NEPHROS INC
Form 424B3
August 26, 2009
PROSPECTUS

28,972,659 Shares of Common Stock

This prospectus relates to the resale or other disposition of up to 28,972,659 shares of our common stock, which shares consist of (i) 19,515,412 outstanding shares of our common stock, (ii) 9,112,566 shares of our common stock issuable upon the exercise of our Class D Warrants, (iii) 144,681 shares of our common stock issuable upon the exercise of our placement agent warrants, and (iv) 200,000 shares of our common stock issuable upon the exercise of our underwriter warrants, that are beneficially owned by the selling stockholders listed on page 21 of this prospectus or their transferees. The selling stockholders may sell any, all or none of the shares of our common stock offered under this prospectus and any supplements to this prospectus from time to time, in one or more transactions.

We are registering the shares of common stock offered under this prospectus as required by the terms of certain registration rights agreements between the selling stockholders and us, as described in the section entitled the "Selling Stockholders." We will not receive any proceeds from the sale of shares of our common stock sold by the selling stockholders. However, we may receive up to $8,035,616 of proceeds in connection with the exercise for cash by the selling stockholders of warrants to purchase certain of the shares of our common stock that may be offered and sold under this prospectus.

Our shares of common stock are quoted on the Over-the-Counter Bulletin Board under the symbol "NEPH.OB." On August 18, 2009, the last reported sale price of our common stock on the Over-the-Counter Bulletin Board was $2.28 per share.

INVESTING IN OUR COMMON STOCK INVOLVES CERTAIN RISKS. AS YOU REVIEW THIS PROSPECTUS, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DESCRIBED IN THE SECTION OF THIS PROSPECTUS TITLED "RISK FACTORS" BEGINNING ON PAGE 5.

None of the Securities and Exchange Commission, any state securities commission or any other regulatory body 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 August 25, 2009.

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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.

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 5 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. Although it is our intention to execute an agreement with the U.S. Department of Defense to utilize this appropriation before it expires in September 2009, such an agreement has not been executed as of August 21, 2009. We have defined the project scope and objectives in connection with this appropriation and submitted a proposal to the Office of Naval Research in February 2009. We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

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.

The Offering

Securities offered by the selling stockholders	28,972,659 shares of common stock of Nephros, par value $0.001 per share, held by the selling stockholders, are being offered by this prospectus. (1)(2)
Shares outstanding before the Offering	40,238,110 shares of common stock (3)
Use of Proceeds	The shares being offered pursuant to this prospectus are being sold by the selling stockholders, and we will not receive any proceeds from the sale of the shares by the selling stockholders. We might receive proceeds in connection with the exercise of the Warrants for cash, the underlying shares of which may be sold by the selling stockholders under this prospectus.

(1) Includes (i) 9,112,566 shares of our common stock issuable upon conversion of our Class D Warrants with an exercise price per share equal to $0.706 per share, or Class D Warrants, issued by us to certain selling stockholders in connection with our September 2007 financing, (ii) 144,681 shares of our common stock issuable upon conversion Placement Agent warrants with an exercise price per share equal to $0.706 per share, or Placement Agent Warrants, issued by us to certain selling stockholders in connection with our September 2007 financing and (iii) 200,000 shares of our common stock issuable upon conversion of our underwriter warrants with an exercise price per share equal to $7.50 per share, or Underwriter Warrants, issued by us to certain selling stockholders in connection with our initial public offering. We refer to the Class D Warrants, the Placement Agent Warrants and the Underwriter Warrants, (collectively, the Warrants.

(2) (i) The following selling stockholders received our common stock and Class D Warrants, as further described under the section entitled “Selling Stockholders”, in connection with our September 2007 financing: Lambda Investors LLC, Enso Global Equities Master Partnership LP, GPC 76, LLC, Lewis P. Schneider, Southpaw Credit Opportunity Master Fund LP (received no warrants), 3V Capital Master Fund Ltd. (received no warrants), and Distressed/High Yield Trading Opportunities Ltd. (received no warrants) (referred to collectively as the 2007 Investors); (ii) the following selling stockholders received Placement Agent Warrants in connection with our September 2007 financing: National Securities Corporation, Mark Goldwasser, Brian Friedman, Malcolm Plett, Peter Menachem, Tom Holly, Andrew J. Deniken and David Garrity; and (iii) the following selling stockholders received Underwriter Warrants in connection with our initial public offering: Gary Shemano, William Corbett, Howard Davis, David Weinstein, Doug Kaiser, Frank Salvatore, Michael Bresner, Mark Goldwasser, Brian Friedman, Robert Daskal and National Securities Corporation.

(3) As of August 17, 2009. This amount does not include the 9,457,247 shares of common stock issuable upon conversion of the Warrants.

Corporate Information

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

prospectus.

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 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. We have contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters in an amount not to exceed $866,000 and have submitted a proposal for 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 we are unsuccessful in being awarded the second contract or 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.

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.

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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 the 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.

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 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 August 17, 2009, our directors and executive officers and their affiliates beneficially owned approximately 54% of our outstanding common stock. As of August 17, 2009, Lambda Investors LLC beneficially owned 53.6% of our outstanding common stock. To our knowledge, as of August 17, 2009, AFS Holdings One LLC beneficially owned 7.8% of our outstanding common stock and Stagg Capital Group LLC beneficially owned 9.3% 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 our initial public offering and our subsequent financings. 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," "believ "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

The selling stockholders will receive all of the net proceeds from the sales of shares of our common stock offered under this prospectus. The Company might receive up to $8,035,616 of proceeds in connection with the exercise of the Warrants for cash, the underlying shares of which may be sold by the selling stockholders. Although the timing and amount of any such proceeds are uncertain, such proceeds, if received, will be used for working capital.

DETERMINATION OF OFFERING PRICE

The selling stockholders may sell shares from time to time in negotiated transactions, brokers' transactions or a combination of such methods at market prices prevailing at the time of the sale or at negotiated prices.

SELLING STOCKHOLDERS

The following table sets forth the shares beneficially owned, as of August 17, 2009, by the selling stockholders (as represented to us by the selling stockholders or based on their most recent filings with the SEC) prior to the offering contemplated by this prospectus, the number of shares each selling stockholder is offering by this prospectus and the number of shares which each would own beneficially if all such offered shares are sold.

Beneficial ownership is determined in accordance with the rules of the SEC and includes generally voting and/or investment power with respect to securities. Shares of common stock subject to warrants, options or convertible stock currently exercisable or convertible, or exercisable or convertible within 60 days of August 17, 2009, are deemed outstanding for the purpose of computing the percentage beneficially owned by the person holding such warrants, options or convertible stock but are not deemed outstanding for the purpose of computing the percentage beneficially owned by any other person.

Selling Stockholders	Number of Shares of Common Stock Beneficially Owned Before Any Sale	Number of Shares of Common Stock Subject to the Sale of this Prospectus	Number of Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Pursuant to this Prospectus(1)
Lambda Investors LLC	21,572,432(2)	21,572,432	0
Stagg Capital Group LLC	3,749,558(3)	3,749,558	0
Enso Global Equities Master Partnership LP	1,723,001(4)	1,723,001	0
Southpaw Credit Opportunity Master Fund LP	871,872(5)	871,872	0
GPC 76, LLC	202,342(6)	202,342	0
Kudu Partners	146,582(7)	146,582	0
LJHS Company	146,582(8)	146,582	0
Lewis P. Schneider	107,805(9)	107,805	0
Ralph Weill	107,804(10)	107,804	
Malcolm Plett	100,000(11)(26)	100,000	0
Mark Goldwasser	5,876(12)(26)	5,876	0
Brian Friedman	4,000(13)(26)	4,000	0
Gary Shemano	71,015(14)	71,015	0
David Garrity	17,181(15)(27)	17,181	0
National Securities Corporation	25,000(16)	25,000	0
Howard Davis	35,508(17)	35,508	0
William Corbett	35,507(18)	35,507	0
Peter Menachem	12,500(19)(26)	12,500	0
Tom Holly	15,000(20)(26)	15,000	0
David Weinstein	11,614(21)	11,614	0
Michael Bresner	5,000(22)	5,000	0
Robert Daskal	3,000(23)(26)	3,000	0
Doug Kaiser	1,740(24)	1,740	0
Frank Salvatore	1,740(25)	1,740	0
Total	28,972,659	28,972,659	0

(1) Assumes that the selling stockholders will sell all of their shares of common stock subject to sale pursuant to this prospectus. There is no assurance that the selling stockholders will sell all or any of their shares of common stock.

(2) Represents 14,381,621 shares of our common stock and 7,190,811 shares of our common stock issuable upon conversion of Class D Warrants. Lambda Investors LLC, or Lambda, is a private investment fund formed for the purpose of making various investments. Wexford Capital LLC, or Wexford, is the managing member of Lambda. Mr. Charles E. Davidson and Mr. Joseph M. Jacobs serve as the managing members of Wexford. Wexford may, by reason of its status as managing member of Lambda, be deemed to beneficially own the shares of our common stock beneficially owned by Lambda. Each of Charles E. Davidson and Joseph M.

Jacobs may, by reason of his status as a controlling person of Wexford, be deemed to beneficially own the shares of our common stock beneficially owned by Lambda. Each of Charles E. Davidson, Joseph M. Jacobs and Wexford shares the power to vote and to dispose of the shares of our common stock beneficially owned by Lambda. Each of Wexford and Messrs. Davidson and Jacobs disclaims beneficial ownership of the shares of our common stock owned by Lambda. Further information is set forth in the Schedule 13D filed with the SEC by Lambda, Wexford, Mr. Davidson and Mr. Jacobs on October 1, 2007.

(3) The amount shown as beneficially owned represents 3,749,558 shares of common stock. Stagg Capital Group LLC, a Delaware limited liability company ("Stagg Capital") serves as the investment advisor to an investment fund that holds the shares and Scott A. Stagg, a citizen of the United States, 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. Stagg Capital and Mr. Stagg have the power to vote and dispose of the shares. Pursuant to Rule 13d-4, Stagg Capital and Mr. Stagg disclaim all such beneficial ownership. Further information is set forth in the Schedule 13D/A filed with the SEC on August 21, 2008.

(4) The amount shown as beneficially owned represents 1,723,001 shares of our common stock issuable upon the conversion of Class D Warrants. Enso Global Equities Master Partnership, LP, or Enso, is a private investment fund formed for the purpose of making various investments. Enso Capital Management, Ltd. is the general partner of Enso. Enso Capital Management LLC is the investment manager of Enso. Mr. Joshua Fink serves as Director of Enso Capital Management, Ltd. (general partner of Enso), and as Chief Executive Officer and Chief Investment Officer of Enso Capital Management LLC. Enso Capital Management, Ltd. may, by reason of its status as general partner of Enso, be deemed to beneficially own the shares beneficially owned by Enso. Enso Capital Management LLC may, by reason of its status as investment manager of Enso, be deemed to beneficially own the shares beneficially owned by Enso. Joshua A. Fink may, by reason of his status as controlling person of Enso Capital Management LLC, be deemed to beneficially own the shares of our common stock beneficially owned by Enso. Each of Enso Capital Management, Ltd., Enso Capital Management LLC and Joshua A. Fink shares the power to vote and to dispose of the shares beneficially owned by Enso. Each of Enso Capital Management, Ltd., Enso Capital Management LLC and Mr. Fink disclaims beneficial ownership of the shares owned by Enso except, with respect to Mr. Fink, to the extent of his interests in each partner of Enso.

(5) The amount shown as beneficially owned represents 871,872 shares of our common stock. Southpaw Credit Opportunity Master Fund LP, or Master Fund, serves as a master fund investment vehicle for investments by Southpaw Credit Opportunity Fund (FTE) Ltd. and Southpaw Credit Opportunity Partners LP. Southpaw Asset Management LP, or Southpaw Management, provides investment management services to private individuals and institutions, including Master Fund. Southpaw Holdings LLC, or Southpaw Holdings, serves as the general partner of Southpaw Management. Mr. Kevin Wyman and Mr. Howard Golden are principals of Southpaw Holdings. Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden share the power to vote and dispose the shares. Pursuant to Rule 13d-4, Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden disclaim all such beneficial ownership. Further information is set forth in the Schedule 13D filed with the SEC by Master Fund, Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden on October 17, 2007, as amended by Amendment 1 thereto filed on May 30 2008, and the Form 4 filed with the SEC by Southpaw Management on June 10, 2009.

(6) The amount shown as beneficially owned represents 75,458 shares of our common stock and 126,884 shares of our common stock issuable upon conversion of Class D Warrants. Southpaw Asset Management LP, or Southpaw Management, provides investment management services to private individuals and institutions, including GPC 76 LLC. Southpaw Holdings LLC, or Southpaw Holdings, serves as the general partner of Southpaw Management. Mr. Kevin Wyman and Mr. Howard Golden are principals of Southpaw Holdings. Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden share the power to vote and dispose of the shares. Pursuant to Rule 13d-4, Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden disclaim all such beneficial ownership. Further information is set forth in the Schedule 13D filed with the SEC by Master Fund, Southpaw Management, Southpaw Holdings, Mr. Wyman and Mr. Golden on October 17, 2007, as amended by Amendment 1 thereto filed on May 30, 2008.

(7) The amount shown as beneficially owned represents 146,582 shares of our common stock. La Plata River Partners, LLC is the general partner of Kudu Partners, L.P. William Lupien is the sole member of La Plata River Partners, LLC. Mr. Lupien has dispositive power and voting control over the shares of our common stock.

(8) The amount shown as beneficially owned represents 146,582 shares of our common stock. LJHS Company is a family investment partnership. Each of James McLeod, Heather McLeod Yowel, Lisa McLeod Stephenson and Scott McLeod are the owners of LJHS Company. Scott McLeod and Jack McLeod each have dispositive power and voting control over the shares of our common stock.

(9) The amount shown as beneficially owned represents 71,870 shares of our common stock and 35,935 shares of our common stock issuable upon conversion of Class D Warrants.

(10) The amount shown as beneficially owned represents 71,869 shares of our common stock and 35,935 shares of our common stock issuable upon conversion of Class D Warrants.

(11) The amount shown as beneficially owned represents 100,000 shares of our common stock issuable upon conversion of Placement Agent Warrants.

(12) The amount shown as beneficially owned represents 5,876 shares of our common stock issuable upon conversion of Underwriter Warrants.

(13) The amount shown as beneficially owned represents 4,000 shares of our common stock issuable upon conversion of Underwriter Warrants.

(14) The amount shown as beneficially owned represents 71,015 shares of our common stock issuable upon conversion of Underwriter Warrants.

(15) The amount shown as beneficially owned represents 17,181 shares of our common stock issuable upon conversion of Placement Agent Warrants.

(16) The amount shown as beneficially owned represents 25,000 shares of our common stock issuable upon conversion of Underwriter Warrants

(17) The amount shown as beneficially owned represents 35,508 shares of our common stock issuable upon conversion of Underwriter Warrants.

(18) The amount shown as beneficially owned represents 35,507 shares of our common stock issuable upon conversion of Underwriter Warrants.

(19) The amount shown as beneficially owned represents 12,500 shares of our common stock issuable upon conversion of Placement Agent Warrants.

(20) The amount shown as beneficially owned represents 15,000 shares of our common stock issuable upon conversion of Placement Agent Warrants.

(21) The amount shown as beneficially owned represents 11,614 shares of our common stock issuable upon conversion of Underwriter Warrants.

(22)

The amount shown as beneficially owned represents 5,000 shares of our common stock issuable upon conversion of Underwriter Warrants.

(23) The amount shown as beneficially owned represents 3,000 shares of our common stock issuable upon conversion of Underwriter Warrants.

(24) The amount shown as beneficially owned represents 1,740 shares of our common stock issuable upon conversion of Underwriter Warrants.

(25) The amount shown as beneficially owned represents 1,740 shares of our common stock issuable upon conversion of Underwriter Warrants.

(26) National Securities Corporation, or NSC, has advised us that the listed selling stockholder is an associated person of NSC, received these warrants as a designee of NSC in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. NSC was entitled to receive these securities as partial compensation for its services as placement agent or underwriter in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

(27) Dinosaur Securities LLC, or Dinosaur, has advised us that the listed selling stockholder is an associated person of Dinosaur, received these warrants as a designee of Dinosaur in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. Dinosaur was entitled to receive these securities as partial compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

Material Relationships

Paul A. Mieyal and Arthur H. Amron are members of our board of directors. Dr. Mieyal and Mr. Amron are employed by Wexford, a registered investment advisory firm that manages Lambda, a selling stockholder.

Agreements with the Selling Stockholders

September 2007 Financing

In connection with our September 2007 financing, we entered into the Registration Rights Agreement with the 2007 Investors pursuant to which we agreed to file an initial resale registration statement no later than 60 days after we filed the Information Statement with the SEC. The Information Statement was filed on October 24, 2007, and we filed the initial resale registration statement on December 20, 2007. We agreed to use our commercially reasonable best efforts to have such registration statement declared effective within 240 days after filing the definitive version of the Information Statement.

In connection with our September 2007 financing, we issued the Placement Agent Warrants to National Securities Corporation, or NSC, Dinosaur Securities LLC, or Dinosaur, and their designees. Pursuant to such Placement Agent Warrants, we agreed to register the shares issuable under the Placement Agent Warrants on one or more resale registration statements, treating the shares issuable upon conversion of the Placement Agent Warrants as Registrable Securities (as defined in the Registration Rights Agreement) and as shares of common stock issuable upon exercise of the Class D Warrants and treating the holders of the Placement Agent Warrants as holders of the Class D Warrants. We also granted NSC and Dinosaur a right of first refusal to act as co-lead placement agents for any future private offering of our securities or as co-lead managing underwriters for any future public offering of our securities. Such right of first refusal terminated on March 19, 2009, and we have no repurchase right with respect to such right.

In connection with our September 2007 financing, we entered into an Investor Rights Agreement with the 2007 Investors pursuant to which we agreed to take such corporate actions as may be required, among other things, to

entitle Lambda, one of the selling stockholders, (i) to nominate two individuals having reasonably appropriate experience and background (the "Lambda Nominees") to our board to serve as directors until their respective successor(s) are elected and qualified, (ii) to nominate each successor to the Lambda Nominees, provided that any successor shall have reasonably appropriate experience and background, and (iii) to direct the removal from the Board of any director nominated under the foregoing clauses (i) or (ii). Under the Investor Rights Agreement, we are required to convene meetings of the Board at least once every three months. If we fail to do so, a Lambda director will be empowered to convene such meeting.

The Investor Rights Agreement also provides that, except as Lambda may otherwise agree in writing, Lambda will have the right (i) to engage, directly or indirectly, in the same or similar business activities or lines of business as us and (ii) to do business with any of our clients, competitors or customers, with the result that we shall have no right in or to such activities or any proceeds or benefits therefrom, and neither Lambda nor any officer, director, partner, manager, employee or affiliate of Lambda ("Lambda Person") will be liable to us or our stockholders for breach of any fiduciary duty by reason of any such activities of Lambda or of such Lambda Person's participation therein. A Lambda Person who is serving as one of our officers or directors may not, at the same time, serve as an officer or director of any entity whose principal business activity is (i) the development or sale of medical devices for the treatment of end stage renal disease or (ii) water filtration. In the event that Lambda or any Lambda Person acquires knowledge of a potential transaction or matter that may be a corporate opportunity for both Lambda and us other than in the case of a "director-related opportunity" (as defined below), Lambda and such Lambda Person will have no duty to communicate or present such corporate opportunity to us. In addition, in the event that a Lambda director acquires knowledge of a potential transaction or matter that may be a corporate opportunity for both us and Lambda, such corporate opportunity will belong to Lambda, unless such corporate opportunity is a director-related opportunity, in which case such corporate opportunity will belong to us. A "director-related opportunity", under the Investor Rights Agreement, means a potential transaction or matter that may be a corporate opportunity for both us and Lambda where knowledge of such corporate opportunity is made known to a Lambda Person who is serving as our director as a result of his serving as our director prior to (x) Lambda or any other Lambda Person acquiring knowledge of such corporate opportunity, or (y) such Lambda Person acquiring knowledge of such corporate opportunity other than as a result of such Lambda Person's serving as a director.

2004 Initial Public Offering

In connection with our initial public offering, we entered into a Warrant Agreement, dated as of September 24, 2004, with The Shemano Group, Inc., or Shemano, whereby we issued the Underwriter Warrants to Shemano and its designees. Pursuant to the Warrant Agreement, we agreed that, if at any time during the five years following the initial public offering, we proposed to register any shares of our common stock, we must include the shares of our common stock issuable upon conversion of the Underwriter Warrants in such registration statement on the same terms and conditions as the securities otherwise being sold in such registration. Therefore, this prospectus relates to the 200,000 shares of our common stock issuable upon conversion of the Underwriter Warrants.

Copies of the Registration Rights Agreement, the Placement Agent Warrant and the Investor Rights Agreement as described above have been filed as exhibits to our Current Report on Form 8-K filed with the SEC on September 25, 2007. A copy of the Warrant Agreement as described above has been filed as an exhibit to our Registration Statement on Form S-1 (No. 333-116162), as amended, filed with the SEC on August 26, 2004. This summary is qualified in its entirety by reference to each of these documents, which are incorporated herein by reference. We urge you to read these documents carefully for more details regarding the provisions we describe in this prospectus and for other provisions that may be important to you.

PLAN OF DISTRIBUTION

We anticipate that the selling stockholders and their pledgees, donees, transferees and other successors-in-interest may sell all or a portion of the shares offered by this prospectus from time to time on securities exchanges or in private transactions, at fixed prices, at market prices prevailing at the time of sale, at prices reasonably related to the market price or at negotiated prices. Sale of the shares offered by this prospectus may be effected by one or more of the following methods:

- ordinary brokerage transactions and transactions in which the broker solicits purchases;

- sales to one or more brokers or dealers as principal, and resale by those brokers or dealers for their account, including resales to other brokers and dealers;

- block trades in which a broker or dealer attempts to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- privately negotiated transactions with purchasers;
- an exchange distribution in accordance with the rules of the applicable exchange;
- settlement of short sales entered into after the date of this prospectus;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. No such broker-dealer will receive compensation in excess of that permitted by NASD Rule 2440 and IM-2440. In no event will any broker-dealer receive total compensation in excess of 8%. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

We are not aware as of the date of this prospectus of any agreements between any selling stockholder and any broker-dealers regarding the sale of the shares offered by this prospectus, although we have made no inquiry in that regard. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

We will file, during any period during which we are required to do so under our registration rights agreement with the selling stockholders, one or more post-effective amendments to the registration statement of which this prospectus is a part to describe any material information with respect to the plan of distribution not previously disclosed in this

prospectus or any material change to such information in this prospectus.

An aggregate of 1,756,374 shares of common stock issuable upon exercise of warrants held by National Securities Corporation, Dinosaur Securities LLC and/or “related persons” of National Securities Corporation and Dinosaur Securities LLC were subject to a 180 day lock-up in accordance with the requirements of NASD Rule 2710(g)(1) and could not be sold, pledged, assigned, transferred or hypothecated for a period of 180 days from May 5, 2008, which was the effective date of the original registration statement, except in accordance with the requirements of NASD Rule 2710(g)(2).

Each selling stockholder may be deemed to be an "underwriter" within the meaning of the Securities Act. Any broker, dealer or other agent executing a sell order on behalf of the selling stockholders may be considered to be an underwriter within the meaning of the Securities Act, in which case commissions received by any of these brokers, dealers or agents and profit on any resale of the shares may be considered to be underwriting commissions under the Securities Act.

The selling stockholders may also sell shares under Rule 144 of the Securities Act, if available, rather than under this prospectus.

All costs, fees and expenses of registration incurred in connection with the offering will be borne by us. All selling and other expenses incurred will be borne by each selling stockholder. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the beneficial ownership of our common stock as of August 17, 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	53.6%
Stagg Capital Group LLC(3)	3,749,558	9.3%
AFS Holdings One LLC (4)	3,150,597	7.8%
Arthur H. Amron (5)	10,000	*
Lawrence J. Centella (6)	63,410	*
Ernest Elgin III	0	*
Gerald J. Kochanski (7)	62,500	*
Paul A. Mieyal (8)	10,000	*
James S. Scibetta (9)	20,001	*
All executive officers and directors as a group (5-9)	165,911	*

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

(1) Percentages are based on 40,238,110 shares of common stock issued and outstanding as of August 17, 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 10,000 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 5,000 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of August 17, 2009.

(6) Mr. Centella's address is c/o Nephros, Inc., 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Centella include 35,000 shares issuable upon exercise of options granted under the 2004 Plan.

(7) 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 August 17, 2009.

(8) 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 10,000 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 5,000 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of August 17, 2009.

(9) Mr. Scibetta's address is c/o Nephros, Inc., 41 Grand Avenue, River Edge, New Jersey 07661. The shares identified as being beneficially owned by Mr. Scibetta consist of 20,001 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 19,999 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of August 17, 2009.

DESCRIPTION OF COMMON STOCK

Our authorized capital stock consists of 60,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of August 17, 2009, there were approximately 40,238,110 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. 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.

LEGAL MATTERS

The legality of the common stock 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 and on our website at 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;

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- 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 and August 20, 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. 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.