As filed with the Securities and Exchange Commission on December 22, 2010

Registration No. 333-169728

SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D. C. 20549

AMENDMENT NO. 2 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 Telephone: (919) 781-4000 Facsimile: (919) 781-4865

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

Alexander M. Donaldson, Esq. Wyrick Robbins Yates & Ponton LLP 4101 Lake Boone Trail, Suite 300 Raleigh, Nor

offering. o

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered ^{$(1)(2)$}	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 ⁽³⁾				
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 ⁽⁴⁾	175,000,000	\$ 0.02	\$ 3,500,000	\$ 249.55
Warrants to purchase 161,793,248 shares of our common stock ⁽⁵⁾	175,000,000			
Common stock, \$0.001 par value per share, issuable upon exercise of the warrants ⁽⁶⁾	161,793,248	\$ 0.02	\$ 3,235,865	\$ 230.72
Total ⁽⁷⁾			\$ 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 (2) share, and warrants, (b) shares of common stock issuable upon the exercise of the subscription rights, (c) the warrants issuable upon exercise of the subscription rights, and (d) shares of our common stock that are issuable

⁽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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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 DECEMBER 22, 2010

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-transferable subscription right for each share of common stock owned by you at 5:00 p.m., Eastern Time, on [], 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 [].

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 shares × 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 Units × 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 Investors is not receiving any compensation for its purchase commitment. Any Units purchased by Lambda Investors

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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 [], unless we extend the subscription period in our sole discretion. 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 December 17, 2010, the closing sales price for our common stock was \$0.11 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 <u>Risk Factors</u> 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 [].

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OLpur TM and H ₂ H TM are among our trademarks for which U.S. registrations are pending. H ₂ H is a registered				

OLpurTM and H₂HTM are among our trademarks for which U.S. registrations are pending. H₂H 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.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. 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;

 $OLpur H_2H$, 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 H₂H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved, our OLpur H₂H 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.

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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 H₂H 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 H₂H 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 H₂H 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

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 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. Our annual meeting of stockholders will be held on January 10, 2011, at which we will ask our stockholders to approve, among other proposals, the increase in our authorized shares of common stock at that meeting. The increase in our authorized shares of common stock is a condition 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. We will ask our stockholders to approve a proposal to effect the reverse stock split at our upcoming annual meeting of stockholders. 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.

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

The Rights Offering

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

Securities Offered

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

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 shares × 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 warrant to purchase Units would be exercisable for up to 386 shares (418 Units × 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. 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 [].

Expiration Date

5:00 p.m., Eastern Time, on [], subject to extension or earlier termination at our sole discretion. 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 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

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

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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, you 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:

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 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 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 <u>19</u> 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.

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 [], 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 shares × 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 Units × 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 prive 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 February 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 independent directors (none of whom are affiliated with Lambda Investors) after consideration of the financing

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

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

No. There is no minimum subscription requirement to consummate the rights offering. 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 must 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 will not be able to complete the rights offering. We will seek stockholder approval for such amendment at our annual meeting of stockholders to be held on January 10, 2011. 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 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

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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 has approved an increase in the number of shares authorized for issuance under the 2004 Plan to 39,814,340, and we will be asking our stockholders to approve this amendment at our upcoming annual meeting of stockholders to be held on January 10, 2011. If this amendment to the 2004 Plan and a proposed 1-for-20 reverse stock split are both approved by our stockholders and 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 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

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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 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, you 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. 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 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 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 has approved an increase in the number of shares authorized for issuance under the 2004 Plan to 39,814,340, and we will be asking our stockholders to approve this amendment at our upcoming annual meeting of stockholders to be held on January 10, 2011. If this amendment to the 2004 Plan and a proposed 1-for-20 reverse stock split are both approved by our stockholders and 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.

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, 8th Floor New York, NY 10004 Attn: Reorganization Department

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

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

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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).

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RISK FACTORS

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

Risks Related to Our Company

Our independent registered public 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.

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 February 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.

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If we do not receive FDA approval for our OLpur H₂H 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 H₂H 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 H₂H 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_2H 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 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

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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 H₂H 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 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 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.

Clinical studies required for our ESRD therapy products are costly and time-consuming, and their outcome3s uncer

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.

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

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

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

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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 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.

Product liability associated with the production, marketing and sale of our products, and/or the expense of a fadefendin

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 time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including:

fines; injunctions; civil penalties; recalls or seizures of products;

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

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

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

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

Access to the appropriations from the U.S. Department of Defense regarding the development of a dual-stage water ultrafilter could be subject to unanticipated delays which could adversely affect our potential revenues.

Our business strategy with respect to our DSU products depends in part on the successful development of DSU products for use by the military. Beginning in January 2008, we contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters under a first contract in an amount not to exceed \$866,000. In August 2009, we entered into a second contract with a value not to exceed \$2 million. These contracts would utilize the Federal appropriations from the U.S. Department of Defense not to exceed \$3 million that have been approved for this purpose. If there are unanticipated delays in receiving the appropriations from the U.S. Department of Defense, our operations and potential revenues may be adversely affected. Further, if we do not successfully complete the contract work or renew the contract work in the event that the research and development needs additional work to reach completion, our operations and potential revenues may be adversely affected.

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

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

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

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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.

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.

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

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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 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 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 for the manufacture of our products or major components of our arrangements 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 for the manufacture of our products or major components for the manufacture of our products or major components for the manufacture 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 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

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that we expect to use to manufacture our OLpur H₂H 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;

there are unexpected side effects, complications or other safety issues associated with such products; and government or third party reimbursement for the cost of such products is available at reasonable rates, if at all. Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance and endurance standards. Our water filtration products and technology may not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial, military, industrial or retail applications.

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

If our products are commercialized, we may face significant challenges in obtaining market acceptance of 55 uch products are commercialized.

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 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

If we cannot develop adequate distribution, customer service and technical support networks, then we may not be a

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.

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

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.

also reduce our potential revenues.

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.

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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 ourESRD therapy products may be limit

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

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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 needadditional capital in the future. 65

under the ticker symbol NEPH, and the last reported sales price of our common stock on the OTC Bulletin Board on

December 17, 2010 was \$0.11 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.

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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 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 w

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.

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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 []. 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 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.

We have filed a proxy statement with the SEC in which, among other things, we are asking our stockholders to approve 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. If approved by stockholders, our

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board of directors intends to implement the 1-for-20 reverse stock split immediately following the completion 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.

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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 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. 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

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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.

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

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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 certificate7of incorp

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.

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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, projects and similar words and phrases are intended to identify such forward-looking statements. seeks. estimates. 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.

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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 February 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 December 17, 2010, the closing sale price of our common stock on the OTC Bulletin Board was \$0.11 per share.

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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; and8,191,827 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.

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

	September			
	Actual	Pro Forma ⁽¹⁾	Pro Forma as Adjusted ⁽²⁾	
	(Dollars in	(Dollars in Thousands)		
Cash and cash equivalents	\$421	\$3,721	\$3,644	
Accounts payable and accrued expenses	\$884	\$1,134	\$1,134	
Promissory note ⁽³⁾		500	500	
Total liabilities	\$884	\$1,634	\$1,634	
Stockholders equity:				
Preferred stock, \$0.001 par value: 5,000,000 shares authorized on a	n			
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	a			
as adjusted basis; 41,811,048, 216,811,048 and 10,840,52 shares	42	217	11	
issued and outstanding on an actual, pro forma and pro forma as				
adjusted basis ⁽⁴⁾				
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 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.

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

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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 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	\$	