

NEPHROS INC  
Form S-1/A  
January 27, 2011

As filed with the Securities and Exchange Commission on January 27, 2011

**Registration No. 333-169728**

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

**AMENDMENT NO. 4  
TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933**

**NEPHROS, INC.**

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

Delaware  
*(State or Other Jurisdiction of  
Incorporation or Organization)*

3841  
*(Primary Standard Industrial  
Classification Code Number)*

13-3971809  
*(I. R. S. Employer  
Identification No.)*

**41 Grand Avenue  
River Edge, New Jersey 07661  
(201) 343-5202**

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

**Paul A. Mieyal**  
**Acting Chief Executive Officer**  
**Nephros, Inc.**  
**41 Grand Avenue**  
**River Edge, New Jersey 07661**  
**(201) 343-5202**

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

*Copies to:*

**Alexander M. Donaldson, Esq.**  
**Wyrick Robbins Yates & Ponton LLP**  
**4101 Lake Boone Trail, Suite 300**  
**Raleigh, North Carolina 27607**  
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**Approximate date of commencement of proposed sale to the public:** As promptly as practicable after this registration statement becomes effective and the satisfaction or waiver of certain other conditions described herein.

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

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

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

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

Alexander M. Donaldson, Esq. Wyrick Robbins Yates & Ponton LLP 4101 Lake Boone Trail, Suite 300 Raleigh, North Carolina

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offering.

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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TABLE OF CONTENTS**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered <sup>(1)(2)</sup>	Amount to be registered	Proposed maximum aggregate offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
Non-transferable subscription rights to purchase Units <sup>(3)</sup>				
Units underlying the subscription rights, each consisting of 4.185496618 shares of common stock, \$0.001 par value per share, and a warrant to purchase 0.924532845 shares of our common stock	175,000,000			
Common stock, \$0.001 par value per share <sup>(4)</sup>	175,000,000	\$ 0.02	\$ 3,500,000	\$ 249.55
Warrants to purchase 161,793,248 shares of our common stock <sup>(5)</sup>	175,000,000			
Common stock, \$0.001 par value per share, issuable upon exercise of the warrants <sup>(6)</sup>	161,793,248	\$ 0.02	\$ 3,235,865	\$ 230.72
Total <sup>(7)</sup>			\$ 6,735,865	\$ 480.27

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

This registration statement relates to (a) the subscription rights to purchase common stock, \$0.001 par value per share, and warrants, (b) shares of common stock issuable upon the exercise of the subscription rights, (c) the (2) warrants issuable upon exercise of the subscription rights, and (d) shares of our common stock that are issuable upon exercise of the warrants.

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

(4) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum offering price of our common stock of \$0.02.

Pursuant to Rule 457(g), no separate registration fee is payable with respect to the warrants being offered hereby (5) since the warrants are being registered on the same registration statement as the securities to be offered pursuant thereto.

(6) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum exercise price of \$0.02.

The registration fee is being offset, pursuant to Rule 457(p) of the Securities Act, by the \$959 of registration fees (7) paid in connection with the registrant's filing of Registration Statement No. 333-167022 (initially filed on May 21, 2010, as amended on June 18, 2010, and withdrawn on October 1, 2010).

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration**

**statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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TABLE OF CONTENTS

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation or sale is not permitted.

**PRELIMINARY PROSPECTUS**

**SUBJECT TO COMPLETION DATED JANUARY 27, 2011**

## **NEPHROS, INC.**

### **Up to 175,000,000 Shares of Common Stock and Warrants to Purchase up to 161,793,248 Shares of Common Stock Issuable upon Exercise of Non-transferrable Rights to Subscribe for such Shares and Warrants**

We are distributing, at no charge, to holders of our common stock, non-transferable subscription rights to purchase up to 175,000,000 Units. We refer to this offering as the rights offering. In this rights offering, you will receive one non-transferrable subscription right for each share of common stock owned by you at 5:00 p.m., Eastern Time, on January 31, 2011, which we refer to as the record date. Each non-transferable subscription right will entitle you to purchase 4.185496618 Units at a subscription price of \$0.02 per Unit, which we refer to as the basic subscription privilege. Each Unit consists of one share of our common stock and a warrant to purchase 0.924532845 shares of our common stock at the exercise price of \$0.02 per share for a period of five years following the issue date of the warrant, which will be the closing date of the rights offering, which we expect to be March 7, 2011.

There is no minimum number of Units you must purchase, but you may not purchase fractional Units. To determine the number of Units you may purchase under your basic subscription privilege, multiply the number of shares of our common stock you own by 4.185496618 and round down to the nearest whole number. For example, if you own 100 shares of our common stock, you will be entitled to subscribe for up to 418 Units ( $100 \text{ shares} \times 4.185496618 = 418.5496618$ , rounded down to 418, the nearest whole number) under your basic subscription privilege. Similarly, the warrant to purchase 0.924532845 shares of our common stock included with each Unit you purchase will only be exercisable for a number of shares rounded down to the nearest whole number. For example, if you purchase 418 Units, the warrants included with those Units would be exercisable for up to 386 shares ( $418 \text{ Units} \times 0.924532845 = 386.4547292$ , rounded down to 386, the nearest whole number).

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional Units not subscribed for by other rights holders in the offering at the same subscription price of \$0.02 per Unit, subject to certain limitations. If an insufficient number of Units is available to fully satisfy all over-subscription privilege requests, the available Units will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of Units each such holder subscribed for under the basic subscription privilege. To the extent you properly exercise your over-subscription privilege for an amount of Units that exceeds the number of unsubscribed Units available to you, any excess subscription payment received by the subscription agent will be promptly returned to you, without interest or deduction.

There is no certainty that any Units will be purchased pursuant to the rights offering, and there is no minimum purchase requirement as a condition to our accepting subscriptions. We are not entering into any standby purchase agreement or similar agreement with respect to the purchase of Units not subscribed for through the exercise of subscription privileges by our stockholders, except that our largest stockholder, Lambda Investors LLC, has

committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266 Units under the purchase agreement. See The Rights Offering Background of the Rights Offering Purchase Agreement with Lambda Investors. Lambda

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TABLE OF CONTENTS

Investors is not receiving any compensation for its purchase commitment. Any Units purchased by Lambda Investors and the shares and warrants to purchase shares of our common stock underlying them are not being registered pursuant to the registration statement of which this prospectus is a part, and thus may not be offered or sold except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act of 1933, as amended. See Plan of Distribution.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on February 28, 2011, unless we extend the subscription period in our sole discretion, but in no event by more than 60 days from the date of this prospectus. However, our board of directors reserves the right to cancel the rights offering at any time, for any reason.

If the rights offering is cancelled, all subscription payments received by the subscription agent will be returned promptly.

Shares of our common stock are quoted on the OTC Bulletin Board under the ticker symbol NEPH. On January 26, 2011, the closing sales price for our common stock was \$0.105 per share. The shares of common stock issued in the rights offering will also be quoted on the OTC Bulletin Board under the same ticker symbol. Neither the warrants nor the subscription rights will be listed for trading on any stock exchange or market or quoted on the OTC Bulletin Board.

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

**The purchase of Units involves substantial risks. See Risk Factors beginning on page 19 of this prospectus to read about important factors you should consider before subscribing for Units.**

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

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

The date of this prospectus is [ ], 2011.

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TABLE OF CONTENTS

**NEPHROS, INC.**  
**TABLE OF CONTENTS**

<u>Prospectus Summary</u>	<u>1</u>
<u>Questions and Answers Relating to the Rights Offering</u>	<u>11</u>
<u>Risk Factors</u>	<u>19</u>
<u>Special Note Regarding Forward-Looking Statements</u>	<u>39</u>
<u>Use of Proceeds</u>	<u>40</u>
<u>Determination of Offering Price</u>	<u>40</u>
<u>Dilution</u>	<u>41</u>
<u>Dividend Policy</u>	<u>41</u>
<u>Capitalization</u>	<u>41</u>
<u>Market for Our Common Stock</u>	<u>43</u>
<u>The Rights Offering</u>	<u>44</u>
<u>Plan of Distribution</u>	<u>59</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>61</u>
<u>Business</u>	<u>72</u>
<u>Management</u>	<u>89</u>
<u>Executive Compensation</u>	<u>93</u>
<u>Certain Relationships and Related Transactions</u>	<u>96</u>
<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>99</u>
<u>Description of Common Stock</u>	<u>100</u>
<u>Description of Warrants</u>	<u>101</u>
<u>Legal Matters</u>	<u>102</u>
<u>Experts</u>	<u>102</u>
<u>Where You Can Find More Information</u>	<u>102</u>
<u>Disclosure of SEC Position on Indemnification for Securities Law Violations</u>	<u>102</u>
<u>Financial Statements</u>	<u>F-1</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>

OLpur™ and H<sub>2</sub>H™ are among our trademarks for which U.S. registrations are pending. H<sub>2</sub>H is a registered European Union trademark. We have assumed that the reader understands that these terms are source-indicating.

Accordingly, such terms appear throughout the remainder of this prospectus without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

## **ABOUT THIS PROSPECTUS**

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.

i

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TABLE OF CONTENTS

## 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. You should carefully read the more detailed information contained in this prospectus, including the section entitled Risk Factors beginning on page 19 and our financial statements for the years ended December 31, 2008 and 2009, and the nine months ended September 30, 2010, and related notes appearing elsewhere in this prospectus. We refer to Nephros, Inc. and its consolidated subsidiary as Nephros, the Company, we, our, and us.*

### About the Company

We are a medical device company developing and marketing filtration products for therapeutic applications, infection control, and water purification.

Our hemodiafiltration, or HDF, system is designed to improve the quality of life for the End-Stage Renal Disease, or ESRD, patient while addressing the critical financial and clinical needs of the care provider. ESRD is a disease state characterized by the irreversible loss of kidney function. The Nephros HDF system removes a range of harmful substances more effectively, and with greater capacity, than existing ESRD treatment methods, particularly with respect to substances known collectively as middle molecules. These molecules have been found to contribute to such conditions as dialysis-related amyloidosis, carpal tunnel syndrome, degenerative bone disease and, ultimately, mortality in the ESRD patient. Nephros ESRD products are sold and distributed throughout Europe and are currently being used in over 50 clinics in Europe.

We currently have three HDF products in various stages of development to deliver improved therapy to ESRD patients:

OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters), which is, to our knowledge, the only filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

OLpur H<sub>2</sub>H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

OLpur NS2000 system, our stand-alone HDF machine and associated filter technology.

We have also developed our OLpur HD 190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpur MD series, but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpur HD190 was designed for use with either hemodialysis or hemodiafiltration machines, and received its approval in June 2005 from the U.S. Food and Drug Administration, or FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as middle molecules because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H<sub>2</sub>H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved, our OLpur H<sub>2</sub>H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our OLpur MDHDF filter system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profiles), and therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process.

TABLE OF CONTENTS

In addition, independent studies in Europe have indicated that, when compared with dialysis as it is currently offered in the United States, HDF can reduce the patient's mortality risk by up to 35%. We believe that the OLpur MDHDF filter series and the OLpur H<sub>2</sub>H will provide these benefits to ESRD patients at competitive costs and without the need for ESRD treatment providers to make significant capital expenditures in order to use our products. We also believe that the OLpur NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

In January 2006, we introduced our new Dual Stage Ultrafilter, or DSU, water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpur H<sub>2</sub>H and MD Mid-Dilution filter technologies for ESRD therapy provided the foundation for a proprietary multi-stage water filter that we believe is cost effective, reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,000 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of October 20, 2006), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

Due to the ongoing concerns of maintaining water quality, on October 7, 2008, we filed a 510(k) application for approval to market our DSU to dialysis clinics for in-line purification of dialysate water. On July 1, 2009, the FDA approved the DSU to be used to filter biological contaminants from water and dialysate concentrate used in hemodialysis procedures.

In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter. We obtained approval from the IRBs and completed the clinical trial near the end of the second quarter in 2008. The clinical data was compiled, analyzed, summarized and submitted with our FDA 510(k) in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately \$1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal

of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use

TABLE OF CONTENTS

purposes. Approximately \$1,178,000 of revenue has been recognized on this new project since September 2009 of which approximately \$755,000 was recognized on this new project during the nine months ended September 30, 2010.

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

At September 30, 2010, we had cash and cash equivalents totaling approximately \$421,000 and tangible assets of approximately \$1,682,000. At that time, we estimated that these funds would allow us to keep operating into the fourth quarter of 2010. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. The receipt of this letter had a detrimental impact on our ongoing capital raising efforts. As a result, we determined, in consultation with the investment banking firm we had engaged, Dawson James Securities, Inc. ( Dawson James ), that raising capital through conventional sources was no longer feasible. We subsequently terminated our engagement of Dawson James on September 16, 2010.

After having considered all possible financing alternatives, on October 1, 2010, with the unanimous approval of our independent directors who are unaffiliated with Lambda Investors LLC ( Lambda Investors ), we issued a six-month senior secured note to Lambda Investors in the principal amount of \$500,000. We expect that the proceeds from the note will allow us to fund our operations into March 2011, which we previously estimated to be February 2011. The terms of the Lambda Investors note are discussed in more detail under the heading The Rights Offering Background of the Rights Offering Loan from Lambda Investors.

As required under the terms of the note, we are conducting this rights offering to raise up to \$3,500,000 from our existing stockholders. 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.

To effect the rights offering, we must amend our certificate of incorporation to increase the number of authorized shares of common stock. At our annual meeting of stockholders held on January 10, 2011, our stockholders approved, among other proposals, the increase in our authorized shares of common stock. The increase in our authorized shares of common stock is a condition to the closing of the rights offering. We intend to file a certificate of amendment to our certificate of incorporation providing for such share increase immediately prior to the closing of 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.

Lambda Investors is our largest stockholder and as of the record date beneficially owned approximately 43.9% of our outstanding common stock, including warrants to purchase an aggregate of 7,190,811 shares of our common stock.

## **Proposed Reverse Stock Split**

If the rights offering is completed, we intend to effect, subject to approval by our stockholders, a 1-for-20 reverse stock split immediately after the completion of the rights offering. Our stockholders approved a proposal to effect the reverse stock split at our annual meeting of stockholders held on January 10, 2011. In the 1-for-20 reverse stock split, our board of directors intends to cash out fractional shares at a price equal to the average closing sale price of shares of common stock for the ten trading days immediately prior to the date the 1-for-20 reverse stock split becomes effective, or, if no such sale takes place on such days, the average of the closing bid and ask prices for such days, in each case as

officially reported by the OTC Bulletin Board, which we refer to as the cash out price. If the shares currently held by you and the shares purchased by you in this offering result in a fractional interest following the 1-for-20 reverse stock split, then such fractional interests will be cashed out at the cash out price, which may be less than or greater than the \$0.02 per Unit subscription price.



TABLE OF CONTENTS

## Corporate Information

We are incorporated in Delaware and our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey 07661. Our telephone number is (201) 343-5202 and our website address is [www.nephros.com](http://www.nephros.com).

Information contained in, or accessible through, our website does not constitute part of this prospectus.

## Where You Can Find More Information

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

TABLE OF CONTENTS

## The Rights Offering

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

### Securities Offered

We are distributing to holders of our common stock, at no charge, one non-transferable subscription right for each share of our common stock owned as of 5:00 p.m., Eastern Time, on the record date, either as a holder of record or, in the case of shares held of record by brokers, dealers, custodian banks or other nominees on a stockholder's behalf, as a beneficial owner of such shares. Each subscription right entitles you to purchase 4.185496618 Units, each consisting of one share of our common stock and a warrant to purchase 0.92453 shares of our common stock at an exercise price of \$0.02 per share for a period of five years following the issue date of the warrant, which will be the closing date of the rights offering, which we expect to be March 7, 2011.

### Basic Subscription Privilege

For each share that you own, you will have a basic subscription privilege to buy from us 4.185496618 Units at a subscription price of \$0.02 per Unit. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights. If you choose to exercise your rights, there is no minimum number of Units you must purchase, but you may not purchase fractional Units. To determine the number of Units you may purchase under your basic subscription privilege, multiply the number of shares of our common stock you own by 4.185496618 and round down to the nearest whole number. For example, if you own 100 shares of our common stock, you will be entitled to subscribe for up to 418 Units ( $100 \text{ shares} \times 4.185496618 = 418.5496618$ , rounded down to 418, the nearest whole number) under your basic subscription privilege. Similarly, the warrant to purchase 0.92453 shares of our common stock included with each Unit you purchase will only be exercisable for a number of shares rounded down to the nearest whole number. For example, if you purchase 418 Units, the warrants included with those Units would be exercisable for up to 386 shares ( $418 \text{ Units} \times 0.924532845 = 386.4547292$ , rounded down to 386, the nearest whole number).

### Over-Subscription Privilege

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional Units not subscribed for by other rights holders in the offering at the same subscription price of \$0.02 per Unit. If an insufficient number of Units is available to fully satisfy all over-subscription privilege requests, the available Units will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of Units each such holder subscribed for under the basic

TABLE OF CONTENTS

subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction promptly after expiration of the subscription period.

Subscription Price

\$0.02 per Unit, payable in cash. To be effective, any payment related to the exercise of a right must clear prior to the expiration of the subscription period.

Record Date

5:00 p.m., Eastern Time, on January 31, 2011.

Expiration Date

5:00 p.m., Eastern Time, on February 28, 2011, 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.

Non-Transferability of Rights

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

No Board Recommendation

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

Purchase Commitment of Lambda Investors

Our largest stockholder, Lambda Investors LLC, has committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266 Units under the purchase agreement. See The Rights Offering Background of the Rights Offering Purchase Agreement with Lambda Investors. Lambda Investors is not receiving any compensation for its purchase commitment. Any Units purchased by Lambda Investors and the shares and warrants to purchase shares of our common stock underlying them are not

TABLE OF CONTENTS

being registered pursuant to the registration statement of which this prospectus is a part, and thus may not be offered or sold except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act of 1933, as amended. See Plan of Distribution.

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 Units offered pursuant to this rights offering.

Extension, Cancellation and Amendment

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

Procedures for Exercising Rights

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

Payment Adjustments

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

TABLE OF CONTENTS

receive interest or a deduction on any payments refunded to you under the rights offering.

How Rights Holders Can Exercise Rights Through Others

If you hold our common stock 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.

How Foreign Stockholders and Other Stockholders Can Exercise Rights

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

Possible Restrictions on Exercise by Stockholders Residing in Certain States

We will not issue Units to any stockholder 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 Units 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.

Material U.S. Federal Income Tax Considerations

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

Conditions to the Rights Offering

The completion of the rights offering is subject to the following conditions:

8

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TABLE OF CONTENTS

the approval of our stockholders of an increase in our authorized shares of capital stock and common stock;

the term of Lambda Investors' existing warrants that will remain outstanding following the completion of the rights offering must be extended so that such warrants will expire at the same time as the warrants issued in the rights offering;

we must be in compliance with all terms of the promissory note and security agreements evidencing the loan to us from Lambda Investors;

the registration statement of which this prospectus is a part must be declared effective by the SEC; and

we must execute a registration rights agreement with Lambda Investors.

In addition, Lambda Investors' commitment to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, is subject to certain conditions, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering.

See [The Rights Offering](#), [Conditions to the Rights Offering](#) and [Background of the Rights Offering](#), [Purchase Agreement with Lambda Investors](#).

**Use of Proceeds**

Assuming all the Units offered are sold, the gross proceeds from the rights offering and under the purchase agreement with Lambda Investors will be approximately \$3,500,000. Our estimated net proceeds from the rights offering would be \$3,300,000, after deducting our estimated offering expenses of \$200,000. We are obligated to use proceeds from the rights offering to repay the \$500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$40,000) in respect of the loan and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. For a more detailed description of the loan, please see [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 further development of our product candidates, clinical trials, research and development expenses, and administrative expenses. Pending the application of any remaining net proceeds for

TABLE OF CONTENTS

these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities. See Use of Proceeds.

Issuance of Common Stock

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

Shares Outstanding Before the Rights Offering

41,811,048 shares of our common stock were outstanding as of the record date.

Shares Outstanding After Completion of the Rights Offering and the Private Placement of Units with Lambda Investors

As of the record date, we had 41,811,048 shares of our common stock issued and outstanding. If all of the Units offered are sold, we will issue 175,000,000 shares of our common stock in the rights offering and under the purchase agreement with Lambda Investors. Assuming all of the Units 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 and the private placement of Units with Lambda Investors, approximately 216,811,000 shares of our common stock will be outstanding immediately after the completion of the rights offering and the private placement of Units with Lambda Investors, which will equal approximately 10,840,000 shares after giving effect to our proposed 1-for-20 reverse stock split.

Subscription Agent

Continental Stock Transfer & Trust Company.

Information Agent

Morrow & Co. LLC.

Fees and Expenses

We will pay the fees and all of our expenses related to the rights offering. We will also pay Lambda Investors an aggregate of \$100,000 for reimbursement of legal fees incurred in connection with the loan and the rights offering. See Use of Proceeds.

Trading Symbol

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

Risk Factors

Participation in the rights offering and the purchase of Units involve substantial risks. See Risk Factors beginning on page 19 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 Morrow & Co. LLC at (800) 414-4313.

TABLE OF CONTENTS

# 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 non-transferable subscription rights to purchase Units. You will receive one subscription right for each share of common stock you owned as of 5:00 p.m., Eastern Time, on January 31, 2011, the record date. The subscription rights will be evidenced by rights certificates. Each subscription right will entitle the holder to a basic subscription privilege and an over-subscription privilege.

## What is the basic subscription privilege?

For each share that you own, you will have a basic subscription privilege to buy from us 4.185496618 Units at a subscription price of \$0.02 per Unit. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights.

If you choose to exercise your rights, there is no minimum number of Units you must purchase, but you may not purchase fractional Units. To determine the number of Units you may purchase under your basic subscription privilege, multiply the number of shares of our common stock you own by 4.185496618 and round down to the nearest whole number. For example, if you own 100 shares of our common stock, you will be entitled to subscribe for up to 418 Units ( $100 \text{ shares} \times 4.185496618 = 418.5496618$ , rounded down to 418, the nearest whole number) under your basic subscription privilege. Similarly, the warrant to purchase 0.92453 shares of our common stock included with each Unit you purchase will only be exercisable for a number of shares rounded down to the nearest whole number. For example, if you purchase 418 Units, the warrants included with those Units would be exercisable for up to 386 shares ( $418 \text{ Units} \times 0.924532845 = 386.4547292$ , rounded down to 386, the nearest whole number).

## What is the over-subscription privilege?

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional Units not subscribed for by other rights holders in the offering at the same subscription price of \$0.02 per Unit. If an insufficient number of Units is available to fully satisfy all over-subscription privilege requests, the available Units will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of Units each such holder subscribed for under the basic subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction promptly after expiration of the subscription period.

## Why are we conducting the rights offering?

We are conducting the rights offering to raise capital for our operations. Without additional capital, we will not have sufficient funds to continue our operations. With the proceeds from the note we issued to Lambda Investors, we estimate that we will be able to fund our operations into March 2011. The rights offering is expected to close in early March 2011. Upon the closing of the rights offering, we must first use proceeds to repay the \$500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$40,000) and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the



rights offering. We intend to use the remaining net proceeds, if any, for general corporate purposes, including further development of our product candidates, clinical trials, research and development expenses, and administrative 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 \$0.02 per Unit 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 175,000,000 Units consisting of shares and warrants to purchase shares of our common stock, and that it be made at a subscription price of \$0.02 per Unit to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.02 per Unit subscription price, were approved by a special committee of our

## TABLE OF CONTENTS

independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing alternatives available to us. In an effort to minimize the dilutive effect of the rights offering, Lambda Investors proposed that it would surrender for cancellation warrants (after giving effect to the anti-dilution provisions contained therein that will be triggered by the rights offering) to purchase a number of shares equal to the total number of shares underlying the warrants to be issued in the rights offering. The special committee considered, among other things, that (i) 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, and (ii) even if we were able to make such an offering, without any inducement for Lambda Investors to surrender for cancellation a portion of its existing warrants as it has agreed to do in the rights offering, the dilution suffered by current investors would have been approximately equal to or greater than the dilution that participating investors will be subject to in the rights offering. See The Rights Offering Dilution. The \$0.02 per Unit subscription price was not based on any discount to the market price of our common stock. The subscription price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the Units being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price.

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

No. You may exercise any number of your subscription rights, or you may choose not to exercise any subscription rights. However, if you choose not to fully exercise your basic subscription privilege and other stockholders fully exercise their basic subscription privilege, the percentage of our common stock owned by these other stockholders will increase relative to your ownership percentage, and your voting and other rights will likewise be significantly diluted. In addition, if you do not exercise your basic subscription privilege in full, you will not be entitled to subscribe to purchase additional Units pursuant to the over-subscription privilege and your ownership percentage in our common stock and related voting and other rights may be further diluted relative to those stockholders that do.

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

The subscription rights may be exercised at any time beginning on the date of this prospectus and prior to 5:00 p.m., Eastern Time, on the expiration date, which is February 28, 2011. 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, subject to the approval of Lambda Investors, 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 or change my election to exercise my subscription rights?**

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 Units 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

12

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TABLE OF CONTENTS

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. However, one of the conditions to Lambda Investors' obligation to exercise its basic subscription privilege is that stockholders not affiliated with Lambda Investors subscribe for at least 50% of the Units offered in 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 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 subscription price of a Unit or that anyone purchasing Units 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. To complete the rights offering, our stockholders had to approve an amendment to our certificate of incorporation to increase the authorized shares of capital stock from 95,000,000 shares to 905,000,000 shares and the authorized shares of common stock from 90,000,000 to 900,000,000 shares. This amendment is necessary to ensure we have enough shares to effect the rights offering. Without the increase in the authorized shares, we would not be able to complete the rights offering. We received stockholder approval for such amendment at our annual meeting of stockholders held on January 10, 2011. We intend to file a certificate of amendment to our certificate of incorporation providing for such share increase immediately prior to the closing of the rights offering. Additional conditions to the rights offering include that the registration statement of which this prospectus is a part must be declared effective by the SEC and that we execute a registration rights agreement with Lambda Investors.

We must also be in compliance with all terms of the promissory note and security agreements evidencing the loan to us by Lambda Investors.

Further, the term of Lambda Investors' existing warrants that will remain outstanding following the completion of the rights offering will be amended so that such warrants expire at the same time as the warrants issued in the rights offering, which will have a five-year term. We will amend Lambda Investors' remaining warrants as part of completing the rights offering.

In addition, Lambda Investors' commitment to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, is subject to certain conditions, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering.

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

As of the record date, warrants to purchase 8,191,827 shares of our common stock were outstanding. Upon completion of the rights offering, warrants to purchase 7,519,246 of those shares will become exercisable for an aggregate of 337,108,164 shares at an exercise price of \$0.02 per share as a result of the

## TABLE OF CONTENTS

full-ratchet anti-dilution provisions contained in those warrants. Following the closing of the rights offering, and after giving effect to these anti-dilution provisions, Lambda Investors has agreed to surrender for cancellation warrants to purchase 161,793,248 shares of our common stock, which will equal the number of shares underlying warrants issued as part of the Units, assuming all Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold. If Lambda Investors purchases 60,194,226 Units under the purchase agreement, it will receive warrants to purchase 55,651,539 shares of our common stock. In addition, following the closing of the rights offering, Lambda Investors' existing warrants to purchase 161,793,247 shares that remain outstanding will be amended to expire at the same time as the warrants issued in the rights offering, which will have a five-year term. Assuming all Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold and after giving effect to the surrender of existing warrants by Lambda Investors, immediately after the completion of the rights offering and the private placement of Units with Lambda Investors we will have outstanding warrants to purchase an aggregate of 337,108,164 shares of our common stock at an exercise price of \$0.02 per share and warrants to purchase another 672,581 shares of our common stock that will not be affected by the rights offering.

The rights offering will have no effect on any of our outstanding options. We currently have 2,696,976 shares of common stock authorized for issuance under our 2004 Stock Incentive Plan, which we refer to as the 2004 Plan, of which 1,650,708 remain eligible for future grant. Our board of directors and our stockholders, at our annual meeting of stockholders held on January 10, 2011, approved an increase in the number of shares authorized for issuance under the 2004 Plan to 39,814,340. If this amendment to the 2004 Plan and a proposed 1-for-20 reverse stock split are both implemented by our board, we will have 1,990,717 shares authorized for issuance under the 2004 Plan.

### **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 on the record date have the same basic subscription and over-subscription privileges as other stockholders. We caution you that the board of directors or members of the executive management team do not make any recommendation regarding your exercise of subscription rights.

### **Have any stockholders committed to purchase any Units?**

Lambda Investors, our largest stockholder, has committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266 Units under the purchase agreement. See *The Rights Offering Background of the Rights Offering Purchase Agreement with Lambda Investors*. Lambda Investors is not receiving any compensation for its purchase commitment. Any Units purchased by Lambda Investors and the shares and warrants to purchase shares of our common stock underlying them are not being registered pursuant to the registration statement of which this prospectus is a part, and thus may not be offered or sold except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act of 1933, as amended. See *Plan of Distribution*.

If Lambda Investors purchases 60,194,226 Units under the purchase agreement, it will acquire 60,194,226 shares of our common stock and receive warrants to purchase 55,651,539 shares of our common stock. Assuming Lambda Investors purchases no additional Units or shares of our common stock, does not exercise any of its existing warrants and surrenders warrants to purchase 161,793,248 shares for cancellation, as contemplated if all Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold, Lambda Investors will own 74,575,847 shares, or approximately 34.4%, of our issued and outstanding shares of common stock and warrants to purchase 217,444,786 shares of our common stock

## TABLE OF CONTENTS

following the closing of the rights offering, representing beneficial ownership of 67.2% of our common stock. Consequently, Lambda Investors would continue to be able to exercise substantial control over matters requiring stockholder approval upon completion of the rights offering. Please see [Risk Factors](#) [Risks Related to the Rights Offering](#) [Lambda Investors will continue to be able to exercise substantial control over matters requiring stockholder approval upon completion of the rights offering](#) and [Risks Related to Our Common Stock and Warrants](#) [Our directors, executive officers and principal stockholders control, and upon completion of the rights offering will continue to 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](#) for more information.

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

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

If you hold your shares of our common stock 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 with a foreign address or a stockholder with an APO or FPO address?**



The subscription agent will not mail rights certificates to you if you are a stockholder 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.

## **After I send in my payment and rights certificate, may I cancel my exercise of subscription rights?**

No. All exercises of subscription rights are irrevocable, even if you later learn information that you consider to be unfavorable to the exercise of your subscription rights. You should not exercise your subscription rights unless you are certain that you wish to purchase Units at the subscription price of \$0.02 per Unit.

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

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 and warrants underlying the Units purchased in the rights offering.

## TABLE OF CONTENTS

Subject to state or foreign securities laws and regulations, we have the discretion to delay distribution of any shares and warrants underlying Units 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, warrants and options will be outstanding after the rights offering?**

As of the record date, we had 41,811,048 shares of our common stock issued and outstanding. If all of the Units offered are sold, we will issue 175,000,000 shares of our common stock in the rights offering and under the purchase agreement with Lambda Investors. Assuming all of the Units 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 and the private placement of Units with Lambda Investors, approximately 216,811,000 shares of our common stock will be outstanding immediately after the completion of the rights offering and the private placement of Units with Lambda Investors, which will equal approximately 10,840,000 shares after giving effect to our proposed 1-for-20 reverse stock split.

On the record date, warrants to purchase 8,191,827 shares of our common stock were outstanding. Upon completion of the rights offering, warrants to purchase 7,519,246 of those shares will become exercisable for an aggregate of 337,108,164 shares at an exercise price of \$0.02 per share as a result of the full-ratchet anti-dilution provisions contained in those warrants. Following the closing of the rights offering, and after giving effect to these anti-dilution provisions, Lambda Investors has agreed to surrender for cancellation warrants to purchase 161,793,248 shares of our common stock, which will equal the number of shares underlying warrants issued as part of the Units, assuming all of the Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold. After giving effect to the surrender for cancellation by Lambda Investors of such warrants to purchase 161,793,248 shares of our common stock, immediately after the completion of the rights offering and the private placement of Units with Lambda Investors, we will have outstanding warrants to purchase an aggregate of 337,108,164 shares of our common stock at an exercise price of \$0.02 per share and warrants to purchase another 672,581 shares of our common stock will not be affected by the rights offering. After giving effect to our proposed 1-for-20 reverse stock split, we anticipate having outstanding warrants to purchase approximately 16,889,000 shares of our common stock.

The rights offering will have no effect on any of our outstanding options. We currently have 2,696,976 shares of common stock authorized for issuance under the 2004 Plan, of which 1,650,708 remain eligible for future grant. Our board of directors and our stockholders, at our annual meeting of stockholders held on January 10, 2011, approved an increase in the number of shares authorized for issuance under the 2004 Plan to 39,814,340. If this amendment to the 2004 Plan and a proposed 1-for-20 reverse stock split are both implemented by our board, we will have 1,990,717 shares authorized for issuance under the 2004 Plan. After giving effect to the proposed 1-for-20 reverse stock split, we anticipate having outstanding options to purchase approximately 44,000 shares of our common stock.

### **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. The total proceeds to us from the rights offering will depend on the number of subscription rights that are exercised. For every 100,000 Units subscribed for in the rights offering, we will raise \$20,000 in gross proceeds. Assuming all the Units offered are sold, the gross proceeds from the rights offering and under the purchase agreement with Lambda Investors will be \$3,500,000. It is estimated that the expenses of the rights offering will be \$200,000, and an estimated \$620,000 of the

proceeds will be used to pay the principal, interest and fees associated with the note to Lambda Investors.

## **Are there risks in exercising my subscription rights or purchasing Units?**

Yes. The exercise of your subscription rights involves substantial risks. Exercising your subscription rights involves the purchase of shares of our common stock and warrants underlying the Units. The purchase of Units 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.

16

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TABLE OF CONTENTS

## **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 or warrants be listed on a stock exchange or national market?**

No. Neither the subscription rights nor warrants to purchase our common stock will be listed for trading on any stock exchange or market or on the OTC Bulletin Board.

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

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

## **May stockholders 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, we reserve the right in some states to require stockholders, 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 Units?**

We are not charging any fee or sales commission to issue subscription rights to you or to issue shares and warrants 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?**

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 The Rights Offering Material U.S. Federal Income Tax Consequences. You should consult your tax advisor as to the particular consequences to you of the rights offering.

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

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

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

TABLE OF CONTENTS

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 Morrow & Co., LLC, our information agent for this offering, at (203) 658-9400 (for brokerage firms and banks) or toll-free at (800) 414-4313 (for stockholders).

TABLE OF CONTENTS

## **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**

#### **If we do not successfully complete the rights offering, we expect that we will have to cease and wind down operations.**

We are in immediate need of capital. We expect that our funds on hand will allow us to operate into March 2011. The rights offering is expected to close in early March 2011. If we do not complete the rights offering in March 2011, we will not have sufficient resources to fund our operations. In that event, we will be forced to cease and wind down operations unless we can find another source of financing immediately, which we believe would be extremely difficult and may not be possible on acceptable terms or at all.

#### **Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2009, expressed substantial doubt about our ability to continue as a going concern.**

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

The accompanying financial statements have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses since inception 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 will be forced to cease operations and you will lose all of your investment in our 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 September 30, 2010, we had an accumulated deficit of approximately \$91,243,000 primarily as a result of our research and development expenses and selling, general and administrative expenses. 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 action of the FDA on our 501(k) application for our hemodiafiltration system;  
the completion and success of additional clinical trials and of our regulatory approval processes for each of our ESRD therapy products in our target territories;  
the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;

our ability to effectively and efficiently manufacture, market and distribute our products;  
our ability to sell our products at competitive prices which exceed our per unit costs; and  
the consolidation of dialysis clinics into larger clinical groups.



TABLE OF CONTENTS

**We require additional financing in the near future to fund our operations.**

At September 30, 2010, we had cash and cash equivalents totaling approximately \$421,000 and tangible assets of approximately \$1,682,000. As of September 30, 2010, we estimated that these funds would allow us to keep operating only into the fourth quarter of 2010. We expect that the \$500,000 we raised in September 2010 from the issuance of the note to Lambda Investors will allow us to operate into March 2011. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, we will be forced to cease operations and you will lose all of your investment in our company.

**If we do not receive FDA approval for our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter our operations will be significantly and adversely harmed.**

We have not received approval from the FDA for our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial.

We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

We can give no assurance when or if our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter will be approved by the FDA. If we fail to ultimately receive FDA approval, our operations would be significantly and adversely harmed.

**We have limited experience selling our DSU water filtration system to dialysis clinics, and we might be unsuccessful in increasing our sales.**

Our business strategy depends in part on our ability to sell our DSU water filtration system to hospitals and other healthcare facilities that include dialysis clinics. On July 1, 2009, we received approval from the FDA to market our DSU to dialysis clinics. We have limited experience at sales and marketing. If we are unsuccessful at manufacturing, marketing and selling our DSU, our operations and potential revenues might be adversely affected.

**Certain customers individually account for a large portion of our product sales, and the loss of any of these customers could have a material adverse effect on our sales.**

For the year ended December 31, 2009, two customers accounted for 87% of our product sales. In addition, those customers represented 78% of our accounts receivable as of December 31, 2009. We believe that the loss of either or

both of these customers would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customers and/or self-distribute in the territories currently served by such customers.

**We cannot sell our ESRD therapy 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. We have not obtained FDA approval for any of our ESRD therapy products, except for our HD190 filter, and cannot sell any of our other ESRD therapy products in the United States unless and until we obtain such approval. 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 obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the

TABLE OF CONTENTS

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 MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage Ultrafilter (DSU). We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance.

In addition to the pre-market notification required pursuant to Section 510(k) of the FDC Act, the FDA could require us to obtain pre-market approval of our ESRD therapy products under Section 515 of the FDC Act, either because of legislative or regulatory changes or because the FDA does not agree with our determination that we are eligible to use the Section 510(k) pre-market notification process. The Section 515 pre-market approval process is a significantly more costly, lengthy and uncertain approval process and could materially delay our products coming to market. If we do obtain clearance for marketing of any of our devices under Section 510(k) of the FDC Act, then any changes we wish to make to such device that could significantly affect safety and effectiveness will require clearance of a notification pursuant to Section 510(k), and we may need to submit clinical and manufacturing comparability data to obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the United States.

The clearance and/or approval processes in the European Community and in the United States 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 any FDA approval for any of our ESRD therapy 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 with respect to the European Community or the United States would prevent us from selling our affected products in these regions. If we cannot sell some of our products in these 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.

If we are successful in our initial marketing efforts in some or all of our Target European Market and the United States, then we plan to market our ESRD therapy products in several countries outside of our Target European Market and the United States, including Korea and China, Canada and Mexico. Requirements pertaining to the sale of medical devices vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our ESRD therapy products in many of these 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 ESRD therapy products outside of our Target European Market and the United States, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

**Clinical studies required for our ESRD therapy products are costly and time-consuming, and their outcome is uncertain.**

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the

We cannot sell our ESRD therapy products, including certain modifications thereto, until we obtain the requisite regulatory

patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of

TABLE OF CONTENTS

action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our ESRD therapy products are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our ESRD therapy 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 ESRD therapy product;  
adverse medical events or side effects in treated subjects; and  
lack of effectiveness of the ESRD therapy 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 FDA policy for device approval during the period of product development and FDA regulatory review of each submitted new device application. We may encounter similar delays in foreign countries. 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 ESRD therapy product in countries, including the U.S., in which our products are not yet approved for sale, which may result in significant expense and delay. The FDA and foreign regulatory authorities 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 FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our ESRD therapy products. It is possible that the FDA or foreign regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are

positive.

TABLE OF CONTENTS

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

We cannot assure you that our ESRD therapy products will be safe. Under the FDC Act, we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and product malfunctions that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

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

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

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

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to gain market acceptance of our ESRD therapy 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 ESRD therapy products.

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

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of \$5,000,000 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 in certain amounts; 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

We cannot assure you that our ESRD therapy products will be safe and we are required under applicable law to report

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

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

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our ESRD therapy products. If we violate the FDC Act or other regulatory requirements at any





Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 16 granted U.S. patents will expire at various times from 2018 to 2022, assuming they are properly maintained.

TABLE OF CONTENTS

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 our trademarks and trade names are not adequately protected, then we may not be able to build brand loyalty and our sales and revenues may suffer.**

If we are not able to secure and enforce protection of our trade secrets through enforcement of our confidentiality a

Our registered or unregistered trademarks or trade names may be challenged, cancelled, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build brand loyalty. Over the long term, if we are unable to establish a brand based on our trademarks and trade names, then we may not be able to compete effectively and our sales and revenues may suffer.

TABLE OF CONTENTS

**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 OLpur MDHDF filter series and our other products, including the DSU. 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.

**We will not control the independent manufacturers of our products, which may affect our ability to deliver our products in a timely manner. If we are not able to ensure the timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.**

Independent manufacturers of medical devices will manufacture all of our products and components. We have contracted with our CM to assemble and produce our OLpur MD190, MD220 and possibly other filters, including our DSU, and have an agreement with FS, a manufacturer of medical and technical membranes for applications like dialysis, to produce the fiber for the OLpur MDHDF filter series. As with any independent contractor, these manufacturers will not be employed or otherwise controlled by us and will be generally free to conduct their business at their own discretion. For us to compete successfully, among other things, our products must be manufactured on a timely basis in commercial quantities at costs acceptable to us. If one or more of our independent manufacturers fails to deliver our products in a timely manner, then we may not be able to find a substitute manufacturer. If we are not or if potential customers believe that we are not able to ensure timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.

**The loss or interruption of services of any of our manufacturers could slow or stop production of our products, which would limit our ability to generate sales and revenues.**

Because we are likely to rely on no more than two contract manufacturers to manufacture each of our products and major components of our products, a stop or significant interruption in the supply of our products or major components by a single manufacturer, for any reason, could have a material adverse effect on us. We expect most of our contract manufacturers will enter into contracts with us to manufacture our products and major components and that these contracts will be terminable by the contractors or us at any time under certain circumstances. We have not made alternative arrangements for the manufacture of our products or major components and we cannot be sure that acceptable alternative arrangements could be made on a timely basis, or at all, if one or more of our manufacturers

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

failed to manufacture our products or major components in accordance with the terms of our arrangements. If any such failure occurs and we are unable to obtain acceptable alternative arrangements for the manufacture of our products or major components of our products, then the production and sale of our products could slow down or stop and our cash flow would suffer.

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

Approval or clearance of our ESRD therapy products could be delayed 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

TABLE OF CONTENTS

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 ESRD therapy 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 ESRD therapy 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. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H<sub>2</sub>H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. 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 ESRD therapy 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 ESRD therapy 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 ESRD therapy products manufactured in such facilities and our revenues may be materially adversely affected.

**If our products are commercialized, we may face significant challenges in obtaining market acceptance of such 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 ESRD therapy products in the marketplace by both potential users, including ESRD 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 ESRD therapy 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 ESRD 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;

If we are not able to maintain sufficient quality controls, then the approval or clearance of our ESRD therapy products

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.

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TABLE OF CONTENTS

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 ESRD 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 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 you 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 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 in our Target European Market and elsewhere outside of the United States. We expect that our revenues from our Target European Market will initially account for a significant portion of our revenues. 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.

**If we are unable to keep our key management and scientific personnel, then we are likely to face significant delays at a critical time in our corporate development and our business is likely to be damaged.**

Our success depends upon the skills, experience and efforts of our management and other key personnel, including our chief executive officer, certain members of our scientific and engineering staff and our marketing executives. As a relatively new company, much of our corporate, scientific and technical knowledge is concentrated in the hands of these few individuals. We do not maintain key-man life insurance on any of our management or other key personnel.

The recent resignation of our Chief Executive Officer or the loss of the

TABLE OF CONTENTS

services of one or more of our present management or other key personnel could significantly delay the development and/or launch of our products as there could be a learning curve of several months or more for any replacement personnel. Furthermore, competition for the type of highly skilled individuals we require is intense and we may not be able to attract and retain new employees of the caliber needed to achieve our objectives. Failure to replace key personnel could have a material adverse effect on our business, financial condition and operations.

## **Risks Related to the ESRD Therapy Industry**

**We expect to face significant competition from existing suppliers of renal replacement therapy devices, supplies and services. If we are not able to compete with them effectively, then we may not be profitable.**

We expect to compete in the ESRD therapy market with existing suppliers of hemodialysis and peritoneal dialysis devices, supplies and services. Our competitors include Fresenius Medical Care AG and Gambro AB, currently two of the primary machine manufacturers in hemodialysis, as well as B. Braun Biotech International GmbH, and Nikkiso Corporation and other smaller machine manufacturers in hemodialysis. B. Braun Biotech International GmbH, Fresenius Medical Care AG, Gambro AB and Nikkiso Corporation also manufacture HDF machines. These companies and most of our other competitors have longer operating histories and substantially greater financial, marketing, technical, manufacturing and research and development resources and experience than we have. Our competitors could use these resources and experiences to develop products that are more effective or less costly than any or all of our products or that could render any or all of our products obsolete. Our competitors could also use their economic strength to influence the market to continue to buy their existing products.

We do not have a significant established customer base and may encounter a high degree of competition in further developing one. Our potential customers are a limited number of nephrologists, national, regional and local dialysis clinics and other healthcare providers. The number of our potential customers may be further limited to the extent any exclusive relationships exist or are entered into between our potential customers and our competitors. We cannot assure you that we will be successful in marketing our products to these potential customers. If we are not able to develop competitive products and take and hold sufficient market share from our competitors, we will not be profitable.

**Some of our competitors own or could acquire dialysis clinics throughout the United States, our Target European Market and other regions of the world. We may not be able to successfully market our products to the dialysis clinics under their ownership. If our potential market is materially reduced in this manner, then our potential sales and revenues could be materially reduced.**

Some of our competitors, including Fresenius Medical Care AG and Gambro AB, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. In 2005, Gambro AB divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, Inc., whereby DaVita, Inc. will purchase a significant amount of renal products and supplies from Gambro AB Renal Products. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius Medical Care AG Form 20-F Annual Report for the year ended December 31, 2009, Fresenius Medical Care AG provides treatment in its own dialysis clinics to approximately 195,651 patients in

its facilities around the world including facilities located in the North America. According to DaVita, Inc.'s Annual Report for the year ended December 31, 2009, DaVita, Inc. provides treatment in 1,530 outpatient dialysis centers serving approximately 118,000 patients in the United States.

We believe that there is currently a trend among ESRD therapy providers towards greater consolidation. If such consolidation takes the form of our competitors acquiring independent dialysis clinics, rather than such dialysis clinics banding together in independent chains, then more of our potential customers would also be our competitors. If our competitors continue to grow their networks of dialysis clinics, whether organically or through consolidation, and if we cannot successfully market our products to dialysis clinics owned by these competitors or any other competitors and do not acquire clinics ourselves, then our revenues could be adversely affected.

TABLE OF CONTENTS

**If the size of the potential market for our products is significantly reduced due to pharmacological or technological advances in preventative and alternative treatments for ESRD, then our potential sales and revenues will suffer.**

Pharmacological or technological advances in preventative or alternative treatments for ESRD could significantly reduce the number of ESRD patients needing our products. These pharmacological or technological advances may include:

the development of new medications, or improvements to existing medications, which help to delay the onset or prevent the progression of ESRD in high-risk patients (such as those with diabetes and hypertension);

the development of new medications, or improvements in existing medications, which reduce the incidence of kidney transplant rejection; and

developments in the use of kidneys harvested from genetically-engineered animals as a source of transplants.

If these or any other pharmacological or technological advances reduce the number of patients needing treatment for ESRD, then the size of the market for our products may be reduced and our potential sales and revenues will suffer.

**If government and other third party reimbursement programs discontinue their coverage of ESRD treatment or reduce reimbursement rates for ESRD products, then we may not be able to sell as many units of our ESRD therapy products as otherwise expected, or we may need to reduce the anticipated prices of such products and, in either case, our potential revenues may be reduced.**

Providers of renal replacement therapy are often reimbursed by government programs, such as Medicare or Medicaid in the United States, or other third-party reimbursement programs, such as private medical care plans and insurers. We believe that the amount of reimbursement for renal replacement therapy under these programs has a significant impact on the decisions of nephrologists, dialysis clinics and other health care providers regarding treatment methods and products. Accordingly, changes in the extent of coverage for renal replacement therapy or a reduction in the reimbursement rates under any or all of these programs may cause a decline in recommendations or purchases of our products, which would materially adversely affect the market for our products and reduce our potential sales. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could also reduce our potential revenues.

**As the number of managed health care plans increases in the United States, amounts paid for our ESRD therapy products by non-governmental programs may decrease and we may not generate sufficient revenues to be profitable.**

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of

these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our ESRD therapy products or sell fewer units, and, in either case, our potential revenues would suffer.

**If HDF does not become a preferred therapy for ESRD, then the market for our ESRD therapy products may be limited and we may not be profitable.**

A significant portion of our success is dependent on the acceptance and implementation of HDF as a preferred therapy for ESRD. There are several treatment options currently available and others may be developed. HDF may not increase in acceptance as a preferred therapy for ESRD. If it does not, then the market for our ESRD therapy products may be limited and we may not be able to sell a sufficient quantity of our products to be profitable.

TABLE OF CONTENTS

**If the per-treatment costs for dialysis clinics using our ESRD therapy products are higher than the costs of clinics providing hemodialysis treatment, then we may not achieve market acceptance of our ESRD therapy products in the United States and our potential sales and revenues will suffer.**

If the cost of our ESRD therapy products results in an increased cost to the dialysis clinic over hemodialysis therapies and such cost is not separately reimbursable by governmental programs or private medical care plans and insurers outside of the per-treatment fee, then we may not gain market acceptance for such products in the United States unless HDF therapy becomes the standard treatment method for ESRD. If we do not gain market acceptance for our ESRD therapy products in the United States, then the size of our market and our anticipated sales and revenues will be reduced.

**Proposals to modify the health care system in the United States or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, then our margins and our profitability will be adversely affected.**

A substantial portion of the cost of treatment for ESRD in the United States is currently reimbursed by the Medicare program at prescribed rates. Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the U.S. Congress passed landmark healthcare legislation. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We anticipate that the U.S. Congress and state legislatures will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in the Medicare program could affect the pricing of our ESRD therapy products. As we are not yet established in our business and it will take some time for us to begin to recoup our research and development costs, our profit margins are likely initially to be lower than those of our competitors and we may be more vulnerable to small decreases in price than many of our competitors.

Health administration authorities in countries other than the United States may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the United States, these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates for dialysis products.

Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our ESRD therapy products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

**If patients in our Target European Market were to reuse dialyzers, then our potential product sales could be materially adversely affected.**

In the United States, a majority of dialysis clinics reuse dialyzers that is, a single dialyzer is disinfected and reused by the same patient. However, the trend in our Target European Market is towards not reusing dialyzers, and some countries (such as France, Germany, Italy and the Netherlands) actually forbid the reuse of dialyzers. As a result, each

If HDF does not become a preferred therapy for ESRD, then the market for our ESRD therapy products may be limited.

patient in our Target European Market can generally be expected to purchase more dialyzers than each United States patient. The laws forbidding reuse could be repealed and it may become generally accepted to reuse dialyzers in our Target European Market, just as it currently is in the United States. If reuse of dialyzers were to become more common among patients in our Target European Market, then there would be demand for fewer dialyzer units and our potential product sales could be materially adversely affected.

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

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

If we raise \$3,500,000 in gross proceeds from the rights offering and under the purchase agreement with Lambda Investors, we expect that we will be able to operate through the fourth quarter of 2011. Thereafter we will need additional capital. There can be no assurance that we will be able to raise additional capital at that



TABLE OF CONTENTS

time. If we are unable to raise capital when needed, we will not be able to execute our business strategy and accomplish our objectives, we will 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 175,000,000 Units consisting of shares and warrants to purchase shares of our common stock, and that it be made at a subscription price of \$0.02 per Unit to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.02 per Unit 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. In an effort to minimize the dilutive effect of the rights offering, Lambda Investors proposed that it would surrender for cancellation a portion of its existing warrants containing anti-dilution provisions that will be triggered by the rights offering. The number of shares underlying such cancelled warrants would equal the total number of shares underlying the warrants to be issued in the rights offering. The special committee considered, among other things, that (i) 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, and (ii) even if we were able to make such an offering, without any inducement for Lambda Investors to surrender for cancellation a portion of its existing warrants as it has agreed to do in the rights offering, the dilution suffered by current investors would have been greater than the dilution participating stockholders will be subject to in the rights offering. See The Rights Offering Dilution. The \$0.02 per Unit subscription price was not based on any discount to the market price of our common stock. The subscription price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the Units 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. These factors include, among other things: the FDA's action regarding our 501(k) application for our hemodiafiltration system; 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; and sales of our common stock.

Once you exercise your subscription rights, you may not revoke them. We cannot assure you that the market price of our common stock will not decline after you elect to exercise your subscription rights. If you exercise your subscription rights and, afterwards, the public trading market price of our common stock decreases below the subscription price, you will have committed to buying shares of our common stock at a price above the prevailing market price and could have an immediate unrealized loss. Our common stock is quoted on the OTC Bulletin Board

Even assuming a successful completion of the rights offering, we will need additional capital in the future. 65

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under the ticker symbol NEPH, and the last reported sales price of our common stock on the OTC Bulletin Board on January 26, 2011 was \$0.105 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.

32

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TABLE OF CONTENTS

**If you do not exercise your subscription rights at all, your percentage ownership and voting rights in our company will be significantly diluted.**

If you choose not to exercise your subscription rights, you will retain your current number of shares of common stock of our company. However, if you choose not to exercise your subscription rights and all of the Units offered are sold to other stockholders, you will experience significant (over 80%) dilution in your percentage ownership and voting rights in our company as other stockholders acquire an aggregate of 175,000,000 shares of common stock and warrants to purchase 161,793,248 shares of common stock in the rights offering.

**Even if you do exercise your subscription rights in full, your percentage ownership and voting rights in our company will be diluted to the extent that existing warrants containing anti-dilution provisions triggered by the rights offering are held and exercised by stockholders other than you.**

Upon completion of the rights offering, warrants to purchase 7,519,246 shares of our common stock will become exercisable for an aggregate of 337,108,164 shares at an exercise price of \$0.02 per share as a result of full-ratchet anti-dilution provisions contained in those warrants. Following the closing of the rights offering, and after giving effect to these anti-dilution provisions, Lambda Investors has agreed to surrender for cancellation warrants to purchase 161,793,248 shares of our common stock, which will equal the number of shares underlying warrants issued as part of the Units, assuming all Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold. After giving effect to the surrender for cancellation by Lambda Investors of such warrants to purchase 161,793,248 shares of our common stock, existing warrants to purchase 167,795,670 shares of our common stock will remain outstanding. To the extent such warrants are exercised by stockholders other than you, you will experience dilution in your percentage ownership and voting rights in our company, even if in the rights offering you exercise your basic subscription privilege in full. For example, if warrants to purchase 25%, or 41,948,917, of such shares were exercised by stockholders other than you, you would see your percentage ownership and voting rights decrease by about 10%. If warrants to purchase 50%, or 83,897,835, of such shares were exercised by stockholders other than you, you would see your percentage ownership and voting rights decrease by about 18%. If warrants to purchase 75%, or 125,846,752, of such shares were exercised by stockholders other than you, you would see your percentage ownership and voting rights decrease by about 25%. If warrants to purchase 100%, or all 167,795,670, of such shares were exercised by stockholders other than you, you would see your percentage ownership and voting rights decrease by about 31%.

**Lambda Investors will continue to be able to exercise substantial control over matters requiring stockholder approval upon completion of the rights offering.**

As of the record date, Lambda Investors beneficially owned approximately 43.9% of the outstanding shares of our common stock (which includes warrants to purchase an aggregate of 7,190,811 shares of our common stock). Lambda Investors has committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266

If you do not exercise your subscription rights at all, your percentage ownership and voting rights in our company will

Units under the purchase agreement. See The Rights Offering Background of the Rights Offering Purchase Agreement with Lambda Investors. If Lambda Investors purchases these 60,194,226 Units, the beneficial ownership percentage of Lambda Investors following completion of the rights offering will increase to approximately 67.2% of our common stock (after giving effect to the anti-dilution provisions contained in its existing warrants and its surrender of a portion of these warrants upon completion of the rights offering). If this occurs, it will enhance the ability Lambda Investors already has to exercise substantial control over matters requiring stockholder approval. Your interests as a holder of common stock may differ from the interests of Lambda Investors.

TABLE OF CONTENTS

**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 offering to repay the \$500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$40,000) and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. We intend to use the remaining net proceeds, if any, for general corporate purposes, including further development of our product candidates, clinical trials, research and development expenses, and administrative 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 wishing to purchase Units 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 February 28, 2011. 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, or if you exercise your over-subscription privilege and are not allocated all of the Units for which you over-subscribe, neither we nor the subscription agent will have any obligation with respect to the subscription rights except to return, without interest, any subscription payments to you.

**The shares purchased by you in this offering may be cashed out pursuant to the proposed 1-for-20 reverse stock split.**

On January 10, 2011, our stockholders approved a 1-for-20 reverse stock split of our outstanding shares of common stock. A 1-for-20 reverse stock split reduces the number of shares outstanding: for example, if you own 1,000 shares prior to the 1-for-20 reverse split, you will own a total of 50 shares after the split. Our board of directors intends to implement the 1-for-20 reverse stock split immediately following the completion

## TABLE OF CONTENTS

of this offering. In the 1-for-20 reverse stock split, our board of directors intends to cash out fractional shares at a price equal to the average closing sale price of shares of common stock for the ten trading days immediately prior to the date the 1-for-20 reverse stock split becomes effective, or, if no such sale takes place on such days, the average of the closing bid and ask prices for such days, in each case as officially reported by the OTC Bulletin Board, which we refer to as the cash out price. If the shares currently held by you and the shares purchased by you in this offering result in a fractional interest following the 1-for-20 reverse stock split, then such fractional interests will be cashed out at the cash out price, which may be less than or greater than the \$0.02 per Unit subscription price.

### **Our future capital needs could result in dilution of your investment.**

Our board of directors may determine from time to time that we need to raise additional capital by issuing additional shares of our common stock or other securities. These issuances could dilute the ownership interests of purchasers of our securities in this offering and may dilute the per share book value of our common stock or other securities. Investors in future stock offerings also may have rights, preferences and privileges that are senior to, and that adversely affect, our then current shareholders.

## **Risks Related to Our Common Stock and Warrants**

### **There currently is a limited market for our common stock.**

Our common stock is quoted on the Over-the-Counter, or OTC, Bulletin Board. Prior to January 22, 2009, our common stock was listed on the AMEX. Trading in our common stock on both AMEX and the OTC Bulletin Board has been very limited, which could affect the price of our stock. We have no plans, proposals, arrangements or understandings with any person with regard to the development of an active trading market for our common stock, and no assurance can be given that an active trading market will develop.

### **The prices at which shares of our common stock trade have been and will likely continue to be volatile.**

Since January 1, 2008, our common stock has traded at prices ranging from a high of \$2.63 to a low of \$0.01 per share. Due to the lack of an active 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:

- The action by the FDA on our 501(k) application for our hemodiafiltration system;
- 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;  
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.



TABLE OF CONTENTS

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.

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

The warrants being issued in connection with the rights offering will be exercisable immediately upon issuance and will expire five years thereafter. The market price of our common stock may fall below the exercise price for these warrants prior to their expiration. Any warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the holders of warrants.

**There is no public market for the warrants to purchase common stock in this offering.**

There is no established public trading market for the warrants included in the Units being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for quotation or listing of the warrants on the OTC Bulletin Board any securities exchange or market or on the OTC Bulletin Board. Without an active market, the liquidity of the warrants will be limited.

There can be no assurance that a market will ever develop for the warrants. Even if a market for the warrants does develop, the price of the warrants may fluctuate and liquidity may be limited. If a market for the warrants does not develop, then purchasers of the warrants may be unable to resell the warrants or sell them only at an unfavorable price for an extended period of time, if at all. Resale prices of the warrants will depend on many factors, including:

our operating performance and financial condition;  
our ability to continue the effectiveness of the registration statement, of which this prospectus is a part, covering warrants and the common stock issuable upon exercise of the warrants;  
the interest of securities dealers in making a market; and  
the market for similar securities.

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

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

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

settle the warrants for cash, the market for such warrants may be limited, such warrants may expire worthless and, as a result, an investor may have paid the full price solely for the shares of common stock included in the Units.

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

No warrants will be exercisable and we will not be obligated to issue shares of common stock unless the shares of common stock issuable upon such exercise have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Because the exemptions from

TABLE OF CONTENTS

qualification in certain states for resales of warrants and for issuances of common stock by the issuer upon exercise of a warrant may be different, a warrant may be held by a holder in a state where an exemption is not available for issuance of common stock upon an exercise and the holder will be precluded from exercise of the warrant. As a result, the warrants may be deprived of any value, the market for the warrants may be limited, the holders of the warrants may not be able to exercise their warrants and they may expire worthless if the common stock issuable upon such exercise is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside.

**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 or quoted on any market of the NASDAQ Stock Market 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.

**Our fourth amended and restated certificate of incorporation, as amended, limits liability of our directors and officers, which could discourage you or other stockholders from bringing suits against our directors or officers in circumstances where you think they might otherwise be warranted.**

Our fourth amended and restated certificate of incorporation, as amended, provides, with specific exceptions required by Delaware law, that our directors are not personally liable to us or our stockholders for monetary damages for any action or failure to take any action. In addition, we have agreed to, and our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws provide for, mandatory indemnification of directors and officers to the fullest extent permitted by Delaware law. These provisions may discourage stockholders from bringing suit against a director or officer for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against any of our directors or officers.

An investor will only be able to exercise a warrant if the issuance of common stock upon such exercise has been reg

**If and to the extent we are found liable in certain proceedings or our expenses related to those or other legal proceedings become significant, then our liquidity could be materially adversely affected and the value of our stockholders' interests in us could be impaired.**

In April 2002, we entered into a letter agreement with Hermitage Capital Corporation ( Hermitage ), as selling agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, we entered into a settlement agreement with Hermitage pursuant to which, among other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement; and we agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between us and Lancer Offshore, Inc., warrants exercisable until February 2006 to purchase an aggregate of 60,000 shares of common stock for \$2.50 per share (or 17,046 shares of our common stock for \$8.80 per share, if adjusted for the reverse stock split pursuant to the antidilution provisions

TABLE OF CONTENTS

of such warrant, as amended). Because Lancer Offshore, Inc. never satisfied the closing conditions and, consequently, a closing has not been held, we have not issued any warrants to Hermitage in connection with our settlement with them. In June 2004, Hermitage threatened to sue us for warrants it claims are due to it under its settlement agreement with us as well as a placement fee and additional warrants it claims are, or will be, owed in connection with our initial public offering completed on September 24, 2004, as compensation for allegedly introducing us to one of the underwriters. We had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. We have not heard from Hermitage since then.

If and to the extent we are found to have significant liability to Hermitage in any lawsuit Hermitage may bring against us, then our liquidity could be materially adversely affected and/or our stockholders could experience dilution in their investment in us and the value of our stockholders' interests in us could be impaired.

**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 relatively new 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 Certain Risks and Uncertainties section could impair our business operations or otherwise cause our operating results or prospects to be

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation

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 a portion or all of their investment.

## TABLE OF CONTENTS

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company's securities. As a result, 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.

As of December 31, 2007, management reported a material weakness in our internal control over financial reporting due to an insufficient number of resources in the accounting and finance department that does not allow for a thorough review process. Throughout fiscal year 2008, we implemented the following measures which resulted in the remediation of this material weakness as of December 31, 2008:

Developed procedures to implement a formal quarterly closing calendar and process and held quarterly meetings to address the quarterly closing process;

Established a detailed timeline for review and completion of financial reports to be included in our Forms 10-Q and 10-K;

Enhanced the level of service provided by outside accounting service providers to further support and provide additional resources for internal preparation and review of financial reports and supplemented our internal staff in accounting and related areas; and

Employed the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-Q and 10-K.

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

Certain statements in this prospectus constitute forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. The words or phrases "can be," "may," "could," "would," "expects," "seeks," "estimates," "projects" and similar words and phrases are intended to identify such forward-looking statements.

These forward-looking statements may include, among other things, statements concerning the expectations of Nephros regarding its business, growth prospects, revenue trends, operating costs, working capital requirements, competition, results of operations, and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends, and similar expressions concerning matters that are not historical facts. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the preceding pages, and we caution you that any forward-looking information provided by or on behalf of us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.





TABLE OF CONTENTS

## USE OF PROCEEDS

Assuming all the Units offered are sold, the gross proceeds from the rights offering and under the purchase agreement with Lambda Investors will be \$3,500,000, with net proceeds, after deducting estimated offering expenses of \$200,000, of approximately \$3,300,000. We are conducting the rights offering in part to raise capital for our operations. Without additional capital, we currently anticipate that we will not be able to continue our operations beyond March 2011.

We are obligated to use proceeds from the rights offering to repay the \$500,000 loan from Lambda Investors, plus all accrued interest thereon, as well as an 8% sourcing/transaction fee (\$40,000) and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. We intend to use the remaining net proceeds, if any, for general corporate purposes, including further development of our product candidates, clinical trials, research and development expenses, and administrative expenses. Pending the application of any remaining net proceeds for these purposes, we intend to invest them generally in short-term, investment-grade, interest-bearing securities.

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

## DETERMINATION OF OFFERING PRICE

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 175,000,000 Units consisting of shares and warrants to purchase shares of our common stock, and that it be made at a subscription price of \$0.02 per Unit to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.02 per Unit 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. In an effort to minimize the dilutive effect of the rights offering, Lambda Investors proposed that it would surrender for cancellation a portion of its existing warrants containing anti-dilution provisions that will be triggered by the rights offering. The number of shares underlying such cancelled warrants would equal the total number of shares underlying the warrants to be issued in the rights offering. The special committee considered, among other things, that (i) 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, and (ii) even if we were able to make such an offering, without any inducement for Lambda Investors to surrender for cancellation a portion of its existing warrants as it has agreed to do in the rights offering, the dilution suffered by current investors would have been approximately equal to or greater than the dilution that participating investors will be subject to in the rights offering. See [The Rights Offering](#) [Dilution](#).

The \$0.02 per Unit subscription price was not based on any discount to the market price of our common stock. The subscription price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the Units being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price. After the date of this prospectus, our common stock may trade at prices above or below the subscription price. The subscription price does not necessarily bear any relationship to any established criteria for value. You should not consider the subscription price as an indication of value of our company or our common stock. You should not assume or expect that, after the rights offering, our shares of common stock will trade at or above the subscription price in any given time period. The market price of our common stock may decline during or after the rights offering, and you may not

be able to sell the shares of our common stock purchased during the rights offering at a price equal to or greater than the subscription price. You should obtain a current quote for our common stock before exercising your subscription rights and make your own assessment of our business and financial condition, our prospects for the future, and the terms of this rights offering. On January 26, 2011, the closing sale price of our common stock on the OTC Bulletin Board was \$0.105 per share.

TABLE OF CONTENTS

## **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the \$0.02 offering price per Unit and the pro forma net tangible book value per share. Our historical net tangible book value as of September 30, 2010 was approximately \$798,000, or approximately \$0.02 per share. Historical net tangible book value per share is determined by dividing our net tangible book value by the actual number of outstanding shares of common stock. Dilution in historical net tangible book value per share represents the difference between the amount per share paid by the purchaser of shares of common stock in this offering and the pro forma net tangible book value per share of common stock immediately after the closing of this offering.

After giving effect to the assumed sale of 175,000,000 Units in the rights offering and under the purchase agreement with Lambda Investors, with an offering price of \$0.02 per Unit, but excluding any issuance of shares of common stock to holders of warrants issued as part of the Units, and after deducting estimated offering expenses payable by us of \$200,000, our pro forma net tangible book value as of September 30, 2010 would have been approximately \$4,138,000, or \$0.02 per share of common stock. This would represent no dilution in pro forma net tangible book value per share to our stockholders for their existing shares or for the Units they purchase in this offering.

The shares outstanding as of September 30, 2010 used to calculate the information in this section exclude the following items:

893,282 shares issuable upon the exercise of stock options outstanding on September 30, 2010; and  
8,191,827 shares issuable upon the exercise of warrants outstanding on September 30, 2010.

## **DIVIDEND POLICY**

We do not anticipate paying any dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our board of directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our board of directors may deem relevant. Additionally, our ability to pay future dividends may be restricted by the terms of any debt financing, tax considerations and applicable law.

## **CAPITALIZATION**

The following table sets forth our historical, pro forma and pro forma as adjusted cash and cash equivalents and capitalization as of September 30, 2010. The pro forma and pro forma as adjusted information gives effect to as assumed \$3,500,000 equity raise from this rights offering.

For purposes of this table, we have assumed that the rights offering is fully subscribed, resulting in \$3,500,000 in gross proceeds. However, it is not possible to predict how many Units will be subscribed for in this rights offering, and therefore, how much gross proceeds will actually be raised.

TABLE OF CONTENTS

This table should be read in conjunction with our consolidated financial statements and the notes thereto included in this prospectus.

	September 30, 2010		
	Actual	Pro Forma <sup>(1)</sup>	Pro Forma as Adjusted <sup>(2)</sup>
	(Dollars in Thousands)		
Cash and cash equivalents	\$421	\$3,721	\$3,644
Accounts payable and accrued expenses	\$884	\$1,134	\$1,134
Promissory note <sup>(3)</sup>		500	500
Total liabilities	\$884	\$1,634	\$1,634
Stockholders' equity:			
Preferred stock, \$0.001 par value: 5,000,000 shares authorized on an actual, pro forma and pro forma as adjusted basis; no shares issued and outstanding on an actual, pro forma and pro forma as adjusted basis			
Common stock, \$0.001 par value: 90,000,000, 900,000,000 and 90,000,000 shares authorized on an actual, pro forma and pro forma as adjusted basis; 41,811,048, 216,811,048 and 10,840,52 shares issued and outstanding on an actual, pro forma and pro forma as adjusted basis <sup>(4)</sup>	42	217	11
Additional paid-in capital	91,957	95,282	95,488
Deficit accumulated during the development stage	(91,201)	(91,201)	(91,201)
Total stockholders' equity	798	4,298	4,298
Total capitalization	\$1,682	\$5,932	\$5,932

Gives pro forma effect to \$3,500,000 of gross proceeds from the rights offering, less \$200,000 of offering costs, (1) and the proposed amendment of our certificate of incorporation to increase the authorized shares of our common stock from 90,000,000 to 900,000,000 shares we intend to effect prior to the rights offering.

Gives pro forma effect to the events set forth in (1) above, as adjusted for the 1-for-20 reverse stock split and the (2) concurrent amendment of our certificate of incorporation to decrease the authorized shares of our common stock from 900,000,000 to 90,000,000 shares we intend to effect immediately after completion of the rights offering.

We are obligated to use proceeds of the rights offering to prepay all amounts due under this note. See Use of (3) Proceeds.

In addition to the issued shares as disclosed above, as of September 30, 2010, we had 9,085,109, 375,791,391 and (4) 18,789,569 shares of common stock issuable upon exercise of outstanding warrants and options on an actual, pro forma and pro forma as adjusted basis, respectively.

42

TABLE OF CONTENTS**MARKET FOR OUR COMMON STOCK**

On January 22, 2009 the AMEX removed our common stock from trading on the AMEX. Until such date, our common stock had been trading on the AMEX under the symbol NEP. Effective February 4, 2009, our common stock is now quoted on the OTC Bulletin Board under the symbol NEPH. The following table sets forth the high and low sales prices for our common stock as reported on the AMEX and the high and low bid and ask prices for our common stock as reported on AMEX or the Over the Counter Bulletin Board for each quarter listed.

Quarter Ended	High	Low
March 31, 2008	\$ 1.60	\$ .33
June 30, 2008	\$ .97	\$ .50
September 30, 2008	\$ .65	\$ .24
December 31, 2008	\$ .48	\$ .05
March 31, 2009	\$ .15	\$ .04
June 30, 2009	\$ 1.77	\$ .01
September 30, 2009	\$ 2.63	\$ .99
December 31, 2009	\$ 1.75	\$ .70
March 31, 2010	\$ 1.30	\$ .65
June 30, 2010	\$ 1.14	\$ .36
September 30, 2010	\$ .48	\$ .16
December 31, 2010	\$ .23	\$ .08
From January 1, 2011 to January 26, 2011	\$ .11	\$ .08

As of December 31, 2010, there were 35 holders of record and approximately 900 beneficial holders of our common stock.

On January 26, 2011, the last reported sale price of our common stock on the OTC Bulletin Board was \$0.105 per share.

TABLE OF CONTENTS

# THE RIGHTS OFFERING

## Background of the Rights Offering

### Need for Capital

At September 30, 2010, we had cash and cash equivalents totaling approximately \$421,000 and tangible assets of approximately \$1,682,000. At that time, we estimated that these funds would allow us to keep operating into the fourth quarter of 2010. We expect that the \$500,000 we raised in September 2010 through the issuance of the note to Lambda Investors will allow us to operate into March 2011. We must seek and obtain additional financing to fund our operations. For the past two years, we have significantly reduced expenses while attempting to properly capitalize our company.

### Fundraising Activities and Impact on Our Stockholders

We raised \$1,250,000 in a private placement in July 2009 at a purchase price which did not trigger the anti-dilution provisions of any of our outstanding warrants. Since then we have been actively attempting to raise additional funding without success. The departure of our Chief Executive Officer in late March 2010 significantly impaired our fundraising abilities. In addition, the quotation of our stock on the OTC Bulletin Board rather than AMEX, as it was previously, our lack of a permanent Chief Executive Officer, the continued lack of a response from the FDA on our 510(k) application for our hemodiafiltration, or HDF, system and our declining stock price presented significant challenges to fundraising. Given these facts, we were advised by the investment banking firm we had engaged, Dawson James Securities, Inc., that the terms on which we could potentially attract investors would likely require a significant discount to the trading price, a significant warrant component and other unfavorable terms. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our HDF system. The receipt of this letter had a detrimental impact on our ongoing capital raising efforts. As a result, we determined, in consultation with Dawson James, that raising capital through conventional sources was no longer feasible. We subsequently terminated our engagement of Dawson James on September 16, 2010.

We considered the unfavorable terms we might be required to agree to in order to raise capital from third party investors against our need for capital and our current stockholders' interests. We were concerned that even if there was an available option to raise a small amount of capital, it would trigger the anti-dilution provisions of certain of our existing warrants to the detriment of most of our stockholders, who would not be participating in the financing, and yet not provide us with sufficient funds to advance our business plan in any meaningful way.

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

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

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

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

Lambda Investors is making a significant concession with regard to its agreement to surrender a portion of its existing warrants upon completion of the rights offering to the direct benefit of our stockholders; and

Lambda Investors is committing to purchase through a private placement 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering.

44

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## TABLE OF CONTENTS

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

### **Loan from Lambda Investors**

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

On October 1, 2010, Lambda Investors loaned us \$500,000 pursuant to a secured promissory note. The note bears interest at the rate of 12% per annum and matures on April 1, 2011, at which time all principal and accrued interest will be due. However, we have agreed to prepay amounts due under the note out of any cash proceeds from the rights offering, or any other equity or debt financing, or the sale of any assets outside the ordinary course of business, in each case prior to the maturity date. If we do not pay the principal and interest under the note when due, the interest rate increases to 16% per annum. We may prepay the note without penalty at any time.

The note is secured by a first priority lien on all of our assets, including our intellectual property, inventions, work in process and any other property.

As long as indebtedness remains outstanding under the note, we will be subject to certain covenants which, among other things, 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.

Lambda Investors is entitled to an 8% sourcing/transaction fee (\$40,000) in respect of the note and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the note and the rights offering. The legal fees will be paid upon the closing of the rights offering or, in the case of fees and expenses relating to the note, upon the maturity of the note, if earlier.

### **Purchase Agreement with Lambda Investors**

As required under the terms of the note, we are conducting this rights offering to raise up to \$3,500,000 from our existing stockholders. Lambda Investors has committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266 Units under the purchase agreement. Lambda Investors is not receiving any compensation for its purchase commitment.

Any Units purchased by Lambda Investors and the shares and warrants to purchase shares of our common stock underlying them are not being registered pursuant to the registration statement of which this prospectus is a part, and



thus may not be offered or sold except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act of 1933, as amended. See Plan of Distribution. We will enter into a registration rights agreement with Lambda Investors in connection with the rights offering. The registration rights agreement will cover the shares of our common stock (including shares issuable upon exercise of warrants) underlying any Units sold under the purchase agreement with Lambda Investors. See Certain Relationships and Related Transactions for a description of the registration rights agreement with Lambda Investors.

A copy of the purchase agreement and the registration rights agreement with Lambda Investors have been filed as exhibits to the registration statement of which this prospectus is a part.

## TABLE OF CONTENTS

In addition, Lambda Investors has agreed to surrender for cancellation a portion of its existing warrants containing anti-dilution provisions that will be triggered by the rights offering. The number of shares underlying such cancelled warrants would equal the total number of shares underlying the warrants to be issued in the rights offering and under the purchase agreement with Lambda Investors. Further, the term of Lambda Investors' existing warrants that will remain outstanding following the completion of the rights offering will be amended so that such warrants will expire at the same time as the warrants issued in the rights offering, which will have a five-year term.

Lambda Investors is our largest stockholder and as of December 31, 2010 beneficially owns approximately 43.9% of our outstanding common stock (which includes warrants to purchase an aggregate of 7,190,811 shares of our common stock). The warrants held by Lambda Investors have an exercise price of \$0.90 per share and contain full-ratchet anti-dilution provisions (see Dilution below). The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors. Arthur Amron, one of our directors, is a partner and general counsel of Wexford Capital. Paul A. Mieyal, another of our directors and Acting Chief Executive Officer, is a vice president of Wexford Capital.

## **Our Business Prospects**

We have applied to the FDA for approval to sell our hemodiafiltration system in the United States. On June 30, 2010, we received a letter from the FDA which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration system. We had an in-person meeting with the FDA on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

Our hemodiafiltration system and related products are approved for marketing in Europe and Canada. Currently, our hemodiafiltration products are sold and distributed throughout Europe and are being used in over 50 clinics in Europe.

Our OLpur HD 190 high-flux dialyzer cartridge, designed for use with either hemodialysis or hemodiafiltration machines, received FDA approval in June 2005.

Also, our Dual Stage Ultrafilter, or DSU, water filtration system was approved by the FDA in July 2009 to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. Our goal for the DSU is to expand distribution to the hospital market and identify other short term applications. In July 2010, AmeriWater Corporation adopted the DSU as a standard component of its MRO portable reverse osmosis water treatment systems for dialysis.

In March 2010, we entered into a development agreement with STERIS Corporation whereby STERIS and we are jointly developing filtration-based products for medical device applications.

Finally, pursuant to a contract with the Office of Naval Research, we are working on the development of a potable dual-stage military water purifying filter as part of a Marine Corps Advanced Technology Demonstration project.

## **Reasons for the Rights Offering**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 175,000,000 Units consisting of shares and warrants to purchase shares of our common

stock, and that it be made at a subscription price of \$0.02 per Unit to encourage our other stockholders to participate. A special committee of our independent directors (none of whom are affiliated with Lambda Investors) approved the loan and the rights offering after carefully evaluating our imminent need for additional capital. The special committee considered alternative capital raising methods that could be available to us and analyzed, among other things, the low likelihood of effecting another form of financing, as well as the length of time necessary to complete any such alternative financings. It also considered the costs and expenses associated with alternative financings. In conducting its analysis, a key

## TABLE OF CONTENTS

factor considered by the special committee was the importance of reducing dilution to our existing stockholders. The special committee also considered the dilution that would be caused by the rights offering as well as by alternative financings.

The special committee believes that the rights offering provides the least dilutive alternative to our existing stockholders. An equity financing, whether public or private, would dilute existing stockholders because such an offering would likely include only a few of our existing stockholders, if any. The rights offering affords each of our existing stockholders the ability to protect, though not fully preserve, his or her ownership percentage. In addition, the sales price in any alternative financing most likely would be at a discount to market price. On January 26, 2011, the closing price of our common stock as reported on the OTC Bulletin Board, was \$0.105 per share. We have issued and outstanding warrants to purchase an aggregate of 7,519,246 shares that contain full-ratchet anti-dilution provisions. In the event we sell any equity security or security convertible into equity security at a purchase price less than the \$0.90 exercise price of these warrants, the exercise price of the warrants would automatically adjust to the same price as that paid in the financing and the number of shares underlying these warrants would automatically be increased so that the aggregate exercise price of the warrant remains the same as in effect prior to the financing. Most recently, our stock price has traded below \$0.90 per share from time to time since the fourth quarter of 2009 and continuously since May 3, 2010. Given our current stock price, any alternative financing would be effected at a purchase price below \$0.90 per share, which would trigger the full-ratchet anti-dilution provisions in these warrants, resulting in a significant increase in the number of shares underlying them. Any such significant increase in the number of shares underlying our outstanding warrants by operation of these full-ratchet anti-dilution provisions would have a significantly dilutive effect on our existing stockholders and would present a disincentive for outside sources of capital to purchase our equity, as Lambda Investors, which holds over 95% of these warrants, would not cancel any of its warrants under an alternative transaction to the rights offering. Lambda Investors has agreed to surrender for cancellation warrants (after giving effect to the anti-dilution provisions contained therein that will be triggered by the rights offering) to purchase a number of shares equal to the total number of shares underlying the warrants to be issued as part of the Units, upon completion of the rights offering and the private placement of Units with Lambda Investors, which, in terms of dilution, is to the benefit of our stockholders.

## **Proposed Reverse Stock Split**

If the rights offering is completed, we intend to effect a 1-for-20 reverse stock split immediately after the completion of the rights offering. Our stockholders approved the reverse stock split at our annual meeting of stockholders held on January 10, 2011. In the 1-for-20 reverse stock split, we will cash out fractional shares at a price equal to the average closing sale price of shares of common stock for the ten trading days immediately prior to the date the 1-for-20 reverse stock split becomes effective, or, if no such sale takes place on such days, the average of the closing bid and ask prices for such days, in each case as officially reported by the OTC Bulletin Board, which we refer to as the cash out price. If the shares currently held by you and the shares purchased by you in this rights offering result in a fractional interest following the 1-for-20 reverse stock split, then such fractional interests will be cashed out at the cash out price, which may be less than or greater than the \$0.02 per Unit subscription price.

## **Dilution**

Our commitment to undertake the rights offering was a condition of the loan provided to us by Lambda Investors on September 29, 2010. The terms of the rights offering are intended to minimize dilution to those of our existing stockholders who participate in the rights offering when compared to other potential equity offerings, given that, in connection with and following the completion of the rights offering, Lambda Investors will surrender for cancellation warrants (after giving effect to the anti-dilution provisions contained therein that will be triggered by the rights

offering) to purchase a number of shares equal to the total number of shares underlying the warrants to be issued in the rights offering. Assuming the rights offering is fully subscribed, warrants to purchase an aggregate of 161,793,248 shares would be issued and Lambda Investors would surrender existing warrants for the same number of shares. If Lambda Investors purchases 60,194,226 Units, but makes no additional purchase of Units, Lambda Investors would be issued warrants to purchase 55,651,538 shares of our common stock as part of the Units. The term of the remaining  
Lambda Investors

47

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TABLE OF CONTENTS

warrants will be extended so that such warrants will expire at the same time as the warrants issued in the rights offering, which will have a five-year term.

Set forth below are certain historical and alternative pro forma dilution calculations, based on the following assumptions:

a fully subscribed \$3,500,000 rights offering of 175,000,000 shares with a purchase price of \$0.02 per share, with no warrants issued in the offering and no surrender of warrants by Lambda Investors;  
the \$3,500,000 rights offering we are undertaking pursuant to this prospectus of 175,000,000 Units, each consisting of one share of our common stock and a warrant to purchase 0.924532845 shares of common stock, at a subscription price of \$0.02 per unit, and the surrender by Lambda Investors of warrants exercisable for a number of shares equal to the number of shares underlying the warrants to be issued as part of the Units;  
a stockholder who owns 1% of our outstanding shares of common stock and exercises its basic subscription privilege in full; and  
a stockholder who owns 1% of our outstanding shares of common stock and does not participate in the rights offering.

	As of December 31, 2010	Pro Forma Assuming Rights Offering of 175,000,000 Shares at \$0.02 Per Share and No Surrender of Lambda Warrants <sup>(1)</sup>	Pro Forma Assuming Rights Offering of 175,000,000 Units at \$0.02 Per Unit and Surrender of Lambda Warrants <sup>(2)</sup>
Shares common stock outstanding	41,811,048	216,811,048	216,811,048
Shares issuable pursuant to options	893,282	893,282	893,282
Shares issuable pursuant to non-Lambda warrants <sup>(3)</sup>	1,001,016	14,194,250	120,335,959
Shares issuable pursuant to Lambda warrants	7,190,811	323,586,495	217,444,786
Total Shares	52,885,511	555,485,075	555,485,075
Beneficial ownership of hypothetical stockholder who owns 1% of our common stock and fully participates in rights offering	528,855 (1.0%)	2,742,375 (0.49%)	3,231,318 (0.58%)
Beneficial ownership of hypothetical stockholder who owns 1% of our common stock and does not participate in rights offerings	528,855 (1.0%)	528,855 (0.09%)	528,855 (0.09%)

(1) Assumes no warrants are issued in the rights offering.

(2) Assumes Lambda Investors will surrender for cancellation warrants to purchase 161,793,248 shares of our common stock, which will equal the number of shares underlying warrants that will be issued as part of the Units. Also assumes Lambda Investors purchases 60,194,226 Units.

(3) Includes warrants to purchase shares of our common stock held by investors other than Lambda Investors which contain full-ratchet anti-dilution provisions triggered by the rights offerings.

We also considered, hypothetically, the dilutive effect to our stockholders of a \$3,500,000 equity financing with outside investors at various discounts to our stock price and warrants issued to the new investors and concluded that while it was highly unlikely that we could find investors who would be interested in such a transaction, if we could find investors for such a financing, the dilutive effect would be greater than that of the rights offering we are undertaking pursuant to this prospectus.

After weighing the factors discussed above and the effect of the rights offering of generating \$3,500,000 in gross proceeds (before expenses), assuming the rights offering is fully subscribed, as additional capital for us, we believe that the rights offering is the best alternative to raise capital and is in the best interests of our company and our stockholders. We believe that the rights offering will strengthen our financial condition

## TABLE OF CONTENTS

through generating additional cash, while potentially minimizing dilution to our existing stockholders. However, our board of directors is not making any recommendation as to whether you should exercise your subscription rights.

### **The Subscription Rights**

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. Each subscription right entitles you to purchase, at a subscription price of \$0.02 per Unit, 4.185496618 Units, each consisting of one share of our common stock and a warrant to purchase 0.924532845 shares of our common stock at an exercise price of \$0.02 per share for a period of five years following the closing of the rights offering.

#### **Basic Subscription Privilege**

For each share that you own, you will have a basic subscription privilege to buy from us 4.185496618 Units at a subscription price of \$0.02 per Unit. You may exercise your basic subscription privilege for some or all of your rights, or you may choose not to exercise your rights. If you choose to exercise your rights, there is no minimum number of Units you must purchase, but you may not purchase fractional Units. To determine the number of Units you may purchase under your basic subscription privilege, multiply the number of shares of our common stock you own by 4.185496618 and round down to the nearest whole number. For example, if you own 100 shares of our common stock, you will be entitled to subscribe for up to 418 Units ( $100 \text{ shares} \times 4.185496618 = 418.5496618$ , rounded down to 418, the nearest whole number) under your basic subscription privilege. Similarly, the warrant to purchase 0.92453 shares of our common stock included with each Unit you purchase will only be exercisable for a number of shares rounded down to the nearest whole number. For example, if you purchase 418 Units, the warrants included with those Units would be exercisable for up to 386 shares ( $418 \text{ Units} \times 0.924532845 = 386.4547292$ , rounded down to 386, the nearest whole number).

#### **Over-Subscription Privilege**

If you exercise your basic subscription privilege in full, you may also exercise an over-subscription privilege to subscribe for additional Units not subscribed for by other rights holders in the offering at the same subscription price of \$0.02 per Unit. If an insufficient number of Units is available to fully satisfy all over-subscription privilege requests, the available Units will be allocated proportionately among rights holders who exercise their over-subscription privileges based on the number of Units each such holder subscribed for under the basic subscription privilege. The subscription agent will return any excess payments by mail without interest or deduction promptly after expiration of the subscription period.

### **Effects of Rights Offering and Purchase of Units by Lambda Investors on Ownership of Certain Beneficial Owners and Management**

The following table sets forth information regarding the beneficial ownership of our common stock as of December 31, 2010 by (i) each person known to us to own beneficially more than 5% of our common stock, based on any such person's or entity's filings with the SEC as of that date, (ii) each director and executive officer and (iii) all directors and



executive officers as a group, and the potential effects of the rights offering on these parties and their beneficial ownership of our common stock.

TABLE OF CONTENTS

The information provided in the table below is based on our records, information filed with the SEC and information provided to us, except where otherwise noted.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership before Rights Offering	Percentage of class <sup>(1)</sup>	Amount of Beneficial Ownership after Rights Offering <sup>(2)</sup>	Amount of Beneficial Ownership after 1-for-20 Reverse Stock Split	Percentage of class <sup>(3)</sup>
Lambda Investors LLC <sup>(4)</sup>	21,572,432	43.9 %	292,020,633	14,601,031	67.2 %
Stagg Capital Group LLC <sup>(5)</sup>	3,759,558	8.9 %	22,501,436	1,125,071	9.4 %
Arthur H. Amron <sup>(6)</sup>	21,667	*	112,354	5,617	*
Lawrence J. Centella <sup>(7)</sup>	41,667	*	216,064	10,803	*
Gerald J. Kochanski <sup>(8)</sup>	156,393	*	785,832	39,292	*
Paul A. Mieyal <sup>(9)</sup>	21,667	*	112,354	5,617	*
James S. Scibetta <sup>(10)</sup>	40,834	*	211,744	10,857	*
All executive officers and directors as a group <sup>(4) (10)</sup>	282,228	*	1,463,492	73,175	*

\* Represents less than 1% of the outstanding shares of our common stock.

(1) Applicable percentage ownership is based on 41,811,048 shares of common stock outstanding as of December 31, 2010, together with applicable options and warrants for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors including voting and investment power with respect to shares. Common stock subject to options and warrants exercisable on or within 60 days after December 31, 2010 are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options or warrants, but not for computing the percentage ownership of any other person.

(2) Assumes all 175,000,000 Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold, the cancellation of Lambda Investors existing warrants to purchase 161,793,248 shares of common stock and that the named stockholders exercise their basic subscription privileges, and in lieu of exercising its basic subscription privilege, Lambda Investors purchases an equivalent number of Units through a private placement.

(3) Assumes 175,000,000 Units offered in the rights offering and under the purchase agreement with Lambda Investors are sold and that the named stockholders exercise their basic subscription privileges, and in lieu of exercising its basic subscription privilege, Lambda Investors purchases an equivalent number of Units through a private placement. Applicable percentage ownership is based on 10,840,552 shares of common stock outstanding upon completion of the rights offering and after giving effect to the proposed 1-for-20 reverse stock split. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors including voting and investment power with respect to shares. Common stock subject to options and warrants exercisable on or within 60 days after the estimated date for the completion of the rights offering are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options or warrants, but not for computing the percentage ownership of any other person.

(4) Based in part on information provided in Schedule 13D/A filed on February 12, 2010. The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors, by Charles E. Davidson in his capacity as chairman and managing member of Wexford Capital LP and by Joseph M. Jacobs in his capacity as president and managing member of Wexford Capital LP. The address of each of Lambda Investors, Wexford Capital LP, Mr. Davidson and Mr. Jacobs is c/o

Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. Each of Wexford Capital LP, Mr. Davidson and Mr. Jacobs disclaims beneficial ownership of the shares of our common stock owned by Lambda Investors except, in the case of Mr. Davidson and Mr. Jacobs, to the extent of their respective interests in each member of Lambda Investors. Includes 7,190,811 shares issuable on or prior to November 14, 2012 upon exercise of warrants held by Lambda Investors having an exercise price of \$0.90 per share. These warrants contain a full-ratchet anti-dilution provision which provides that if the per share price of the common stock contained in each unit offered by this prospectus is less than the warrant's current exercise price (i) the exercise price of the warrant will be reduced to the per share price of the shares in each unit and (ii) the number of shares covered by the warrant will be increased to an amount derived by multiplying the number of shares

TABLE OF CONTENTS

covered by the warrant by (x) the per share exercise price in effect before the completion of the offering divided by (y) the new exercise price (which will be the per share price of each share contained in a unit). Lambda Investors is controlled by Wexford Capital LP. Arthur H. Amron, one of our directors, is a partner and General Counsel of Wexford Capital LP. Paul A. Mieyal, our Acting Chief Executive Officer and one of our directors, is a Vice President of Wexford Capital LP.

(5) Based in part on information provided in Schedule 13D/A filed with the SEC on August 21, 2008. Stagg Capital Group, LLC ( Stagg Capital ) serves as the investment advisor to an investment fund that holds the shares and Scott A. Stagg is the managing member of StaggCapital. By reason of such relationships, Stagg Capital and Mr. Stagg may be deemed to be indirect beneficial owners of the shares.

(6) Mr. Amron s address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Amron consist of 21,667 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 13,333 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of December 31, 2010.

(7) Mr. Centella s address is the Company address. The shares identified as being beneficially owned by Mr. Centella include 41,667 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 13,333 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of December 31, 2010.

(8) Mr. Kochanski s address is the Company address. The shares identified as being beneficially owned by Mr. Kochanski consist of 156,393 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 194,177 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of December 31, 2010.

(9) Mr. Mieyal s address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Mieyal consist of 21,667 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 13,333 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of December 31, 2010.

(10) Mr. Scibetta s address is the Company address. The shares identified as being beneficially owned by Mr. Scibetta consist of 40,834 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 21,666 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of December 31, 2010.

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

You may exercise your subscription rights at any time prior to 5:00 p.m., Eastern Time, on February 28, 2011, the expiration date for the rights offering, subject to extension at our sole discretion, but in no event by more than 60 days from the date of this prospectus. If you do not exercise your subscription rights before the expiration date of the rights offering, your subscription rights will expire and will have no value. We will not be required to issue Units to you if the subscription agent receives your rights certificate or payment after the expiration date, regardless of when you sent the rights certificate and payment, unless you send the documents in compliance with the guaranteed delivery procedures described under **Guaranteed Delivery Procedures** below.

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

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

TABLE OF CONTENTS

## **Conditions to the Rights Offering**

To complete the rights offering, our stockholders had to approve an amendment to our certificate of incorporation to increase the authorized shares of capital stock from 95,000,000 shares to 905,000,000 shares and the authorized shares of common stock from 90,000,000 to 900,000,000 shares. This amendment is necessary to ensure we have enough shares to effect the rights offering. Without the increase in the authorized shares, we would not be able to complete the rights offering. Our stockholders approved the amendment at our annual meeting of stockholders held on January 11, 2011. We intend to file a certificate of amendment to our certificate of incorporation providing for such share increase immediately prior to the closing of the rights offering. Additional conditions to the rights offering include that the registration statement of which this prospectus is a part must be declared effective by the SEC and that we execute a registration rights agreement with Lambda Investors.

We must also be in compliance with all terms of the promissory note and security agreements evidencing the loan to us by Lambda Investors.

Further, the term of Lambda Investors' existing warrants that will remain outstanding following the completion of the rights offering will be amended so that such warrants expire at the same time as the warrants issued in the rights offering, which will have a five-year term. We will amend Lambda Investors' remaining warrants as part of completing the rights offering.

In addition, Lambda Investors' commitment to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, is subject to certain conditions, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering.

## **Method of Exercising Subscription Rights**

The exercise of subscription rights is irrevocable and may not be cancelled or modified. Your subscription rights will not be considered exercised unless the subscription agent receives from you, your broker, custodian or nominee, as the case may be, all of the required documents properly completed and executed and your full subscription price payment in cash at or prior to 5:00 p.m., Eastern time, on February 28, 2011, the expiration date of the rights offering. Rights holders may exercise their rights as follows:

### **Subscription by Registered Holders**

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

### **Subscription by DTC Participants**

Banks, trust companies, securities dealers and brokers that hold shares of our common stock on the rights offering record date as nominee for more than one beneficial owner may, upon proper showing to the subscription agent,

exercise their subscription privilege on the same basis as if the beneficial owners were record holders on the rights offering record date through the Depository Trust Company, or DTC. Such holders may exercise these rights through DTC's PSOP Function on the agent's subscription over PTS procedure and instructing DTC to charge their applicable DTC account for the subscription payment for the new shares or indicating to DTC that such holder intends to pay for such rights through the delivery to the Company by the holder of an equivalent amount of principal and accrued and unpaid interest of indebtedness owed by the Company to such holder, or a combination thereof, and deliver such amount to the subscription agent. DTC must receive the subscription instructions and payment for the new shares by the rights expiration date. Except as described under the subsection titled "Guaranteed Delivery Procedures," subscriptions accepted by the subscription agent via a Notice of Guaranteed Delivery must be delivered to the subscription agent with payment before the expiration of the subscription period.

TABLE OF CONTENTS

## **Subscription by Beneficial Owners**

Rights holders who are beneficial owners of shares of our common stock and whose shares are registered in the name of a broker, custodian bank or other nominee, and rights holders who hold common stock certificates and would prefer to have an institution conduct the transaction relating to the rights on their behalf, should instruct their broker, custodian bank or other nominee or institution to exercise their rights and deliver all documents and payment on their behalf, prior to the expiration date. A rights holder's subscription rights will not be considered exercised unless the subscription agent receives from such rights holder, its broker, custodian, nominee or institution, as the case may be, all of the required documents and such holder's full subscription price payment.

## **Payment Method**

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

check or bank draft payable to Continental Stock Transfer & Trust Company (acting as subscription agent for Nephros, Inc.), drawn on a U.S. bank;  
U.S. Postal money order payable to Continental Stock Transfer & Trust Company (acting as subscription agent for Nephros, Inc.) ; or  
wire transfer of immediately available funds directly to the account maintained by Continental Stock Transfer & Trust Company as agent for Nephros, Inc., for purposes of accepting subscriptions in the rights offering, at JPMorgan Chase, ABA # 021-000021, Account # 475-508351 FBO Nephros, Inc. Subscription, with reference to the rights holder's name.

Rights certificates received after 5:00 p.m., Eastern Time, on February 28, 2011, the expiration date of the rights offering, will not be honored, and we will return your payment to you as soon as practicable, without interest or deduction.

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

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

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

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



## **Payment Adjustments**

If you send a payment that is insufficient to purchase the number of Units requested, or if the number of Units 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

## TABLE OF CONTENTS

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

## **Medallion Guarantee May Be Required**

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

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

you are an eligible institution.

## **Subscription Price**

As a condition to making the loan, Lambda Investors required that we undertake a rights offering to raise additional funds to meet our ongoing financial requirements and to repay the loan. In its loan proposal, Lambda Investors specified a rights offering of 175,000,000 Units consisting of shares and warrants to purchase shares of our common stock, and that it be made at a subscription price of \$0.02 per Unit to encourage our other stockholders to participate. The loan and the rights offering, as proposed by Lambda Investors, including the \$0.02 per Unit 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. In an effort to minimize the dilutive effect of the rights offering, Lambda Investors proposed that it would surrender for cancellation a portion of its existing warrants containing anti-dilution provisions that will be triggered by the rights offering. The number of shares underlying such cancelled warrants would equal the total number of shares underlying the warrants to be issued in the rights offering. The special committee considered, among other things, that (i) 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, and (ii) even if we were able to make such an offering, without any inducement for Lambda Investors to surrender for cancellation a portion of its existing warrants as it has agreed to do in the rights offering, the dilution suffered by current investors would have been approximately equal to or greater than the dilution that participating investors will be subject to in the rights offering. See *The Rights Offering Dilution*. The \$0.02 per Unit subscription price was not based on any discount to the market price of our common stock. The subscription price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the Units being offered in the rights offering. We did not consult with any financial or other advisor in determining the subscription price.

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

We also cannot assure you that you will be able to sell shares of our common stock purchased during the rights offering at a price equal to or greater than the \$0.02 subscription price per Unit. We urge you to obtain a current quote for our common stock before exercising your subscription rights or subscribe for a Unit.

## **Withdrawal and Termination**

We reserve the right to withdraw the rights offering prior to the expiration of the rights offering for any reason. We may terminate the rights offering, in whole or in part, if at any time before completion of the rights offering there is

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

TABLE OF CONTENTS

## **Cancellation Rights**

Our board of directors may cancel the rights offering at any time prior to the time the rights offering expires for any reason. If we cancel the rights offering, we will issue a press release notifying stockholders of the cancellation and all subscription payments received by the subscription agent will be returned, without interest or deduction, as soon as practicable. The cancellation of the rights offering must be approved by Lambda Investors because undertaking the rights offering is a condition to the loan from Lambda Investors.

## **Subscription Agent**

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

## **Information Agent**

The information agent for this rights offering is Morrow & Co. LLC. We will pay all fees and expenses of the information agent related to the rights offering and have also agreed to indemnify the information agent from certain liabilities that it may incur in connection with the rights offering. The information agent can be contacted at the following address and telephone number:

Morrow & Co. LLC  
407 West Avenue  
Stamford, CT 06902  
(203) 658-9400 (for brokerage firms and banks)  
(800) 414-4313 (for stockholders)

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

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

If delivery by hand/mail/overnight courier:  
Continental Stock Transfer & Trust Company  
17 Battery Place, 8<sup>th</sup> Floor  
New York, NY 10004  
(212) 509-4000, ext. 536

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

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

## Guaranteed Delivery Procedures

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

## TABLE OF CONTENTS

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

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

## **Fees and Expenses**

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

## **Notice to Nominees**

If you are a broker, custodian bank or other nominee holder that holds shares of our common stock for the account of others on the record date, you should notify the beneficial owners of the shares for whom you are the nominee of the rights offering as soon as possible to learn their intentions with respect to exercising their subscription rights. You should obtain instructions from the beneficial owner, as set forth in the instructions we have provided to you for your distribution to beneficial owners. If the beneficial owner so instructs, you should complete the appropriate rights certificate and submit it to the subscription agent with the proper subscription payment. If you hold shares of our common stock for the account(s) of more than one beneficial owner, you may exercise the number of subscription rights to which all beneficial owners in the aggregate otherwise would have been entitled had they been direct holders of our common stock on the record date, provided that you, as a nominee record holder, make a proper showing to the subscription agent by submitting the form entitled Nominee Holder Certification, which is provided with your rights offering materials. If you did not receive this form, you should contact the subscription agent to request a copy.

## **Beneficial Owners**

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

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

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

## **Validity of Subscriptions**

We will resolve all questions regarding the validity and form of the exercise of your subscription rights, including time of receipt and eligibility to participate in the rights offering. Our determination will be final and binding. Once made, subscriptions and directions are irrevocable, and we will not accept any alternative, conditional or contingent subscriptions or directions. We reserve the absolute right to reject any subscriptions or directions not properly submitted or the acceptance of which would be unlawful. You must resolve any irregularities in connection with your subscriptions before the subscription period expires, unless waived by us

## TABLE OF CONTENTS

in our sole discretion. Neither the subscription agent nor we shall be under any duty to notify you or your representative of defects in your subscriptions. A subscription will be considered accepted, subject to our right to withdraw or terminate the rights offering, only when a properly completed and duly executed rights certificate and any other required documents and the full subscription payment have been received by the subscription agent. Our interpretations of the terms and conditions of the rights offering will be final and binding.

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

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

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

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

### **Stockholder Rights**

You will have no rights as a holder of the shares of our common stock you purchase in the rights offering, if any, until certificates representing the shares of our common stock are issued to you or your account at your record holder is credited with the shares of our common stock purchased in the rights offering. You will have no right to revoke your subscriptions after your rights certificate or the Beneficial Owner Election Form, the full subscription payment and any other required documents have been delivered to the subscription agent.

### **State Securities Law Matters**

The issuance and exercise of subscription rights is subject to compliance with state securities laws and regulations. Although we intend to distribute the rights to all stockholders, we reserve the right in some states to require stockholders, if they wish to participate, to state and agree upon exercise of their respective rights that they are acquiring the shares for investment purposes only, and that they have no present intention to resell or transfer any shares acquired. This rights offering is not being made and our securities are not being offered in any jurisdiction where the offer is not permitted under applicable local laws. We have the right, in our sole discretion, to not effect registration or qualification of the subscription rights in any state or other jurisdiction, or take any other action required by any state or other jurisdiction to allow the offer to take place in that state or jurisdiction. If you reside in a state or other jurisdiction in which registration, qualification or other action is necessary with which we choose not to comply, you will not be eligible to participate in the rights offering.

### **Foreign Stockholders**

We will not mail this prospectus or rights certificates to stockholders with addresses that are outside the United States or that have an army post office or foreign post office address. The subscription agent will hold these rights certificates for their account. To exercise subscription rights, our foreign stockholders and stockholders that have an army post office or foreign post office address must notify us prior to 11:00 a.m., Eastern Time, at least five business



days prior to the expiration of the rights offering and demonstrate to our satisfaction that the exercise of such subscription rights does not violate the laws of the jurisdiction of such stockholder.

## **No Revocation or Change**

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

TABLE OF CONTENTS

## **Material U.S. Federal Income Tax Consequences**

For U.S. federal income tax purposes, you should not recognize income or loss upon receipt or exercise of these subscription rights to purchase Units. However, neither we nor our counsel are expressing an opinion regarding the tax treatment of this distribution.

EACH HOLDER OF SUBSCRIPTION RIGHTS IS URGED TO CONSULT ITS TAX ADVISOR REGARDING THE SPECIFIC FEDERAL, STATE, LOCAL AND FOREIGN INCOME AND OTHER TAX CONSIDERATIONS OF THE RECEIPT OF SUBSCRIPTION RIGHTS IN THE RIGHTS OFFERING AND THE OWNERSHIP, EXERCISE AND DISPOSITION OF THE SUBSCRIPTION RIGHTS.

## **No Recommendation to Rights Holders**

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

## **Listing**

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

## **Shares of Our Common Stock Outstanding After Completion of the Rights Offering and the Private Placement of Unitss with Lambda Investors**

As of the record date, we had 41,811,048 shares of our common stock issued and outstanding. If all of the Units offered are sold, we will issue 175,000,000 shares of our common stock in the rights offering and under the purchase agreement with Lambda Investors. Assuming all of the Units 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 and the private placement of Units with Lambda Investors, approximately 216,811,000 shares of our common stock will be outstanding immediately after the completion of the rights offering and the private placement of Units with Lambda Investors, which will equal approximately 10,840,000 shares after giving effect to our proposed 1-for-20 reverse stock split.

## **Additional Information**

If you have any questions or need further information or assistance concerning the method of subscribing or about the rights offering, please contact Morrow & Co., LLC, our information agent for this offering, at (203) 658-9400 (for brokerage firms and banks) or toll-free at (800) 414-4313 (for stockholders).



TABLE OF CONTENTS

## PLAN OF DISTRIBUTION

On or about February 4, 2011, we will distribute the rights, rights certificates and copies of this prospectus to individuals who owned shares of our common stock on the record date. We have not employed any brokers, dealers or underwriters in connection with the solicitation or exercise of rights in the rights offering and no commissions, fees or discounts will be paid in connection with the rights offering. While certain of our directors, officers and other employees may solicit responses from you, those directors, officers and other employees will not receive any commissions or compensation for their services other than their normal compensation. We have agreed to pay the subscription agent and the information agent customary fees plus certain expenses in connection with the rights offering.

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

If delivering by Hand/Mail/Overnight Courier:

Continental Stock Transfer & Trust Company  
17 Battery Place, 8th Floor  
New York, NY 10004  
(212) 509-4000, ext. 536

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

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

You should direct any questions or requests for assistance concerning the method of subscribing for Units to Morrow & Co., LLC, our information agent, at (203) 658-9400 (for brokerage firms and banks) or toll-free at (800) 414-4313 (for stockholders).

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

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

We are not entering into any standby purchase agreement or similar agreement with respect to the purchase of any Units not subscribed for through exercise of subscription privileges by our stockholders, except that Lambda Investors has committed to purchase, through a private placement evidenced by a purchase agreement, 60,194,226 Units, which amount equals the number of Units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of \$0.02 per Unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 87,500,000 of the Units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors

has the right to purchase, at the rights offering subscription price, that number of Units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 60,194,266 Units under the purchase agreement. See The Rights Offering Background of the Rights Offering Purchase Agreement with Lambda Investors. Lambda Investors is not receiving any compensation for its purchase commitment.

TABLE OF CONTENTS

Any Units purchased by Lambda Investors and the shares and warrants to purchase shares of our common stock underlying them are not being registered pursuant to the registration statement of which this prospectus is a part, and thus may not be offered or sold except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act of 1933, as amended. Prior to the closing of the private placement of Units with Lambda Investors, we will file a post-effective amendment to this registration statement to deregister any Units remaining unsold at the expiration of the rights offering.

We will enter into a registration rights agreement with Lambda Investors in connection with the rights offering. The registration rights agreement will cover the shares of our common stock (including shares issuable upon exercise of the warrants) underlying any Units sold under the purchase agreement with Lambda Investors. See **Certain Relationships and Related Transactions** for a description of the registration rights agreement with Lambda Investors.

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

The issuance and exercise of subscription rights is subject to compliance with state securities laws and regulations.

Although we intend to distribute the rights to all stockholders, we reserve the right in some states to require stockholders, if they wish to participate, to state and agree upon exercise of their respective rights that they are acquiring the shares for investment purposes only, and that they have no present intention to resell or transfer any shares acquired. Our securities are not being offered in any jurisdiction where the offer is not permitted under applicable local laws. We have the right, in our sole discretion, to not effect registration or qualification of the subscription rights in any state or other jurisdiction.

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

TABLE OF CONTENTS

# **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OPERATIONS**

## **Immediate Need for Capital**

We have incurred significant losses in our operations in each quarter since our inception. In addition, we have not generated positive cash flow since our inception. 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. Prior to the loan from Lambda Investors on September 29, 2010, our funds would have been depleted in the fourth quarter of 2010. After the loan from Lambda Investors, we now expect to be able to operate into March 2011. Therefore, notwithstanding this loan, we still need to raise operating funds through either the licensing or sale of our technologies or public or private offerings of our securities. Although we are investigating strategic funding opportunities, we might not be able to raise funds on a timely basis or on acceptable terms or at all. Without additional capital from the rights offering, we do not expect to be able to continue our operations.

## **Going Concern**

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this prospectus which expressed doubt as to our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We are in immediate need of capital and are undertaking this rights offering to raise capital. Even if this rights offering is successful, 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, including the completion of this rights offering, we will be forced to cease our operations.

## **Business Overview**

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190 and MD220, which are dialyzers (our OLpur MDHDF Filter Series ), OLpur<sub>2</sub>H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines. We began selling our OLpur MD190 dialyzer in some parts of our Target European Market (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) in March 2004, and have developed units suitable for clinical evaluation for our OLpur H<sub>2</sub>H product. We are developing our OLpur NS2000 product by modifying an existing HDF platform and incorporating our proprietary H<sub>2</sub>H technology.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval for our ESRD products, establishing manufacturing and marketing relationships and establishing our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European n Market and the United States upon their approval by appropriate regulatory authorities. We submitted to the FDA our 510(k) application in November 2008 for approval of our OLpur H<sub>2</sub>H module and OLpur MD 220 filter. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.



TABLE OF CONTENTS

We have also applied our filtration technologies to water filtration and in 2006 we introduced our new Dual Stage Ultrafilter (the DSU) water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli.

In the fourth quarter of 2008, we also filed a 510(k) with the FDA for approval to use our DSU product with reverse osmosis (RO) water systems found within dialysis centers and hospitals. Due the nature of this application our DSU will be categorized as a medical device and therefore requires a 510(k). While waiting for FDA action on both of our ESRD and DSU 510(k) applications we redirected much of our resources to our sales and marketing efforts of our DSU product here in the US in its non-medical device applications. Our goal is to expand distribution to the hospital market and identify other short term applications. Following its review of our DSU 510(k) application, the FDA requested additional information from us. On February 24, 2009, we provided a formal response to the FDA. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately \$1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately \$1,178,000 of revenue has been recognized on this second project since September 2009, of which approximately \$755,000 was recognized in the nine months ended September 30, 2010.

Since our inception, we have incurred annual net losses. As of September 30, 2010, we had an accumulated deficit of \$91,243,000, and we expect to incur additional losses in the foreseeable future. We recognized net losses of \$2,026,000 and \$6,337,000 for the years ended December 31, 2009 and 2008, respectively, and a net loss of \$1,268,000 for the nine months ended September 30, 2010.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through September 30, 2010, we received net offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately \$53.3 million in the aggregate. An additional source of finances was our license agreement with Asahi, pursuant to which we received an up front license fee of \$1.75 million in March 2005.

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

- 1) receiving regulatory approval for each of our ESRD therapy products and our DSU product in our target territories;
- 2) the completion and success of additional clinical trials;

62

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TABLE OF CONTENTS

- 3) the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
  - 4) our ability to effectively and efficiently manufacture, market and distribute our products;
  - 5) our ability to sell our products at competitive prices which exceed our per unit costs;
  - 6) the consolidation of dialysis clinics into larger clinical groups; and
- 7) the current U.S. healthcare plan is to bundle reimbursement for dialysis treatment which may force dialysis clinics to change therapies due to financial reasons.

To the extent we are unable to succeed in accomplishing (1) through (7), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (6), the impact could either be positive, in the case where dialysis clinics consolidate into independent chains, or negative, in the case where competitors acquire these dialysis clinics and use their own products, as competitors have historically tended to use their own products in clinics they have acquired.

## Recently Issued and Adopted Accounting Standards

We follow accounting standards set by the Financial Accounting Standards Board ( FASB ). The FASB sets generally accepted accounting principles ( GAAP ) that we follow to ensure we consistently report our financial condition, results of operations, and cash flows. References to GAAP issued by the FASB in these footnotes are to the *FASB Accounting Standards Codification*,<sup>TM</sup> sometimes referred to as the Codification or ASC. In June 2009, the FASB issued ASC

Topic 105, Generally Accepted Accounting Principals, which became the single source of authoritative nongovernmental U.S. GAAP, superseding existing FASB, American Institute of Certified Public Accountants ( AICPA ), Emerging Issues Task Force ( EITF ), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant SEC guidance organized using the same topical structure in separate sections and has been adopted by us for the year ended December 31, 2009. This has an impact on our financial disclosures since all future references to authoritative accounting literature will be referenced in accordance with ASC Topic 105.

In December 2009, the FASB issued an amendment to ASC Topic 810 Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities. This amendment to ASC Topic 810 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. The amendment, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under the amendment to ASC Topic 810 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We adopted the pronouncement on January 1, 2010 resulting in no impact to our consolidated financial statements.

In February 2010, the FASB issued an amendment which requires that an SEC filer, as defined, evaluate subsequent events through the date that the financial statements are issued. The update also removed the requirement for an SEC filer to disclose the date through which subsequent events have been evaluated. The adoption of this guidance on January 1, 2010 did not have a material effect on our consolidated financial statements.

In January 2010, the FASB issued an amendment to ASC Topic 820 Improving Disclosures about Fair Value Measurements, which amends the existing fair value measurement and disclosure guidance currently included in ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value

measurements. Specifically, the amendment to ASC Topic 820 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In

## TABLE OF CONTENTS

addition, this amendment also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This amendment is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of this amendment did not impact our consolidated financial statements or results of operations.

## **New Accounting Pronouncements**

In April 2010, the FASB issued an Accounting Standards Update which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The amendments in this standard provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This standard is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. This standard is effective for the Company on January 1, 2011. We are currently evaluating the impact that the adoption of this standard will have on our consolidated financial condition, results of operations, and disclosures.

## **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management's subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this prospectus, we believe that the following accounting policies require the application of significant judgments and estimates.

### **Revenue Recognition**

Revenue is recognized in accordance with ASC Topic 605. Four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed and determinable; and (iv) collectability is reasonably assured.

We recognize revenue related to product sales when delivery is confirmed by its external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by our customers.

### **Stock-Based Compensation**

We account for stock-based compensation in accordance with ASC 718 by recognizing the fair value of stock-based compensation in net income. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based

awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

64

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## TABLE OF CONTENTS

### **Accounts Receivable**

We provide credit terms to our customers in connection with purchases of our products. We periodically review customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect our best estimate of potential losses.

### **Inventory Reserves**

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

### **Accrued Expenses**

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

## **Results of Operations**

### **Fluctuations in Operating Results**

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

## **The Fiscal Year Ended December 31, 2009 Compared to the Fiscal Year Ended December 31, 2008**

### Product Revenues

Total product revenues for the year ended December 31, 2009 were \$2,661,000 compared to \$1,473,000 for the year ended December 31, 2008. The \$1,188,000, or 81%, increase is primarily due to \$1,093,000 related to revenue generated from the Office of Naval Research project in the United States. The revenue derived from this project was \$1,093,000 for the twelve months ended December 31, 2009 compared to \$196,000 for the same period in 2008, which was the project's initial period beginning in January 2008. Sales of the OLpur MD190 and MD220 Dialyzers in Europe were \$1,265,000 for the twelve months ended December 31, 2009 compared to \$1,228,000 for the same period in 2008. This \$37,000 or 3% increase in revenue was impacted by the adverse currency translation of the Euro to the U.S. dollar. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Although the sales price of these units, which is in Euro, remained constant approximately \$53,000 was lost due to currency translation. In addition, revenues in the United States from sales of the Dual Stage Ultrafilter (the DSU) water filter were \$303,000 for the twelve months ended December 31, 2009 compared to \$49,000 for the same period in 2008. The DSU represents a new and complementary product line introduced in 2008.



## TABLE OF CONTENTS

### **Cost of Goods Sold**

Cost of goods sold was \$1,744,000 for the year ended December 31, 2009 compared to \$1,064,000 for the year ended December 31, 2008. The \$680,000, or 64%, increase is primarily due to costs related to the Office of Naval Research project in the United States. The cost of goods sold related to the Office of Naval Research project was \$692,000 for the twelve months ended December 31, 2009 compared to \$141,000 for the same period in 2008, an increase of \$551,000. The increased cost is correlated to the higher revenue recognized from this project for the year ended December 31, 2009 compared to the same period in 2008. Cost of goods sold related to the OLpur MD190 and MD220 Dialyzers sold in Europe for the year ended December 31, 2009 was \$969,000 an increase of \$46,000, or 5%, over the comparable period in 2008. This increase was due primarily to higher sales volume. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Cost of goods sold related to the DSU water filters sold in the United States were \$83,000 for the year ended December 31, 2009. The DSU represents a new and complementary product line introduced in 2008 and there were no cost of goods sold incurred for the year ended December 31, 2008.

### **Research and Development**

Research and development expenses were \$280,000 for the year ended December 31, 2009 compared to \$1,977,000 for the year ended December 31, 2008, a decrease of \$1,697,000 or 86%. This decrease is related to the fact that a clinical trial was conducted in 2008 and there was no clinical trial conducted during 2009. Clinical trial expenses decreased by approximately \$964,000 during the twelve months ended December 31, 2009 compared to the same period in 2008. Related reductions in personnel and lab testing resulted in reduced expenses of \$491,000 and \$226,000 respectively during the twelve months ended December 31, 2009 compared to the same period in 2008. A reduction in travel expenses in the amount of \$23,000 was offset by an increase of \$13,000 in development expenses related to the DSU water filter during the twelve months ended December 31, 2009 compared to the same period in 2008.

### **Depreciation and Amortization Expense**

Depreciation expense was \$231,000, for the year ended December 31, 2009 compared to \$447,000 for the year ended December 31, 2008, a decrease of \$216,000, or 48.3%. An additional \$59,000 of depreciation was recorded in 2008 related to furniture and fixtures and tooling to reflect the assessed utility of these assets as of December 31, 2008.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses were \$2,812,000 for the year ended December 31, 2009 compared to \$4,702,000 for the year ended December 31, 2008, a decrease of \$1,890,000 or 40%. A reduction in personnel and related expenses resulted in a decrease of \$1,072,000 for the twelve months ended December 31, 2009 compared to the same period in 2008. Reductions of \$246,000 in legal expenses, \$232,000 in marketing expenses, \$186,000 in recruiting expenses, \$70,000 in insurance expenses and \$85,000 in facility expenses for the twelve months ended December 31, 2009 compared to the same period in 2008 were also achieved. The legal expense reduction was due to less activity and transition to a new law firm in 2009. Marketing activities related to trade shows were curtailed in 2009. Recruiting fees were incurred for four hires in 2008 and none in 2009. The reduction in facility expenses resulted from both the Ireland and U.S. offices moving to less expensive locations for 2009.

**Interest Income**

Interest income was \$9,000 for the year ended December 31, 2009 compared to \$199,000 for the year ended December 31, 2008. The decrease of \$190,000, or 95.5%, reflects the impact of having less cash on hand in 2009 compared to 2008 and therefore, fewer investments to generate interest income.

**Interest Expense**

We incurred approximately \$2,000 of interest expense for the year ended December 31, 2009. This interest relates primarily to financing of premiums for product liability insurance. No interest expense was incurred during 2008. We had no outstanding debt during 2009 or 2008.

TABLE OF CONTENTS

**Impairment of Auction Rate Securities and Gain on sale of investments**

During the fiscal year 2008, we had investments in auction rate securities ( ARS ) which are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction fails and the holders of the ARS are unable to liquidate their investment through such auction. With the liquidity issues experienced in global credit and capital markets, the ARS held by us had experienced multiple failed auctions since February 2008, and as a result, we did not consider these affected ARS liquid in the first quarter of 2008. Accordingly, while we had classified its ARS as current assets as of January 1, 2008, we reclassified them as noncurrent assets at March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, we wrote down ARS with an original par value of \$4,400,000 to an estimated fair value of \$4,286,000 as of March 31, 2008. We reviewed impairments associated with the above in accordance with ASC Topic 320 to determine the classification of the impairment as temporary or other-than-temporary. We determined the ARS classification to be other-than-temporary, and charged an impairment loss of \$114,000 on the ARS to its results of operations for the three months ended March 31, 2008 and twelve months ended December 31, 2008.

During the three months ended June 30, 2008, \$300,000 of principal on our ARS had been paid back by the debtor, resulting in our investment in ARS having decreased from \$4,400,000 to \$4,100,000 (par value) at June 30, 2008. The net book value of our ARS at June 30, 2008 was \$3,986,000, due to the approximate \$114,000 impairment recorded at March 31, 2008. On July 22, 2008 we sold our ARS to a third party at 100% of par value, for proceeds of \$4,100,000. We reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with ASC Topic 320, the ARS, classified as Trading Securities, were valued at their fair value of \$4,100,000 at June 30, 2008. The adjustment of the investment's carrying value from \$3,986,000 net book value to \$4,100,000 fair value resulted in an Unrealized Holding Gain of \$114,000 which is included in our Statement of Operations for the three and six months ended June 30, 2008.

We subsequently reversed the Unrealized Holding Gain and recorded in the results of operations for the twelve months ended December 31, 2008, a Realized Gain on Sale of Investments of \$114,000 in July 2008 due to the sale transaction being executed.

We had no investments in Auction Rate Securities during the year ended December 31, 2009.

**Other Income**

Other income in the amount of approximately \$373,000 and \$181,000 for the years ended December 31, 2009 and December 31, 2008, respectively, resulted primarily from receipt of New York State Qualified Emerging Technology Company ( QETC ) tax refunds in each of these periods. Tax credits for the years 2006 and 2007 were received and recognized during the year ended December 31, 2009. The tax credit for the year 2005 was received and recognized during the year ended December 31, 2008.

**Nine Months Ended September 30, 2010 Compared to the Nine Months Ended September 30, 2009**

## Revenues

Total revenues for the nine months ended September 30, 2010 were approximately \$2,421,000 compared to approximately \$1,869,000 for the nine months ended September 30, 2009. Total revenues increased approximately \$552,000. The increase of approximately 30% is due to increased revenue of approximately \$260,000 in sales of our DSU in the United States for the nine months ended September 30, 2010 over the same period in 2009. Approximately \$73,000 of the increased DSU sales was related to the development agreement with STERIS Corporation, of which approximately \$33,000 is related to the recognition of revenue previously deferred and the remaining \$40,000 is related to the achievement of a milestone during the three months ended September 30, 2010. Revenue from sales of our MD filters in our Target European Market was approximately \$324,000 higher for the nine months ended September 30, 2010 compared to the same period in 2009. Approximately \$369,000 of the European revenue increase was due to more units sold, offset partially by \$45,000 in losses due to foreign currency exchange rate fluctuation. Unit sales in Europe increased approximately 42% for the nine months ended September 30, 2010 compared to the same period in

## TABLE OF CONTENTS

2009. Partially offsetting the increases above was a decrease in net product billings of approximately \$32,000 related to our contract with the Office of U.S. Naval Research during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

### **Cost of Goods Sold**

Cost of goods sold was approximately \$1,446,000 for the nine months ended September 30, 2010 compared to approximately \$1,251,000 for the nine months ended September 30, 2009. The increase of \$195,000 or 16% is due to increased costs of approximately \$110,000 related to increased sales of our DSU in the United States for the nine months ended September 30, 2010 over the same period in 2009. Costs related to revenue from sales of our MD filters in our Target European Market was approximately \$208,000 higher for the nine months ended September 30, 2010 compared to the same period in 2009. Costs related to the contract with the Office of U.S. Naval Research were approximately \$123,000 lower for the nine months ended September 30, 2010 compared to the same period in 2009 due to the use of a subcontractor rather than personnel.

### **Research and Development**

Research and development expenses were approximately \$259,000 for the nine months ended September 30, 2010 compared to approximately \$212,000 for the nine months ended September 30, 2009, an increase of \$47,000 or 22%. Approximately \$44,000 of the increase was wages primarily due to personnel working on research projects other than the contract with the Office of U.S. Naval Research. The remaining \$3,000 increase is due to increased spending on testing materials during the nine months ended September 30, 2010 compared to the same period in 2009.

### **Depreciation Expense**

Depreciation expense was approximately \$98,000 for the nine months ended September 30, 2010 compared to approximately \$190,000 for the nine months ended September 30, 2009, a decrease of 48%. The decrease of approximately \$92,000 is primarily due to several assets having been fully depreciated as of year end 2009 resulting in no depreciation expense for those assets during the nine months ended September 30, 2010. There were no disposals of assets during the nine months ended September 30, 2010.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses were approximately \$1,903,000 for the nine months ended September 30, 2010 compared to approximately \$2,093,000 for the nine months ended September 30, 2009, a decrease of \$190,000 or 9%. The decrease is primarily due to a decrease in personnel related expenses of approximately \$224,000 during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. This decrease was partially offset by increased legal costs of approximately \$34,000 during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

### **Interest Income**

Interest income was approximately \$1,000 for the nine months ended September 30, 2010 compared to approximately \$8,000 for the nine months ended September 30, 2009. The decrease of approximately \$7,000 or 88% is due to the decrease in investments held during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

**Interest Expense**

There was no interest expense for the nine months ended September 30, 2010. We incurred approximately \$2,000 of interest expense for the nine months ended September 30, 2009. This interest relates primarily to financing of premiums for product liability insurance.

**Other income (expense)**

Other income in the amount of approximately \$16,000 for the nine months ended September 30, 2010 resulted from the reversal of a prior year's accrual determined to no longer be necessary. Other income in the amount of approximately \$328,000 for the nine months ended September 30, 2009 resulted primarily from receipt of New York State Qualified Emerging Technology Company tax refunds for years 2006 and 2007.

TABLE OF CONTENTS

## Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the years ended December 31, 2009 and December 31, 2008 or the nine months ended September 30, 2010.

## Liquidity and Capital Resources

At September 30, 2010, we had cash and cash equivalents totaling approximately \$421,000 and tangible assets of approximately \$1,682,000. On September 29, 2010, Lambda Investors loaned us \$500,000, which we expect will allow us to operate into March 2011. If we do not complete this rights offering, we expect that we will be forced to wind down our operations. See **Going Concern** above.

Even if we complete this rights offering, we will need significant additional funding to continue our operations. There can be no assurance that any such funding will be available to us on acceptable terms or at all. Our future liquidity sources and requirements will depend on many factors, including:

- the level of stockholder participation in the rights offering
- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;

- the action of the FDA on our 501(k) application for our hemodiafiltration system.
- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the timing and costs associated with obtaining United States regulatory approval or the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory pre requisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MDHDF filter series, for which the CE mark was obtained in July 2003);
- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

- for the marketing and sales of our products;
- to obtain appropriate regulatory approvals and expand our research and development with respect to our ESRD therapy products;

- to continue our ESRD therapy product engineering;
- to pursue business opportunities with respect to our DSU water-filtration product; and
- for working capital purposes.

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





TABLE OF CONTENTS

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In the event that our plans change, our assumptions change or prove inaccurate, or if our existing cash resources, together with other funding resources including increased sales of our products, otherwise prove to be insufficient to fund our operations and we are unable to obtain additional financing, we will be required to adopt alternatives, such as curtailing our planned activities or ceasing our operations.

At September 30, 2010, we had an accumulated deficit of approximately \$91,243,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering in September 2004, from licensing revenue received from Asahi Kasei Medical Co., Ltd. ( Asahi ) in March 2005, a private placement of convertible debenture in June 2006 and a private investment in public equity in September 2007 and a private placement in July 2009.

Net cash used in operating activities was \$2,612,000 for the year ended December 31, 2009 compared to \$5,725,000 for the year ended December 31, 2008.

During 2009, the net cash used in operating activities was \$3,113,000 less than the net cash used in operating activities during 2008. The most significant items contributing to the reduction in cash used in operating cash are highlighted below:

our net loss in 2009 was \$2,026,000 compared to \$6,337,000 in 2008. This represents an improvement of \$4,311,000 in operating cash in 2009. Noncash adjustments to reconcile net loss to net cash used in operating activities were: stock-based compensation was \$108,000 and \$155,000 in 2009 and 2008 respectively, a reduction of \$47,000, depreciation expense was \$231,000 and \$447,000 in 2009 and 2008 respectively, a reduction of \$216,000 and an increase to the inventory reserve of \$18,000 in 2009.

during 2009, our accounts receivable, other current assets and other assets increased by \$193,000. This compares to a decrease of \$236,000 in 2008. This represents a \$429,000 use of operating cash in 2009.

during 2009, our inventory decreased by \$75,000. This compares to an increase in inventory of \$409,000 in 2008. This represents a \$484,000 source of operating cash in 2009.

during 2009, accounts payable and accrued expenses decreased by \$807,000. This compares to an increase in accounts payable and accrued expenses of \$183,000 during 2008. This represents a \$990,000 use of operating cash in 2009.

Net cash used by investing activities was \$21,000 for the year ended December 31, 2009 compared to \$4,599,000 of net cash provided by investing activities for the year ended December 31, 2008. In 2009, \$28,000 was used to purchase equipment and \$7,000 was provided by the maturity of a short-term investment. In 2008, \$4,693,000 was provided due to the maturity of short-term investments. Approximately \$97,000 of funds was used to purchase property, plant and equipment and \$3,000 was provided by the sale of equipment.

Net cash provided by financing activities was \$1,336,000 for the year ended December 31, 2009 resulting from the sale of common stock of \$1,251,000 and proceeds from the exercise of stock options of \$85,000. There were no financing activities in 2008.

Net cash used in operating activities was approximately \$641,000 for the nine months ended September 30, 2010 compared to approximately \$1,870,000 for the nine months ended September 30, 2009. The most significant items contributing to this decrease of approximately \$1,229,000 cash used in operating activities during the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 are highlighted below:

during the 2010 period, our net loss decreased by approximately \$275,000;  
during the 2010 period, we recorded deferred revenue of \$67,000, whereas there was no deferred revenue in the 2009  
period;

70

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TABLE OF CONTENTS

during the 2010 period, depreciation expense decreased by approximately \$92,000; our accounts receivable decreased by approximately \$168,000 during the 2010 period compared to an increase of approximately \$114,000 during the 2009 period; our prepaid expenses and other assets decreased by approximately \$67,000 in the 2010 period compared to a decrease of approximately \$49,000 in the 2009 period; and our accounts payable and accrued expenses increased by approximately \$129,000 in the aggregate in the 2010 period compared to a decrease of approximately \$638,000 in the 2009 period.

Offsetting the above changes are the following items:

during the 2010 period, our stock-based compensation expense increased by approximately \$2,000; and our inventory decreased by approximately \$28,000 during the 2010 period compared to a decrease of approximately \$118,000 during the 2009 period.

Net cash used in investing activities was approximately \$6,000 for the nine months ended September 30, 2010, compared to net cash provided by investing activities of approximately \$7,000 for the nine months ended September 30, 2009. Net cash used in investing activities for the nine months ended September 30, 2010 was for the purchase of tooling equipment. Net cash provided by investing activities was approximately \$7,000 for the nine months ended September 30, 2009 and resulted from the maturities of short-term investments.

Financing activities provided net cash of approximately \$72,000 for the nine months ended September 30, 2010 resulting from the issuance of common stock due to the exercise of stock options.

On July 24, 2009, we raised gross proceeds of \$1,251,000 through the private placement to eight accredited investors of an aggregate of 1,345,161 shares of our common stock and warrants to purchase an aggregate of 672,581 shares of our common stock, representing 50% of the shares of common stock purchased by each investor. We sold the shares to investors at a price per share equal to \$0.93. The warrants have an exercise price of \$1.12, are exercisable immediately and will terminate on July 24, 2014. For the nine months ended September 30, 2009, \$84,000 of cash was also provided by the exercise of stock options.

## Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2009:

	Payments Due in Period					More than 5 Years
	Total	Within 1 Year	Years 1 - 3	Years 3 - 5		
Leases	\$ 186,000	\$ 101,000	\$ 85,000	\$	\$	
Employment Contracts	244,000	195,000	49,000			
Total	\$ 430,000	\$ 296,000	\$ 134,000	\$	\$	

## Certain Risks and Uncertainties

Certain statements in this prospectus, including certain statements contained in Description of Business and Management's Discussion and Analysis, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases can be, may, could, would, expects, believes, seeks, estimates, projects and similar phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to

various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

71

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TABLE OF CONTENTS

## **BUSINESS**

### **Overview**

Founded in 1997, we are a Delaware corporation that has been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. In January 2006, we introduced our new Dual Stage Ultrafilter (the DSU ) water filtration system, which represents a new and complementary product line to our existing ESRD therapy business.

We currently have three products in various stages of development in the HDF modality to deliver improved therapy to ESRD patients:

OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); to our knowledge, the only filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

OLpur H<sub>2</sub>H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

OLpur NS2000 system, our stand-alone HDF machine and associated filter technology.

We have also developed our OLpur HD 190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpur MD series but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpur HD190 was designed for use with either hemodialysis or hemodiafiltration machines, and received its approval from the U.S. Food and Drug Administration, or FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act, in June 2005.

OLpur and H<sub>2</sub>H are among our trademarks for which U.S. registrations are pending. H<sub>2</sub>H is a registered European Union trademark. We have assumed that the reader understands that these terms are source-indicating. Accordingly, such terms appear throughout the remainder of this prospectus without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as middle molecules because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H<sub>2</sub>H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved in 2010, our OLpur H<sub>2</sub>H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profiles), and therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. In addition, independent studies in Europe have indicated that, when compared with dialysis as it is currently offered in the United States, HDF can reduce the patient's mortality risk by up to 35%. We believe that the OLpur MDHDF filter series and the OLpur H<sub>2</sub>H will provide these benefits to ESRD patients at competitive costs and without the need for ESRD treatment providers to make significant capital expenditures in order to use our products. We also believe that the OLpur NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

In the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption ( IDE ) application for the clinical evaluation of our OLpur H<sub>2</sub>H module and OLpur MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. An in-person meeting with the FDA took place on September 10, 2010 to

TABLE OF CONTENTS

discuss the issues raised in the FDA letter. We are evaluating our future course of action. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

In January 2006, we introduced our new Dual Stage Ultrafilter (the DSU) water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpur H<sub>2</sub>H and MD Mid-Dilution filter technologies for ESRD therapy provided the foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of November 11, 2009), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

Due to the ongoing concerns of maintaining water quality, on October 7, 2008, we filed a 510(k) application for approval to market our DSU to dialysis clinics for in-line purification of dialysate water. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

During the twelve months ended December 31, 2009, we were granted four new patents. In the U.S., we were issued patent #7,534,349 for a Dual Stage Ultrafilter with pump mechanism and/or shower feature. In Canada, we were issued patent #2,430,575 for a valve mechanism used in Infusion Fluid systems which is a feature used on our H<sub>2</sub>H module and patent #2,396,852 for an Ionic Enhanced Dialysis/Diafiltration system which is related to mid-dilution HDF. In China, we were issued patent #200510092067.3 for a Dual Stage Hemodiafiltration cartridge used in its OLpur MD HDF Filter.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately \$1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately \$1,178,000 of revenue has been recognized on this second project since September 2009, of which approximately \$755,000 was recognized during the nine months ended September 30, 2010.

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.



TABLE OF CONTENTS

## Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements included in this prospectus which expresses doubt as to our ability to continue as a going concern. The financial statements included in this prospectus 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. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred losses in our operations in each quarter since inception. For the years ended December 31, 2009 and 2008, we incurred net losses of \$2,026,000 and \$6,337,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2009 and 2008. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

At December 31, 2009, we had \$1,004,000 in cash and cash equivalents. There can be no assurance that our cash and cash equivalents will provide the liquidity we need to continue our operations. (See Certain Risks and Uncertainties .) These operating plans primarily include the continued development and support of our business in the European and Canadian markets, organizational changes necessary to enhance the commercialization of our water filtration business and the completion of current year milestones which are included in the Office of Naval Research appropriation.

We are undertaking this rights offering to raise capital to support our continued operations. If this rights offering is not completed, we do not expect we will be able to continue operating and would begin to wind down our operations.

If this rights offering is successful, we will continue to investigate additional funding opportunities by talking to various potential investors who could provide financing. However, there can be no assurance that we will be able to obtain further financing, do so on reasonable terms or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we may not be able to continue our operations.

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

## Delisting of Stock from AMEX

On September 12, 2008, we received a letter from the NYSE Alternext US LLC (formerly, the American Stock Exchange or AMEX ) notifying us of our noncompliance with certain continued listing standards.

In response to that letter, we submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions we have taken, or will take, that would bring us into compliance with the continued listing standards by April 30, 2009.

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On January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan of compliance regarding the following listing standards to which we were in noncompliance of:

Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;

Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and

74

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## TABLE OF CONTENTS

Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

The AMEX further stated that the AMEX intended to strike our common stock from the AMEX by filing a delisting application with the SEC pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we decided not to seek an appeal of the AMEX's intention to delist our common stock.

On January 22, 2009, we were informed by the AMEX that they had suspended trading in our common stock effective immediately. Immediately following the notification, our common stock was no longer traded on the AMEX.

Effective February 4, 2009, our common stock was quoted on the Over the Counter Bulletin Board under the symbol NEPH.OB .

In a letter dated April 13, 2009, we received a copy of the AMEX's application to strike our common stock from the AMEX.

## **Current ESRD Therapy Options**

Current renal replacement therapy technologies include (1) two types of dialysis, peritoneal dialysis and hemodialysis, (2) hemofiltration and (3) hemodiafiltration, a combination of hemodialysis and hemofiltration. Dialysis can be broadly defined as the process that involves movement of molecules across a semipermeable membrane. In hemodialysis, hemofiltration or hemodiafiltration, the blood is exposed to an artificial membrane outside of the body. During Peritoneal Dialysis (PD), the exchange of molecules occurs across the membrane lining of the patient's peritoneal cavity. While there are variations in each approach, in general, the three major categories of renal replacement therapy in the marketplace today are defined as follows:

### *Dialysis*

*Peritoneal Dialysis*, or PD, uses the patient's peritoneum, the membrane lining covering the internal abdominal organs, as a filter by introducing injectable-grade dialysate solution into the peritoneal cavity through a surgically implanted catheter. After some period of time, the fluid is drained and replaced. PD is limited in use because the peritoneal cavity is subject to scarring with repeated episodes of inflammation of the peritoneal membrane, reducing the effectiveness of this treatment approach. With time, a PD patient's kidney function continues to deteriorate and peritoneal toxin removal alone may become insufficient to provide adequate treatment. In such case the patient may switch to an extracorporeal renal replacement therapy such as hemodialysis or hemodiafiltration.

*Hemodialysis* uses an artificial kidney machine to remove certain toxins and fluid from the patient's blood while controlling external blood flow and monitoring patient vital signs. Hemodialysis patients are connected to a dialysis machine via a vascular access device. The hemodialysis process occurs in a dialyzer cartridge with a semi-permeable membrane which divides the dialyzer into two chambers: while the blood is circulated through one chamber, a premixed solution known as dialysate circulates through the other chamber. Toxins and excess fluid from the blood cross the membrane into the dialysate solution through a process known as diffusion.

*Hemofiltration* is a cleansing process without dialysate solution where blood is passed through a semi-permeable membrane, which filters out solute particles.

*Hemodiafiltration*, or HDF, in its basic form combines the principles of hemodialysis with hemofiltration. HDF uses dialysate solution with a negative pressure (similar to a vacuum effect) applied to the dialysate solution to draw additional toxins from the blood and across the membrane. This process is known as convection. HDF thus combines diffusion with convection, offering efficient removal of small solutes by diffusion, with improved removal of larger substances (i.e., middle molecules) by convection.



## TABLE OF CONTENTS

Hemodialysis is the most common form of extracorporeal renal replacement therapy and is generally used in the United States. Hemodialysis fails, in our opinion, to address satisfactorily the long-term health or overall quality of life of the ESRD patient. We believe that the HDF process, which is currently available in our Target European Market and Japan, offers improvement over other dialysis therapies because of better ESRD patient tolerance, superior blood purification of both small and middle molecules, and a substantially improved mortality risk profile.

### **Current Dialyzer Technology used with HDF Systems**

In our view, treatment efficacy of current HDF systems is limited by current dialyzer technology. As a result of the negative pressure applied in HDF, fluid is drawn from the blood and across the dialyzer membrane along with the toxins removed from the blood. A portion of this fluid must be replaced with a man-made injectable grade fluid, known as substitution fluid, in order to maintain the blood's proper fluid volume. With the current dialyzer technology, fluid is replaced in one of two ways: pre-dilution or post-dilution.

With pre-dilution, substitution fluid is added to the blood before the blood enters the dialyzer cartridge. In this process, the blood can be over-diluted, and therefore more fluid can be drawn across the membrane. This enhances removal of toxins by convection. However, because the blood is diluted before entering the device, it actually reduces the rate of removal by diffusion; the overall rate of removal, therefore, is reduced for small molecular weight toxins (such as urea) that rely primarily on diffusive transport.

With post-dilution, substitution fluid is added to blood after the blood has exited the dialyzer cartridge. This is the currently preferred method because the concentration gradient is maintained at a higher level, thus not impairing the rate of removal of small toxins by diffusion. The disadvantage of this method, however, is that there is a limit in the amount of plasma water that can be filtered from the blood before the blood becomes too viscous, or thick. This limit is approximately 20% to 25% of the blood flow rate. This limit restricts the amount of convection, and therefore limits the removal of middle and larger molecules.

### **The Nephros Mid-Dilution Diafiltration Process**

Our OLpur MDHDF filter series uses a design and process we developed called Mid-Dilution Diafiltration, or MDF. MDF is a fluid management system that optimizes the removal of both small toxins and middle-molecules by offering the advantages of pre-dilution HDF and post-dilution HDF combined in a single dialyzer cartridge. The MDF process involves the use of two stages: in the first stage, blood is filtered against a dialysate solution, therefore providing post-dilution diafiltration; it is then overdiluted with sterile infusion fluid before entering a second stage, where it is filtered once again against a dialysate solution, therefore providing pre-dilution diafiltration. We believe that the MDF process provides improved toxin removal in HDF treatments, with a resulting improvement in patient health and concurrent reduction in healthcare costs.

### **Our ESRD Therapy Products**

Our products currently available or in development with respect to ESRD Therapy include:

#### **OLpur MDHDF Filter Series**

OLpur MD190 and MD220 constitute our dialyzer cartridge series that incorporates the patented MDF process and is designed for use with existing HDF platforms currently prevalent in our Target European Market and Japan. Our MDHDF filter series incorporates a unique blood-flow architecture that enhances toxin removal with essentially no cost increase over existing devices currently used for HDF therapy.

Laboratory bench studies have been conducted on our OLpur MD190 by members of our research and development staff and by a third party. We completed our initial clinical studies to evaluate the efficacy of our OLpur MD190 as compared to conventional dialyzers in Montpellier, France in 2003. The results from this clinical study support our belief that OLpur MD190 is superior to post-dilution hemodiafiltration using a standard high-flux dialyzer with respect to  $\beta_2$ -microglobulin clearance. In addition, clearances of urea, creatinine, and phosphate met the design specifications proposed for the OLpur MD190 device. Furthermore, adverse event data from the study suggest that hemodiafiltration with our OLpur MD190 device was well tolerated by the patients and safe.

TABLE OF CONTENTS

We have initiated longer term clinical studies in the United Kingdom, France, Germany, Italy and Spain to further demonstrate the therapeutic benefits