

NEPHROS INC  
Form S-1  
October 02, 2009

As filed with the Securities and Exchange Commission on October 2, 2009

Registration No. 333-\_\_\_\_\_

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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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)

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Ernest Elgin III

President and 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)

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Approximate date of commencement of proposed sale to the public: As promptly as practicable after this registration statement becomes effective and the satisfaction or waiver of certain other conditions described herein.

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

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

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

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

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

Large accelerated filer  .. Accelerated filer  ..  
 Non-accelerated filer  .. (Do not check if smaller reporting company) Smaller reporting company  x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum aggregate offering price per unit (2)	Proposed maximum aggregate offering price(2)	Amount of registration fee(3)
Common stock, \$0.001 par value per share	\$ —	—\$	—\$	—
Preferred stock, \$0.001 par value per share	—	—	—	—
Warrants	—	—	—	—
Units	—	—	—	—
<b>Total</b>	<b>\$ 100,000,000</b>	<b>—\$</b>	<b>100,000,000</b>	<b>\$ 5,580</b>

(1) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate number of warrants to purchase common stock or preferred stock, and such indeterminate number of units as shall have an aggregate initial offering price not to exceed \$100,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder. The proposed maximum offering price per unit

will be determined, from time to time, by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock as may be issued upon conversion of or exchange for preferred stock that provide for conversion or exchange, upon exercise of warrants or pursuant to the antidilution provisions of any of such securities. In addition, pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transaction.

- (2) The proposed maximum offering price per unit will be determined from time to time by the Registrant in connection with, and at the time of, the issuance of the securities and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3, as amended.
- (3) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on the proposed maximum aggregate offering price of all securities listed.

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.

SUBJECT TO COMPLETION — DATED OCTOBER 2, 2009

PROSPECTUS

\$100,000,000  
Common Stock  
Preferred Stock  
Warrants  
Units

From time to time, we may offer up to \$100,000,000 of any combination of the securities described in this prospectus, either individually or in units, in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering. We may also offer common stock upon conversion of preferred stock, or common stock or preferred stock upon the exercise of warrants.

Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. We will specify in any accompanying prospectus supplement the terms of any offering. You should read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

We will sell these securities directly to our stockholders or to other purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our shares of common stock are quoted on the Over-the-Counter Bulletin Board under the symbol "NEPH.OB." On September 30, 2009, the last reported sale price of our common stock on the Over-the-Counter Bulletin Board was \$1.42 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

You are urged to carefully read this prospectus, the prospectus supplement relating to any specific offering of securities and all information incorporated by reference herein and therein.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under "Risk Factors" beginning on page [6] and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of 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 [ ], 2009.

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## TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	1
PROSPECTUS SUMMARY	2
RISK FACTORS	6
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	21
USE OF PROCEEDS	22
PLAN OF DISTRIBUTION	22
DESCRIPTION OF COMMON STOCK	23
DESCRIPTION OF PREFERRED STOCK	25
DESCRIPTION OF WARRANTS	26
DESCRIPTION OF UNITS	27
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	28
LEGAL MATTERS	29
EXPERTS	29
WHERE YOU CAN FIND MORE INFORMATION	29
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	29
DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS	30

OLpur™ and H2H™ 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 filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Prospectus supplements may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein by reference and the additional information under the heading “Where You Can Find More Information” before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

Unless the context otherwise requires, “Nephros,” “the company,” “we,” “us,” “our” and similar names refer to Nephros, Inc. a our subsidiary, Nephros International Limited.

## 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 or incorporated by reference in this prospectus, including the section entitled “Risk Factors” on page [6 ] and our financial statements for the years ended December 31, 2007 and 2008, and the quarter ended June 30, 2009, and related notes, which are incorporated by reference. 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 H2H, 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 in 2009, our OLpur H2H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.



We submitted a 501(k) application for our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter to the FDA 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. Per FDA guidelines, the FDA generally reviews additional information within 90 days. As of the date of this prospectus, we have not received a response from the FDA.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profiles), and therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. In addition, independent studies in Europe have indicated that, when compared with dialysis as it is currently offered in the United States, HDF can reduce the patient's mortality risk by up to 35%. We believe that the OLpur MDHDF filter series and the OLpur 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, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,000 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 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 are developing a personal potable water purification system for use by soldiers. Work on this project commenced in January 2008 and we billed \$196,000 during the year ended December 31, 2008. In December 2007, the U.S. Department of Defense Appropriations Act appropriated an additional \$2 million to continue the development of a dual stage ultra reliable personal water filtration system. In August 2009, we were awarded a new \$2 million research contract from the Office of Naval Research, or ONR, for development of a potable dual-stage military water purifying filter. The research contract was an expansion of our current 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 the Nephros 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 ONR 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. We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We believe that the military product development efforts will have broad consumer applications as well and have begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.



## Recent Developments

On July 24, 2009, we raised gross proceeds of \$1,251,000 through the private placement to eight accredited investors of an aggregate of 1,345,161 shares of our common stock and warrants to purchase an aggregate of 672,581 shares of our common stock, representing 50% of the shares of common stock purchased by each investor. We sold the shares to investors at a price per share equal to \$0.93. The warrants have an exercise price of \$1.12, are exercisable immediately and will terminate on July 24, 2014. Each investor agreed that it will not sell, pledge, sell short or otherwise dispose of any of the purchased shares until January 31, 2010. The proceeds from the private placement will be used for ongoing operations and other general corporate purposes, including the launch of our recently FDA-approved Dual Stage Ultrafilters and, if approved by the FDA, the preparation to launch our OLpur MD220 Dialyzers and H2H Hemodiafiltration Module in the United States.

## Corporate Information

We are incorporated in Delaware and our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey 07661. Our telephone number is (201) 343-5202 and our website address is [www.nephros.com](http://www.nephros.com). Information contained in, or accessible through, our website does not constitute part of this prospectus.

## Offerings Under This Prospectus

We may offer shares of our common stock and preferred stock and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$100,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

This prospectus may not be used to consummate a sale of any securities unless it is accompanied by a prospectus supplement.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we offer securities through agents or underwriters, we will include in the applicable prospectus supplement:

- the names of those agents or underwriters;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

## Common Stock

We may issue shares of our common stock from time to time. The holders of common stock are entitled to one vote per share on all matters to be voted upon by stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of any preferred stock then outstanding.

#### Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Our board of directors will determine the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by stockholders. Convertible preferred stock will be convertible into our common stock or exchangeable for our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

If we sell any series of preferred stock under this prospectus and applicable prospectus supplements, we will fix the rights, preferences, privileges and restrictions of the preferred stock of such series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the applicable prospectus supplement related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

#### Warrants

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock or preferred stock, and the warrants may be attached to or separate from these securities. We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into warrant agreements with a bank or trust company that we select to be our warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement related to the particular series of warrants being offered, as well as the warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, the form of warrant agreement or warrant certificate containing the terms of the warrants we are offering before the issuance of the warrants.

#### Units

We may issue units consisting of common stock, preferred stock and/or warrants for the purchase of common stock or preferred stock in one or more series. In this prospectus, we have summarized certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the SEC, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

## RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained or incorporated by reference in this prospectus, before you decide whether to buy our common stock. 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, 2008, 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 our Annual Report on Form 10-K for the period ended December 31, 2008, expressing doubt as to our ability to continue as a going concern. The financial statements included in our Form 10-K were prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations, raises substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We might require additional financing to fund operations or potential acquisitions. If financing is not available, we might not be able to grow as we plan.

At June 30, 2009, we had cash, cash equivalents and short-term investments totaling approximately \$890,000 million and tangible assets of approximately \$2,340,000 million. In the future, we might be required to seek additional financing to fund operations or potential acquisition opportunities. Despite our recent private placement from which we raised gross proceeds of \$1,251,000, as described above under "Recent Developments," the recent downturn in the capital markets and the general economic slowdown could prevent us from raising additional capital or obtaining additional financing on favorable terms, if at all. If we cannot raise sufficient capital, our ability to operate and to grow through acquisitions or otherwise respond to competitive pressures would be significantly limited.

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 June 30, 2009, we had an accumulated deficit of \$89,097,000 primarily as a result of our research and development expenses and selling, general and administrative expenses and non-cash expenses related to converted bonds in 2007. 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 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 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. 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, 2008, one of our customers accounted for 78% of our product sales. Also, this customer represented 66% of our accounts receivable as of December 31, 2008. We believe that the loss of this customer would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

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, or 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. Although we received approval of our Investigational Device Exemption in March 2007 to begin clinical trials in the United States, until we complete the requisite U.S. human clinical trials and submit pre-market notification to the FDA pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or FDC Act, or otherwise comply with FDA requirements for a 510(k) approval, we will not be eligible for FDA approval for any of our products, except for our HD190 filter.

In addition to the pre-market notification required pursuant to Section 510(k) of the FDC Act, the FDA could require us to obtain pre-market approval of our ESRD therapy products under Section 515 of the FDC Act, either because of legislative or regulatory changes or because the FDA does not agree with our determination that we are eligible to use the Section 510(k) pre-market notification process. The Section 515 pre-market approval process is a significantly more costly, lengthy and uncertain approval process and could materially delay our products coming to market. If we do obtain clearance for marketing of any of our devices under Section 510(k) of the FDC Act, then any changes we wish to make to such device that could significantly affect safety and effectiveness will require clearance of a notification pursuant to Section 510(k), and we may need to submit clinical and manufacturing comparability data to

obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the United States.

The clearance and/or approval processes in the European Community and in the United States can be lengthy and uncertain, and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or any FDA approval for any of our ESRD therapy products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals with respect to the European Community or the United States would prevent us from selling our affected products in these regions. If we cannot sell some of our products in these regions, or if we are delayed in selling while awaiting 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 (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) 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, 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 have 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 in November 2008 with our 510(k) application for these products. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Per FDA guidelines, the FDA generally reviews additional information within 90 days. As of the date of this prospectus, we have not received a response from the FDA.

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, 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 generate revenues from such products.

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

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

- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and
  - if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

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

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

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of \$5,000,000 for our products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and adversely affect the demand for our products, our ability to generate sales and our profitability.

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

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

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

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

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our 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;
- 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 or non-renewal 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 have 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 in an aggregate amount of \$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 13 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 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, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

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

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

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

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

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

Approval or clearance of our ESRD therapy products could be delayed by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our ESRD therapy products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our ESRD therapy products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur 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.

Even with approval to market our ESRD therapy products in the European Community, the United States and other countries, 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 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 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 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 2007 Form 20-F annual report, Fresenius Medical Care AG provides treatment in its own dialysis clinics to approximately 173,863 patients in approximately 2,238 facilities around the world of which approximately 1,602 facilities are located in the North America. According to DaVita, Inc.'s 2007 Annual Report, DaVita, Inc. provides treatment in 1,359 outpatient dialysis centers serving approximately 107,000 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 also reduce our potential revenues.

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

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our ESRD therapy products or sell fewer units, and, in either case, our potential revenues would suffer.

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

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

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. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reform proposals. We cannot predict whether these reform proposals will be 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 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 Our Common Stock

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.

Future sales of our common stock could cause the market price of our common stock to decline.

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



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

In the two years ended September 30, 2009, 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:

- 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;
  - achievement or rejection of regulatory approvals by our competitors or us;
- 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.

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.

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.

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

As of September 30, 2009, our directors and executive officers and their affiliates beneficially owned approximately 44.7% of our outstanding common stock. As of September 30, 2009, Lambda Investors LLC beneficially owned 44.2% of our outstanding common stock. To our knowledge, as of September 30, 2009, AFS Holdings One LLC beneficially owned 7.6% of our outstanding common stock and Stagg Capital Group LLC beneficially owned 9.0% of our outstanding common stock, based on their respective most recent filings with the SEC. See “Security Ownership of Certain Beneficial Owners and Management.”

Our principal stockholders may have significant influence over our policies and affairs, including the election of directors. Should they act as a group, they will have the power to elect all of our directors and to control the vote on substantially all other corporate matters without the approval of other stockholders. Furthermore, such concentration of voting power could enable those stockholders to delay or prevent another party from taking control of our company even where such change of control transaction might be desirable to other stockholders.

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 “Risk Factors” section could impair our business operations or otherwise cause our operating results or prospects to be below expectations of investors and market analysts, which could adversely affect the market price of our common stock. As a result, investors in our common stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company’s securities. 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.

We may use our financial resources in ways with which you do not agree and in ways that may not yield a favorable return.

Our management has broad discretion over the use of our financial resources, including the net proceeds from any financing, including any sales made pursuant to the registration statement of which this prospectus is a part. Stockholders may not deem such uses desirable. Our use of our financial resources may vary substantially from our currently planned uses. We cannot assure you that we will apply such proceeds effectively or that we will invest such proceeds in a manner that will yield a favorable return or any return at all.

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.

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 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 the company's 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," "believes," "seeks," "estimates," "projects" and similar words and phrases are intended to identify such forward-looking statements. These forward-looking statements may include, among other things, statements concerning the expectations of Nephros regarding its business, growth prospects, revenue trends, operating costs, working capital requirements, competition, results of operations, and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends, and similar expressions concerning matters that are not historical facts. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the preceding pages, and we caution you that any forward-looking information provided by or on behalf of us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by

such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## USE OF PROCEEDS

We cannot assure you that we will receive any proceeds in connection with securities offered pursuant to this prospectus. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, including further development of our product candidates, clinical trials, research and development expenses, general and administrative expenses. We will set forth in the prospectus supplement our intended use for the net proceeds received from the sale of any securities. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities.

## PLAN OF DISTRIBUTION

We may offer securities under this prospectus from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities (1) through underwriters or dealers, (2) through agents or (3) directly to one or more purchasers, or through a combination of such methods. We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to the prevailing market prices; or
- negotiated prices.

We may directly solicit offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in a prospectus supplement any underwriter or agent involved in the offer or sale of the securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale, and we will provide the name of any underwriter in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of the securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

With respect to underwritten public offerings, negotiated transactions and block trades, we will provide in the applicable prospectus supplement any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute

to payments they may be required to make in respect thereof.



We do not expect that shares of our common stock sold pursuant to the registration statement of which this prospectus is a part will be authorized for quotation and trading on any stock exchange. Such shares will be quoted on the Over-the-Counter Bulletin Board. The applicable prospectus supplement will contain information, where applicable, as to any listing, if any, on any securities market or other securities exchange of the securities covered by the prospectus supplement. To facilitate the offering of the securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing the applicable security in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if the securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in other transactions with us, or perform other services for us, in the ordinary course of their business.

#### DESCRIPTION OF COMMON STOCK

Our authorized common stock consists of 60,000,000 shares, \$0.001 par value per share. As of September 30, 2009, there were 41,604,798 shares of common stock outstanding and no shares of preferred stock outstanding.

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of our common stock entitled to vote in any election of directors may elect all of the directors standing for election. Our certificate of incorporation provides for the division of our board of directors into three classes of directors, with each class as nearly equal in number as possible, serving staggered, three-year terms. See “Anti-Takeover Effects of Provisions of Our Charter Documents” below for a further discussion of this provision.

Apart from preferences that may be applicable to any holders of preferred stock outstanding at the time, holders of our common stock are entitled to receive dividends, if any, ratably as may be declared from time to time by the Board out of funds legally available therefor. Upon our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive ratably our net assets available after the payment of all liabilities and liquidation preferences on any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

#### Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

#### Over-the-Counter Bulletin Board

Our common stock is not listed for quotation on any stock exchange. Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol “NEPH.OB.” On September 30, 2009, the last reported sale price of our common stock was \$1.42 per share.

Anti-Takeover Effects of Provisions of Our Charter Documents

Our certificate of incorporation and bylaws may have anti-takeover effects. These provisions are intended to avoid costly takeover battles, lessen our vulnerability to a hostile change of control and enhance the ability of our board of directors to maximize stockholder value in connection with any unsolicited offer to acquire us. However, these anti-takeover provisions, which are summarized below, could also discourage, delay or prevent the merger or acquisition of our company by means of a tender offer, a proxy contest or otherwise, that a stockholder may consider in its best interest, and the removal of incumbent officers and directors.

#### Blank Check Preferred Stock

As discussed above, under the terms of our certificate of incorporation, our board of directors has authority, without any further vote or action by our stockholders, to issue up to 5,000,000 shares of blank check preferred stock. Our board of directors may issue shares of preferred stock on terms calculated to discourage, delay or prevent a change of control of our company or the removal of our management.

#### Classified Board of Directors

As noted above, our certificate of incorporation provides for the division of our board of directors into three classes of directors, with each class as nearly equal in number as possible, serving staggered, three-year terms. Approximately one-third of our board of directors will be elected each year. This classified board provision could discourage a third party from making a tender offer for our shares or attempting to obtain control of our company. It could also delay stockholders who do not agree with the policies of the board of directors from removing a majority of the board of directors for two years.

#### Removal of Directors

Our certificate of incorporation provides that our directors may be removed only for cause and only upon the affirmative vote of the holders of at least a majority of the outstanding shares of our common stock entitled to vote for such directors. This provision may discourage, delay or prevent the removal of incumbent officers and directors.

#### Limited Actions by Stockholders

Our certificate of incorporation and our by-laws provide that any action required or permitted to be taken by our stockholders must be effected at an annual or special meeting of stockholders or by the unanimous written consent of our stockholders. Our certificate of incorporation provides that, subject to certain exceptions, only our board of directors, the chairman of our board of directors, our president, vice president or secretary may call special meetings of our stockholders. Accordingly, a stockholder may be prevented from calling a special meeting for stockholder consideration of a proposal over the opposition of our board of directors and stockholder consideration of a proposal may be delayed until the next annual meeting.

#### Investor Rights Agreement

In September 2007, in connection with a convertible debt financing, we entered into an Investor Rights Agreement with Lambda Investors LLC, Southpaw Credit Opportunity Master Fund LP, 3V Capital Master Fund Ltd, Distressed/High Yield Trading Opportunities, Ltd., Kudu Partners, L.P. and LJHS Company, referred to collectively as the Investors, all of whom became holders of our common stock upon the conversion of the notes purchased by them in that offering. Pursuant to that agreement:

- we agreed to take such corporate actions as may be required to, among other things, entitle Lambda to (i) nominate the Lambda Nominees (as defined in the Investor Rights Agreement) to our board of directors to serve as directors until their respective successor(s) are elected and qualified, (ii) nominate each successor to such Lambda nominees, provided that any successor shall have reasonably appropriate experience and background, and (iii) direct the removal from the board of any director nominated under the foregoing clauses (i) or (ii). Under the agreement, we are required to convene meetings of our board at least once every three months. If we fail to do so, a Lambda director will be empowered to convene such meeting; and

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the Investors other than Lambda agreed to vote all shares of our common stock, and any other capital stock or other securities of ours, that they hold for the election to our board of the Lambda nominees and for the removal from the Board of the Lambda nominees proposed to be removed in accordance with clause (iii) above, and not to vote for the removal of any Lambda director except pursuant to direction from Lambda pursuant to clause (iii) above.

## DESCRIPTION OF PREFERRED STOCK

Our authorized preferred stock consists of 5,000,000 shares, \$0.001 par value per share. As of September 30, 2009, there were no shares of preferred stock outstanding.

Our board of directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by our stockholders. As of the date of this prospectus, no shares of preferred stock were outstanding. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation and could have the effect of delaying, deferring or preventing a change in control of our company.

We will fix the rights, preferences, privileges and restrictions of the preferred stock of each series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description will include any or all of the following, as required:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;

- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
  - any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable.

The General Corporation Law of the State of Delaware, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

#### Transfer Agent and Registrar

The transfer agent and registrar for any shares of preferred stock will be set forth in the applicable prospectus supplement.

### DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of any warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. With respect to any warrants that we offer, specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to a current report on Form 8-K, incorporated by reference in this prospectus:

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, the exercise price for shares of our common stock or preferred stock and the number of shares of common stock or preferred stock to be received upon exercise of the warrants;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
  - any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositories, execution or paying agents, transfer agents, registrars or other agents;

- the proposed listing, if any, of the warrants or the common stock issuable upon exercise of the warrants on any securities exchange;
- if applicable, the date from and after which the warrants and the common stock will be separately transferable;
  - if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
    - information with respect to book-entry procedures, if any;



- the anti-dilution provisions of the warrants, if any;
- any redemption or call provisions;
- whether the warrants are to be sold separately or with other securities as parts of units; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

#### Transfer Agent and Registrar

The transfer agent and registrar for any warrants will be set forth in the applicable prospectus supplement.

#### DESCRIPTION OF UNITS

We might issue units comprised of shares of common stock, shares of preferred stock and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We will file as exhibits to the registration statement of which this prospectus is a part, the form of unit agreement, warrant and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

We may choose to evidence each series of units by unit certificates that we would issue under a separate agreement. If we choose to evidence the units by unit certificates, we will enter into the unit agreements with a unit agent and will indicate the name and address of the unit agent in the applicable prospectus supplement relating to the particular series of units.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the beneficial ownership of our common stock as of September 30, 2009, by (i) each person known to us to own beneficially more than five percent (5%) of our common stock, based on such persons' or entities' most recent filings with the SEC; (ii) each director, director nominee and executive officer; and (iii) all directors, director nominees and executive officers as a group:

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of class (1)
Lambda Investors LLC (2)	21,572,432	44.2%
Stagg Capital Group LLC(3)	3,749,558	9.0%
AFS Holdings One LLC (4)	3,150,597	7.6%
Arthur H. Amron (5)	15,000	*
Lawrence J. Centella (6)	63,410	*
Ernest Elgin III (7)	187,500	*
Gerald J. Kochanski (8)	62,500	*
Paul A. Mieyal (9)	15,000	*
James S. Scibetta (10)	26,667	*
All executive officers and directors as a group (5-10)	370,077	*

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

(1) Percentages are based on 41,604,798 shares of common stock issued and outstanding as of September 30, 2009.

(2) Based in part on information provided in Schedule 13D filed on October 1, 2007. The shares beneficially owned by Lambda Investors LLC may be deemed beneficially owned by Wexford Capital LLC, which is the managing member of Lambda Investors LLC, by Charles E. Davidson in his capacity as chairman and managing member of Wexford Capital LLC and by Joseph M. Jacobs in his capacity as president and managing member of Wexford Capital LLC. The address of each of Lambda Investors LLC, Wexford Capital LLC, Mr. Davidson and Mr. Jacobs is c/o Wexford Capital LLC, 411 West Putnam Avenue, Greenwich, CT 06830. Each of Wexford Capital LLC, Mr. Davidson and Mr. Jacobs disclaims beneficial ownership of the shares of Common Stock owned by Lambda Investors LLC except, in the case of Mr. Davidson and Mr. Jacobs, to the extent of their respective interests in each member of Lambda Investors LLC. Includes 7,190,811 shares issuable on or prior to November 14, 2012 upon exercise of warrants held by Lambda Investors LLC having an exercise price of \$0.90 per share.

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

(4) Based in part on information provided in Schedule 13G filed with the SEC on January 8, 2009 by AFS Holdings One LLC. AFS reported that it beneficially owns 3,150,597 shares of our common stock and has sole voting and dispositive power with respect to those shares.

(5) Mr. Amron's address is c/o Wexford Capital LLC, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Amron consist of 15,000 shares issuable upon exercise of options granted under the 2004 Plan.

(6) Mr. Centella's address is 3331 N. Ridge Ave, Arlington Heights, IL 60004. The shares identified as being beneficially owned by Mr. Centella include 35,000 shares issuable upon exercise of options granted under the 2004

Plan.

28

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- (7) Mr. Elgin's address is the Company address. The shares identified as being beneficially owned by Mr. Elgin consist of 187,500 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 637,500 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 30, 2009.
- (8) Mr. Kochanski's address is the Company address. The shares identified as being beneficially owned by Mr. Kochanski consist of 62,500 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 212,500 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 30, 2009.
- (9) Mr. Mieyal's address is c/o Wexford Capital LLC, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Mieyal consist of 15,000 shares issuable upon exercise of options granted under the 2004 Plan.
- (10) Mr. Scibetta's address is the Company address. The shares identified as being beneficially owned by Mr. Scibetta consist of 26,667 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 13,333 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 30, 2009.

#### LEGAL MATTERS

The legality of the securities being offered hereby will be passed upon for us by Wyrick Robbins Yates & Ponton, LLP, Raleigh, North Carolina.

#### EXPERTS

Our financial statements at and for the years ended December 31, 2007 and 2008, incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2008, have been audited by Rothstein Kass & Company P.C., an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, which report includes an explanatory paragraph related to the Company's ability to continue as a going concern. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings are also available to the public free of charge at the SEC's website at [www.sec.gov](http://www.sec.gov) and on our website at [www.nephros.com](http://www.nephros.com).

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The information incorporated by reference is an important part of this prospectus. We incorporate by reference the following documents that have been filed with the SEC by us (except for information furnished to the SEC that is not deemed to be "filed" for purposes of the Exchange Act):

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, filed March 31, 2008;
- Our Amendment No. 1 on Form 10-K/A for the fiscal year ended December 31, 2008, filed April 30, 2009;

- Our Quarterly Reports on Form 10-Q for the first and second fiscal quarters of 2009, filed May 15, 2009 and August 14, 2009, respectively; and

- Our Current Reports on Form 8-K filed January 14, January 26, February 4, June 24, July 30, August 20 and August 31, 2009.

We will, at no cost, furnish each person, including any beneficial owner, to whom this prospectus is delivered, a copy of the information we incorporate by reference in this prospectus at no cost by writing or telephoning us at Nephros, Inc. at 41 Grand Avenue, River Edge, New Jersey 07661, telephone (201) 343-5202. We maintain a website at [www.nephros.com](http://www.nephros.com). Information contained on our website is not incorporated by reference into this prospectus and you should not consider information contained on our website to be a part of this prospectus.

#### DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides for indemnification of directors and officers of the Registrant to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. We have obtained liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of the registrant. Our Second Amended and Restated By-Laws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the DGCL. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

PART II  
INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable by the registrant in connection with the sale of the securities being registered. All amounts are estimates.

SEC Filing Fee	\$ 5,580
Printing expenses	\$ 3,000
Legal Fees and Expenses	\$ 20,000
Accounting Fees and Expenses	\$ 5,000
Miscellaneous	\$ 2,000
Total	\$ 35,580

## Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or DGCL, permits a corporation, under specified circumstances, to indemnify its directors, officers, employees or agents against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors, officers, employees or agents of the corporation, if such directors, officers, employees or agents acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reason to believe their conduct was unlawful. In a derivative action, that is one by or in the right of the corporation, indemnification may be made only for expenses actually and reasonably incurred by directors, officers, employees or agents in connection with the defense or settlement of an action or suit, and only with respect to a matter as to which they will have acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made if such person will have been adjudged liable to the corporation, unless and only to the extent that the court in which the action or suit was brought will determine upon application that the defendant directors, officers, employees or agents are fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides for indemnification of our directors and officers of the registrant to the fullest extent permitted by the DGCL. Our Second Amended and Restated By-Laws provides that we will generally indemnify our directors, officers, employees or agents to the fullest extent permitted by the law against all losses, claims, damages or similar events. We have obtained liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of our company.

## Item 15. Recent Sales of Unregistered Securities.

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

In September 2007, we entered into a Subscription Agreement with Lambda Investors LLC, or Lambda, GPC 76, LLC, Lewis P. Schneider and Enso Global Equities Partnership LP (collectively, the "New Investors") pursuant to

which the New Investors purchased an aggregate of approximately \$12.7 million principal amount of Series A 10% Secured Convertible Notes due 2008 (the “Purchased Notes”) of Nephros, for the face value thereof (the “Offering”).



Concurrently with the Offering, Nephros entered into an Exchange Agreement with each of Southpaw Credit Opportunity Master Fund LP, 3V Capital Master Fund Ltd, Distressed/High Yield Trading Opportunities, Ltd., Kudu Partners, L.P. and LJHS Company (collectively, the “Exchange Investors” and together with the New Investors, the “Investors”), pursuant to which the Exchange Investors agreed to exchange the principal and accrued but unpaid interest in an aggregate amount of approximately \$5.6 million under the 6% Secured Convertible Notes due 2012 (“Old Notes”) of Nephros, for new Series B 10% Secured Convertible Notes due 2008 in an aggregate principal amount of \$5.3 million (the “Exchange Notes”).

All principal and accrued but unpaid interest under the New Notes automatically converted into (i) an aggregate of 18,255,128 shares of our common stock, par value \$0.001 per share at a conversion price per share equal to \$0.706 and (ii) in the case of Purchased Notes, but not Exchange Notes, Class D Warrants to purchase an aggregate of 9,112,566 shares of common stock with an exercise price per share equal to \$0.706.

National Securities Corporation, or NSC, and Dinosaur Securities, LLC, or Dinosaur, acted as co-placement agents in connection with the Financing pursuant to an Engagement Letter, dated June 6, 2007 and a Placement Agent Agreement dated September 18, 2007. The co-placement agents received (i) an aggregate cash fee equal to 8% of the face amount of the Purchased Notes, allocated and paid 6.25% to NSC and 1.75% to Dinosaur, and (ii) warrants with a term of five years from the date of issuance to purchase an aggregate of 1,756,374 shares of common stock at an exercise price of \$0.706 per share.

All of the securities described above were issued under the exemption from registration provided by Section 4(2) of the Securities Act.

#### Item 16. Exhibits

(a) Exhibits. The following exhibits are filed as part of this registration statement:

Exhibit No.	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(5)
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on November 13, 2007. (14)
3.5	Second Amended and Restated By-Laws of the Registrant.(16)
4.1	Specimen of Common Stock Certificate of the Registrant.(1)
4.2	Form of Underwriter’s Warrant.(1)
4.3	Warrant for the purchase of shares of common stock dated January 18, 2006, issued to Marty Steinberg, Esq., as Court-appointed Receiver for Lancer Offshore, Inc.(17)
4.4	Form of Series A 10% Secured Convertible Note due 2008 convertible into Common Stock and Warrants. (15)
4.5	Form of Series B 10% Secured Convertible Note due 2008 convertible into Common Stock.(15)
4.6	Form of Class D Warrant.(15)
4.7	Form of Placement Agent Warrant.(15)
4.8	Form of Investor Warrant issued on July 24, 2009. (20)
5.1*	

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Opinion of Wyrick Robbins Yates & Ponton LLP as to the legality of the securities being registered.

- 10.1 Amended and Restated 2000 Nephros Equity Incentive Plan.(1)(2)
- 10.2 2004 Nephros Stock Incentive Plan.(1)(2)
- 10.3 Amendment No. 1 to 2004 Nephros Stock Incentive Plan.(2)(5)
- 10.4 Amendment No. 2 to the Nephros, Inc. 2004 Stock Incentive Plan.(14)
- 10.5 Form of Subscription Agreement dated as of June 1997 between the Registrant and each Purchaser of Series A Convertible Preferred Stock. (1)
- 10.6 Amendment and Restatement to Registration Rights Agreement, dated as of May 17, 2000 and amended and restated as of June 26, 2003, between the Registrant and the holders of a majority of Registrable Shares (as defined therein). (1)

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- 10.7 Employment Agreement dated as of November 21, 2002 between Norman J. Barta and the Registrant. (1)(2)
- 10.8 Amendment to Employment Agreement dated as of March 17, 2003 between Norman J. Barta and the Registrant. (1)(2)
- 10.9 Amendment to Employment Agreement dated as of May 31, 2004 between Norman J. Barta and the Registrant. (1)(2)
- 10.10 Employment Agreement effective as of July 1, 2007 between Nephros, Inc. and Norman J. Barta. (14)
- 10.11 Form of Employee Patent and Confidential Information Agreement.(1)
- 10.12 Form of Employee Confidentiality Agreement.(1)
- 10.13 Settlement Agreement and Mutual Release dated June 19, 2002 between Plexus Services Corp. and the Registrant.(1)
- 10.14 Settlement Agreement dated as of January 31, 2003 between Lancer Offshore, Inc. and the Registrant. (1)
- 10.15 Settlement Agreement dated as of February 13, 2003 between Hermitage Capital Corporation and the Registrant. (1)
- 10.16 Supply Agreement between Nephros, Inc. and Membrana GmbH, dated as of December 17, 2003. (1)(3)
- 10.17 Amended Supply Agreement between Nephros, Inc. and Membrana GmbH dated as of June 16, 2005. (3)(7)
- 10.18 Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of May 12, 2003. (1)(3)
- 10.19 Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of March 22, 2005 supercedes prior Agreement dated May 12, 2003. (3)(8)
- 10.20 HDF-Cartridge License Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
- 10.21 Subscription Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
- 10.22 Non-employee Director Compensation Summary.(2)(6)
- 10.23 Named Executive Officer Summary of Changes to Compensation.(2)(6)
- 10.24 Stipulation of Settlement Agreement between Lancer Offshore, Inc. and Nephros, Inc. approved on December 19, 2005. (8)
- 10.25 Consulting Agreement, dated as of January 11, 2006, between the Company and Bruce Prashker. (2)(8)
- 10.26 Summary of Changes to Chief Executive Officer's Compensation.(2)(8)
- 10.27 Offer of Employment Agreement, dated as of February 24 2006, between the Company and Mark W. Lerner. (2)(8)
- 10.28 Form of 6% Secured Convertible Note due 2012 for June 1, 2006 Investors.(9)
- 10.29 Form of Common Stock Purchase Warrant.(9)
- 10.30 Form of Subscription Agreement, dated as of June 1, 2006.(9)
- 10.31 Form of Registration Rights Agreement, dated as of June 1, 2006.(9)
- 10.32 Form of 6% Secured Convertible Note due 2012 for June 30, 2006 Investors.(10)
- 10.33 Form of Subscription Agreement, dated as of June 30, 2006.(10)
- 10.34 Employment Agreement between Nephros, Inc. and William J. Fox, entered into on August 2, 2006. (2)(11)
- 10.35 Addendum to the Commercial Contract between Nephros, Inc. and Bellco S.p.A, effective as of January 1, 2007. (3)(12)
- 10.36 Form of Subscription Agreement between Nephros and Subscriber.(15)
- 10.37

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- Exchange Agreement, dated as of September 19, 2007, between Nephros and the Holders. (15)
- 10.38 Registration Rights Agreement, dated as of September 19, 2007, among Nephros and the Investors. (15)
- 10.39 Investor Rights Agreement, dated as of September 19, 2007, among Nephros and the Covered Holders as defined therein. (15)
- 10.40 Placement Agent Agreement, dated as of September 18, 2007, among Nephros, NSC and Dinosaur. (15)

- 10.41 License Agreement, dated October 1, 2007, between the Trustees of Columbia University in the City of New York, and Nephros. (17)
- 10.42 Employment Agreement, dated as of April 1, 2008, between Nephros, Inc. and Gerald Kochanski. (2) (18)
- 10.43 Separation Agreement, dated as of April 28, 2008, between Nephros, Inc. and Mark W. Lerner. (2) (18)
- 10.44 Separation Agreement and Release, dated as of September 15, 2008, between Nephros, Inc. and Norman J. Barta. (2) (19)
- 10.45 Employment Agreement, dated as of September 15, 2008, between Nephros, Inc. and Ernest A. Elgin III. (2) (19)
- 10.46 Distribution Agreement between Nephros, Inc. and OLS, dated as of November 26, 2008.(20)
- 10.47 Lease Agreement between Nephros International LTD and Coldwell Banker Penrose & O'Sullivan dated November 30, 2008.(20)
- 10.48 Distribution Agreement between Nephros, Inc. and Aqua Services, Inc., dated as of December 3, 2008.(20)
- 10.49 Sales Management Agreement between Nephros, Inc. and Steve Adler, dated as of December 16, 2008.(20)
- 10.50 Amendment No. 3 to the Nephros, Inc. 2004 Stock Incentive Plan.(20)
- 10.51 Form of Subscription Agreement between Nephros, Inc. and various investors, dated July 24, 2009. (20)
- 21.1 Subsidiaries of Registrant.(12)
- 23.1\* Consent of Rothstein Kass, Certified Public Accountants.
- 23.2\* Consent of Wyrick Robbins Yates & Ponton LLP (contained in Exhibit 5.1).

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\*Filed herewith.

- (1) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1, File No. 333-116162.
- (2) Management contract or compensatory plan arrangement.
- (3) Portions omitted pursuant to a request for confidential treatment.
- (4) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K Filed with the Securities and Exchange Commission on March 3, 2005.
- (5) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (No. 333-127264), as filed with the Securities and Exchange Commission on August 5, 2005.
- (6) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on May 16, 2005.
- (7) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on August 15, 2005.
- (8) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB, filed with the Securities and Exchange Commission on April 20, 2006.
- (9) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2006.
- (10) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 7, 2006.
- (11) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 4, 2006.
- (12)

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Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2006, filed with the Securities and Exchange Commission on April 10, 2007.

- (13) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 13, 2007.
- (14) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the Securities and Exchange Commission on November 13, 2007.

- (15) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2007.
- (16) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2007.
- (17) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008.
- (18) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the Securities and Exchange Commission on May 15, 2008.
- (19) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008, filed with the Securities and Exchange Commission on November 14, 2008.
- (20) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 14, 2009.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933 (the "Act"); (ii) to reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information in this registration statement; and (iii) to include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

(2) That, for the purpose of determining any liability under the Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the

registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.



(5) That, for the purpose of determining liability of the Registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, or SEC, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned Registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(d) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

(2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.



SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of River Edge, State of New Jersey, on October 2, 2009.

NEPHROS, INC.

Date: October 2, 2009

By: /s/ Ernest A. Elgin III  
 Name: Ernest A. Elgin III  
 Title: President, Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL PERSONS BY THESE PRESENTS, that the persons whose signatures appear below each severally constitutes and appoints Ernest A. Elgin, III and Gerald J. Kochanski, and each of them, his true and lawful attorney-in-fact and agent, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective and post-effective amendments) to this registration statement, and to file the same, with all exhibits, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all which said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do, or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ernest A. Elgin III Ernest A. Elgin III	President, Chief Executive Officer (Principal Executive Officer) and Director	October 2, 2009
/s/ Gerald J. Kochanski Gerald J. Kochanski	Chief Financial Officer (Principal Financial and Accounting Officer)	October 2, 2009
/s/ Arthur H. Amron Arthur H. Amron	Director	October 2, 2009
/s/ Lawrence J. Centella Lawrence J. Centella	Director	October 2, 2009
/s/ Paul A. Mieyal Paul A. Mieyal	Director	October 2, 2009

Director

October 2, 2009

/s/ James S. Scibetta  
James S. Scibetta

S-1

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