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:

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One Jefferson Road
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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.

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 Factorial Telephone (973) 966-8223 Factorial Telephon

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 o

Accelerated filer o

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

### **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 (4)(5)

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.

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

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 warrantholders 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 warrantholders 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 <u>Risk Factors</u> 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 prosp 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.

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## **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<sup>TM</sup>. BACTiglas<sup>TM</sup> 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 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 warrantholders. 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.

### Where You Can Find More Information

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

### The 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 warrantholder 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 warrantholders 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 Warrantholders and Other Stockholders or Warrantholders Can Exercise Rights The subscription agent will not mail rights certificates to you if you are a stockholder or warrantholder 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, you rights will expire and will have no value.

Possible Restrictions on Exercise by Stockholders or Warrantholders Residing in Certain States

We will not issue shares to any stockholder or warrantholder 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 warrantholders 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

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 warrantholders 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

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 warrantholders.

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 warrantholders, including Lambda Investors, your percentage ownership of our Company will be significantly diluted after the completion of the rights offering.

### 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 warrantholder with a foreign address or a stockholder or warrantholder with an APO or FPO address?

The subscription agent will not mail rights certificates to you if you are a stockholder or warrantholder 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, you rights will expire and will have no value. See The Rights Offering Foreign Stockholders and Warrantholders.

### 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 warrantholders 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 warrantholders.

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.

### 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 warrantholders 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 warrantholders, we reserve the right in some states to require stockholders and warrantholders, 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.

### 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.
Acet # 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.

### **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 warrantholders, each as further described in the note, (b) any other equity or debt financing, or (c) the issuance or incurrence of any other indebtedness or the sale of any assets

outside the ordinary course of business, in each case prior to the maturity date. In addition, the net proceeds of any offering, financing, asset disposition or other external liquidity generating transaction would need to be first applied to our existing indebtedness which, while reducing our level of indebtedness, cannot be assured to be sufficient for our continuing cash requirements and cash needs.

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

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

We have not been profitable since our inception in 1997. As of December 31, 2012, we had an accumulated deficit of approximately \$97,530,000, primarily as a result of historical operating losses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures, including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

the market acceptance of our technologies and products in each of our target markets; our ability to effectively and efficiently manufacture, market and distribute our products; our ability to sell our products at competitive prices which exceed our per unit costs; and our ability to continue to develop products and maintain a competitive advantage in our industry.

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

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

such products will be safe for use; such products will be effective; such products will be cost-effective;

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

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected

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