

NEPHROS INC
Form 424B3
February 13, 2014

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-193215

PROSPECTUS

NEPHROS, INC.

**Up to 9,166,667 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 9,166,667 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 January 30, 2014, which we refer to as the record date. Each non-transferable subscription right will entitle you to purchase 0.28673 of a share of our common stock at a subscription price of \$0.30 per share, which we refer to as the 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.

Subject to the satisfaction of certain conditions including compliance with all obligations under a \$1.5 million note, related security agreement and the other transaction documents between Lambda Investors and us, Lambda Investors has advised us that it intends to exercise its subscription privilege in full and, to the extent that after the closing of the rights offering there still remain unsubscribed shares of common stock, Lambda Investors will have the right, but not the obligation, to purchase any or all such remaining unsubscribed shares within ten days of the closing of the Rights Offering.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on March 14, 2014, 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 OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, under the ticker symbol “NEPH.” On January 30, 2014, the closing sales price for our common stock was \$0.40 per share. The shares of common stock issued in the rights offering will also be quoted on the OTCQB under the same ticker symbol. The subscription rights will not be listed for trading on any stock exchange or market or quoted on the OTCQB.

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.

The date of this prospectus is February 12, 2014.

NEPHROS, INC.

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Questions and Answers Relating to the Rights Offering	10
Risk Factors	16
Special Note Regarding Forward-Looking Statements	30
Use of Proceeds	31
Determination of Offering Price	31
Dilution	32
Dividend Policy	32
Capitalization	33
Market for Our Common Stock	34
The Rights Offering	35
Plan of Distribution	44
Management's Discussion and Analysis of Financial Condition and Results of Operations	46
Business	56
Management	66
Executive Compensation	73
Certain Relationships and Related Transactions	81
Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	83

Description of Common Stock	86
Certain Material U.S. Federal Income Tax Considerations	86
Legal Matters	88
Experts	88
Where You Can Find More Information	88
Disclosure of SEC Position on Indemnification for Securities Law Violations	89
Financial Statements	F-1
Report of Independent Registered Public Accounting Firm	F-2

ABOUT THIS PROSPECTUS

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

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

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. For a more complete understanding of our business 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 for the removal of biological contaminants from water, bicarbonate concentrate and/or blood. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to optimize the three elements critical to filter performance:

- Filtration - as low as 0.005 microns
- Flow rate - minimal disruption
- Filter life - up to 12 months

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis (HD). 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 ultrafilters for sale to customers in four markets:

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

Our Target Markets

Dialysis Centers - Water/Bicarbonate. To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate. Water and bicarbonate concentrate are essential ingredients for making dialysate, the liquid that removes waste material from the blood. Within the U.S., there are approximately 5,700 clinics with 100,000 dialysis machines providing over 50 million dialysis treatments to 370,000 patients annually.

Medicare is the main payer for dialysis treatment in the U.S. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate concentrate quality set by the Association for the Advancement of Medical Instrumentation (AAMI), the American National Standards Institute (ANSI) and the International Standards Organization (ISO). We anticipate that the stricter standards approved by these organizations in 2009 will be adopted by Medicare in the near future.

Published studies have shown that the use of ultrapure dialysate can make patients healthier and reduce their dependence on erythropoietin (EPO), an expensive drug used in conjunction with HD. By reducing the level of dialysate contaminants, specifically cytokine-inducing substances that can pass into a patient's blood stream, cytokine levels within a patient stay low, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient's responsiveness to EPO is enhanced, consequently the overall need for the drug is reduced.

We believe that our ultrafilters are attractive to dialysis centers because they exceed currently approved and newly proposed standards for water and bicarbonate concentrate purity, assist in achieving those standards and may help dialysis centers reduce costs associated with the amount of EPO required to treat a patient. Our in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine.

Dialysis Centers - Blood. The current standard of care in the U.S. for patients with chronic renal failure is HD, a process in which toxins are cleared via diffusion. Patients typically receive HD treatment at least 3 times weekly for 3-4 hours per treatment. HD is most effective in removing smaller, easily diffusible toxins. For patients with acute renal failure, the current standard of care in the U.S. is hemofiltration (HF), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD. However, HF treatment is performed on a daily basis, and typically takes 12-24 hours.

Hemodiafiltration (HDF) is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the U.S., HDF is much more prevalent in Europe and is performed in approximately 16% of patients. Clinical experience and literature show the following multiple clinical and patient benefits of HDF:

- Enhanced clearance of middle and large molecular weight toxins
- Improved survival - up to a 35% reduction in mortality risk
- Reduction in the occurrence of dialysis-related amyloidosis
- Reduction in inflammation
- Reduction in medication such as EPO and phosphate binders
- Improved patient quality of life
- Reduction in number of hospitalizations and overall length of stay

However, like HF, HDF can be resource intensive and can require a significant amount of time to deliver one course of treatment.

We have developed a modified approach to HDF which is more patient-friendly, less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration (mid-HDF) system and it consists of our OLPur H2H Module and OLPur MD 220 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 MD 220 Hemodiafilter for use with a UF controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States. Like HD, online 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 U.S. Food and Drug Administration ("FDA") to date.

We have completed preparation of our OLPur H2H Modules and have manufactured initial lots of our OLPur MD220 Hemodiafilters. We are currently finalizing our service contract and site selection in readiness for market release. We expect to place a mid-HDF system in a U.S. dialysis clinic in Q1, 2014. We have not begun to broadly market our mid-HDF system and are actively seeking a commercialization partner in the U.S.

Hospitals and Other Healthcare Facilities. Our ultrafilters are designed to be a component of the water treatment system to provide water for drinking and washing.

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.

We offer our individual water purification device (IWPD), which allows a soldier in the field to derive biologically safe water from any fresh water source. Our IWPD is available in both in-line and point-of-use configurations. Our IWPD is one of the few portable filters that has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by U.S. Army Public Health Command (USAPHC) and U.S. Army Test and Evaluation Command (ATEC) for deployment. To date, we have received purchase orders for approximately 2,000 IWPDs from individual units of the U.S. armed forces.

In January 2013, the U.S. Army issued a request for proposal (RFP) relating to an IWPD, Nephros submitted its response to this RFP on February 25, 2013. On March 29, 2013, we received notification from the U.S. Army that the Government has completed the initial evaluation of our proposal and found Nephros to be within the competitive range to commence negotiations. We also received a request for 180 of our IWPD to be used as test assets during the Limited User Evaluation phase of the source selection. 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. On November 5, 2013 we received notification from the U.S. Army that they are still in the technical evaluation phase of the solicitation.

On May 28, 2013 and June 7, 2013, we signed distributor agreements with W.S. Darley & Company and Source One Distribution Inc. respectively to assist with our distribution to the U.S. Military. On July 10, 2013 we signed a distributor agreement with Atlantic Diving Supply, Inc.

We submitted information in response to a request for information (RFI) from the U.S. Marines Corps Warfighting Laboratory (MCWL). The MCWL was seeking to obtain market research information from sources capable of fully satisfying the requirement for a commercial-off-the-shelf individual water purifier device capable of meeting the requirements of NSF Protocol P248. On September 19, 2013 we were awarded the contract for 30 (thirty) UF-40L units. In October 2013, Marines at the Mountain Warfare Training Center in Bridgeport, California, tested the Marine Austere Patrolling System, a prototype including, among other things, the Nephros filters, a high-efficiency solar panel utilizing space technology, and coordinating rechargeable batteries. Ongoing testing of the water and power systems is expected to conclude next spring.

Recent Developments

On October 30, 2013, we initiated a voluntary recall of our point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. We initiated the voluntary recall of these POU filters because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. In addition, we received reports from one customer of high bacterial counts that may be associated with the breakage of fiber in four filters. According to the reports received, one death and one infection may have occurred due to the failure mode associated with this voluntary recall.

Investigation into these reports is ongoing. Prior to receiving the complaints mentioned previously, we received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber, since it began marketing the products. We have had no reports of adverse events associated with these 29 complaints. We are recalling all production lots of these POU filters, and are also requesting that customers remove and discard certain labeling/promotional materials for the products. We initiated the voluntary recall of the DSU in-line ultrafilter because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. We are requesting that customers remove and discard certain labeling/promotional materials for the product.

Immediate Need for Capital and Recent Loan from Lambda Investors LLC

As of September 30, 2013, we had cash and cash equivalents totaling approximately \$168,000 and tangible assets of approximately \$609,000.

Due to our dwindling cash position, on November 12, 2013, we issued a senior secured note to Lambda Investors LLC in the principal amount of \$1,500,000. 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 \$2,750,000 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 September 30, 2013, Lambda Investors is our largest stockholder and beneficially owns approximately 37.3% of our outstanding common stock and, on a fully-diluted basis, owns approximately 53.4% 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 full ratchet anti-dilution protection for certain warrants will be triggered in connection with the rights offering as the \$0.30 per share price is less than the \$0.40 exercise price for these warrants. Following the rights offering, these warrants will be exercisable for 11,742,100 shares of common stock at an exercise price of \$0.30 per share compared to the 8,806,575 shares of common stock and \$0.40 exercise price prior to the rights offering. Also, in connection with the November 2013 loan from Lambda Investors, the Company agreed to amend the expiration date of the existing warrants held by Lambda Investors from March 10, 2017 to the date which is the five year anniversary of the closing of this rights offering.

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	<p>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.</p> <p>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.</p> <p>In either case, each subscription right entitles you to purchase 0.28673 of a share of our common stock at an exercise price of \$0.30 per share.</p>
Subscription Privilege	<p>The subscription privilege will entitle you to purchase 0.28673 of a share of our common stock at a subscription price of \$0.30 per share. You may exercise your 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.</p>
Subscription Price	<p>\$0.30 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.</p>
Record Date	<p>5:00 p.m., Eastern Time, on January 30, 2014.</p>
Expiration Date	<p>5:00 p.m., Eastern Time, on March 14, 2014, 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, 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.</p>
Non-Transferability of Rights	<p>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 OTCQB or on any stock exchange or trading markets.</p>
No Board Recommendation	<p>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</p>

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 subscription privilege in full, subject to certain conditions being satisfied including the following:

the business, assets, financial condition, operations, results of operations and prospects of the Company are substantially as have been represented to Lambda Investors on November 12, 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.

To the extent that after the closing of the Rights Offering there still remain unsubscribed shares of common stock, Lambda Investors will have the right, but not the obligation, to purchase any or all such remaining unsubscribed shares within ten days of the closing of the Rights Offering.

We are obligated to use proceeds from the rights offering to repay the \$1,500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$120,000) in respect of the loan and an aggregate of \$75,000 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 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	<p>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.</p>
Payment Adjustments	<p>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, 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.</p>
How Rights Holders Can Exercise Rights	
Through Others	<p>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 believe you are entitled to participate in the rights offering but you have not received this form.</p>
How Foreign Stockholders or Warrantheolders and Other Stockholders or Warrantheolders Can Exercise Rights	<p>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.</p>
Possible Restrictions on Exercise by Stockholders or Warrantheolders Residing in Certain States	<p>We will not issue shares to any stockholder or warrant holder 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.</p>
Certain Material U.S. Federal Income Tax Considerations	<p>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.</p>

Conditions to the Rights Offering	<p>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.”</p>
Use of Proceeds	<p>Assuming all the shares offered are sold, the gross proceeds from the rights offering will be approximately \$2,750,000. Our estimated net proceeds from the rights offering will be \$2,582,500, after deducting our estimated offering expenses of \$167,500.</p> <p>We are obligated to use proceeds from the rights offering to repay the \$1,500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$120,000) in respect of the loan and an aggregate of \$75,000 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 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.”</p>
Issuance of Common Stock	<p>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.</p>
Shares Outstanding Before the Rights Offering	<p>18,082,043 shares of our common stock were outstanding as of the record date.</p>
Shares Outstanding After Completion of the Rights Offering	<p>As of the record date, we had 18,082,043 shares of our common stock issued and outstanding. We will issue 9,166,667 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 27,248,710 shares of our common stock will be outstanding immediately after the completion of the rights offering.</p>
Subscription Agent	<p>Continental Stock Transfer & Trust Company.</p>
Fees and Expenses	<p>We will pay the fees and all of our expenses related to the rights offering. We will also pay Lambda Investors an aggregate of \$75,000 for reimbursement of legal fees incurred in connection with the loan and the rights offering. See “Use of Proceeds.”</p>

Trading Symbol	Shares of our common stock are currently listed for quotation on the OTCQB under the ticker symbol “NEPH” and the shares to be issued in connection with the rights offering will also be listed on the OTCQB under the same symbol. The subscription rights will not 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 John C. Houghton at (201) 343-5202, ext. 101.

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 January 30, 2014, the record date. The subscription rights will be evidenced by rights certificates. Each subscription right will entitle the holder to a subscription privilege.

What is the subscription privilege?

The subscription privilege gives our stockholders the opportunity to purchase 0.28673 of a share of our common stock at a subscription price of \$0.30 per share. You may exercise your 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.

Why are we conducting the rights offering?

We are conducting the rights offering to raise capital for our operations. Without additional capital, we may 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 the second quarter of 2014. The rights offering is expected to close on March 14, 2014. Upon the closing of the rights offering, we must first use proceeds to repay the \$1,500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$120,000) in respect of the loan and an aggregate of \$75,000 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 \$0.30 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 9,166,667 shares of our common stock, and that it be made at a subscription price of \$0.30 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 \$0.30 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 \$0.30 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 subscription privilege and other stockholders fully exercise their 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.

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 March 14, 2014. 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 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 13,887,598 shares of our common stock were outstanding.

Also, in connection with the November 2013 loan from Lambda Investors, the Company agreed to amend the expiration date of the existing warrants held by Lambda Investors from March 10, 2017 to the date which is the five year anniversary of the closing of this rights offering. Immediately prior to 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 warrants held by Lambda Investors have an exercise price of \$0.40 per share and certain warrants have full ratchet anti-dilution protection. The full ratchet anti-dilution protection for certain warrants will be triggered in connection with the rights offering as the \$0.30 per share price is less than the \$0.40 exercise price for these warrants. Following the rights offering, these warrants will be exercisable for 11,742,100 shares of common stock at an exercise price of \$0.30 per share compared to the 8,806,575 shares of common stock and \$0.40 exercise price prior to the rights offering.

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 subscription privilege 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 subscription privilege in full, subject to certain conditions being satisfied including the following:

the business, assets, financial condition, operations, results of operations and prospects of the Company are substantially as have been represented to Lambda Investors on November 12, 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.

To the extent that after the closing of the rights offering there still remain unsubscribed shares of common stock, Lambda Investors will have the right, but not the obligation, to purchase any or all such remaining unsubscribed shares within ten days of the closing of the rights offering.

We are obligated to use proceeds from the rights offering to repay the \$1,500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$120,000) in respect of the loan and an aggregate of \$75,000 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.

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 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 18,082,043 shares of our common stock issued and outstanding. We plan to issue up to an aggregate of 9,166,667 shares of our common stock in the rights offering pursuant to our stockholders' and/or warrant holders' subscription privilege. To the extent that after the closing of the rights offering there still remain unsubscribed shares, Lambda Investors will have the right, but not the obligation, to purchase any or all such remaining unsubscribed shares within ten days of the closing of the rights offering. Assuming all 9,166,667 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 27,248,710 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 \$2,750,000. It is estimated that the expenses of the rights offering will be \$167,500, and an estimated \$1.8 million 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 OTCQB.

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

No. Our common stock will continue to trade on the OTCQB under the ticker symbol “NEPH,” and the shares of common stock issued in the rights offering will also be quoted on the OTCQB 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 subscription 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, 8th 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 John C. Houghton, our President, Chief Executive Officer and Acting Chief Financial Officer, at (201) 343-5202, ext. 101.

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 into the second quarter of 2014. 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 November 12, 2013, we issued a senior secured note to Lambda Investors LLC in the principal amount of \$1.5 million. We expect that the proceeds from the note will allow us to fund our operations into the second quarter of 2014. The note bears interest at the rate of 12% per annum and matures on May 12, 2014, 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 Investors 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, we will be subject to certain covenants which, among other items, restrict our ability to merge with another company, sell a material amount of our assets, incur any additional indebtedness, repay any existing indebtedness, or declare or pay any dividends in cash, property or securities. These restrictions significantly impact our future alternatives to enter into strategic transactions and limit our ability to obtain additional or other financing because our assets have been pledged as collateral for repayment of our indebtedness. We have agreed to prepay amounts due under the note with the cash proceeds from (a) a rights offering and an offering of a discounted exercise price to public warrant holders, each as further described in the note, (b) any other equity or debt financing, or (c) the issuance or incurrence of any other indebtedness or the sale of any assets outside the ordinary course of business, in each case prior to the maturity date. In addition, the net proceeds of any offering, financing, asset disposition or other external liquidity generating transaction would need to be first applied to our existing indebtedness which, while reducing our level of indebtedness, cannot be assured to be sufficient for our continuing cash requirements and cash needs.

In the event that we default under the senior secured note or we are unable to repay the indebtedness when it becomes due, Lambda Investors 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.

If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our medically approved products.

On October 30, 2013, we initiated a voluntary recall of our point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. We initiated the voluntary recall of these POU filters because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. In addition, we received reports from one customer of

high bacterial counts that may be associated with the breakage of fiber in four filters. According to the reports received, one death and one infection may have occurred due to the failure mode associated with this voluntary recall. Investigation into these reports is ongoing. Prior to receiving the complaints mentioned previously, we received 29 additional complaints of high bacterial counts that may be associated with the breakage of filter fiber, since it began marketing the products. We have had no reports of adverse events associated with these 29 complaints. We are recalling all production lots of these POU filters, and are also requesting that customers remove and discard certain labeling/promotional materials for the products. We initiated the voluntary recall of the DSU in-line ultrafilter because the FDA informed us that promotional materials for these non-medical water filtration products were determined to promote claims which constitute marketing the product as a medical device. We are requesting that customers remove and discard certain labeling/promotional materials for the product.

If we violate the FDC Act or other regulatory requirements (either with respect to our POU or DSU ultrafilters or otherwise) at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including:

- fines;
- injunctions;

- civil penalties;
- recalls or seizures of products;
- total or partial suspension of the production of our products;
- withdrawal of any existing approvals or pre-market clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations that we not be allowed to enter into government contracts; and
- criminal prosecution.

Any of the above could have a material adverse effect on our business, financial condition and results of operations.

We cannot assure you that our products will be safe or that there will not be product-related deaths, serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.

We cannot assure you that our products will be safe or that there will not be product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm.

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

Under the Food, Drug and Cosmetic Act (FDC Act), we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could

result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;

- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and

- if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products.

Product liability associated with the production, marketing and sale of our products, and/or the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our reputation.

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. In particular, the voluntary recalls of the POU and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance for our products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and adversely affect the demand for our products, our ability to generate sales and our profitability.

Some of the agreements that we may enter into with manufacturers of our products and components of our products may require us:

- to obtain product liability insurance; or
- to indemnify manufacturers against liabilities resulting from the sale of our products.

For example, the agreement with our contract manufacturer, or CM, requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, provided they do not arise out of our CM's breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, then we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

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

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

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

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance and endurance standards. Our water filtration products and technology may not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial, military, industrial or retail applications.

Many of the same factors that may affect our ability to achieve acceptance of our chronic renal failure therapy products in the marketplace will also apply to our water filtration products, except for those related to side effects, clinical trials and third party reimbursement.

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

In order to commercialize our products, we need to be able to produce them in a cost-effective way on a large scale to meet commercial demand, while maintaining extremely high standards for quality and reliability. If we fail to successfully commercialize our products, then we will not be profitable.

We expect to rely on a limited number of independent manufacturers to produce our products. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, if any, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute our products effectively and/or customers may decide not to order our products and, in either case, our sales and revenues will suffer.

Our strategy requires us to distribute our products and provide a significant amount of customer service and maintenance and other technical service. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost-effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or

decide not, to order our products and our sales and revenues will suffer.

We have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.

Our business strategy depends in part on our ability to sell our products to hospitals and other healthcare facilities that include dialysis clinics. We have limited experience with respect to sales and marketing. If we are unsuccessful at manufacturing, marketing and selling our products, our operations and potential revenues will be materially adversely affected.

We cannot sell our products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. If we fail to receive, or experience a significant delay in receiving, such approvals and clearances, then we may not be able to get our products to market and enhance our revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We have obtained a Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our 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. We received clearance from the FDA to market our OLpur MD220 Hemodiafilter and OLpur H2H Module for use with a hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of chronic renal failure patients. We have not yet begun to market these products in the U.S.

There is no assurance that any existing products that have not yet been approved, or any new products developed by us in the future, will be approved for marketing. The clearance and/or approval processes can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or regulatory approval for any of our existing or new products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals would prevent us from selling our affected products in the applicable regions. If we cannot sell some of our products in such regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

We intend to market our products globally. Requirements pertaining to the sale of our products vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our products in many countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our products in a particular region, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

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

Before obtaining regulatory approvals for the commercial sale of any of our products, other than those for which we have already received marketing approval in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our products are safe and effective, we will not obtain marketing approvals from the applicable regulatory authorities. In particular, one or more of our products may not exhibit the expected medical benefits, may cause harmful side effects, may not be effective in treating dialysis patients or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

• slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;

- lower than expected retention rates of subjects in a clinical trial;

• inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;

- delays in approvals from a study site's review board, or other required approvals;
- longer treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product;
- adverse medical events or side effects in treated subjects; and
- lack of effectiveness of the product being tested.

Even if we obtain positive results from clinical studies for our products, we may not achieve the same success in future studies of such products. Data obtained from clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in regulatory policy for device approval during the period of product development and regulatory review of each submitted new device application. Moreover, regulatory approval may entail limitations on the indicated uses of the device. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products. Additionally, we may be unable to complete our clinical trials if we are unable to obtain additional capital.

We may be required to design and conduct additional clinical trials.

We may be required to design and conduct additional clinical trials to further demonstrate the safety and efficacy of our products, which may result in significant expense and delay. Regulatory agencies may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials, a possible failure to conduct clinical trials in complete adherence to certain regulatory standards, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our products. It is possible that regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales and revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. Any future laws, regulations, interpretations, applications or enforcements could delay or prevent regulatory approval or clearance of our products and our ability to market our products. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

Protecting our intellectual property in our technology through patents may be costly and ineffective. If we are not able to adequately secure or enforce protection of our intellectual property, then we may not be able to compete effectively and we may not be profitable.

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent

that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 17 granted U.S. patents will expire at various times from 2018 to 2026, assuming they are properly maintained.

The protection provided by our patents, and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. Numerous publications may have been disclosed by, and numerous patents may have been issued to, our competitors and others relating to methods and devices for dialysis of which we are not aware and additional patents relating to methods and devices for dialysis may be issued to our competitors and others in the future. If any of those publications or patents conflict with our patent rights, or cover our products, then any or all of our patent applications could be rejected and any or all of our granted patents could be invalidated, either of which could materially adversely affect our competitive position.

Litigation and other proceedings relating to patent matters, whether initiated by us or a third party, can be expensive and time-consuming, regardless of whether the outcome is favorable to us, and may require the diversion of substantial financial, managerial and other resources. An adverse outcome could subject us to significant liabilities to third parties or require us to cease any related development, product sales or commercialization activities. In addition, if patents that contain dominating or conflicting claims have been or are subsequently issued to others and the claims of these patents are ultimately determined to be valid, then we may be required to obtain licenses under patents of others in order to develop, manufacture, use, import and/or sell our products. We may not be able to obtain licenses under any of these patents on terms acceptable to us, if at all. If we do not obtain these licenses, we could encounter delays in, or be prevented entirely from using, importing, developing, manufacturing, offering or selling any products or practicing any methods, or delivering any services requiring such licenses.

If we file patent applications or obtain patents in foreign countries, we will be subject to laws and procedures that differ from those in the United States. Such differences could create additional uncertainty about the level and extent of our patent protection. Moreover, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be as favorable to us. Many non-U.S. jurisdictions, for example, prohibit patent claims covering methods of medical treatment of humans, although this prohibition may not include devices used for such treatment.

If we are not able to secure and enforce protection of our trade secrets through enforcement of our confidentiality and non-competition agreements, then our competitors may gain access to our trade secrets, we may not be able to compete effectively and we may not be profitable. Such protection may be costly and ineffective.

We attempt to protect our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. If these employees or other parties breach our confidentiality agreements and non-competition agreements, or if these agreements are not sufficient to protect our technology or are found to be unenforceable, then our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Policing unauthorized use of our trade secrets is difficult and expensive, particularly because of the global nature of our operations. The laws of other countries may not adequately protect our trade secrets.

If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales and revenues will suffer.

Approval or clearance of our products could be withdrawn, delayed or denied by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United

States.

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.

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

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

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;

- we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;

Local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;

- political instability could disrupt our operations;

Some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and

- some countries could impose additional taxes or restrict the import of our products.

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

Risks Related to 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 subscription privilege, you may experience dilution to your percentage ownership of our outstanding shares of common stock as a result of the rights offering. Current stockholders may be diluted on an actual basis even if they exercise their 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 57.3% 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 subscription privilege in full. To the extent that after the closing of the rights offering there still remain unsubscribed shares of common stock, Lambda Investors will have the right, but not the obligation, to purchase any or all such remaining unsubscribed shares within ten days of the closing of the rights offering. See “The Rights Offering — Background of the Rights Offering — Participation of Lambda Investors.” Lambda Investors may acquire, through the exercise of its subscription privilege and its option to purchase any shares that remain unsubscribed for after the closing of the rights offering, 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 Investors 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 \$2,750,000 in gross proceeds from the rights offering, we expect that we will be able to operate into the second 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 up to 9,166,667 shares of our common stock, and that it be made at a subscription price of \$0.30 per share to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.30 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 \$0.30 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.

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 OTCQB under the ticker symbol "NEPH," and the last reported sales price of our common stock on the OTCQB on January 30, 2014 was \$0.40 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 \$1,500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$120,000) in respect of the loan and an aggregate of

\$75,000 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 March 14, 2014. 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 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.

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 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 OTCQB. Trading in our Common Stock on the OTCQB has been very limited. As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our Common Stock, and our Common Stock may be less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes. There is no guarantee that we will ever become listed on the Nasdaq Capital Market, or any other exchange, or that a liquid trading market for our Common Stock will develop.

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

In the past we have issued Common Stock and warrants in order to raise money. We have also issued stock options and restricted stock as compensation for services and incentive compensation for our employees, directors and consultants. We have shares of Common Stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional Common Stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our Common Stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our Common Stock), or could obligate us to issue additional shares of Common Stock.

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

In connection with the rights offering, holders of our common stock and public warrants that choose not to fully exercise their subscription privilege will be diluted as a result of the rights offering if other shareholders fully exercise their 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 September 30, 2013, our Common Stock has traded at prices ranging from a high of \$3.19 to a low of \$0.10 per share, after giving effect to the 1:20 reverse stock split effected on March 11, 2011. Due to the lack of an active trading market for our Common Stock, you should expect the prices at which our Common Stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our Common Stock. These include, but are not limited to:

- achievement or rejection of regulatory approvals by our competitors or us;
- publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;
- delays or failures in initiating, completing or analyzing clinical trials or the unsatisfactory design or results of these trials;
- announcements of technological innovations or new commercial products by our competitors or us;
 - developments concerning proprietary rights, including patents;
 - regulatory developments in the United States and foreign countries;
 - economic or other crises and other external factors;
 - period-to-period fluctuations in our results of operations;
 - threatened or actual litigation;
 - changes in financial estimates by securities analysts; and
 - sales of our Common Stock.

We are not able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations in recent years that might have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors might seriously harm the market price of our Common Stock, regardless of our operating performance. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

We have never paid dividends and do not intend to pay cash dividends.

We have never paid dividends on our Common Stock and currently do not anticipate paying cash dividends on our Common Stock for the foreseeable future. Consequently, any returns on an investment in our Common Stock in the foreseeable future will have to come from an increase in the value of the stock itself. As noted above, the lack of an active trading market for our Common Stock will make it difficult to value and sell our Common Stock. While our dividend policy will be based on the operating results and capital needs of our business, it is anticipated that all earnings, if any, will be retained to finance our future operations.

Because we are subject to the “penny stock” rules, you may have difficulty in selling our Common Stock.

Our Common Stock is subject to regulations of the SEC relating to the market for penny stocks. Penny stock, as defined by the Penny Stock Reform Act, is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The penny stock regulations generally require that a disclosure schedule explaining the penny stock market and the risks associated therewith be delivered to purchasers of penny stocks and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. The broker-dealer must make a suitability determination for each purchaser and receive the purchaser’s written agreement prior to the sale. In addition, the broker-dealer must make certain mandated disclosures, including the actual sale or purchase price and actual bid offer quotations, as well as the compensation to be received by the broker-dealer and certain associated persons. The regulations applicable to penny stocks may severely affect the market liquidity for your Common Stock and could limit your ability to sell your securities in the secondary market.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our Common Stock.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our Common Stock could be reduced as a result. These provisions include:

• authorizing our board of directors to issue “blank check” preferred stock without stockholder approval;

- providing for a classified board of directors with staggered, three-year terms;

• prohibiting us from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;

- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and

• establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

As a smaller reporting company with little or no name recognition and with several risks and uncertainties that could impair our business operations, we are not likely to generate widespread interest in our Common Stock. Without widespread interest in our Common Stock, our Common Stock price may be highly volatile and an investment in our Common Stock could decline in value.

Unlike many companies with publicly traded securities, we have little or no name recognition in the investment community. We are a relatively new company and very few investors are familiar with either our company or our products. We do not have an active trading market in our Common Stock, and one might never develop, or if it does develop, might not continue.

Additionally, the market price of our Common Stock may fluctuate significantly in response to many factors, many of which are beyond our control. Risks and uncertainties, including those described elsewhere in this “Risk Factors” section could impair our business operations or otherwise cause our operating results or prospects to be below expectations of investors and market analysts, which could adversely affect the market price of our Common Stock. As a result, investors in our Common Stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company’s securities. We may become subject to this type of litigation in the future. Litigation of this type could be extremely expensive and divert management’s attention and resources from running our company.

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

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

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

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

As of September 30, 2013, our directors, executive officers and Lambda Investors beneficially owned approximately 37.3% of our outstanding Common Stock, representing approximately 53.4% 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 subscription privilege will be diluted as a result of the rights offering if Lambda Investors 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 Investors elects to purchase shares that are not subscribed for in the rights offering, Lambda Investors would increase its ownership percentage and obtain greater voting power.

As a result of this ownership, Lambda Investors has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda Investors, whether acting alone or acting with other stockholders, could have the power to elect all of our directors and to control the vote on substantially all other corporate matters without the approval of other stockholders. Furthermore, such concentration of voting power could enable Lambda Investors, whether acting alone or acting with other stockholders, to delay or prevent another party from taking control of our company even where such change of control transaction might be desirable to other stockholders. The interests of Lambda Investors in any matter put before the stockholders may differ from those of any other stockholder.

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

The market price of our Common Stock could decline due to sales of a large number of shares in the market, including sales of shares by Lambda Investors or any other large stockholder, or the perception that such sales could occur. These sales could also make it more difficult or impossible for us to sell equity securities in the future at a time and price that we deem appropriate to raise funds through future offerings of Common Stock. Future sales of our Common Stock by stockholders could depress the market price of our Common Stock.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of Common Stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after holding their shares for six months and affiliates may sell freely after holding their shares for one year, in each case, subject to current public information, notice and other requirements. Any substantial sales of our Common Stock pursuant to Rule 144 may have a material adverse effect on the market price of our Common Stock.

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 similar words. Forward-looking statements are not guarantees of future performance are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

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

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;