**.

As required under the terms of the note, we are conducting this rights offering to raise up to \$3,000,000 from our existing stockholders and warrant holders. If we complete the rights offering, we must repay the principal and accrued interest on the note as well as fees and expenses associated with the note with the proceeds from the rights offering. Other conditions to the closing of the rights offering are discussed under the heading **The Rights Offering** **Conditions to the Rights Offering**.

As of the date of this prospectus, Lambda Investors is our largest stockholder and beneficially owns approximately 31% of our outstanding common stock and, on a fully-diluted basis, owns approximately 53% of our outstanding common stock. The warrants held by Lambda Investors have an exercise price of \$0.40 per share and certain warrants have full ratchet anti-dilution protection.

The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors. Arthur H. Amron, a director of Nephros, is a partner and general counsel of Wexford Capital. Paul Mieyal, a director of Nephros, is a vice president of Wexford Capital.

## **Corporate Information**

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

## **Where You Can Find More Information**

We make available on our website, [www.nephros.com](http://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](http://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.



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## The Rights Offering

*The following summary describes the principal terms of the rights offering, but is not intended to be complete. See the information under the heading *The Rights Offering* in this prospectus for a more detailed description of the terms and conditions of the rights offering.*

### Securities Offered

We are distributing to holders of our common stock, at no charge, one non-transferable subscription right for each share of our common stock owned as of 5:00 p.m., Eastern Time, on the record date, either as a holder of record or, in the case of shares held of record by brokers, dealers, custodian banks or other nominees on a stockholder's behalf, as a beneficial owner of such shares.

We are also distributing to holders of our warrants, at no charge, one non-transferable subscription right for each share of common stock underlying the warrants held by such warrant holder as of 5:00 p.m., Eastern Time, on the record date, under the same terms and conditions.

In either case, each subscription right entitles you to purchase 0.18776 of a share of our common stock at an exercise price of \$0.60 per share.

### Basic Subscription Privilege

The basic subscription privilege will entitle you to purchase 0.18776 of a share of our common stock at a subscription price of \$0.60 per share. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights. If you choose to exercise your rights, there is no minimum number of shares you must purchase. We will not issue any fractional shares. Instead we will round up any fractional shares to the nearest whole share.

### Over-Subscription Privilege

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional shares not subscribed for by other rights holders in the offering at the same subscription price of \$0.60 per share. If an insufficient number of shares is available to fully satisfy all over-subscription privilege requests, the available shares will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of shares each such holder subscribed for under the basic subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction promptly after expiration of the subscription period.

### Subscription Price

\$0.60 per share, payable in cash. To be effective, any payment related to the exercise of a right must clear prior to the expiration of the subscription period.

### Record Date

5:00 p.m., Eastern Time, on April 4, 2013.

### Expiration Date

5:00 p.m., Eastern Time, on May 17, 2013, subject to extension at our sole discretion, but in no event by more than 60 days from the date of this prospectus. We may extend the expiration date by giving oral or written notice to our subscription agent on or before the expiration date,

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followed by a press release no later than 9:00 a.m., Eastern Time, on the next business day after the previously scheduled expiration date.

**Non-Transferability of Rights**

The subscription rights are not transferrable, other than by operation of law, and will not be quoted or listed for trading, as applicable, on the OTC Bulletin Board or on any stock exchange or trading markets.

**No Board Recommendation**

Our board of directors is making no recommendation regarding your exercise of the subscription rights. You are urged to make your decision based on your own assessment of our business and the rights offering. Please see **Risk Factors** for a discussion of the risks involved in investing in our common stock.

**Lambda Investors**

Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders and warrant holders in the rights offering, if any, subject to the following conditions being satisfied:

the business, assets, financial condition, operations, results of operations and prospects of the Company are substantially as have been represented to Lambda Investors on February 4, 2013 in connection with the senior secured note and no change shall have occurred or is reasonably likely to occur solely with the passage of time that is or may be materially adverse to the Company; and

the Company's compliance with its obligations under the note, security agreement and other transaction documents relating to the loan by Lambda Investors.

Lambda Investors may elect to exercise its over-subscription privilege for such number of shares as it determines in its sole discretion.

We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

See **The Rights Offering**, **Background of the Rights Offering**, **Participation of Lambda Investors**.

**No Revocation**

Once you submit the form of rights certificate to exercise any subscription rights, you may not revoke or change your exercise or request a refund of monies paid. All exercises of rights are irrevocable, even if you later learn information about us that you consider to be unfavorable. You should not



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exercise your subscription rights unless you are certain that you wish to purchase shares offered pursuant to this rights offering.

Extension, Cancellation and Amendment

We may extend the expiration date at any time after the record date, but in no event by more than 60 days from the date of this prospectus. If the rights offering is extended, subscriptions received prior to such extension will remain irrevocable. We may choose to extend the rights offering for any reason. For example, we may decide that changes in the market price of our common stock warrant an extension, or we may decide that the degree of stockholder participation in the rights offering is less than the level we desire. We may cancel the rights offering at any time prior to the expiration of the rights offering for any reason. In the event the rights offering is cancelled, all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable. We also reserve the right to amend or modify the terms of the rights offering, as appropriate.

Procedures for Exercising Rights

You may exercise your subscription rights by properly completing and executing your rights certificate and delivering it, together with the subscription price for each share for which you subscribe, to the subscription agent on or prior to the expiration date. If you use the mail, we recommend that you use insured, registered mail, return receipt requested. If you cannot deliver your rights certificate to the subscription agent on time, you may follow the guaranteed delivery procedures described under The Rights Offering Guaranteed Delivery Procedures.

Payment Adjustments

If you send a payment that is insufficient to purchase the number of shares requested, or if the number of shares requested is not specified in the rights certificate, the payment received will be applied to exercise your subscription rights to the extent of the payment. If the payment exceeds the amount necessary for the full exercise of your subscription rights, including any over-subscription privilege exercised and permitted, the excess will be returned to you promptly in cash. You will not receive interest or a deduction on any payments refunded to you under the rights offering.

How Rights Holders Can Exercise Rights

Through Others

If you hold our common stock or warrants through a broker, custodian bank or other nominee, we will ask your broker, custodian bank or other nominee to notify you of the rights offering. If you wish to exercise your rights, you will need to have your broker, custodian bank or other nominee act for you. To indicate your decision, you should complete and return to your broker, custodian bank or other nominee the form entitled Beneficial Owner Election Form. You should receive this form from your broker, custodian bank or other nominee with the other rights offering materials. You should contact your broker, custodian bank or other nominee if you

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believe you are entitled to participate in the rights offering but you have not received this form.

**How Foreign Stockholders or Warranholders and Other Stockholders or Warranholders Can Exercise Rights**

The subscription agent will not mail rights certificates to you if you are a stockholder or warranholder whose address is outside the United States or if you have an Army Post Office or a Fleet Post Office address. Instead, we will have the subscription agent hold the subscription rights certificates for your account. To exercise your subscription rights, you must notify the subscription agent prior to 11:00 a.m., Eastern Time, at least three business days prior to the expiration date, and establish to the satisfaction of the subscription agent that it is permitted to exercise your subscription rights under applicable law. If you do not follow these procedures in time, your rights will expire and will have no value.

**Possible Restrictions on Exercise by Stockholders or Warranholders Residing in Certain States**

We will not issue shares to any stockholder or warranholder who is required to obtain prior clearance or approval from, or submit a notice to, any state or federal regulatory authority to acquire, own or control such shares if we determine that, as of the expiration date of the rights offering, such clearance or approval has not been satisfactorily obtained and any applicable waiting period has not expired.

**Certain Material U.S. Federal Income Tax Considerations**

A holder will not recognize income or loss for U.S. federal income tax purposes in connection with the receipt or exercise of subscription rights in the rights offering. For a detailed discussion, see Certain Material U.S. Federal Income Tax Considerations. You should consult your tax advisor as to the particular consequences to you of the rights offering.

**Conditions to the Rights Offering**

The completion of the rights offering is subject to the registration statement of which this prospectus is a part being declared effective by the SEC. In addition, we reserve the right to amend, extend, cancel, terminate or otherwise modify this rights offering at any time before completion of this rights offering for any reason. See The Rights Offering Conditions to the Rights Offering.

**Use of Proceeds**

Assuming all the shares offered are sold, the gross proceeds from the rights offering will be approximately \$3,000,000. Our estimated net proceeds from the rights offering will be \$2,750,000, after deducting our estimated offering expenses of \$250,000.

We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda

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Investors legal fees incurred in connection with the loan and the rights offering. The terms of the Lambda Investors note are discussed in more detail under the heading The Rights Offering Background of the Rights Offering Loan from Lambda Investors. We intend to use the remaining net proceeds, if any, for general corporate purposes, including working capital and operating expenses. Pending the application of any remaining net proceeds for these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities. See Use of Proceeds.

Issuance of Common Stock

If you purchase shares through the rights offering, we will issue the underlying shares to you as soon as practicable after the completion of the rights offering.

Shares Outstanding Before the Rights Offering

12,025,309 shares of our common stock were outstanding as of the record date.

Shares Outstanding After Completion of the Rights Offering

As of the record date, we had 12,025,309 shares of our common stock issued and outstanding. We will issue 5,000,000 shares of our common stock in the rights offering if it is fully subscribed. Assuming all of the shares offered are sold and no additional shares of our common stock are issued and no outstanding options or warrants are exercised prior to the completion of the rights offering, approximately 17,025,309 shares of our common stock will be outstanding immediately after the completion of the rights offering.

Subscription Agent

Continental Stock Transfer & Trust Company.

Fees and Expenses

We will pay the fees and all of our expenses related to the rights offering. We will also pay Lambda Investors an aggregate of \$50,000 for reimbursement of legal fees incurred in connection with the rights offering. See Use of Proceeds.

Trading Symbol

Shares of our common stock are currently listed for quotation on the OTC Bulletin Board under the ticker symbol NEPH and the shares to be issued in connection with the rights offering will also be listed on the OTC Bulletin Board under the same symbol. Neither the warrants nor the subscription rights will be listed or traded on any market.

Risk Factors

Participation in the rights offering and the purchase of shares involve substantial risks. See Risk Factors beginning on page 16 of this prospectus.

Additional Information

For additional information, please see the description of this offering contained in this prospectus under the heading The Rights Offering or contact Gerald J. Kochanski at (201) 343-5202, ext. 102.

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# **QUESTIONS AND ANSWERS RELATING TO THE RIGHTS OFFERING**

## **What is the rights offering?**

We are distributing, at no charge, to holders of our common stock and warrants non-transferable subscription rights to purchase shares. You will receive one subscription right for each share of common stock and/or each share of common stock underlying a warrant you owned as of 5:00 p.m., Eastern Time, on April 4, 2013, the record date. The subscription rights will be evidenced by rights certificates. Each subscription right will entitle the holder to a basic subscription privilege and an over-subscription privilege.

## **What is the basic subscription privilege?**

The basic subscription privilege gives our stockholders the opportunity to purchase 0.18776 of a share of our common stock at a subscription price of \$0.60 per share. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights.

If you choose to exercise your rights, there is no minimum number of shares you must purchase. We will not issue any fractional shares. Instead we will round up any fractional shares to the nearest whole share.

## **What is the over-subscription privilege?**

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional shares not subscribed for by other rights holders in the offering at the same subscription price of \$0.60 per share. If an insufficient number of shares is available to fully satisfy all over-subscription privilege requests, the available shares will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of shares each such holder subscribed for under the basic subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction promptly after expiration of the subscription period.

## **Why are we conducting the rights offering?**

We are conducting the rights offering to raise capital for our operations. Without additional capital, we will not have sufficient funds to continue our operations. With the proceeds from the note we issued to Lambda Investors, we estimate that we will be able to fund our operations into May 2013. The rights offering is expected to close on May 17, 2013. Upon the closing of the rights offering, we must first use proceeds to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. We intend to use the remaining net proceeds, if any, for general corporate purposes, including working capital and operating expenses. Pending the application of any remaining net proceeds for these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities.

## **How was the \$0.60 per share subscription price determined?**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 5,000,000 shares of our common stock, and that it be made at a subscription price of \$0.60 per share to encourage our other stockholders and warrant holders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.60 per share subscription price, were approved by a special committee of our independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing alternatives available to us.

The \$0.60 per share subscription 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 being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price.

## **Am I required to exercise the subscription rights I receive in the rights offering?**

No. You may exercise any number of your subscription rights, or you may choose not to exercise any subscription rights. However, if you choose not to fully exercise your basic subscription privilege and other stockholders fully exercise their basic subscription privilege, the percentage of our common stock owned by

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these other stockholders will increase relative to your ownership percentage, and your voting and other rights will likewise be significantly diluted. In addition, if you do not exercise your basic subscription privilege in full, you will not be entitled to subscribe to purchase additional shares pursuant to the over-subscription privilege and your ownership percentage in our common stock and related voting and other rights may be further diluted relative to those stockholders that do.

## **How soon must I act to exercise my subscription rights?**

The subscription rights may be exercised at any time beginning on the date of this prospectus and prior to 5:00 p.m., Eastern Time, on the expiration date, which is May 17, 2013. We may extend the expiration date, but in no event by more than 60 days from the date of this prospectus, by giving oral or written notice to our subscription agent on or before the expiration date, followed by a press release no later than 9:00 a.m., Eastern Time, on the next business day after the previously scheduled expiration date. If you elect to exercise any rights, the subscription agent must actually receive all required documents and payments from you prior to the expiration of the subscription period. Although we have the option of extending the expiration of the subscription period, we currently do not intend to do so.

## **May I transfer my subscription rights?**

No, you may not sell, transfer or assign your subscription rights to anyone else because they are not transferable, other than by operation of law.

## **May I revoke, change or cancel my election to exercise my subscription rights?**

Once you submit the form of rights certificate to exercise any subscription rights, you may not revoke, change or cancel your exercise or request a refund of monies paid. All exercises of rights are irrevocable, even if you later learn information about us that you consider to be unfavorable. You should not exercise your subscription rights unless you are certain that you wish to purchase shares offered pursuant to this rights offering.

## **May our board of directors extend, cancel or amend the rights offering?**

Yes. We may extend the expiration date at any time. If the rights offering is extended, subscriptions received prior to such extension will remain irrevocable. We may choose to extend the rights offering for any reason, but in no event by more than 60 days from the date of this prospectus. For example, we may decide that changes in the market price of our common stock warrant an extension, or we may decide that the degree of stockholder participation in the rights offering is less than the level we desire. We may cancel the rights offering at any time prior to the expiration of the rights offering for any reason. In the event the rights offering is cancelled, all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable. We also reserve the right to amend or modify the terms of the rights offering, as appropriate.

## **Are we requiring a minimum subscription to complete the rights offering?**

No. There is no minimum subscription requirement to consummate the rights offering.

## **If the rights offering is not completed, will my subscription payment be refunded to me?**

Yes. The subscription agent will hold all funds it receives in a segregated bank account until completion of the rights offering. If the rights offering is not completed, the subscription agent will return, without interest or deduction, as soon as practicable, all subscription payments. If you own shares in street name, it may take longer for you to receive payment because the subscription agent will return payments through the record holder of the shares.

## **Has our board of directors made a recommendation to our stockholders regarding the rights offering?**

No. Our board of directors is making no recommendation regarding your exercise of the subscription rights. Stockholders and warrant holders who exercise subscription rights risk investment loss on new money invested. We cannot assure you that the market price for our common stock will be above the per share subscription price or that anyone purchasing shares at the subscription price will be able to sell the underlying

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shares in the future at the same price or a higher price. You are urged to make your decision based on your own assessment of our business and the rights offering. Among other things, you should carefully consider the risks described under the heading "Risk Factors" in this prospectus.

## **Are there any conditions to the rights offering?**

Yes. The registration statement of which this prospectus is a part must be declared effective by the SEC.

## **What happens to warrants and options that are outstanding?**

As of the record date, warrants to purchase 14,604,486 shares of our common stock were outstanding. In addition to the rights offering, the Company intends to offer a one-time temporary discount relating to those warrants with a \$0.40 exercise price issued at the close of the March 2011 rights offering. The Company agreed to temporarily reduce the exercise price of such warrants to \$0.30 during the duration of this rights offering. In connection with the loan, Lambda Investors agreed to waive its anti-dilution rights applicable to any of its existing warrants solely with respect to the one-time discount offered to public warrant holders.

Also, in connection with the February 2013 loan from Lambda Investors, the Company agreed to amend the terms of the existing warrants held by Lambda Investors to March 10, 2017 from March 10, 2016. At the time of the rights offering, Lambda Investors has outstanding warrants to purchase an aggregate of 11,589,152 shares of common stock, all at an exercise price of \$0.40 per share.

The rights offering will have no effect on any of our outstanding options.

## **Will members of the board of directors and management be permitted to participate in the rights offering?**

Yes. Members of our board and executive management team who own shares of common stock and/or warrants on the record date have the same basic subscription and over-subscription privileges as other stockholders. We caution you that the board of directors or members of the executive management team do not make any recommendation regarding your exercise of subscription rights.

## **Have any stockholders committed or indicated that they intend to purchase any shares in the rights offering?**

Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders in the rights offering, if any, subject to the following conditions being satisfied:

the business, assets, financial condition, operations, results of operations and prospects of the Company are substantially as have been represented to Lambda Investors on February 4, 2013 in connection with the senior secured note and no change shall have occurred or is reasonably likely to occur solely with the passage of time that is or may be materially adverse to the Company; and  
the Company's compliance with its obligations under the note, security agreement and other transaction documents



relating to the loan by Lambda Investors.

We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

See The Rights Offering Background of the Rights Offering Participation of Lambda Investors.

## **What will happen if I choose not to exercise my subscription rights?**

If you do not exercise any subscription rights, the number of shares of our common stock you own will not change as a result of the rights offering; however, due to the fact that shares will be purchased by other stockholders and warrant holders, including Lambda Investors, your percentage ownership of our Company will be significantly diluted after the completion of the rights offering.

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## **How do I exercise my subscription rights?**

You may exercise your subscription rights by properly completing and executing your rights certificate and delivering it, together with the subscription price for each share for which you subscribe, to the subscription agent on or prior to 5:00 p.m., Eastern Time, on the expiration date. If you use the mail, we recommend that you use insured, registered mail, return receipt requested. If you cannot deliver your rights certificate to the subscription agent on time, you may follow the guaranteed delivery procedures described under [The Rights Offering](#) [Guaranteed Delivery Procedures](#). If you hold shares of our common stock through a broker, custodian bank or other nominee, see [The Rights Offering](#) [Beneficial Owners](#).

## **What should I do if I want to participate in the rights offering, but my shares or warrants are held in the name of my broker, custodian bank or other nominee?**

If you hold your shares of our common stock or warrants in the name of a broker, custodian bank or other nominee, we will ask your broker, custodian bank or other nominee to notify you of the rights offering. If you wish to exercise your rights, you will need to have your broker, custodian bank or other nominee act for you. To indicate your decision, you should complete and return to your broker, custodian bank or other nominee the form entitled [Beneficial Owner Election Form](#). You should receive this form from your broker, custodian bank or other nominee with the other rights offering materials. You should contact your broker, custodian bank or other nominee if you believe you are entitled to participate in the rights offering but you have not received this form.

## **What should I do if I want to participate in the rights offering, but I am a stockholder or warrant holder with a foreign address or a stockholder or warrant holder with an APO or FPO address?**

The subscription agent will not mail rights certificates to you if you are a stockholder or warrant holder whose address is outside the United States or if you have an Army Post Office or a Fleet Post Office address. Instead, we will have the subscription agent hold the subscription rights certificates for your account. To exercise your subscription rights, you must notify the subscription agent prior to 11:00 a.m., Eastern Time, at least three business days prior to the expiration date, and establish to the satisfaction of the subscription agent that it is permitted to exercise your subscription rights under applicable law. If you do not follow these procedures in time, your rights will expire and will have no value. See [The Rights Offering](#) [Foreign Stockholders and Warrant holders](#).

## **When will I receive my new shares?**

As soon as practicable after the closing of the rights offering, the subscription agent will arrange for the issuance of the shares of common stock purchased in the rights offering. Subject to state or foreign securities laws and regulations, we have the discretion to delay distribution of any shares you may have elected to purchase by exercise of your rights in order to comply with state or foreign securities laws.

## **How many shares of our common stock will be outstanding after the rights offering?**

As of the record date, we had 12,025,309 shares of our common stock issued and outstanding. We plan to issue 5,000,000 shares of our common stock in the rights offering pursuant to our stockholders' and/or warrant holders' basic subscription privilege, their over-subscription privileges and Lambda Investors' intention, subject to the conditions described herein, to purchase any shares that are not subscribed for by our other stockholders and warrant holders.

Assuming all 5,000,000 shares offered are sold, no additional shares of our common stock are issued and no outstanding options or warrants are exercised prior to the completion of the rights offering, approximately 17,025,309 shares of our common stock will be outstanding immediately after the completion of the rights offering.

## **How much money will the company receive from the rights offering?**

There is no minimum subscription requirement that must be met for us to close the rights offering. Assuming all the shares of common stock offered are sold, the gross proceeds from the rights offering will be \$3,000,000. It is estimated that the expenses of the rights offering will be \$250,000, and an estimated \$1,556,000 of the proceeds will be used to pay the principal, interest and fees associated with the note to Lambda Investors.

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## **Are there risks in exercising my subscription rights?**

Yes. The exercise of your subscription rights involves substantial risks. Exercising your subscription rights involves the purchase of shares of our common stock. The purchase of shares should be considered as carefully as you would consider any other equity investment. Among other things, you should carefully consider the risks described under the heading "Risk Factors" in this prospectus.

## **If the rights offering is not completed, will my subscription payment be refunded to me?**

Yes. The subscription agent will hold all funds it receives in a segregated bank account until completion of the rights offering. If the rights offering is not completed, all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable. If you own shares in street name, it may take longer for you to receive payment because payments will be returned through the record holder of your shares.

## **Will the subscription rights be listed on a stock exchange or national market?**

No. The subscription rights to purchase our common stock will not be listed for trading on any stock exchange or market or on the OTC Bulletin Board.

## **Will the rights offering affect the listing of the common stock?**

No. Our common stock will continue to trade on the OTC Bulletin Board under the ticker symbol NEPH, and the shares of common stock issued in the rights offering will also be quoted on the OTC Bulletin Board under the same ticker symbol.

## **May stockholders and/or warrant holders in all states participate in the rights offering?**

The issuance and exercise of subscription rights is subject to compliance with state securities laws and regulations. Although we intend to distribute the rights to all stockholders and warrant holders, we reserve the right in some states to require stockholders and warrant holders, if they wish to participate, to state and agree upon exercise of their respective rights 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 rights 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 subscription rights 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 rights offering.

## **What fees or charges apply if I purchase shares?**

We are not charging any fee or sales commission to issue subscription rights to you or to issue shares to our stockholders upon the exercise subscription rights. If you exercise your subscription rights through the record holder of your shares, you are responsible for paying any fees your record holder may charge you.

## **What are the material U.S. federal income tax consequences of exercising subscription rights?**

The receipt and exercise of subscription rights pursuant to the basic subscription privilege or the oversubscription privilege should generally not be taxable for U.S. federal income tax purposes. You should, however, seek specific tax advice from your tax advisor in light of your particular circumstances and as to the applicability and effect of any other tax laws. See Certain Material U.S. Federal Income Tax Considerations.

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## **To whom should I send my forms and payment?**

If your shares are held in the name of a broker, dealer or other nominee, then you should send your subscription documents, rights certificate, and subscription payment to that record holder. If you are the record holder, then you should send your subscription documents, rights certificate, and subscription payment by hand delivery, first class mail or courier service to: Continental Stock Transfer & Trust Company, the subscription agent for the rights offering as follows:

Continental Stock Transfer & Trust Company  
17 Battery Place, 8<sup>th</sup> Floor  
New York, NY 10004  
Attn: Reorganization Department

You also may submit payment by wire transfer of immediately available funds as follows:

JPMorgan Chase  
ABA # 021-000021  
Continental Stock Transfer & Trust Company as agent for Nephros, Inc.  
Acct # 475-508351 FBO Nephros, Inc. Subscription

You are solely responsible for completing delivery to the subscription agent of your subscription documents, rights certificate and payment. We urge you to allow sufficient time for delivery of your subscription materials to the subscription agent.

## **What if I have other questions?**

If you have any questions or need further information or assistance concerning the method of subscribing or about the rights offering, please contact Gerald J. Kochanski, our Chief Financial Officer, at (201) 343-5202, ext. 102.

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## **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 the 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



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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.

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

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

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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.

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

**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 OLpur MD220 Hemodiafilter and OLpur H2H Module for use with a hemodialysis machine that provides

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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

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

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

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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 (FDC Act), 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.



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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

If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement

of which could impair our ability to have manufactured and to sell the affected products.

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**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.

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**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.

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.

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.

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## **Risks Related to the Rights Offering**

### **The rights offering may reduce your percentage ownership in the Company.**

If you own stock and no warrants of the Company, even if you fully exercise your basic subscription privilege, you may experience dilution to your percentage ownership of our outstanding shares of common stock (but excluding the effect of the warrants) as a result of the rights offering. Current stockholders may be diluted on an actual basis even if they exercise their basic subscription privilege to the extent that warrant holders fully or partially exercise their subscription privileges.

If you choose not to exercise your subscription rights, you will retain your current number of shares of common stock and/or warrants. However, if you choose not to exercise your subscription rights and all of the shares offered are sold to other stockholders and/or warrant holders, you will experience significant dilution in your percentage ownership and voting rights in our company.

### **Lambda Investors will continue to be able to exercise substantial control over matters requiring stockholder approval upon completion of the rights offering and will likely increase its ownership percentage.**

As of the record date, Lambda Investors beneficially owned approximately 53.0% of the outstanding shares of our common stock (which includes warrants to purchase an aggregate of 11,589,152 shares of our common stock). Subject to the satisfaction of certain conditions described herein, Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders in the rights offering, if any. See *The Rights Offering Background of the Rights Offering Participation of Lambda Investors*. Lambda Investors may acquire, through the exercise of its basic subscription privilege and over-subscription privilege, as many shares of our common stock as it chooses up to an aggregate of all of the shares offered in the rights offering. As a result, it is likely that Lambda will substantially increase its percentage ownership of the Company both on an actual and fully-diluted basis.

### **Even assuming a successful completion of the rights offering, we may need additional capital in the future.**

If we raise \$3,000,000 in gross proceeds from the rights offering, we expect that we will be able to operate through the first quarter of 2014. However, we cannot assure you that we will be able to operate until that time. After the proceeds from the rights offering are exhausted, we will likely need additional capital. There can be no assurance that we will be able to raise additional capital at that time. If we are unable to raise capital when needed, we may not be able to execute our business strategy and accomplish our objectives, we may be forced to cease operations, and you will lose all or some part of your investment in our company.

### **The subscription price determined for the rights offering is not an indication of the fair value of our common stock.**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 5,000,000 shares of our common stock, and that it be made at a subscription price of

\$0.60 per share to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.60 per share subscription price, were approved by a special committee of our independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing alternatives available to us.

The special committee considered, among other things, that we are not currently in a position to attract an outside investor or investors with a stock offering at a more favorable discount to the current trading price of our stock. The \$0.60 per share subscription 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 being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price. After the date of this prospectus, our common stock may trade at prices above or below the subscription price.



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**The market price of our common stock is volatile and may decline before or after the subscription rights expire.**

The market price of our common stock could be subject to wide fluctuations in response to numerous factors, some of which are beyond our control. Once you exercise your subscription rights, you may not revoke them. We cannot assure you that the market price of our common stock will not decline after you elect to exercise your subscription rights. If you exercise your subscription rights and, afterwards, the public trading market price of our common stock decreases below the subscription price, you will have committed to buying shares of our common stock at a price above the prevailing market price and could have an immediate unrealized loss. Our common stock is quoted on the OTC Bulletin Board under the ticker symbol NEPH, and the last reported sales price of our common stock on the OTC Bulletin Board on April 4, 2013 was \$0.85 per share. Moreover, we cannot assure you that following the exercise of your subscription rights you will be able to sell your common stock at a price equal to or greater than the subscription price. Until shares are delivered upon expiration of the rights offering, you will not be able to sell the shares of our common stock that you purchase in the rights offering.

**Our management will have broad discretion over the use of the net proceeds from the rights offering; you may not agree with how we use the proceeds, and we may not invest the proceeds successfully.**

We must first use proceeds from the rights to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. We intend to use the remaining net proceeds, if any, for general corporate purposes, including working capital and operating expenses. Pending the application of any remaining net proceeds for these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities. Market factors may require our management to allocate portions of the proceeds for other purposes. Accordingly, you will be relying on the judgment of our management with regard to the use proceeds from the rights offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for us.

**We may cancel the rights offering at any time prior to the expiration of the rights offering, and neither we nor the subscription agent will have any obligation to you except to return your subscription payments.**

We may, in our sole discretion, decide to cancel the rights offering prior to the expiration of the rights offering. If the rights offering is cancelled, all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable.

**If you do not act promptly and follow the subscription instructions, your exercise of subscription rights will be rejected.**

Stockholders and warrant holders wishing to purchase shares in the rights offering must act promptly to ensure that all required forms and payments are actually received by the subscription agent prior to the expiration of the rights offering at 5:00 p.m., Eastern Time, on May 17, 2013. If you are a beneficial owner of shares, you must act promptly to ensure that your broker, dealer, custodian bank or other nominee acts for you and that all required forms and

The market price of our common stock is volatile and may decline before or after the subscription rights expire.

payments are actually received by the subscription agent prior to the expiration of the subscription period. We are not responsible if your broker, dealer, custodian bank or nominee fails to ensure that all required forms and payments are actually received by the subscription agent prior to the expiration of the subscription period. If you fail to complete and sign the required subscription forms, send an incorrect payment amount or otherwise fail to follow the subscription procedures that apply to your exercise in the rights offering prior to the expiration of the subscription period, the subscription agent may, depending on the circumstances, reject your subscription or accept it only to the extent of the payment received. Neither we nor the subscription agent will undertake to contact you concerning an incomplete or incorrect subscription form or payment, nor are we under any obligation to correct such forms or payment. We have the sole discretion to determine whether a subscription exercise properly complies with the subscription procedures.

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**You will not receive interest on subscription funds, including any funds ultimately returned to you.**

You will not earn any interest on your subscription funds while they are being held by the subscription agent pending the closing of this rights offering. In addition, if we cancel the rights offering, or if you exercise your over-subscription privilege and are not allocated all of the shares for which you over-subscribe, neither we nor the subscription agent will have any obligation with respect to the subscription rights except to return, without interest, any subscription payments to you.

**Risks Related to Owning Our Common Stock**

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

Our Common Stock currently does not meet all of the requirements for initial listing on a registered stock exchange. Our Common Stock is quoted on the 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 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;

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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;

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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**

As a smaller reporting company with little or no name recognition and with several risks and uncertainties that could

**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. In connection with the rights offering, 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 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.



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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.

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements in this prospectus constitute forward-looking statements. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines 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 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 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, is set forth in our filings with the SEC, including our other periodic reports filed with the SEC. We urge you to read those documents free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov). We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

## **USE OF PROCEEDS**

Assuming all the shares offered are sold, the gross proceeds from the rights offering will be \$3,000,000, with net proceeds, after deducting estimated offering expenses of \$250,000, of approximately \$2,750,000. We



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are conducting the rights offering in part to raise capital for our operations. Without additional capital, we currently anticipate that we will not be able to continue our operations beyond May 2013.

We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. The terms of the Lambda Investors note are discussed in more detail under the heading "The Rights Offering - Background for the Rights Offering - Loan from Lambda Investors." We intend to use the remaining net proceeds, if any, for general corporate purposes, including working capital and operating expenses. Pending the application of any remaining net proceeds for these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities.

Our management will retain broad discretion in the allocation of the net proceeds of this offering.

## **DETERMINATION OF OFFERING PRICE**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 5,000,000 shares of our common stock, and that it be made at a subscription price of \$0.60 per share to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.60 per share subscription price, were approved by a special committee of our independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing alternatives available to us.

The \$0.60 per share subscription 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 shares being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price.

After the date of this prospectus, our common stock may trade at prices above or below the subscription price. The subscription price does not necessarily bear any relationship to any established criteria for value. You should not consider the subscription price as an indication of value of our company or our common stock. You should not assume or expect that, after the rights offering, our shares of common stock will trade at or above the subscription price in any given time period. The market price of our common stock may decline during or after the rights offering, and you may not be able to sell the shares of our common stock purchased during the rights offering at a price equal to or greater than the subscription price. You should obtain a current quote for our common stock before exercising your subscription rights and make your own assessment of our business and financial condition, our prospects for the future, and the terms of this rights offering. On April 4, 2013, the closing sale price of our common stock on the OTC Bulletin Board was \$ \$0.85 per share.

## **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the \$0.60 offering price per share and the pro forma net tangible book value per share. Our historical net tangible book value (deficit) as of December 31, 2012 was approximately \$(595,000), or approximately \$(0.05) per share. Historical net tangible book value per share is determined by dividing our net tangible book value

by the actual number of outstanding shares of common stock. Dilution in historical net tangible book value per share represents the difference between the amount per share paid by the purchaser of shares of common stock in this offering and the pro forma net tangible book value per share of common stock immediately after the closing of this offering.

After giving effect to the assumed sale of 5,000,000 shares in the rights offering, with an offering price of \$0.60 per share, and after deducting estimated offering expenses payable by us of \$250,000, our pro forma net tangible book value as of December 31, 2012 would have been approximately \$2,155,000, or \$0.13 per share of common stock. This would represent dilution of \$0.47 per share for each share purchased in the offering.

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

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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.

**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.

**CAPITALIZATION**

The following table sets forth our historical and pro forma cash and cash equivalents and capitalization as of December 31, 2012. The pro forma information gives effect to as assumed \$3,000,000 equity raise from this rights offering and the \$1,300,000 loan from Lambda Investors. For purposes of this table, we have assumed that the rights offering is fully subscribed, resulting in \$3,000,000 in gross proceeds. This table should be read in conjunction with our consolidated financial statements and the notes thereto included in this prospectus.

	December 31, 2012	
	Actual	Pro Forma <sup>(1)</sup>
Cash and cash equivalents	\$47,000	\$2,797,000
Accounts payable and accrued expenses	\$1,391,000	\$1,391,000
License and supply fee payable	\$1,318,000	\$1,318,000
Deferred revenue	\$1,414,000	\$1,414,000
Promissory note <sup>(2)</sup>	\$0	\$1,300,000
Total liabilities	\$4,123,000	\$5,423,000
Stockholders' equity:		
Preferred stock, \$0.001 par value: 5,000,000 shares authorized on an actual and pro forma basis; no shares issued and outstanding on an actual and pro forma basis	\$0	\$0
Common stock, \$0.001 par value: 90,000,000 and 90,000,000 shares authorized on an actual and pro forma basis; 11,949,824 and 16,949,824 shares issued and outstanding on an actual and pro forma basis <sup>(3)</sup>	\$12,000	\$16,000
Additional paid-in capital	\$96,847,000	\$99,593,000
Accumulated other comprehensive income	\$76,000	\$76,000
Accumulated deficit	\$(97,530,000)	\$(97,530,000)
Total stockholders' equity	\$(595,000)	\$2,155,000
Total capitalization	\$3,528,000	\$7,575,000

(1) Gives pro forma effect to \$3,000,000 of gross proceeds from the rights offering, less \$250,000 of offering costs.

(2) Gives pro forma effect to \$1,300,000 of gross proceeds from the loan by Lambda Investors. We are obligated to use proceeds of the rights offering to prepay all amounts due under this note. See Use of Proceeds.

(3)

In addition to the issued shares as disclosed above, as of December 31, 2012, we had 2,294,714 and 14,679,971 shares of common stock issuable upon exercise of outstanding warrants and options on an actual and pro forma as adjusted basis, respectively.

TABLE OF CONTENTS**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.



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# THE RIGHTS OFFERING

## Background of the Rights Offering

### Need for Capital

On December 31, 2012, we had cash and cash equivalents totaling approximately \$47,000 and tangible assets of approximately \$1,419,000. We expect that the \$1,300,000 we raised in February 2013 through the issuance of the note to Lambda Investors will allow us to operate into May 2013. We must seek and obtain additional financing to fund our operations. For the past two years, we have significantly reduced expenses while attempting to properly capitalize our company.

### Fundraising Activities and Impact on Our Stockholders

We raised \$1,200,000 in a private placement in July 2009 at a purchase price which did not trigger the anti-dilution provisions of any of our outstanding warrants. Then in March 2011, we announced the completion of a rights offering and private placement that together resulted in gross proceeds of approximately \$3.2 million and estimated net proceeds of approximately \$2.3 million for the Company after deducting certain payments to Lambda Investors and after estimated expenses of the rights offering. In the rights offering, Nephros sold 4,964,864 units at \$0.40 per unit for gross proceeds of approximately \$2.0 million, resulting in the issuance of 4,964,854 shares of common stock and warrants to purchase an aggregate of 4,590,171 shares of common stock. The warrants expire on March 10, 2016 and have an exercise price of \$0.40 per share. All amounts are reported on a post-reverse stock split basis.

Since then we have been actively attempting to raise additional funding without success. We considered the unfavorable terms we might be required to agree to in order to raise capital from third party investors against our need for capital and our current stockholders' interests.

At present we have an immediate need for capital. For all of the reasons stated above, we have no other alternative for financing in the immediate term in which it is required. If we do not raise capital through the rights offering, we will likely need to initiate wind down proceedings, and our common stockholders most likely would receive nothing in a bankruptcy.

We believe the February loan and the rights offering provides several benefits to our stockholders:

the Lambda Investors loan provides us with the immediate funds we need to continue our business and affords us the time needed to raise additional funds through the rights offering;

the rights offering allows all of our stockholders and warrant holders to participate on terms that would not otherwise be available to many of them;

Subject to the satisfaction of certain conditions including compliance with all obligations under the note, security agreement and the other transaction documents relating to the note and no material adverse change having occurred with respect to the business, assets, and financial condition of the Company, Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders in the rights offering, if any.

We believe that stockholders and warrant holders who participate fully in the rights offering will suffer less dilution than they would likely experience in alternative financings. Stockholders and warrant holders who do not participate in the rights offering will suffer substantial dilution. See Dilution.

## **Loan from Lambda Investors**

We carefully considered our capital needs and the short time that our cash would allow us to continue operations. Given the imminent shortage of funds and our inability to complete any alternative financing within the necessary time, a special committee of our independent directors (none of whom are affiliated with Lambda Investors) requested that our largest investor, Lambda Investors, loan us funds and propose a means for capitalizing our company.

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

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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. However, 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. If we do not pay principal and interest under the note when due, the interest rate increases to 16% per annum. In connection with the note, we have agreed to pay Lambda Investors an 8%, or \$104,000, sourcing/transaction fee. In addition, we will pay Lambda Investors' legal fees and other expenses incurred in connection with the note in the amount of \$50,000 as well as Lambda Investors' legal fees and other expenses incurred in connection with the rights offering in the amount of \$50,000. Those payments will be paid upon the completion of the rights offering or, if earlier, upon the maturity of the note. As additional consideration, we agreed to extend by one year the expiration date of all of Lambda's outstanding warrants to March 2017. In addition, we have undertaken to conduct the rights offering described in this prospectus. During the period when the rights offering is open, we expect to offer to our public warrant holders holding the warrants issued at the close of the March 2011 rights offering a one-time right, at their option, to exercise such warrants for an exercise price of \$0.30 per share discounted from \$0.40 per share.

### **Participation of Lambda Investors**

As required under the terms of the note, we are conducting this rights offering to raise up to \$3,000,000 from our existing stockholders and warrant holders.

Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders in the rights offering, if any, subject to the following conditions being satisfied:

the business, assets, financial condition, operations, results of operations and prospects of the Company are substantially as have been represented to Lambda Investors on February 4, 2013 in connection with the senior secured note and no change shall have occurred or is reasonably likely to occur solely with the passage of time that is or may be materially adverse to the Company; and  
the Company's compliance with its obligations under the note, security agreement and other transaction documents relating to the loan by Lambda Investors.

We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

In connection with the February 2013 loan from Lambda Investors, we entered into a registration rights agreement with Lambda Investors whereby we are required to register with the SEC for resale the shares of our common stock purchased by Lambda Investors in this rights offering. See "Plan of Distribution and Certain Relationships and Related Transactions" for a description of the registration rights agreement with Lambda Investors. A copy of the registration rights agreement with Lambda Investors has been filed as an exhibit to the registration statement of which this prospectus is a part.

As of December 31, 2012, Lambda Investors is our largest stockholder and beneficially owns approximately 31% of our outstanding common stock and, on a fully-diluted basis, owns approximately 53% of our outstanding common stock. The warrants held by Lambda Investors have an exercise price of \$0.40 per share and certain warrants have full ratchet anti-dilution protection. Lambda Investors has agreed to that the Company could offer public warrant holders

of the Company holding warrants issued at the close of the March 2011 rights offering a one-time right, at their option to exercise their warrants for an exercise price of \$0.30 per share discounted from \$0.40 per share, but such incentive discount would not be afforded to Lambda Investors. In connection with the proposed rights offering, we agreed to amend the terms of the existing warrants held by Lambda Investors to March 10, 2017 from March 10, 2016, and Lambda Investors agreed to waive its anti-dilution rights applicable to any of its existing warrants solely with respect to the one-time incentive discount offered to public warrant holders.

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The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors. Arthur Amron, one of our directors, is a partner and general counsel of Wexford Capital and Paul A. Mieyal, another of our directors, is a vice president of Wexford Capital.

## **Reasons for the Rights Offering**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 5,000,000 shares of our common stock, and that it be made at a subscription price of \$0.60 per share to encourage our other stockholders and warrant holders to participate. A special committee of our independent directors (none of whom are affiliated with Lambda Investors) approved the loan and the rights offering after carefully evaluating our imminent need for additional capital. The special committee considered alternative capital raising methods that could be available to us and analyzed, among other things, the low likelihood of effecting another form of financing, as well as the length of time necessary to complete any such alternative financings. It also considered the costs and expenses associated with alternative financings. The special committee also considered the dilution that would be caused by the rights offering as well as by alternative financings.

## **The Subscription Rights**

We are distributing to holders of our common stock and warrants, at no charge, one non-transferable subscription right for each share of our common stock owned as of 5:00 p.m., Eastern Time, on the record date, either as a holder of record or, in the case of shares held of record by brokers, dealers, custodian banks or other nominees on a stockholder's behalf, as a beneficial owner of such shares. Each subscription right entitles you to purchase 0.18776 of a share at a subscription price of \$0.60 per share.

## **Basic Subscription Privilege**

For each share and/or each share of common stock underlying a warrant that you own, you will have a basic subscription privilege to buy 0.18776 of a share from us at a subscription price of \$0.60 per share. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights. If you choose to exercise your rights, there is no minimum number of shares you must purchase, but you may not purchase fractional shares. Subject to the satisfaction of certain conditions including compliance with all obligations under the note, security agreement and the other transaction documents relating to the note and no material adverse change having occurred with respect to our business, assets, and financial condition, Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders and warrant holders in the rights offering, if any. We will not issue any fractional shares. Instead we will round up any fractional shares to the nearest whole share.

## **Over-Subscription Privilege**

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional shares not subscribed for by other rights holders in the offering at the same subscription price of \$0.60 per share. If an insufficient number of shares is available to fully satisfy all over-subscription privilege requests, the available shares will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of shares each such holder subscribed for under the basic subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction

promptly after expiration of the subscription period. Lambda Investors may elect to exercise its over-subscription privilege for such number of shares as it determines in its sole discretion.

## **Expiration of Rights Offering and Extensions, Amendments and Termination**

You may exercise your subscription rights at any time prior to 5:00 p.m., Eastern Time, on May 17, 2013, the expiration date for the rights offering, subject to extension at our sole discretion, but in no event by more than 60 days from the date of this prospectus. If you do not exercise your subscription rights before the expiration date of the rights offering, your subscription rights will expire and will have no value. We will not

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be required to issue shares to you if the subscription agent receives your rights certificate or payment after the expiration date, regardless of when you sent the rights certificate and payment, unless you send the documents in compliance with the guaranteed delivery procedures described under **Guaranteed Delivery Procedures** below.

We may extend the expiration date at any time. If the rights offering is extended, subscriptions received prior to such extension will remain irrevocable. We may choose to extend the rights offering for any reason. For example, we may decide that changes in the market price of our common stock warrant an extension, or we may decide that the degree of stockholder participation in the rights offering is less than the level we desire. We may cancel the rights offering at any time prior to the expiration of the rights offering for any reason. In the event the rights offering is cancelled, all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable. We also reserve the right to amend or modify the terms of the rights offering, as appropriate.

We may extend the expiration date by giving oral or written notice to our subscription agent on or before the expiration date, followed by a press release no later than 9:00 a.m., Eastern Time, on the next business day after the previously scheduled expiration date.

## **Conditions to the Rights Offering**

As a condition to the rights offering, the registration statement of which this prospectus is a part must be declared effective by the SEC.

## **Method of Exercising Subscription Rights**

The exercise of subscription rights is irrevocable and may not be cancelled or modified. Your subscription rights will not be considered exercised unless the subscription agent receives from you, your broker, custodian or nominee, as the case may be, all of the required documents properly completed and executed and your full subscription price payment in cash at or prior to 5:00 p.m., Eastern time, on May 17, 2013, the expiration date of the rights offering. Rights holders may exercise their rights as follows:

### **Subscription by Registered Holders or Warrantholders**

Rights holders who are registered holders of our common stock or individuals with warrants to purchase our common stock may exercise their subscription privilege by properly completing and executing the rights certificate together with any required signature guarantees and forwarding it, together with payment in full in cash, of the subscription price for each share of the common stock for which they subscribe, to the subscription agent at the address set forth under the subsection entitled **Delivery of Subscription Materials and Payment**, on or prior to the expiration date.

### **Subscription by DTC Participants**

Banks, trust companies, securities dealers and brokers that hold shares of our common stock or warrants on the rights offering record date as nominee for more than one beneficial owner may, upon proper showing to the subscription agent, exercise their subscription privilege on the same basis as if the beneficial owners were record holders on the rights offering record date through the Depository Trust Company, or DTC. Such holders may exercise these rights through DTC's PSOP Function on the agent's subscription over PTS procedure and instructing DTC to charge their applicable DTC account for the subscription payment for the new shares or indicating to DTC that such holder intends to pay for such rights through the delivery to the Company by the holder of an equivalent amount of principal and

accrued and unpaid interest of indebtedness owed by the Company to such holder, or a combination thereof, and deliver such amount to the subscription agent. DTC must receive the subscription instructions and payment for the new shares by the rights expiration date. Except as described under the subsection titled Guaranteed Delivery Procedures, subscriptions accepted by the subscription agent via a Notice of Guaranteed Delivery must be delivered to the subscription agent with payment before the expiration of the subscription period.

### **Subscription by Beneficial Owners**

Rights holders who are beneficial owners of shares of our common stock or warrants and whose shares or warrants are registered in the name of a broker, custodian bank or other nominee, and rights holders who hold common stock or warrant certificates and would prefer to have an institution conduct the transaction



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relating to the rights on their behalf, should instruct their broker, custodian bank or other nominee or institution to exercise their rights and deliver all documents and payment on their behalf, prior to the expiration date. A rights holder's subscription rights will not be considered exercised unless the subscription agent receives from such rights holder, its broker, custodian, nominee or institution, as the case may be, all of the required documents and such holder's full subscription price payment.

## **Payment Method**

Payments must be made in full in U.S. currency by:

check or bank draft payable to Continental Stock Transfer & Trust Company (acting as subscription agent for Nephros, Inc.), drawn on a U.S. bank;  
U.S. Postal money order payable to Continental Stock Transfer & Trust Company (acting as subscription agent for Nephros, Inc.), or  
wire transfer of immediately available funds directly to the account maintained by Continental Stock Transfer & Trust Company as agent for Nephros, Inc., for purposes of accepting subscriptions in the rights offering, at JPMorgan Chase, ABA # 021-000021, Account # 475-508351 FBO Nephros, Inc. Subscription, with reference to the rights holder's name.  
Rights certificates received after 5:00 p.m., Eastern Time, on May 17, 2013, the expiration date of the rights offering, will not be honored, and we will return your payment to you as soon as practicable, without interest or deduction.

The subscription agent will be deemed to have received payment upon:

clearance of any uncertified check deposited by the subscription agent;  
receipt by the subscription agent of any certified check or bank draft, drawn on a U.S. bank;  
receipt by the subscription agent of any U.S. Postal money order; or  
receipt by the subscription agent of any appropriately executed wire transfer.

You should read the instruction letter accompanying the rights certificate carefully and strictly follow it. **DO NOT SEND RIGHTS CERTIFICATES OR PAYMENTS TO US.** Except as described below under Guaranteed Delivery Procedures, we will not consider your subscription received until the subscription agent has received delivery of a properly completed and duly executed rights certificate and payment of the full subscription amount. The risk of delivery of all documents and payments is on you or your nominee, not us or the subscription agent.

The method of delivery of subscription rights certificates and payment of the subscription amount to the subscription agent will be at the risk of the holders of subscription rights. If sent by mail, we recommend that you send those certificates and payments by overnight courier or by registered mail, properly insured, with return receipt requested, and that a sufficient number of days be allowed to ensure delivery to the subscription agent and clearance of payment before the expiration of the subscription period. Because uncertified personal checks may take at least five or more business days to clear, we urge you to pay or arrange for payment by means of certified check made payable to Continental Stock Transfer & Trust Company (acting as subscription agent for Nephros, Inc.) to avoid missing the opportunity to exercise your subscription rights should you decide to exercise them.

## **Payment Adjustments**

If you send a payment that is insufficient to purchase the number of shares requested, or if the number of shares requested is not specified in the rights certificate, the payment received will be applied to exercise your subscription rights to the extent of the payment. If the payment exceeds the amount necessary for the full exercise of your

subscription rights, including any over-subscription privilege exercised and permitted, the excess will be returned to you promptly in cash. You will not receive interest or a deduction on any payments refunded to you under the rights offering.

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## **Medallion Guarantee May Be Required**

Your signature on each subscription rights certificate must be guaranteed by an eligible institution, such as a member firm of a registered national securities exchange or a member of the Financial Industry Regulatory Authority, Inc., or a commercial bank or trust company having an office or correspondent in the United States, subject to standards and procedures adopted by us, unless:

your subscription rights certificate provides that shares are to be delivered to you as record holder of those subscriptions rights; or

you are an eligible institution.

## **Subscription Price**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 5,000,000 shares our common stock, and that it be made at a subscription price of \$0.60 per share to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.60 per share subscription price, were approved by a special committee of our independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing alternatives available to us.

The \$0.60 per share subscription 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 being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price.

We cannot assure you that the market price of our common stock will not decline during or after the rights offering.

We also cannot assure you that you will be able to sell shares of our common stock purchased during the rights offering at a price equal to or greater than the \$0.60 subscription price per share. We urge you to obtain a current quote for our common stock before exercising your subscription rights or subscribing for a share.

## **Withdrawal and Termination**

We reserve the right to withdraw the rights offering prior to the expiration of the rights offering for any reason. We may terminate the rights offering, in whole or in part, if at any time before completion of the rights offering there is any judgment, order, decree, injunction, statute, law or regulation entered, enacted, amended or held to be applicable to the rights offering that in the sole judgment of our board of directors would or might make the rights offering or its completion, whether in whole or in part, illegal or otherwise restrict or prohibit completion of the rights offering. We may waive any of these conditions and choose to proceed with the rights offering even if one or more of these events occur. If we terminate the rights offering, in whole or in part, all affected subscription rights will expire without value, and all excess subscription payments received by the subscription agent will be returned, without interest, as soon as practicable.

## **Cancellation Rights**

Our board of directors may cancel the rights offering at any time prior to the time the rights offering expires for any reason. If we cancel the rights offering, we will issue a press release notifying stockholders of the cancellation and all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as

practicable.

## **Subscription Agent**

The subscription agent for this rights offering is Continental Stock Transfer & Trust Company. We will pay all fees and expenses of the subscription agent related to the rights offering and have also agreed to indemnify the subscription agent from certain liabilities that it may incur in connection with the rights offering.

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## **Delivery of Subscription Materials and Payment**

All subscription rights certificates, payments of the subscription price (unless submitted by wire transfer), nominee holder certifications and/or notice of guaranteed delivery, to the extent applicable to your exercise of rights, must be delivered to Continental Stock Transfer & Trust Company as follows:

If delivery by hand/mail/overnight courier:

Continental Stock Transfer & Trust Company  
17 Battery Place, 8<sup>th</sup> Floor  
New York, NY 10004  
(917) 262-2378

Your delivery other than in the manner or to the address listed above will not constitute valid delivery.

You should direct any questions or requests for assistance concerning the method of subscribing for shares or for additional copies of this prospectus to the information agent.

## **Guaranteed Delivery Procedures**

The subscription agent will grant you three business days after the expiration date to deliver the rights certificate if you follow the following instructions for providing the subscription agent notice of guaranteed delivery. On or prior to the expiration date, the subscription agent must receive payment in full in cash and/or securities, as provided herein, for all shares subscribed for through the exercise of the basic subscription privilege and the over-subscription privilege, together with a properly completed and duly executed notice of guaranteed delivery substantially in the form accompanying this prospectus either by mail or overnight carrier, that specifies the name of the holder of the rights and the number of shares subscribed for. If applicable, it must state separately the number of shares subscribed for through the exercise of the over-subscription privilege and a member firm of a registered national securities exchange, a member of the Financial Industry Regulatory Authority, Inc., or a commercial bank or trust company having an office or correspondent in the United States must guarantee that the properly completed and executed subscription rights certificate for all shares of common stock subscribed for will be delivered to the subscription agent within three business days after the expiration date. The subscription agent will then conditionally accept the exercise of the rights and will withhold the certificates for shares of common stock until it receives the properly completed and duly executed rights certificate within that three-business-day time period.

In the case of holders of rights that are held of record through DTC, those rights may be exercised by instructing DTC to transfer rights from that holder's DTC account to the subscription agent's DTC account, together with payment of the full subscription price. The notice of guaranteed delivery must be guaranteed by a commercial bank, trust company or credit union having an office, branch or agency in the United States or by a member of a Stock Transfer Association approved medallion program such as STAMP, SEMP or MSP.

Notices of guaranteed delivery and payments (unless submitted by wire transfer) should be mailed or delivered to the appropriate address (or, for wire transfer payments, to the appropriate account) set forth under Delivery of Subscription Materials and Payment.

## **Fees and Expenses**

We will pay all fees charged by the subscription agent. You are responsible for paying any other commissions, fees, taxes or other expenses incurred in connection with the exercise of the subscription rights or subscribing for shares. Neither the subscription agent nor we will pay such expenses.

## **Notice to Nominees**

If you are a broker, custodian bank or other nominee holder that holds shares of our common stock or warrants for the account of others on the record date, you should notify the beneficial owners of the shares for whom you are the nominee of the rights offering as soon as possible to learn their intentions with respect to exercising their subscription rights. You should obtain instructions from the beneficial owner, as set forth in the instructions we have provided to you for your distribution to beneficial owners. If the beneficial owner so instructs, you should complete the appropriate rights certificate and submit it to the subscription agent with the proper subscription payment. If you hold shares of our common stock or warrants for the account(s) of more

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than one beneficial owner, you may exercise the number of subscription rights to which all beneficial owners in the aggregate otherwise would have been entitled had they been direct holders of our common stock or warrants on the record date, provided that you, as a nominee record holder, make a proper showing to the subscription agent by submitting the form entitled Nominee Holder Certification, which is provided with your rights offering materials. If you did not receive this form, you should contact the subscription agent to request a copy.

## **Beneficial Owners**

If you are a beneficial owner of shares of our common stock or warrants or will receive your subscription rights through a broker, custodian bank or other nominee, we will ask your broker, custodian bank or other nominee to notify you of the rights offering. If you wish to exercise your subscription rights, you will need to have your broker, custodian bank or other nominee act for you. To indicate your decision with respect to your subscription rights, you should complete and return to your broker, custodian bank or other nominee the form entitled Beneficial Owner Election Form. You should receive this form from your broker, custodian bank or other nominee with the other rights offering materials. If you wish to obtain a separate subscription rights certificate, you should contact the nominee as soon as possible and request that a separate subscription rights certificate be issued to you. You should contact your broker, custodian bank or other nominee if you do not receive this form, but you believe you are entitled to participate in the rights offering. We are not responsible if you do not receive the form from your broker, custodian bank or nominee or if you receive it without sufficient time to respond.

## **Non-Transferability of Subscription Rights**

Your subscription rights are not transferable, other than by operation of law, and may be exercised only by you. You may not sell, transfer or assign your subscription rights to anyone else.

## **Validity of Subscriptions**

We will resolve all questions regarding the validity and form of the exercise of your subscription rights, including time of receipt and eligibility to participate in the rights offering. Our determination will be final and binding. Once made, subscriptions and directions are irrevocable, and we will not accept any alternative, conditional or contingent subscriptions or directions. We reserve the absolute right to reject any subscriptions or directions not properly submitted or the acceptance of which would be unlawful. You must resolve any irregularities in connection with your subscriptions before the subscription period expires, unless waived by us in our sole discretion. Neither the subscription agent nor we shall be under any duty to notify you or your representative of defects in your subscriptions. A subscription will be considered accepted, subject to our right to withdraw or terminate the rights offering, only when a properly completed and duly executed rights certificate and any other required documents and the full subscription payment have been received by the subscription agent. Our interpretations of the terms and conditions of the rights offering will be final and binding.

## **Segregated Account; Return of Funds**

The subscription agent will hold funds received in payment for shares in a segregated account pending completion of the rights offering. The subscription agent will hold this money in escrow until the rights offering is completed or is withdrawn and canceled. If the rights offering is canceled for any reason, all subscription payments received by the subscription agent will be returned, without interest or penalties, as soon as practicable.

## **Certificates for Shares of Common Stock**

As soon as practicable after the completion of the rights offering, the subscription agent will arrange for issuance to each subscriber of the shares of common stock purchased in the rights offering.

### **Stockholder Rights**

You will have no rights as a holder of the shares of our common stock you purchase in the rights offering, if any, until certificates representing the shares of our common stock are issued to you or your account at your record holder is credited with the shares of our common stock purchased in the rights



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offering. You will have no right to revoke your subscriptions after your rights certificate or the Beneficial Owner Election Form, the full subscription payment and any other required documents have been delivered to the subscription agent.

### **State Securities Law Matters**

The issuance and exercise of subscription rights is subject to compliance with state securities laws and regulations. Although we intend to distribute the rights to all stockholders and warrant holders, we reserve the right in some states to require stockholders and warrant holders, if they wish to participate, to state and agree upon exercise of their respective rights 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 rights 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 subscription rights 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 rights offering.

### **Foreign Stockholders and Warrant holders**

We will not mail this prospectus or rights certificates to stockholders and warrant holders with addresses that are outside the United States or that have an army post office or foreign post office address. The subscription agent will hold these rights certificates for their account. To exercise subscription rights, our foreign stockholders and warrant holders and stockholders and warrant holders that have an army post office or foreign post office address must notify us prior to 11:00 a.m., Eastern Time, at least five business days prior to the expiration of the rights offering and demonstrate to our satisfaction that the exercise of such subscription rights does not violate the laws of the jurisdiction of such stockholder.

### **No Revocation or Change**

Once you submit the form of rights certificate to exercise any subscription rights, you are not allowed to revoke or change the exercise or request a refund of monies paid. All exercises of subscription rights are irrevocable, even if you learn information about us that you consider to be unfavorable. You should not exercise your subscription rights unless you are certain that you wish to purchase shares at the subscription price.

### **No Recommendation to Rights Holders**

Our board of directors is making no recommendation regarding your exercise of the subscription rights. You are urged to make your decision based on your own assessment of our business and the rights offering. Please see Risk Factors for a discussion of some of the risks involved in investing in the shares.

### **Listing**

The subscription rights will not be listed for trading on the OTC Bulletin Board or any stock exchange or market. The shares of our common stock issuable upon exercise of the subscription rights and upon exercise of the warrants will be listed on the OTC Bulletin Board under the ticker symbol NEPH.

## **Shares of Our Common Stock Outstanding After Completion of the Rights Offering**

As of the record date, we had 12,025,309 shares of our common stock issued and outstanding. If all of the shares offered are sold, we will issue 5,000,000 shares of our common stock in the rights offering. Assuming all of the shares offered are sold and no additional shares of our common stock are issued and no outstanding options or warrants are exercised prior to the completion of the rights offering, approximately 17,025,309 shares of our common stock will be outstanding immediately after the completion of the rights offering.

### **Additional Information**

If you have any questions or need further information or assistance concerning the method of subscribing or about the rights offering, please contact Gerald J. Kochanski at (201) 343-5202, ext 102.

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## PLAN OF DISTRIBUTION

On or about April 17, 2013, we will distribute the rights, rights certificates and copies of this prospectus to individuals who owned shares of our common stock and/or owned warrants on the record date. We have not employed any brokers, dealers or underwriters in connection with the solicitation or exercise of rights in the rights offering and no commissions, fees or discounts will be paid in connection with the rights offering. While certain of our directors, officers and other employees may solicit responses from you, those directors, officers and other employees will not receive any commissions or compensation for their services other than their normal compensation. We have agreed to pay the subscription agent and the information agent customary fees plus certain expenses in connection with the rights offering.

If you wish to exercise your subscription rights and subscribe for shares in the rights offering, you should complete the subscription rights certificate and return it with payment in cash and/or securities, as provided herein, for the shares subscribed, to the subscription agent, Continental Stock Transfer & Trust Company, at the following address:

If delivering by Hand/Mail/Overnight Courier:  
Continental Stock Transfer & Trust Company  
17 Battery Place, 8<sup>th</sup> Floor  
New York, NY 10004  
(917) 262-2378

You may also pay for your subscription of shares by wire transfer of immediately available funds as follows:

JPMorgan Chase  
ABA # 021-000021  
Continental Stock Transfer & Trust Company as agent for Nephros, Inc.  
Acct # 475508351 FBO Nephros, Inc. Subscription

You should direct any questions or requests for assistance concerning the method of subscribing for shares to Gerald J. Kochanski at (201) 343-5202, ext. 102.

You are solely responsible for completing delivery to the subscription agent of your subscription documents, rights certificate and payment. We urge you to allow sufficient time for delivery of your subscription materials to the subscription agent. See The Rights Offering Method of Exercising Subscription Rights.

In the event that the rights offering is not fully subscribed, holders of rights who exercise all of their rights pursuant to their basic subscription privilege will have the opportunity to subscribe for unsubscribed rights pursuant to the over-subscription privilege. See further the section of this prospectus entitled The Rights Offering.

Subject to the satisfaction of certain conditions including compliance with all obligations under the note, security agreement and the other transaction documents relating to the note and no material adverse change having occurred with respect to the business, assets, and financial condition of the Company, Lambda Investors has advised us that it intends to exercise its basic subscription privilege in full and to purchase any shares of common stock that are not subscribed for by our other stockholders in the rights offering, if any. See The Rights Offering Background of the Rights Offering Participation of Lambda Investors.

We are not entering into any other similar agreements with respect to the purchase of any shares not subscribed for through exercise of subscription privileges by our stockholders. See The Rights Offering Background of the Rights Offering Participation of Lambda Investors. We are obligated to use proceeds from the rights offering to repay the \$1,300,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$104,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors legal fees incurred in connection with the loan and the rights offering.

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We have entered into a registration rights agreement with Lambda Investors in connection with the rights offering.

The registration rights agreement covers the shares of our common stock sold to Lambda Investors. See Certain Relationships and Related Transactions for a description of the registration rights agreement with Lambda Investors.

Other than as described herein, we do not know of any existing agreements between any stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares of common stock.

The issuance and exercise of subscription rights is subject to compliance with state securities laws and regulations. Although we intend to distribute the subscription rights to all stockholders and warrant holders, we reserve the right in some states to require stockholders and warrant holders, if they wish to participate, to state and agree upon exercise of their respective rights that they are acquiring the shares for investment purposes only, and that they have no present intention to resell or transfer any shares acquired. 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 subscription rights in any state or other jurisdiction.

We have not entered into any agreements regarding stabilization activities with respect to our securities.

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# 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 prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2012 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;

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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.

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## **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,

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\$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,

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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
- for working capital purposes.

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

On March 10, 2011 we completed our rights offering and private placement that together resulted in gross proceeds of approximately \$3.2 million to us. 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 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 common stock and warrants to purchase an aggregate of approximately 4,590,171 million shares of common stock to stockholders who subscribed.

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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 2,782,577 shares of common stock. We received approximately \$1.2 million in gross proceeds from its sale of units to Lambda Investors.

The aggregate net proceeds received by us from the rights offering and private placement were approximately \$2.3 million, after deducting the estimated aggregate expenses of these transactions, the repayment of the \$500,000 note, plus all accrued interest thereon, issued to Lambda Investors, LLC, the payment of an 8% sourcing/transaction fee (\$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.

On March 11, 2011, 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.

At December 31, 2012, we had an accumulated deficit of \$97,530,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue.

The Bellco license agreement provides us with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively and all payments have been received. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay us a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. Anticipated payments from this License Agreement will be a positive source of cash flow to us.

On April 23, 2012, we entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica, an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products (collectively, the "Filtration Products"), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, we have agreed to make minimum annual aggregate purchases from Medica of €300,000, €500,000 and €750,000 for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2012, our aggregate purchase commitments totaled approximately €585,000. For calendar years thereafter, annual minimum amounts will be mutually agreed upon between Medica and us. In exchange for the license, we paid Medica €1,100,000 in two installments: €500,000 on April 23, 2012 and €600,000 on February 4, 2013. The remaining €400,000 is to be paid by June 30, 2013. As part of the agreement, we have granted to Medica 300,000 options to purchase our common stock which will vest over the first three years of the agreement.

On February 4, 2013, the Company issued a senior secured note to Lambda Investors LLC in the principal amount of \$1.3 million. For a more detailed discussion of the terms of the senior secured note, see "Business - Going Concern."



As of the date of this report, we expect that the proceeds from the note will allow us to fund our operations through May 2013. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with the contemplated rights offering or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all

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of your investment in our Company. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$1,547,000 for the year ended December 31, 2012 compared to approximately \$1,296,000 for the year ended December 31, 2011. The most significant items contributing to this net increase of approximately \$251,000 in cash used in operating activities during the year ended December 31, 2012 compared to the year ended December 31, 2011 are highlighted below:

during 2012, our net loss increased by approximately \$902,000, compared to 2011;  
during 2012, we recorded an inventory reserve of \$82,000 compared to \$200,000 in 2011;  
during 2012, we recorded amortization of debt issuance costs of \$0, whereas amortization of debt issuance costs in 2011 were \$40,000;  
during 2012, we recognized a gain on the sale of property and equipment of approximately \$55,000;  
during 2012, our inventory increased by approximately \$147,000 compared to a decrease of approximately \$295,000 during 2011;  
during 2012, our deferred revenue decreased by approximately \$680,000 compared to an increase of approximately \$2,061,000 during 2011; and  
during 2012, our prepaid expenses and other assets decreased by approximately \$4,000 compared to \$76,000 in 2011.  
Offsetting the above changes are the following items:

during 2012, depreciation and amortization expense increased by approximately \$60,000, compared to 2011;  
during 2012, our stock-based compensation expense, a non-cash expense, increased by approximately \$187,000 compared to 2011;  
during 2012, our accounts receivable decreased by approximately \$1,006,000 compared to an increase of approximately \$832,000 during 2011;  
long-term receivable increased by approximately \$778,000 during 2011; and  
during 2012, our accounts payable and accrued expenses increased by approximately \$904,000 in the aggregate compared to a decrease of approximately \$357,000 during 2011.

Net cash used in investing activities for the year ended December 31, 2012 was approximately \$612,000 related primarily to \$8,000 used for the purchase of equipment and \$659,000 for the purchase of intangible assets associated with the Medica License and Supply Agreement and partially offset by proceeds received of approximately \$55,000 related to the sale of property and equipment. There was no cash used or provided by investing activities during the year ended December 31, 2011.

Net cash provided by financing activities was approximately \$503,000 for the year ended December 31, 2012 as a result of the exercise of warrants. Net cash provided by financing activities of approximately \$2,723,000 for the year ended December 31, 2011 resulted from proceeds received related to the issuance of stock of approximately \$3,189,000 and from proceeds received related to the exercise of warrants of approximately \$174,000. For the year ended December 31, 2011, cash provided by financing activities was partially offset by the payment of debt of approximately \$500,000 and the payment of deferred financing costs of approximately \$140,000.

## **Contractual Obligations and Commercial Commitments**

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2012:



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	Payments Due in Period				
	Total	Within 1 Year	Years 1 3	Years 4 5	More than 5 Years
Leases	\$ 113,000	\$ 99,000	\$ 14,000	\$	\$
Employment Contracts	1,402,000	550,000	852,000		
Total	\$ 1,515,000	\$ 649,000	\$ 866,000	\$	\$

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## **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.

### **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.

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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.



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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 25<sup>th</sup>. 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 OLpur H2H Module and OLpur MD220 Hemodiafilter. On April 30, 2012, we announced that we received clearance from the U.S. Food and Drug Administration to market the OLpur H2H Module and OLpur 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 OLpur H2H Modules and manufacturing our OLpur 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.

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

## **Going Concern**

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

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We have incurred significant losses in operations in each quarter since inception. For the years ended December 31, 2012 and 2011, we incurred net losses of \$3,262,000 and \$2,360,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2012 and 2011. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

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. However, 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. If we do not pay principal and interest under the note when due, the interest rate increases to 16% per annum. In connection with the note, we have agreed to pay Lambda Investors an 8%, or \$104,000, sourcing/transaction fee. In addition, we will pay Lambda Investors legal fees and other expenses incurred in connection with the note in the amount of \$50,000 as well as Lambda Investors legal fees and other expenses incurred in connection with the rights offering in the amount of \$50,000. Those payments will be paid upon the completion of the rights offering or, if earlier, upon the maturity of the note. As additional consideration, we agreed to extend by one year the expiration date of all of Lambda's outstanding warrants to March 2017. In addition, we have undertaken to conduct the rights offering described in this prospectus.

During the period when the rights offering is open, we expect to offer to our public warrant holders holding the warrants issued at the close of the March 2011 rights offering a one-time right, at their option, to exercise such warrants for an exercise price of \$0.30 per share discounted from \$0.40 per share.

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

## **Recent Developments**

On April 23, 2012, we entered into a strategic license and supply agreement with Medica S.p.A. for ultrafiltration products granting us global rights, with specific exceptions, to market products based on Medica's proprietary Medisulfone ultrafiltration technology. Under the terms of the agreement, Medica will provide an exclusive license to us for its ultrafiltration technology for the period April 23, 2012 to December 31, 2022. In exchange for the license, we paid Medica €1,100,000 in two installments €500,000 on April 23, 2012 and €600,000 on February 4, 2013. The remaining €400,000 is to be paid by June 30, 2013. As part of the agreement, we have granted to Medica 300,000 options to purchase our common stock which will vest over the first three years of the agreement. For the period April 23, 2014 through December 31, 2022, we will pay Medica a royalty of 3% of net sales of filtration products related to the licensed technology.

## **Manufacturing and Suppliers**

We do not, and do not intend to in the near future, manufacture any of our products and components. With regard to the OLpur MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, with

Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD190, MD220), referred to herein as the Products. Under the agreement, we granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where we do not sell the Products as well as non-European countries, all such countries herein referred to as the Territory.

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In exchange for the rights granted to it under the Bellco license agreement through December 31, 2014, Bellco agreed to pay us installment payments of €500,000, €750,000, €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively, and all three payments have been received. Such installment payments, herein referred to as the Installment Payments, are Bellco's sole financial obligations through December 31, 2014. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to us a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 103,000 units sold, Bellco will pay €4.50 per unit; thereafter, Bellco will pay €4.00 per unit. Bellco must meet minimum sales targets of 15,000 units in each quarter of 2015 and 2016. If Bellco fails to meet a quarterly minimum, the license in Italy, France, Belgium, Spain and Canada will, at our discretion, convert to a non-exclusive one. All sums payable under the agreement will be paid in Euros, as adjusted to account for currency exchange fluctuations between the Euro and the U.S. dollar that occur between July 1, 2011, the effective date of the agreement, and the date of payment.

## **Sales and Marketing**

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

Our New Jersey office oversees global sales and marketing activity of our water filter products. In May 2012 we signed a non-exclusive U.S. distributor agreement with Vantage. In July 2012 we signed non-exclusive U.S. distributor agreements with TQM, Ameriwater and OLS. In February 2013 we announced the signing of a non-exclusive distributor agreement with Chem-Aqua, Inc. to distribute Nephros's innovative ultrafilters in North American healthcare facilities. Chem-Aqua is a global full service provider of water treatment programs and services.

We believe that the addition of Nephros ultrafilters to Chem-Aqua's product line will enable them to offer a comprehensive multi-barrier approach for prevention of waterborne infection in the healthcare institutions they service. Chem-Aqua is now beginning launch efforts for our products, including scheduling training sessions and promoting ultrafilters to the hospital market.

For each prospective market for our water filter products, we continue to pursue alliance opportunities for joint product development and distribution. Our water filter manufacturer in Europe shares certain intellectual property rights with us for one of our Dual Stage Ultrafilter (DSU) designs.

## **Research and Development**

Our research and development efforts continue on several fronts directly related to our current product lines. We are also working on additional machine devices, next-generation user interface enhancements and other product enhancements.

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

expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes.

Approximately \$317,000 and \$463,000 has been billed to the projects during the years ended December 31, 2012 and 2011, respectively. Approximately \$900,000 of revenue has been recognized on the initial research contract which concluded in August 2009. Approximately \$1,800,000 has been recognized on the second research contract awarded in August 2009. This research contract project ended in March 2012.

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In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement of \$40,000 and were eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and further milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of \$100,000 during 2010, of which approximately \$67,000 was recognized in 2010 and approximately \$33,000 was recognized in 2011. The remaining milestones, when completed, will result in additional payments of \$60,000.

## **Major Customers**

For the years ended December 31, 2012 and 2011, four customers accounted for 79% and 83%, respectively, of the Company's sales. In addition, as of December 31, 2012 and 2011, those four customers accounted for 88% and 89%, respectively, of the Company's accounts receivable.

## **Competition**

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

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

offering unique attributes that illustrate our product reliability, user-friendliness, and performance capabilities; selling products to specific customer groups where our unique product attributes are mission-critical; and pursuing alliance opportunities for joint product development and distribution.

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

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

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

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

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we

will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of competing in the ESRD marketplace to include:

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

displaying our products and providing associated literature at major industry trade shows in the United States; initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;

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

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

## **Intellectual Property**

### **Patents**

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

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

As of December 31, 2012, we have eighteen issued U.S. patents; one issued Eurasian patent; seven Mexican patents, four South Korean patents, three Russian patents, six Chinese patents, nine French patents, nine German patents, five Israeli patents, seven Italian patents, three Spanish patents, nine United Kingdom patents, fourteen Japanese patents, three Hong Kong patents, nine Canadian patents, one Australian patent, two patents in Brazil, one patent in Sweden and one patent in Netherlands. Our issued U.S. patents expire between 2018 and 2027. In addition, we have three pending U.S. patent applications, four pending patent applications in Canada, five pending patent applications in the European Patent Office, two pending patent applications in Brazil, one pending patent application in China, four pending patent applications in Israel, two pending patent applications in India and one pending patent application in South Korea. Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal.

### **Trademarks**

As of December 31, 2012, we secured registrations of the trademarks CENTRAPUR, H2H, OLpur and the Arrows Logo in the European Union. Applications for these trademarks are pending registration in the United States. We also have applications for registration of a number of other marks pending in the United States Patent and Trademark Office.

## **Governmental Regulation**

The research and development, manufacturing, promotion, marketing and distribution of our ESRD therapy products in the United States, Europe and other regions of the world are subject to regulation by numerous governmental

authorities, including the FDA, the European Union and analogous agencies.

## **United States**

The FDA regulates the manufacture and distribution of medical devices in the United States pursuant to the FDC Act. All of our ESRD therapy products are regulated in the United States as medical devices by

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the FDA under the FDC Act. Under the FDC Act, medical devices are classified in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

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

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

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

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

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

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

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

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

the design and manufacturing processes be regulated and controlled by the use of written procedures;  
the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;  
any deficiencies in the manufacturing process or in the products produced be investigated;  
detailed records be kept and a corrective and preventative action plan be in place; and



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

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

In addition to the requirements described above, the FDC Act requires that:

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

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

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

## **European Union**

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

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

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

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

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms to the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking

with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. In April 2010, we changed our notified body from TÜV Rheinland to BSI America, Inc. and expanded our scope to include design and development and production of water filters.

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

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

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

### **Reimbursement**

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

### **Product Liability and Insurance**

The production, marketing and sale of kidney dialysis products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our products in the amount of \$5 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.

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

### **Employees**

As of December 31, 2012, we employed a total of 10 employees, 6 of whom were full time and 1 who is employed on a part-time basis. We also have engaged 2 consultants on an ongoing basis. Of the 12 total employees and consultants,

4 are employed in a sales/marketing/customer support capacity, 4 in general and administrative and 4 in research and development.

## **Properties**