NEPHROS INC
Form POS AM
September 30, 2011

As filed with the Securities and Exchange Commission on September 30, 2011

Registration No. 333-169728

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

POST-EFFECTIVE AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NEPHROS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	3841	13-3971809
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I. R. S. Employer Identification No.)

41 Grand Avenue
River Edge, New Jersey 07661
(201) 343-5202
(Address, Including Zip Code, and Telephone Number,
Including Area Code, of Registrant's Principal Executive Offices)

Paul A. Mieyal
Acting Chief Executive Officer
Nephros, Inc.
41 Grand Avenue
River Edge, New Jersey 07661
(201) 343-5202
(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

Copies to:

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Day Pitney LLP
One Jefferson Road
Parsippany, New Jersey 07054
Telephone: (973) 966-6300
Facsimile: (973) 966 1015

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

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

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

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

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

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

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

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 to Form S-1 (this "Post-Effective Amendment") is being filed pursuant to Section 10(a)(3) of the Securities Act of 1933, as amended, to update the Form S-1 Registration Statement (Registration No. 333-169728), which was previously declared effective by the Securities and Exchange Commission on January 31, 2011, to include the audited consolidated financial statements and the notes thereto included in the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, the interim unaudited consolidated financial statements and the notes thereto included in the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, certain of the Registrant's current reports on Form 8-K that have been filed with the SEC since January 31, 2011, and contains an updated prospectus relating to the offering and sale of the securities that were registered on Form S-1. As of the date of filing of this Post-Effective Amendment, no further offering will be made of the units registered on Form S-1. The rights offering was completed on March 10, 2011. Accordingly, this Post-Effective Amendment concerns only the exercise of the warrants underlying the units.

All applicable registration fees were paid at the time of the original filing of such Registration Statement on October 1, 2010.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Post-Effective Amendment No. 2 to the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION — DATED SEPTEMBER 30, 2011

NEPHROS, INC.

Issuance of up to 4,590,171 Shares of Common Stock upon Exercise of Warrants

We previously sold 4,964,854 units, each unit consisting of one share of our common stock and a warrant to purchase 4,590,171 shares of our common stock (the "Units"). The warrants are exercisable for a five-year term following the issue date of the warrants, which was March 10, 2011, and have an exercise price of $0.40 per share. This prospectus relates to the issuance of shares of common stock pursuant to the exercise of the warrants to purchase an aggregate of 4,590,171 shares of common stock.

All costs associated with this registration statement will be borne by us. Shares of our common stock are quoted on the OTC Bulletin Board under the ticker symbol "NEPH." On September 26, 2011, the closing sales price for our common stock was $1.83 per share. The shares of common stock issued in the rights offering will also be quoted on the OTC Bulletin Board under the same ticker symbol. Neither the warrants nor the subscription rights will be listed for trading on any stock exchange or market or quoted on the OTC Bulletin Board.

On March 10, 2011, we completed our rights offering and a private placement that together resulted in gross proceeds of approximately $3.2 million. The aggregate net proceeds were approximately $2.3 million, after deducting the estimated aggregate expenses of these transactions which approximated $200,000, the repayment of the $500,000 note, plus $26,650 of accrued interest thereon, issued to Lambda Investors, LLC, the payment of an 8% sourcing/transaction fee ($40,000) in respect of the note and an aggregate of $100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

After giving effect to the 1:20 reverse stock split on March 11, 2011, our stockholders subscribed for 4,964,854 units in the rights offering and we accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of $0.40. Gross proceeds to us from the sale of these units in the rights offering was approximately $2.0 million. We issued an aggregate of 4,964,854 shares of our common stock and warrants to purchase an aggregate of approximately 4.6 million shares of our common stock to stockholders who subscribed.

Simultaneously with the closing of the rights offering, Lambda Investors, LLC purchased in a private placement 3,009,711 units at the same per unit purchase price of $0.40, pursuant to a purchase agreement between us and Lambda Investors. We issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,579 shares of common stock. Of the $3.2 million in gross proceeds from the rights offering and the private placement, we received approximately $1.2 million in gross proceeds from the sale of units to Lambda Investors.

We effected a reverse stock split, in which every 20 shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:00 p.m. on March 11, 2011, were converted into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to $0.04 per pre-split share for such fractional interests. The number of shares of common stock issued and outstanding was reduced from approximately 201,300,000 pre-split to approximately 10,100,000 post-split. The reverse stock split was effected in connection with

the rights offering and private placement.

The reverse stock split was approved by our stockholders at the annual meeting held on January 10, 2011. The number of shares of common stock subject to outstanding stock warrants and options, and the exercise prices and conversion ratios of those securities, were automatically proportionately adjusted for the 1-for-20 ratio provided for by the reverse stock split.

All of the share and per share amounts discussed in this Post-Effective Amendment have been adjusted to reflect the effect of this reverse split.

Investing in our common stock involves substantial risks. See " Risk Factors " beginning on page 5 of this prospectus to read about important factors you should consider before purchasing our common stock.

We do not intend to sell any more Units.

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

The date of this prospectus is [_____], 2011.

NEPHROS, INC.

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

ABOUT THIS PROSPECTUS

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

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

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. You should carefully read the more detailed information contained in this prospectus, including the section entitled “Risk Factors” beginning on page 5 and our financial statements for the years ended December 31, 2010 and 2009, and the six months ended June 30, 2011, and related notes appearing elsewhere in this prospectus. We refer to Nephros, Inc. and its consolidated subsidiary as “Nephros”, the “Company”, “we”, “our”, and “us”.

About the Company

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

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

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

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); to our knowledge, it is the only filter designed expressly for HDF therapy and employs our proprietary Mid-Dilution Diafiltration technology;
- OLpur H 2 H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and
- OLpur NS2000 system, our stand-alone HDF machine and associated filter technology.

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

OLpur is our registered U.S. trademark and the H2H trademark is pending U.S. registration. 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 report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as “middle molecules” because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

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

In the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption ("IDE") application for the clinical evaluation of our OLpūr H2H module and OLpūr MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. On August 11, 2011, Nephros filed a 510(k) application with the FDA for clearance of the Company's hemodiafiltration system. Nephros believes that, if approved, its technology would be the first FDA-approved on-line HDF therapy available in the U.S. The prior decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

On June 27, 2011, the Company entered into a license agreement, to be effective July 1, 2011, with Bellco S.r.1. as licensee, an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon the written approval of Nephros, other European countries where Nephros does not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by Nephros, Bellco will be required to sell the Products to Nephros' distributors in the Territory.

We currently have multiple products in various stages of development for the ultrafiltration of water and other fluids:

- DSU, our Dual Stage Ultrafilters for use in hospital infection control, hemodialysis, and other applications;
- SSU, our SafeSpout Ultrafilter for endpoint use on sinks;
- MSU, our large capacity Ultrafilter for commercial applications; and
- UF-40, our compact Ultrafilter for use in military applications and outdoor activities, such as hiking.

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

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

On May 10, 2011, we received approval from the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, to market our Dual Stage Ultrafilter (DSU) in Canada to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

On July 21, 2011 the Company announced that it received 510(k) clearance from the U.S. Food and Drug Administration to market its MSU and SSU ultrafilters to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

The Association for the Advancement of Medical Instruments' (AAMI) adoption of more stringent water purity standards for dialysis applications as well as observational studies showing a significant reduction in required erythropoietin dosing when the Nephros DSU is utilized during dialysis therapy has significantly increased interest in the product. We expect to realize accelerating product sales to the U.S. dialysis market as a combined result of these driving factors. We also expect to realize initial sales of DSU products to dialysis markets outside the U.S. in 2012.

We have introduced product line extensions for the hospital infection control market which include a more durable filter design to withstand the higher pressures of hospital plumbing, filter covers to improve the aesthetics of the filters in hospital showers, and the SafeSpout Filter as a convenient endpoint filter to address acute outbreak scenarios. We are investigating a range of additional commercial, industrial, and military opportunities for our DSU technology.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for continued development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract and is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $1,518,000 of revenue has been recognized on this new project since September 2009 of which approximately $249,000 was recognized on this new project during the six months ended June 30, 2011.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, we submitted our UF-40 ultrafilter for consideration as part of the standard issue hydration pack for soldiers in the field. We have been informed by the U.S. Army Public Health Command that our UF-40 filter has been validated to meet the military's NSF P248 standard for emergency military operations as a microbiological water purifier. We believe that our UF-40 filter is the only stand-alone filter to date to have met the performance criteria of the NSF P248 standard without secondary disinfection steps. The Army has not to date issued a Request For Proposal (RFP), and we have no information regarding when or if an RFP applicable to the UF-40 ultrafilter may be put forth by the U.S. Army.

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.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement and are eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and expect to complete the remaining milestones under the agreement by the end of 2011. The remaining milestones, if met, would result in aggregate payments to us of $60,000.

Corporate Information

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

Where You Can Find More Information

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

The Offering

The following summary describes the principal terms of the rights offering, but is not intended to be complete.

Securities Offered	4,590,171 shares of common stock issuable upon exercise of the warrants issued in connection with the Units sold on March 10, 2011.
Exercise Price and Term of Warrants	The warrants have an exercise price of $0.40 per share and are exercisable at any time prior to March 10, 2016. For a more complete description of the terms of the warrants, see “Description of Warrants.”
Use of Proceeds	The proceeds of this offering consist solely of the payment by warrant holders of the exercise price. We plan to use the net proceeds of this offering to further develop our products and for general working capital purposes. For a more complete description of our intended use of proceeds from this offering, see “Use of Proceeds.”
Risk Factors	The exercise of the warrants and the acquisition of our common stock involve substantial risks. See “Risk Factors” beginning on page 5 of this prospectus.
State Securities Law Matters	The issuance and exercise of warrants is subject to compliance with state securities laws and regulations. We reserve the right in some states to require stockholders, if they wish to participate, to state and agree upon exercise of their warrants that they are acquiring the shares for investment purposes only, and that they have no present intention to resell or transfer any shares acquired. This offering is not being made and our securities are not being offered in any jurisdiction where the offer is not permitted under applicable local laws. We have the right, in our sole discretion, to not effect registration or qualification of the shares underlying the warrants in any state or other jurisdiction, or take any other action required by any state or other jurisdiction to allow the offer to take place in that state or jurisdiction. If you reside in a state or other jurisdiction in which registration, qualification or other action is necessary with which we choose not to comply, you will not be eligible to participate in the offering.
Listing	The shares of our common stock issuable upon exercise of the warrants will be listed on the OTC Bulletin Board under the ticker symbol “NEPH.”

Unless otherwise indicated, the information in this prospectus reflects a 1-for-20 reverse split of our common stock, which was effective on March 11, 2011.

RISK FACTORS

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

Risks Related to Our Company

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2010, expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this prospectus expressing doubt as to our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations, raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing or sale of our technologies or 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 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, 2011, we had an accumulated deficit of approximately $93,217,000 primarily as a result of historical operating losses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

- the completion and success of our regulatory approval processes and additional clinical trials for each of our ESRD therapy products in our target territories, including specifically our new 510(k) application for our HDF system;
- 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.

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

We have not received approval from the FDA for our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We

responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission, which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration, or HDF, system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. On August 11, 2011 we submitted a new 510(k) application to market our hemodiafiltration (HDF) system for end-stage renal disease. Upon issuance of a 510(k) application tracking number, the application will be subject to the FDA's standard 90-day review period. The application details our OLpur MD220 diafilter and our OLpur H2H Hemodiafiltration module. Our OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs our proprietary Mid-Dilution diafiltration technology. Our OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. We believe that, if approved, our technology would be the first approved on-line HDF therapy available in the U.S. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

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

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

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

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

For the year ended December 31, 2010, one of our customers accounted for 50% of our product sales and another customer accounted for 29% of our product sales. Also, these customers represented 73% and 12%, respectively, of our accounts receivable as of December 31, 2010. We believe that the loss of either of these customers 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 (“DSU”). We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance.

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

The clearance and/or approval processes in the European Community and in the United States can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management’s time and effort. We may not be able to obtain further CE marking or any FDA approval for any of our ESRD therapy products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific

classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals with respect to the European Community or the United States would prevent us from selling our affected products in these regions. If we cannot sell some of our products in these regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

If we are successful in our initial marketing efforts in some or all of our Target European Market and the United States, then we plan to market our ESRD therapy products in several countries outside of our Target European Market and the United States, including Korea and China, Canada and Mexico. Requirements pertaining to the sale of medical devices vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our ESRD therapy products in many of these countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our ESRD therapy products outside of our Target European Market and the United States, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

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

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. On August 11, 2011 Nephros submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. The application will be subject to the FDA's standard 90-day review period. The application details Nephros's OLpur MD220 diafilter and Nephros's OLpur H2H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution diafiltration technology. Nephros's OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if approved, its technology would be the first approved on-line HDF therapy available in the U.S. The prior decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

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

- slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;
- lower than expected retention rates of subjects in a clinical trial;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's review board, or other required approvals;
- longer treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the ESRD therapy product;
- adverse medical events or side effects in treated subjects; and
- lack of effectiveness of the ESRD therapy product being tested.

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

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

clinical trials if we are unable to obtain additional capital.

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

We may be required to design and conduct additional clinical trials to further demonstrate the safety and efficacy of our ESRD therapy product, 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. Beginning in January 2008, we contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters under a first contract in an amount not to exceed $866,000. In August 2009, we entered into a second contract with a value not to exceed $2 million. These contracts would utilize the Federal appropriations from the U.S. Department of Defense not to exceed $3 million that have been approved for this purpose. If there are unanticipated delays in receiving the appropriations from the U.S. Department of Defense, our operations and potential revenues may be adversely affected. Further, if we do not successfully complete the contract work or renew the contract work in the event that the research and development needs additional work to reach completion, our operations and potential revenues may be adversely affected.

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

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 16 granted U.S. patents will expire at various times from 2018 to 2026, assuming they are properly maintained.

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

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

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

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

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

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

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

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

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

We expect to rely on a limited number of independent manufacturers to produce our OLpur MDHDF filter series and our other products, including the DSU. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, if any, and we may not be able to scale-up 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. As with any independent contractor, this manufacturer 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 H 2 H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

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

If our products are commercialized, we may face significant challenges in obtaining market acceptance of such products, which could adversely affect our potential sales and revenues.

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

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

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

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

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

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

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

We expect to manufacture and to market our products in our Target European Market and elsewhere outside of the United States. We expect that our revenues from our Target European Market will initially account for a significant portion of our revenues. Our international operations are subject to a number of risks, including the following:

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;
- we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;
- local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;
- political instability could disrupt our operations;
- some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and
- some countries could impose additional taxes or restrict the import of our products.

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

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

Our success depends upon the skills, experience and efforts of our management and other key personnel, including our chief executive officer, certain members of our scientific and engineering staff and our marketing executives. As a relatively new company, much of our corporate, scientific and technical knowledge is concentrated in the hands of these few individuals. We do not maintain key-man life insurance on any of our management or other key personnel. The loss of the services of one or more of our present management or other key personnel could significantly delay the development and/or launch of our products as there could be a learning curve of several months or more for any replacement personnel. Furthermore, competition for the type of highly skilled individuals we require is intense and we may not be able to attract and retain new employees of the caliber needed to achieve our objectives. Failure to replace key personnel could have a material adverse effect on our business, financial condition and operations.

Risks Related to the ESRD Therapy Industry

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

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

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

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

Some of our competitors, including Fresenius Medical Care AG and Gambro AB, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. In 2005, Gambro AB divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, Inc., whereby DaVita, Inc. will purchase a significant amount of renal products and supplies from Gambro AB Renal Products. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius Medical Care AG Form 20-F filed February 23, 2011, Fresenius Medical Care

AG provides treatment in its own dialysis clinics to 214,648 patients in its 2,757 facilities around the world including facilities located in the North America. According to a DaVita, Inc. February 4, 2011 press release, as of September 30, 2010, DaVita, Inc. provided treatment in 1,598 outpatient dialysis centers serving approximately 124,000 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. In March 2010, the U.S. Congress passed landmark healthcare legislation. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We anticipate that the U.S. Congress and state legislatures will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in the Medicare program could affect the pricing of our ESRD therapy products. As we are not yet established in our business and it will take some time for us to begin to recoup our research and development costs, our profit margins are likely initially to be lower than those of our competitors and we may be more vulnerable to small decreases in price than many of our competitors.

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

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

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

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

There currently is a limited market for our common stock.

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

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

In the two years ended December 31, 2010, our common stock has traded at prices ranging from a high of $52.60 to a low of $0.20 per share, after giving effect to the 1:20 reverse stock split effected on March 11, 2011. Due to the lack of an active market for our common stock, you should expect the prices at which our common stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our common stock. These include, but are not limited to::

- achievement or rejection of regulatory approvals by our competitors or us, including specifically our 510(k) application to the FDA for our HDF system;
- publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;
- delays or failures in initiating, completing or analyzing clinical trials or the unsatisfactory design or results of these trials;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

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

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations in recent years that might have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance.

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

The warrants are currently exercisable and will expire on March 10, 2016. The market price of our common stock may fall below the exercise price for these warrants prior to their expiration. Any warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the holders of warrants.

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

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

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

No warrants will be exercisable and we will not be obligated to issue shares of common stock unless the shares of common stock issuable upon such exercise have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Because the exemptions from qualification in certain states for resales of warrants and for issuances of common stock by the issuer upon exercise of a warrant may be different, a warrant may be held by a holder in a state where an exemption is not available for issuance of common stock upon an exercise and the holder will be precluded from exercise of the warrant. As a result, the warrants may be deprived of any value, the market for the warrants may be limited, the holders of the warrants may not be able to exercise their warrants and they may expire worthless if the common stock issuable upon such exercise is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside.

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

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

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

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

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

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

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

In April 2002, we entered into a letter agreement with Hermitage Capital Corporation ("Hermitage"), as placement agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, we entered into a settlement agreement with Hermitage pursuant to which, among other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement; and we agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between us and Lancer Offshore, Inc., warrants exercisable until February 2006 to purchase an aggregate of 3,000 shares of common stock for $50.00 per share (or 852 shares of our common stock for $176.00 per share, if adjusted for the reverse stock split pursuant to the antidilution provisions of such warrant, as amended). Because Lancer Offshore, Inc. never satisfied the closing conditions and, consequently, a closing has not been held, we have not issued any warrants to Hermitage in connection with our settlement with them. In June 2004, Hermitage threatened to sue us for warrants it claims are due to it under its settlement agreement with us as well as a placement fee and additional warrants it claims are, or will be, owed in connection with our initial public offering completed on September 24, 2004, as compensation for allegedly introducing us to one of the underwriters. We had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. We have not heard from Hermitage since then.

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

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 all of our equity 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.

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

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

Additionally, the market price of our common stock may fluctuate significantly in response to many factors, many of which are beyond our control. Risks and uncertainties, including those described elsewhere in this "Certain Risks and Uncertainties" section could impair our business operations or otherwise cause our operating results or prospects to be 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.

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

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

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

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

As of September 22, 2011, our directors, executive officers and Lambda Investors LLC, our largest stockholder, beneficially owned approximately 56% of our outstanding common stock.

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

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

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

Prior to our initial public offering we entered into registration rights agreements with many of our existing security holders that entitled them to have an aggregate of 501,012 shares registered for sale in the public market. Moreover, many of those shares, as well as the 9,213 shares we sold to Asahi, could be sold in the public market without registration once they have been held for one year, subject to the limitations of Rule 144 under the Securities Act. In addition, we entered into a registration rights agreement with the holders of our New Notes pursuant to which we granted the holders certain registration rights with respect to the shares of common stock issuable upon conversion of the New Notes and upon exercise of the Class D Warrants. We also entered into a registration rights agreement with Lambda Investors pursuant to which we will register for resale the 3,009,711 shares of common stock and 2,782,579 shares of common stock issuable upon the exercise of warrant purchased by Lambda Investors on March 10, 2011 in a private placement.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for continued development of such products and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predic “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. For such statements, we claim the protection of the Priv Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include the risks that:

- we may not be able to continue as a going concern;
- we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan or effectively market our products including, without limitation, FDA approval of our HDF system;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may encounter problems with our suppliers and manufacturers;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- HDF therapy may not be accepted in the United States and/or our technology and products may not be accepted in current or future target markets, which could lead to failure to achieve market penetration of our products;
- we may not be able to sell our ESRD therapy or water filtration products at competitive prices or profitably;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and
- we may not be able to achieve sales growth in Europe and Canada or expand into other key geographic markets.

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this prospectus, is set forth in our filings with the SEC, including our

Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as amended and our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

USE OF PROCEEDS

We received proceeds from the offer and sale of the Units, net of discounts, commissions and expense, of approximately $2,300,000. In the event of full exercise of all of the warrants, we will receive additional net proceeds of approximately $1,836,068. The actual exercise of any of the warrants, however, is beyond our control and depends on a number of factors, including the market price of our common stock. There can be no assurance that any of the warrants will be exercised.

While we have no specific plan for the proceeds, we expect to use the net proceeds of this offering, if any, to further develop our products and for general working capital purposes. The principal reason for this offering is to provide shares of common stock issuable upon conversion of our outstanding warrants issued in connection with the offer and sale of the Units.

DETERMINATION OF OFFERING PRICE

The exercise price of $0.40 was not based on any discount to the market price of our common stock. The exercise price is not necessarily related to our book value, net worth or any other established criteria of value and may or may not be considered the fair value of our common stock included in the warrants. We did not consult with any financial or other advisor in determining the exercise price. After the date of this prospectus, our common stock may trade at prices above or below the exercise price. You should not consider the exercise price as an indication of value of our company or our common stock. You should not assume or expect that our shares of common stock will trade at or above the exercise price in any given time period. The market price of our common stock may decline during or after this offering, and you may not be able to exercise or sell the shares of our common stock. You should obtain a current quote for our common stock before exercising and make your own assessment of our business and financial condition, our prospects for the future, and the terms of the warrants. On September 26, 2011, the closing sale price of our common stock on the OTC Bulletin Board was $1.83 per share.

DILUTION

Our net tangible book value as of June 30, 2011 was approximately $2,228,000, or approximately $0.22 per share. Net tangible book value per share represents the amount of our total tangible assets, less our total liabilities divided by the number of outstanding shares of common stock. Dilution in net tangible book value per share represents the difference between the amount per share paid by the purchaser of shares of common stock upon the exercise of warrants and the net tangible book value per share of common stock immediately after the exercise of warrants.

After giving effect to the exercise of 4,590,171 warrants that remained outstanding at June 30, 2011 at an exercise price of $0.40, our pro forma net tangible book value as of June 30, 2011 would have been $4,064,068, or $0.28 per share. This represents an immediate increase in net tangible book value of $0.06 per share to existing stockholders and an immediate dilution in net tangible book value of $0.12 per share to warrants exercised from this offering.

The shares outstanding as of June 30, 2011 used to calculate the information in this section exclude

- 657,164 shares issuable upon the exercise of stock options outstanding on June 30, 2011; and
- 12,298,865 shares issuable upon the exercise of warrants outstanding on June 30, 2011.

Unless otherwise indicated, the information in this prospectus reflects a 1-for-20 reverse split of our common stock, which was effective on March 11, 2011.

DIVIDEND POLICY

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

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MARKET FOR OUR COMMON STOCK

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

Quarter Ended	High	Low
March 31, 2008	$ 1.60	$ .33
June 30, 2008	$ .97	$ .50
September 30, 2008	$ .65	$ .24
December 31, 2008	$ .48	$ .05
March 31, 2009	$ .15	$ .04
June 30, 2009	$ 1.77	$ .01
September 30, 2009	$ 2.63	$ .99
December 31, 2009	$ 1.75	$ .70
March 31, 2010	$ 1.30	$ .65
June 30, 2010	$ 1.14	$ .36
September 30, 2010	$ .48	$ .16
December 31, 2010	$ .23	$ .08
March 31, 2011	$ .53	$ .02
June 30, 2011	$ .98	$ .30
From July 1, 2011 through September 26, 2011	$ 2.25	$ .60

As of September 22, 2011, there were 34 holders of record and approximately 1,000 beneficial holders of our common stock.

On September 26, 2011, the last reported sale price of our common stock on the OTC Bulletin Board was $1.83 per share.

PLAN OF DISTRIBUTION

Pursuant to the terms of the warrants, the shares of common stock will be distributed to those warrant holders who surrender their warrant certificate with their subscription form, together with the payment of the exercise price, to our warrant agent, Continental Stock Transfer & Trust Company.

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

Going Concern

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

Recently Issued and Adopted Accounting Standards

We follow accounting standards set by the Financial Accounting Standards Board ("FASB"). The FASB sets generally accepted accounting principles ("GAAP") that we follow to ensure we consistently report our financial condition, results of operations, and cash flows. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification, TM sometimes referred to as the Codification or "ASC." In June 2009, the FASB issued ASC Topic 105, Generally Accepted Accounting Principals, which became the single source of authoritative nongovernmental U.S. GAAP, superseding existing FASB, American Institute of Certified Public Accountants ("AICPA"), Emerging Issues Task Force ("EITF"), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant SEC guidance organized using the same topical structure in separate sections and has been adopted by us for the year ended December 31, 2009. This has an impact on our financial disclosures since all future references to authoritative accounting literature will be referenced in accordance with ASC Topic 105.

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

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

In April 2010, the FASB issued an ASU, Revenue Recognition – Milestone Method, to provide guidance on (i) defining a milestone, and (ii) determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The guidance becomes effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010, with early adoption and retrospective application permitted. The adoption of this amendment did not impact our consolidated financial statements.

In January 2010, the FASB issued an amendment to ASC Topic 820- Improving Disclosures about Fair Value Measurements, which amends the existing fair value measurement and disclosure guidance currently included in ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, the amendment to ASC Topic 820 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, this amendment also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This amendment is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of this amendment did not impact our consolidated financial statements.

New Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income," ("ASU 2011-05") which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after Dec. 15, 2011 with early adoption permitted. The Company does not believe that the adoption of ASU 2011-05 will have a material impact on the Company's consolidated results of operation and financial condition.

In April 2010, the FASB issued an ASU, Revenue Recognition – Milestone Method, to provide guidance on (i) defining a milestone, and (ii) determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The guidance becomes effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010, with early adoption and retrospective application permitted. The Company does not expect that adoption will have a material effect on its results of operations and cash flows or financial position.

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

In January 2010, the FASB issued an amendment to ASC Topic 820- Improving Disclosures about Fair Value Measurements, which amends the existing fair value measurement and disclosure guidance currently included in ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, the amendment to ASC Topic 820 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, this amendment also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This amendment is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of this amendment did not impact our consolidated financial statements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations for the fiscal year ended December 31, 2010 are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management’s subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this prospectus, we believe that the following accounting policies require the application of significant judgments and estimates. There have been no material changes to our critical accounting policies and estimates from the information provided in our Form 10-K and Form 10-K/A for the year ended December 31, 2010.

The discussion and analysis of our consolidated financial condition and results of operations for the six months ended June 30, 2011 are based upon our condensed consolidated financial statements. These condensed consolidated financial statements have been prepared following the requirements of accounting principles generally accepted in the United States ("GAAP") and Rule 8-03 of Regulation S-X for interim periods and require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to potential impairment of investments and share-based compensation expense.

Revenue Recognition

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

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

Stock-Based Compensation

We account for stock-based compensation in accordance with ASC 718 by recognizing the fair value of stock-based compensation in net income. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

Accounts Receivable

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

Inventory Reserves

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

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves identifying services which have been performed on our behalf, and the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for the preclinical development of our products, the manufacturing of clinical materials, and clinical

trials, as well as legal and accounting services provided by professional organizations. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Results of Operations

Fluctuations in Operating Results

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

The Fiscal Year Ended December 31, 2010 Compared to the Fiscal Year Ended December 31, 2009

Product Revenues

Total product revenues for the year ended December 31, 2010 were $2,938,000 compared to $2,661,000 for the year ended December 31, 2009. The $277,000, or 10%, increase is primarily due to increased revenue of approximately $305,000 in sales of our DSU in the United States for the year ended December 31, 2010 over the same period in 2009. Approximately $106,000 of the increased DSU sales was related to the development agreement with STERIS Corporation, of which approximately $66,000 is related to the recognition of revenue previously deferred and the remaining $40,000 is related to the achievement of a milestone in the third quarter of 2010. Revenue from sales of our MD filters in our Target European Market was approximately $220,000 higher for the year ended December 31, 2010 compared to the same period in 2009. Approximately $305,000 of the European revenue increase was due to more units sold, offset partially by $88,000 in losses due to foreign currency exchange rate fluctuation. Unit sales in Europe increased approximately 24% for the year ended December 31, 2010 compared to the same period in 2009. Partially offsetting the increases above was a decrease in net product billings of approximately $248,000 related to our contract with the Office of U.S. Naval Research during the year ended December 31, 2010 compared to the year ended December 31, 2009.

Cost of Goods Sold

Cost of goods sold was $1,816,000 for the year ended December 31, 2010 compared to $1,744,000 for the year ended December 31, 2009. The approximately $72,000, or 4%, increase is primarily due to increased costs of approximately $187,000 related to increased sales of our DSU in the United States for the year ended December 31, 2010 over the same period in 2009. Costs related to revenue from sales of our MD filters in our Target European Market was approximately $127,000 higher for the year ended December 31, 2010 compared to the same period in 2009. Costs related to the contract with the Office of U.S. Naval Research were approximately $242,000 lower for the year ended December 31, 2010 compared to the same period in 2009 due to the use of a subcontractor rather than our personnel.

Research and Development

Research and development expenses were $362,000 for the year ended December 31, 2010 compared to $280,000 for the year ended December 31, 2009, an increase of approximately $82,000 or 29%. Approximately $74,000 of the increase was wages primarily due to personnel working on research projects other than the contract with the Office of U.S. Naval Research. The remaining $8,000 increase is due to increased spending on testing materials during the year ended December 31, 2010 compared to the same period in 2009.

Depreciation and Amortization Expense

Depreciation expense was $129,000, for the year ended December 31, 2010 compared to $231,000 for the year ended December 31, 2009, a decrease of $102,000, or 44%. This decrease is primarily due to several assets having been fully depreciated as of year-end 2009, resulting in no depreciation expense for those assets during the year ended December 31, 2010. There were no disposals of assets during the year ended December 31, 2010.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2,520,000 for the year ended December 31, 2010 compared to $2,812,000 for the year ended December 31, 2009, a decrease of $292,000 or 10%. The decrease is primarily due to a decrease in personnel related expenses of approximately $347,000 and a decrease in marketing expenses of approximately $43,000 during the year ended December 31, 2010 compared to the year ended December 31,

2009. These decreases were partially offset by increased investor relation costs and debt issuance cost of approximately $48,000 and $50,000, respectively, during the year ended December 31, 2010 compared to the year ended December 31, 2009.

Interest Income

Interest income was $1,000 for the year ended December 31, 2010 compared to $9,000 for the year ended December 31, 2009. The decrease of $8,000, or 89%, reflects the impact of having less cash on hand in 2010 compared to 2009 and therefore, fewer investments to generate interest income.

Interest Expense

We incurred $15,000 of interest expense for the year ended December 31, 2010. This interest relates to interest accrued on the $500,000 senior secured note due in the second quarter of 2011. We incurred approximately $2,000 of interest expense for the year ended December 31, 2009. This interest relates primarily to financing of premiums for product liability insurance.

Amortization of Debt Issuance Costs

We account for debt issuance costs in accordance with ASC 835, which requires that these costs be reported in the balance sheet as deferred charges and amortized over the term of the associated debt. Amortization of debt issuance costs of $50,000 for the year ended December 31, 2010 is associated with the senior secured note issued to Lambda Investors LLC. These capitalized costs were fully amortized in the first quarter of 2011. There was no amortization of debt issuance costs in the year ended December 31, 2009.

Other Income

Other income in the amount of approximately $20,000 for the year ended December 31, 2010 resulted primarily from the reversal of a prior year’s accrual of approximately $18,000 determined to no longer be necessary. Other income in the amount of approximately $373,000 for the year ended December 31, 2009 resulted primarily from receipt of New York State Qualified Emerging Technology Company tax refunds for years 2006 and 2007.

Six Months Ended June 30, 2011 Compared to the Six Months Ended June 30, 2010

Revenues

Total revenues for the six months ended June 30, 2011 were approximately $1,318,000 compared to approximately $1,799,000 for the six months ended June 30, 2010. Total revenues decreased approximately $481,000. The decrease of approximately 27% is due to decreased revenue of approximately $420,000, or 63%, during the six months ended June 30, 2011 over the same period in 2010, related to our contract with the Office of U.S. Naval Research, and a $148,000 reduction in sales of our MD filters in our Target European Market. These decreases were partially offset by approximately $54,000 more DSU sales, or 22%, and $33,000 more in revenue related to the STERIS project for the six months ended June 30, 2011 compared to the same period in 2010.

Cost of Goods Sold

Cost of goods sold was approximately $916,000 for the six months ended June 30, 2011 compared to approximately $1,127,000 for the six months ended June 30, 2010. The decrease of approximately $211,000, or 19%, in cost of goods sold is primarily related to our contract with the Office of U.S. Naval Research, where cost of goods sold decreased by approximately $222,000, and a $67,000 reduction in cost of sales of our MD filters in our Target European Market. These decreases were partially offset by increased cost of goods sold of approximately $57,000 related to DSU sales and $21,000 more in costs related to the STERIS project for the six months ended June 30, 2011 compared to the same period in 2010.

Research and Development

Research and development expenses were approximately $204,000 and $143,000 respectively, for the six months ended June 30, 2011 and June 30, 2010. This increase of approximately $61,000 or 43% is primarily due to an increase in research and development personnel related costs of approximately $58,000 during the six months ended June 30, 2011 compared to the same period in 2010.

Depreciation Expense

Depreciation expense was approximately $48,000 for the six months ended June 30, 2011 compared to approximately $68,000 for the six months ended June 30, 2010, a decrease of 29%. The decrease of approximately $20,000 is primarily due to several assets having been fully depreciated as of year-end 2010 resulting in no depreciation expense for those assets during the six months ended June 30, 2011. There were no disposals of assets during the six months ended June 30, 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $1,394,000 for the six months ended June 30, 2011 compared to approximately $1,353,000 for the six months ended June 30, 2010, an increase of $41,000 or 3%. The increase is primarily due to $79,000 bonus expense, an increase in stock compensation expense of $115,000, and $45,000 of severance costs during the six months ended June 30, 2011 compared to the same period in 2010. These increases were partially offset by a reduction in U.S. salary expense of $101,000 and a reduction in legal and other professional service fees in the U.S. of approximately $104,000 during the six months ended June 30, 2011 compared to the same period in 2010.

Interest Income

Interest income was approximately $1,000 for the six months ended June 30, 2011 compared to approximately $1,000 for the six months ended June 30, 2010.

Interest Expense

Interest expense was approximately $12,000 for the six months ended June 30, 2011. This interest relates to interest accrued on the $500,000 senior secured note issued to Lambda Investors LLC, which was paid in March 2011. We had no interest expense for the six months ended June 30, 2010.

Amortization of Debt Issuance Costs

Amortization of debt issuance costs of $40,000 for the six months ended June 30, 2011 is associated with the senior secured note issued to Lambda Investors LLC and paid in March 2011. These capitalized costs have been fully amortized as of June 30, 2011. There was no amortization of debt issuance costs in the six months ended June 30, 2010 as there was no debt during that period.

Other expense

Other expense in the amount of approximately $14,000 for the six months ended June 30, 2011 was a foreign currency loss on invoices paid to an international supplier. Other expense in the amount of approximately $2,000 for the six months ended June 30, 2010 was a currency loss related to an international funds transfer.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the years ended December 31, 2010 and December 31, 2009 or the six months ended June 30, 2011.

Liquidity and Capital Resources

Our future liquidity sources and requirements will depend on many factors, including:

- the cost, timing and results of our efforts to obtain regulatory approval of our products, including specifically our 510(k) application for our HDF system;
- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;
- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the timing and costs associated with obtaining United States regulatory approval or the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MDHDF filter series, for which the CE mark was obtained in July 2003);
- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

- for the marketing and sales of our products;
- to obtain appropriate regulatory approvals and expand our research and development with respect to our ESRD therapy products;
- to continue our ESRD therapy product engineering;
- to pursue business opportunities with respect to our DSU water-filtration product; and
- for working capital purposes.

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

In June 2006, we entered into subscription agreements with certain investors who purchased an aggregate of $5,200,000 principal amount of our 6% Secured Convertible Notes due 2012 (the "Old Notes"). The Old Notes were secured by substantially all of our assets. However, as of September 19, 2007, the Old Notes were exchanged for New Notes as further described in the paragraphs below.

We entered into a Subscription Agreement ("Subscription Agreement") with Lambda Investors LLC ("Lambda") on September 19, 2007 (the "First Closing Date"), GPC 76, LLC on September 20, 2007, Lewis P. Schneider on September 21, 2007 and Enso Global Equities Partnership LP ("Enso") on September 25, 2007 (collectively, the "New Investors") pursuant to which the New Investors purchased an aggregate of $12,677,000 principal amount of our Series A 10% Secured Convertible Notes due 2008 (the "Purchased Notes"), for the face value thereof (the "Offering"). Concurrently with the Offering, we entered into an Exchange Agreement (the "Exchange Agreement") with each of Southpaw Credit Opportunities Master Fund LP, 3V Capital Master Fund Ltd., Distressed/High Yield Trading Opportunities, Ltd., Kudu Partners, L.P. and LJHS Company (collectively, the "Exchange Investors" and together with the New Investors, the "Investors"), pursuant to which the Exchange Investors agreed to exchange the principal and accrued but unpaid interest in an aggregate amount of $5,600,000 under our Old Notes, for our new Series B 10% Secured Convertible Notes due 2008 in an aggregate principal amount of $5,300,000 (the "Exchange Notes", and together with the Purchased Notes, the "New Notes") (the "Exchange", and together with the Offering, the "Financing").

We obtained the approval of our stockholders representing a majority of our outstanding shares to the issuance of shares of our common stock upon conversion of our New Notes and exercise of our Class D Warrants (as defined below) issuable upon such conversion, as further described below. The stockholder approval became effective on November 13, 2007, and the New Notes converted into shares of our common stock on November 14, 2007.

All principal and accrued but unpaid interest (the "Conversion Amount") under our New Notes automatically converted into (i) shares of our common stock at a conversion price per share of our common stock (the "Conversion Shares") equal to $0.706 and (ii) in the case of our Purchased Notes, but not our Exchange Notes, Class D Warrants (the "Class D Warrants") for purchase of shares of our common stock (the "Warrant Shares") in an amount equal to 50% of the number of shares of our common stock issued to the New Investors in accordance with clause (i) above with an exercise price per share of our common stock equal to $18.00 (subject to anti-dilution adjustments). The Class D Warrants have a term of five years and are non-callable by us.

National Securities Corporation ("NSC") and Dinosaur Securities, LLC ("Dinosaur" and together with NSC, the "Placement Agent") acted as co-placement agents in connection with the Financing pursuant to an Engagement Letter, dated June 6, 2007 and a Placement Agent Agreement dated September 18, 2007. The Placement Agent received (i) an aggregate cash fee equal to 8% of the face amount of the Lambda Purchased Note and the Enso Purchased Note allocated and paid 6.25% to NSC and 1.75% to Dinosaur, and (ii) warrants ("Placement Agent Warrant") with a term of five years from the date of issuance to purchase 10% of the aggregate number of shares of our common stock issued upon conversion of the Lambda Purchased Note and the Enso Purchased Note with an exercise price per share of our common stock equal to $18.00.

In connection with the sale of the New Notes, we entered into a Registration Rights Agreement with the Investors, dated as of the First Closing Date (the "Registration Rights Agreement"), pursuant to which we agreed to file an initial resale registration statement ("Initial Resale Registration Statement") with the SEC no later than 60 days after we file a definitive version of our Information Statement on Schedule 14C with the SEC, and we filed such Initial Resale Registration Statement on December 20, 2007. We also agreed to use our commercially reasonable best efforts to have the Initial Resale Registration Statement declared effective within 240 days after filing of a definitive version of our Information Statement on Schedule 14C. The Initial Resale Registration Statement was declared effective on May 5, 2008.

On July 24, 2009, we raised gross proceeds of $1,251,000 through the private placement to eight accredited investors of an aggregate of 67,258 shares of our common stock and warrants to purchase an aggregate of 33,629 shares of its 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 $18.60. The warrants have an exercise price of $22.40, are exercisable immediately and will terminate on July 24, 2014. For the years ended December 31, 2010 and 2009, $72,000 and $85,000 of cash, respectively, was also provided by the exercise of stock options.

On October 1, 2010, we issued a senior secured note to Lambda Investors LLC in the principal amount of $500,000. The note bore interest at the rate of 12% per annum and was to mature on April 1, 2011, at which time all principal and accrued interest would be due. However, we agreed to and did prepay, without penalty, amounts due under the note with the cash proceeds from our rights offering prior to the maturity date. On March 10, 2010 in connection with the completion of the rights offering as discussed below, we repaid in full the $500,000 of principal and $26,650 of accrued interest on the senior secured note issued to Lambda Investors LLC on October 1, 2010.

On March 10, 2011 we completed our rights offering and private placement that together resulted in gross proceeds of approximately $3.2 million to Nephros. Our stockholders subscribed for 4,964,854 units in its previously announced rights offering and we accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of $0.40. Gross proceeds from the sale of these units in the rights offering was approximately

$2.0 million. We issued an aggregate of 4,964,854 shares of common stock and warrants to purchase an aggregate of approximately 4.6 million shares of common stock to stockholders who subscribed.

Simultaneously with the closing of the rights offering, Lambda Investors, LLC purchased in a private placement 3,009,711 units at the same per unit purchase price of $0.40, pursuant to a purchase agreement between us and Lambda Investors. We issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,579 shares of common stock. We received approximately $1.2 million in gross proceeds from its sale of units to Lambda Investors.

The aggregate net proceeds received by us from the rights offering and private placement are estimated to be approximately $2.3 million, after deducting the estimated aggregate expenses of these transactions, the repayment of the $500,000 note, plus all accrued interest thereon, issued to Lambda Investors, LLC, the payment of an 8% sourcing/transaction fee ($40,000) in respect of the note and an aggregate of $100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

On March 11, 2011, we effected a reverse stock split, in which every 20 shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:00 p.m. on March 11, 2011, were converted into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to $0.04 per pre-split share for such fractional interests. The number of shares of common stock issued and outstanding was reduced from approximately 201,300,000 pre-split to approximately 10,100,000 post-split. The reverse stock split was effected in connection with the rights offering and private placement.

At December 31, 2010, we had an accumulated deficit of $91,908,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering in September 2004, from licensing revenue received from Asahi Kasei Medical Co., Ltd. (“Asahi”) in March 2005, a private placement of convertible debenture in June 2006, a private investment in public equity in September 2007, a private placement in July 2009, and the October 2010 issuance of a senior secured note. In March 2011, the rights offering and concurrent private placement to Lambda Investors provided additional capital.

At June 30, 2011, we had an accumulated deficit of approximately $93,217,000 and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, licensing revenue and, most recently, the March 2011 rights offering and concurrent private placement.
At June 30, 2011, we had cash and cash equivalents totaling approximately $1,713,000 and tangible assets of approximately $2,794,000.

The Company entered into a License Agreement with Bellco, as licensee, which is discussed in Footnote 12, Subsequent Events. This Agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. These fixed payments of €1,850,000 or approximately $2,600,000, take place over the next eighteen months. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to Nephros a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. The first fixed payment was received in July 2011. Anticipated payments from this License Agreement will be a positive source of cash flow to the Company.

As of the date of this report, we estimate that these cash flows would allow us to keep operating only into the second quarter of 2013. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in our Company. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was $1,292,000 for the year ended December 31, 2010 compared to $2,612,000 for the year ended December 31, 2009.

During 2010, the net cash used in operating activities was $1,320,000 less than the net cash used in operating activities during 2009. The most significant items contributing to the reduction in cash used in operating cash are highlighted below:

- our net loss in 2010 was $1,933,000 compared to $2,026,000 in 2009. This represents an improvement of $93,000 in operating cash in 2010. Noncash adjustments to reconcile net loss to net cash used in operating activities were:

stock-based compensation was $92,000 and $108,000 in 2010 and 2009 respectively, a reduction of $16,000; depreciation expense was $129,000 and $231,000 in 2010 and 2009 respectively, a reduction of $102,000; a decrease to the inventory reserve of $18,000; an increase in deferred revenue of $33,000 in 2010; an increase in amortization of debt issuance costs of $50,000 in 2010; and an increase in noncash interest of $15,000 in 2010;

- during 2010, our accounts receivable, other current assets and other assets decreased by $249,000. This compares to an increase of $193,000 in 2009. This represents a $442,000 source of operating cash in 2010;
- during 2010, our inventory increased by $98,000. This compares to a decrease in inventory of $57,000 in 2009. This represents a $155,000 use of operating cash in 2010; and
- during 2010, accounts payable and accrued expenses increased by $171,000. This compares to a decrease in accounts payable and accrued expenses of $807,000 during 2009. This represents a $978,000 source of operating cash in 2010.

Net cash used by investing activities was $30,000 for the year ended December 31, 2010 compared to $21,000 for the year ended December 31, 2009. In 2010, $30,000 was used to purchase equipment. In 2009, $28,000 was used to purchase equipment and $7,000 was provided by the maturity of a short-term investment.

Net cash provided by financing activities was $572,000 for the year ended December 31, 2010 resulting from the issuance of a short-term note of $500,000 and proceeds from the exercise of stock options of $72,000. Net cash provided by financing activities was $1,336,000 for the year ended December 31, 2009 resulting from the sale of common stock of $1,251,000 and proceeds from the exercise of stock options of $85,000.

Net cash used in operating activities was approximately $1,088,000 for the six months ended June 30, 2011 compared to approximately $719,000 for the six months ended June 30, 2010. The most significant items contributing to this increase of approximately $369,000 in cash used in operating activities during the six months ended June 30, 2011 compared to the six months ended June 30, 2010 are highlighted below:

- during the 2011 period, our net loss increased by approximately $416,000;
- during the 2011 period, depreciation expense decreased by approximately $20,000;
- our accounts receivable increased by approximately $239,000 during the 2011 period compared to an increase of approximately $78,000 during the 2010 period;
- our accounts payable and accrued expenses decreased by approximately $274,000 in the aggregate in the 2011 period compared to an increase of approximately $192,000 in the 2010 period; and
- our inventory decreased by approximately $410,000 during the 2011 period compared to an increase of approximately $101,000 during the 2010 period.

Offsetting the above changes are the following items:

- during the 2011 period, our stock-based compensation expense, a non-cash expense, increased by approximately $116,000;
- during the 2011 period, we recorded deferred revenue of $33,000, whereas there was no deferred revenue in the 2010 period;
- during the 2011 period, we recorded amortization of debt issuance costs of $40,000, whereas there was no amortization of debt issuance costs in the 2010 period;
- during the 2011 period, we recorded non-cash interest of $12,000, whereas there was no non-cash interest in the 2010 period;
- our prepaid expenses and other assets decreased by approximately $92,000 in the 2011 period compared to a decrease of approximately $44,000 in the 2010 period.

Net cash provided by financing activities was approximately $2,550,000 for the six months ended June 30, 2011, resulting from the issuance of stock, providing cash of $3,190,000, which was partially offset by the payment of debt of $500,000 and the payment of deferred financing costs of $140,000. Financing activities provided net cash of approximately $72,000 for the six months ended June 30, 2010 resulting from the issuance of common stock due to exercise of stock options.

There was no cash provided or used in investing activities for the six months ended June 30, 2011 or during the 2010 comparable period.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2010:

		Payments Due in Period			
	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years

Leases	$87,000	$87,000	$—	$—	$—
Employment Contracts	49,000	49,000	—		
Total	$136,000	$136,000	$—	$—	$—

Certain Risks and Uncertainties

Certain statements in this prospectus, including certain statements contained in “Description of Business” and “Management’s Discussion and Analysis,” constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases “can be,” “may,” “could,” “would,” “expects,” “believes,” “seeks,” “estimates,” “projects” and similar words phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

BUSINESS

Overview

Founded in 1997 as a Delaware corporation, 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 products in various stages of development in the HDF modality to deliver improved therapy to ESRD patients:

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); to our knowledge, it is the only filter designed expressly for HDF therapy and employs 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 from the U.S. Food and Drug Administration, or FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act, in June 2005.

OLpur is our registered U.S. trademark and the H2H trademark is pending U.S. registration. 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 report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as “middle molecules” because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

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.

In the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption ("IDE") application for the clinical evaluation of our OLpūr H2H module and OLpūr MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010 to discuss the issues raised in the FDA letter. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. On August 11, 2011, Nephros filed a 510(k) application with the FDA for clearance of the Company's hemodiafiltration system. Nephros believes that, if approved, its technology would be the first FDA-approved on-line HDF therapy available in the U.S. The prior decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

On June 27, 2011, the Company entered into a license agreement, to be effective July 1, 2011, with Bellco S.r.1. as licensee, an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon the written approval of Nephros, other European countries where Nephros does not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by Nephros, Bellco will be required to sell the Products to Nephros' distributors in the Territory.

We currently have multiple products in various stages of development for the ultrafiltration of water and other fluids:

- DSU, our Dual Stage Ultrafilters for use in hospital infection control, hemodialysis, and other applications;
- SSU, our SafeSpout Ultrafilter for endpoint use on sinks;
- MSU, our large capacity Ultrafilter for commercial applications; and
- UF-40, our compact Ultrafilter for use in military applications and outdoor activities, such as hiking.

In January 2006, we introduced our 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 foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of November 11, 2009), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

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

On May 10, 2011, we received approval from the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, to market our Dual Stage Ultrafilter (DSU) in Canada to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

On July 21, 2011 the Company announced that it received 510(k) clearance from the U.S. Food and Drug Administration to market its MSU and SSU ultrafilters to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

The Association for the Advancement of Medical Instruments' (AAMI) adoption of more stringent water purity standards for dialysis applications as well as observational studies showing a significant reduction in required erythropoietin dosing when the Nephros DSU is utilized during dialysis therapy has significantly increased interest in the product. We expect to realize accelerating product sales to the U.S. dialysis market as a combined result of these driving factors. We also expect to realize initial sales of DSU products to dialysis markets outside the U.S. in 2012.

We have introduced product line extensions for the hospital infection control market which include a more durable filter design to withstand the higher pressures of hospital plumbing, filter covers to improve the aesthetics of the filters in hospital showers, and the SafeSpout Filter as a convenient endpoint filter to address acute outbreak scenarios. We are investigating a range of additional commercial, industrial, and military opportunities for our DSU technology.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra-filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for continued development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract and is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $1,518,000 of revenue has been recognized on this new project since September 2009 of which approximately $249,000 was recognized on this new project during the six months ended June 30, 2011.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, we submitted our UF-40 ultrafilter for consideration as part of the standard issue hydration pack for soldiers in the field. We have been informed by the U.S. Army Public Health Command that our UF-40 filter has been validated to meet the military's NSF P248 standard for emergency military operations as a microbiological water purifier. We believe that our UF-40 filter is the only stand-alone filter to date to have met the performance criteria of the NSF P248 standard without secondary disinfection steps. The Army has not to date issued a Request For Proposal (RFP), and we have no information regarding when or if an RFP applicable to the UF-40 ultrafilter may be put forth by the U.S. Army.

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.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement and are eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and expect to complete the remaining milestones under the agreement by the end of 2011. The remaining milestones, if met, would result in aggregate payments to us of $60,000.

Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements included in this prospectus which expresses doubt as to our ability to continue as a going concern. The financial statements included in this prospectus have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that

might result from the outcome of this uncertainty.

We have incurred significant losses in our operations in each quarter since inception. For the years ended December 31, 2010 and 2009, we have incurred net losses of $1,933,000 and $2,026,000, respectively. For the six months ended June 30, 2011 and 2010, the Company has incurred net losses of $1,309,000 and $893,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2010 and 2009 and for the six months ended June 30, 2011 and 2010.To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

On October 1, 2010, we issued a senior secured note to Lambda Investors LLC, our largest stockholder, in the principal amount of $500,000. The note bore interest at the rate of 12% per annum and was to mature on April 1, 2011, at which time all principal and accrued interest were due. However, we agreed to and did prepay, without penalty, amounts due under the note with the cash proceeds from our rights offering prior to the maturity date. The note was secured by a first priority lien on all of our property, including our intellectual property.

On March 10, 2011 we completed our rights offering and a private placement that together resulted in gross proceeds of approximately $3.2 million to Nephros. The aggregate net proceeds were approximately $2.3 million, after deducting the estimated aggregate expenses of these transactions which approximated $200,000, the repayment of the $500,000 note, plus $26,650 of accrued interest thereon, issued to Lambda Investors, LLC, the payment of an 8% sourcing/transaction fee of $40,000 in respect of the note and an aggregate of $100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

After giving effect to the 1:20 reverse stock split on March 11, 2011, our stockholders subscribed for 4,964,854 units in the rights offering and we accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of $0.40. Gross proceeds to us from the sale of these units in the rights offering was approximately $2.0 million. We issued an aggregate of 4,964,854 shares of our common stock and warrants to purchase an aggregate of approximately 4.6 million shares of our common stock to stockholders who subscribed.

Simultaneously with the closing of the rights offering, Lambda Investors, LLC purchased in a private placement 3,009,711 units at the same per unit purchase price of $0.40, pursuant to a purchase agreement between us and Lambda Investors. We issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,579 shares of common stock. Of the $3.2 million in gross proceeds from the rights offering and the private placement, we received approximately $1.2 million in gross proceeds from the sale of units to Lambda Investors.

We effected a reverse stock split, in which every 20 shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:00 p.m. on March 11, 2011, were converted into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to $0.04 per pre-split share for such fractional interests. The number of shares of common stock issued and outstanding was reduced from approximately 201,300,000 pre-split to approximately 10,100,000 post-split. The reverse stock split was effected in connection with the rights offering and private placement.

The reverse stock split was approved by our stockholders at the annual meeting held on January 10, 2011. The number of shares of common stock subject to outstanding stock warrants and options, and the exercise prices and conversion ratios of those securities, were automatically proportionately adjusted for the 1-for-20 ratio provided for by the reverse stock split.

We entered into a License Agreement with Bellco S.r.l., as licensee ("Bellco). This Agreement provides us with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. These fixed payments of €1,850,000 or approximately $2,600,000, take place over the next eighteen months. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay us a royalty based on the number of units of products sold in the territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. The first fixed payment was received in July 2011. Anticipated payments from this License Agreement will be a positive source of cash flow to us.

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

Delisting of Stock from AMEX

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

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

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

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

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

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

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

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

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

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

Current ESRD Therapy Options

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

- Dialysis
  - Peritoneal Dialysis, or PD, uses the patient's peritoneum, the membrane lining covering the internal abdominal organs, as a filter by introducing injectable-grade dialysate solution into the peritoneal cavity through a surgically implanted catheter. After some period of time, the fluid is drained and replaced. PD is limited in use because the peritoneal cavity is subject to scarring with repeated episodes of inflammation of the peritoneal membrane, reducing the effectiveness of this treatment approach. With time, a PD patient's kidney function continues to deteriorate and peritoneal toxin removal alone may become insufficient to provide adequate treatment. In such case the patient may switch to an extracorporeal renal replacement therapy such as hemodialysis or hemodiafiltration.
  - Hemodialysis uses an artificial kidney machine to remove certain toxins and fluid from the patient's blood while controlling external blood flow and monitoring patient vital signs. Hemodialysis patients are connected to a dialysis machine via a vascular access device. The hemodialysis process occurs in a dialyzer cartridge with a semi-permeable membrane which divides the dialyzer into two chambers: while the blood is circulated through one chamber, a premixed solution known as dialysate circulates through the other chamber. Toxins and excess fluid from the blood cross the membrane into the dialysate solution through a process known as "diffusion."

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

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

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

Current Dialyzer Technology used with HDF Systems

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

- With pre-dilution, substitution fluid is added to the blood before the blood enters the dialyzer cartridge. In this process, the blood can be over-diluted, and therefore more fluid can be drawn across the membrane. This enhances removal of toxins by convection. However, because the blood is diluted before entering the device, it actually

reduces the rate of removal by diffusion; the overall rate of removal, therefore, is reduced for small molecular weight toxins (such as urea) that rely primarily on diffusive transport.

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

The Nephros Mid-Dilution Diafiltration Process

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

Our ESRD Therapy Products

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

OLpur MDHDF Filter Series

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

Laboratory bench studies have been conducted on our OLpur MD190 by members of our research and development staff and by a third party. We completed our initial clinical studies to evaluate the efficacy of our OLpur MD190 as compared to conventional dialyzers in Montpellier, France in 2003. The results from this clinical study support our belief that OLpur MD190 is superior to post-dilution hemodiafiltration using a standard high-flux dialyzer with respect to 2-microglobulin clearance. In addition, clearances of urea, creatinine, and phosphate met the design specifications proposed for the OLpur MD190 device. Furthermore, adverse event data from the study suggest that hemodiafiltration with our OLpur MD190 device was well tolerated by the patients and safe.

We have completed a series of longer term clinical studies in the United Kingdom, France, Germany, Italy and Spain to further demonstrate the therapeutic benefits of our OLpur MDHDF filter series. A multi-center study was started in March 2005. This study encompassed seven centers in France, five centers in Germany and one center in Sweden. Also commencing in 2005 were studies in the United Kingdom and in Italy. A three-month study was conducted in Spain. All enrolled patients in the multi-center and Spain studies completed the investigational period with the Nephros OLpur MDHDF filter devices. Data was very positive, demonstrating improved low-molecular weight protein removal, improvements in appetite, an overall improved distribution of fluids and body composition, and optimal toxin removal and treatment tolerance for patients suffering from limited vascular access. Data was presented at the American Society of Nephrology meeting held in 2006, and the European Dialysis and Transplantation annual meetings held in 2007 and 2008.

We contracted with TÜV Rheinland of North America, Inc., a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, to assist us in obtaining the Conformité Européene, or CE mark, a mark which demonstrates compliance with relevant European Union requirements. We received CE marking on the OLpur MD190 (which also covers other dialyzers in our MDHDF filter series), as well as certification of our overall quality system, on July 31, 2003. In the fourth quarter of 2006 we received CE marking on the DSU. During 2010, we replaced TÜV with BSI America, Inc. as our notified body.

In November 2007, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpur MDHDF filter series for marketing in Canada.

We initiated marketing of our OLpur MD190 in our Target European Market in March 2004. We have established a sales presence in countries throughout our Target European Market, mainly through distributors, and we have developed marketing material in the relevant local languages. We also attend trade shows where we promote our product to several thousand people from the industry. Our OLpur MD220 is a newer product that we began selling in our Target European Market in 2006. The OLpur MD220 employs the same technology as our OLpur MD190, but contains a larger surface area of fiber. Because of its larger surface area, the OLpur MD220 may provide greater clearance of certain toxins than the OLpur MD190, and is suitable for patients of larger body mass.

In the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption (“IDE”) application for the clinical evaluation of our OLpūr H2H module and OLpūr MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Because the FDA had not provided us with any additional requests for information or rendered a decision on our application, we made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, were informed that our application was still under their review process.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. On August 11, 2011 Nephros submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. The application is subject to the FDA's standard 90-day review period. The application details Nephros's OLpur MD220 diafilter and Nephros's OLpur H2H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution diafiltration technology. Nephros's OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if approved, its technology would be the first approved on-line HDF therapy available in the U.S. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

OLpur HD190

OLpur HD190 is our high-flux dialyzer cartridge, designed for use with either hemodialysis or hemodiafiltration machines. The OLpur HD190 incorporates the same materials as our OLpur MD190, but lacks our proprietary mid-dilution architecture.

OLpur H 2 H

OLpur H2H is our add-on module that converts the most common types of hemodialysis machines — that is, those with volumetric ultrafiltration control — into HDF-capable machines allowing them to use our OLpur MDHDF filter. We have completed our OLpur H2H design and laboratory bench testing, all of which were conducted by members of our research and development staff. Our design verification of the OLpur H2H was completed making the device ready for U.S. clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. On August 11, 2011 Nephros submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. Upon issuance of a 510(k) application tracking number, the application will be subject to the FDA's standard 90-day review period. The application details Nephros's OLpur MD220 diafilter and Nephros's OLpur H2H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution diafiltration technology. Nephros's OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if approved, its technology would be the first approved on-line HDF therapy available in the U.S. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

OLpur NS2000

OLpur NS2000 is our standalone HDF machine and associated filter technology, which is in the development stage. The OLpur NS2000 will use a basic HDF platform which will incorporate our H2H technology including our proprietary substitution fluid systems.

We have also designed and developed proprietary substitution fluid filter cartridges for use with the OLpur NS2000, which have been subjected to pre-manufacturing testing. We will need to obtain the relevant regulatory clearances prior to any market introduction of our OLpur NS2000 in the United States.

Our Water Filtration Product

In January 2006, we introduced our Dual Stage Ultrafilter, or DSU, water filtration system. The DSU incorporates our unique and proprietary dual stage filter architecture. Our research and development work on the OLpur H2H and MD filter technologies for ESRD therapy provided the foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to various contaminated water and infection control issues. 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. We believe our DSU offers four distinct advantages over competitors in the water filtration marketplace:

(1) the DSU is, to our knowledge, the only water filter that has the potential to provide the user with a simple sight verification that the filter is properly performing its cleansing function due to our unique dual-stage architecture;
(2) the DSU filters finer biological contaminants than other filters of which we are aware in the water filtration marketplace;
(3) the DSU filters relatively large volumes of water before requiring replacement; and
(4) the DSU continues to protect the user even if the flow is reduced by contaminant volumes, because contaminants do not cross the filtration medium.

With over 5,700 registered hospitals in the United States alone, we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration. We hope to gain a foothold at U.S. and European facilities that seek to become centers of excellence in infection control through the use of our DSU products.

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

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $846,000 and $423,000 has been billed to this second project during the year ended December 31, 2010 and the four months ended December 31, 2009, respectively.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, Nephros submitted its UF-40 ultrafilter for consideration as part of the standard issue hydration pack for soldiers in the field. Nephros has been informed by the U.S. Army Public Health Command that its UF-40 filter has been validated to meet the military's NSF P248 standard for emergency military operations as a microbiological water purifier. Nephros believes that its UF-40 filter is the only stand-alone filter to date to have met the performance criteria of the NSF P248 standard without secondary disinfection steps. The Army has not to date issued a Request For Proposal (RFP), and Nephros has no information regarding when or if an RFP applicable to the UF-40 ultrafilter may be put forth by the U.S. Army.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement and are eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and expect to complete the remaining milestones under the agreement by the end of 2011. The remaining milestones, if met, would result in aggregate payments to us of $60,000.

The adoption by the Association for the Advancement of Medical Instruments, or AAMI, of more stringent water purity standards for dialysis applications as well as observational studies showing a significant reduction in required erythropoietin dosing when the Nephros DSU is utilized during dialysis therapy has significantly increased interest in the product. We have filed a special 510(k) application for our Small Sterile UltraFilter (also called the Safe Spout filter) and Mega Sterile UltraFilter to enable these products to be used in dialysis applications. We expect to realize accelerating product sales to the U.S. dialysis market as a combined result of these driving factors. We also expect to realize initial sales of DSU products to dialysis markets outside the U.S. in 2011.

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.

Our Strategy

We believe that current mortality and morbidity statistics, in combination with quality of life issues faced by the ESRD patient, have generated demand for improved ESRD therapies. We also believe that our products and patented technology offer the ability to remove toxins more effectively than current dialysis therapy, in a cost framework competitive with currently available, less-effective therapies. We also believe the recent changes resulting from the Medicare Improvements for Patients and Providers Act (MIPPA), which sets reimbursement for dialysis treatment costs, lab work and IV drugs into a single “bundled” rate, will have a positive impact toward the adoption of our products as they have the potential to reduce the amount of IV drugs being administered to dialysis patients. The following are some highlights of our current strategy:

Showcase Product Efficacy in our Target European Market: As of March 2004, we initiated marketing in our Target European Market for the OLpur MD220. There is an opportunity for sales of the OLpur MDHDF filters in our Target European Market because there is an established HDF machine base using disposable dialyzers. We have engaged in a series of clinical trials throughout our Target European Market to demonstrate the superior efficacy of our product. We believe that by demonstrating the effectiveness of our MDHDF filter series we will encourage more customers to purchase our products. Our MDHDF filter series has been applied successfully in over 200,000 treatments to date.

Upgrade Fluid Quality feeding Hemodialysis Machines: Promote use of our patented Dual Stage Ultrafilter (DSU), which has been cleared by the FDA for use in hemodialysis applications as a water and bicarbonate concentrate ultrafilter, as a means to achieve a lower overall treatment cost under the new “bundled” reimbursement system. Based on recent observations, we believe a dialysis clinic can lower costs of erythropoietin stimulating agents (ESA), such as Epogen® (EPO), by simply installing DSU filters on the incoming water lines feeding their hemodialysis machines.

Convert Existing Hemodialysis Machines to Hemodiafiltration: We plan to complete our regulatory approval processes in the United States for both our OLpur MDHDF filter series and our OLpur H2H in 2011. If successfully approved, our OLpur H2H product will enable HDF therapy using the most common types of hemodialysis machines together with our OLpur MDHDF filters. Our goal is to achieve market penetration by offering the OLpur H2H for use by healthcare providers inexpensively, thus permitting the providers to use the OLpur H2H without a large initial capital outlay. We do not expect to generate significant positive margins from sales of OLpur H2H. We believe that, if approved in 2011, our OLpur H2H and MDHDF filters will be the first and only HDF therapy available in the United States at that time.

Upgrade Dialysis Clinics to OLpur NS2000: We believe the introduction of the OLpur NS2000 will represent a further upgrade in performance for dialysis clinics by offering a cost-effective stand-alone HDF solution that incorporates the benefits of our OLpur H2H technology if commercialized. We believe dialysis clinics will entertain OLpur NS2000 as an alternative to their current technology at such dialysis clinic’s machine replacement point.

Develop a Foothold in the Healthcare Arena by Offering our DSU as a Means to Control Environment-Acquired Infections: We believe our DSU offers an effective, and cost-effective, solution in conquering certain infection control issues faced by hospitals, nursing homes, assisted living facilities and other patient environments where chemical or heat alternatives have typically failed to adequately address the problem. The DSU provides for simple implementation without large capital expenses. We have established a goal in 2011 to gain a foothold at U.S. facilities that seek to become centers of excellence in infection control through the use of our DSU products.

Pursue our Military Product Development in Conjunction with Value-Adding Partners: For our military development, we are engaging with strategic allies who offer added value with respect to both new product and marketing opportunities. One of our goals in pursuing this project is to maintain and expand our new product development pipeline and achieve new products suitable for both military and domestic applications.

Explore Complementary Product Opportunities: Where appropriate, we are also seeking to leverage our technologies and expertise by applying them to new markets, such as currently being done under a development contract with STERIS Corporation. Our H2H has potential applications in acute patient care and controlled provision of ultrapure fluids in the field. Our DSU represents a new and complementary product line to our existing ESRD therapy business; we believe the Nephros DSU can offer a robust solution to a broad range of contaminated water and infection control issues.

Manufacturing and Suppliers

We do not, and do not intend to in the near future, manufacture any of our products and components. With regard to the OLpur MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, with Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, we granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where we do not sell the Products as well as non-European countries, all such countries herein referred to as the Territory.

In exchange for the rights granted to it under the Bellco license agreement through December 31, 2014, Bellco agreed to pay us installment payments of €500,000, €750,000, €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. Such installment payments, herein referred to as the Installment Payments, are Bellco's sole financial obligations through December 31, 2014. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to us a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, Bellco will pay €4.50 per unit; thereafter, Bellco will pay €4.00 per unit. Bellco must meet minimum sales targets of 15,000 units in each quarter of 2015 and 2016. If Bellco fails to meet a quarterly minimum, the license in Italy, France, Belgium, Spain and Canada will, at our discretion, convert to a non-exclusive one. All sums payable under the agreement will be paid in Euros, as adjusted to account for currency exchange fluctuations between the Euro and the U.S. dollar that occur between July 1, 2011, the effective date of the agreement, and the date of payment.

A contract manufacturer produces the DSU product(s) as ordered.

Sales and Marketing

We have established a distributor network to sell ESRD products in our Target European Market and, when regulatory approval is obtained, intend to establish a similar arrangement in the United States. On February 25, 2010, we announced that we signed an exclusive distribution agreement with Bellco Health Care Inc. ("BHC Medical") to sell and market Nephros' OLpurTM MD 220 filter for on-line HDF therapy in Canada. Under the terms of the Agreement, Nephros and BHC Medical will work together to promote the sale and distribution of Nephros' OLpurTM MD 220 filters through various advertising and promotional campaigns and by working with and training BHC's sales and support staff.

With regard to the OLpur MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, with Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, we granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where we do not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by us, Bellco will be required to sell the Products to our distributors in the Territory.

In exchange for the rights granted to it under the Bellco license agreement through December 31, 2014, Bellco agreed to pay us installment payments of €500,000, €750,000, €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. Such installment payments, herein referred to as the Installment Payments, are Bellco's sole financial obligations through December 31, 2014. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to us a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, Bellco will pay €4.50 per unit; thereafter, Bellco will pay €4.00 per unit. Bellco must meet minimum sales targets of 15,000 units in each quarter of 2015 and 2016. If Bellco fails to meet a quarterly minimum, the license in Italy, France, Belgium, Spain and Canada will, at our discretion, convert to a non-exclusive one. All sums payable under the agreement will be paid in Euros, as adjusted to account for currency exchange fluctuations between the Euro and the U.S. dollar that occur between July 1, 2011, the effective date of the agreement, and the date of payment.

Our New Jersey office oversees sales and marketing activity of our DSU products. We are in discussions with several medical products and filtration products suppliers to act as non-exclusive distributors of our DSU products to medical institutions. For each prospective market for our DSU products, we are pursuing alliance opportunities for joint product development and distribution. In July 2010, we announced a distribution agreement with AmeriWater Corporation and that AmeriWater had adopted the Nephros DSU as a standard component of its MRO portable

reverse osmosis water treatment systems for dialysis. Our DSU manufacturer in Europe shares certain intellectual property rights with us for one of our DSU designs.

Research and Development

Our research and development efforts continue on several fronts directly related to our current product lines. We are also working on additional machine devices, next-generation user interface enhancements and other product enhancements.

In the area of water filtration, we have finalized our initial water filtration product line for the healthcare sector.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $846,000 and $423,000 has been billed to this second project during the year ended December 31, 2010 and the four months ended December 31, 2009, respectively.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, Nephros submitted its UF-40 ultrafilter for consideration as part of the standard issue hydration pack for soldiers in the field. Nephros has been informed by the U.S. Army Public Health Command that its UF-40 filter has been validated to meet the military's NSF P248 standard for emergency military operations as a microbiological water purifier. Nephros believes that its UF-40 filter is the only stand-alone filter to date to have met the performance criteria of the NSF P248 standard without secondary disinfection steps. The Army has not to date issued a Request For Proposal (RFP), and Nephros has no information regarding when or if an RFP applicable to the UF-40 ultrafilter may be put forth by the U.S. Army.

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.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement and are eligible to receive additional payments upon successful completion of product development milestones. During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and expect to complete the remaining milestones under the agreement by the end of 2011. The remaining milestones, if met, would result in aggregate payments to us of $60,000.

Our research and development expenditures were primarily related to development expenses associated with the H2H machine, STERIS development work and related salary expense for the years ended December 31, 2010 and 2009 and were $362,000 and $280,000, respectively.

Competition

The dialyzer and renal replacement therapy market is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical needs of physicians and nephrologists, improve patient outcomes and remain cost-effective for payers.

We compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG, and Gambro AB, currently two of the primary machine manufacturers in hemodialysis. At present, Fresenius Medical Care AG and Gambro AB also manufacture HDF machines.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis products include Gambro AB, Baxter International Inc., Asahi Kasei Medical Co. Ltd., Bellco S.p.A., a subsidiary of the Sorin group, B. Braun Melsungen AG, Nipro Corporation Ltd., Nikkiso Co., Ltd., Terumo Corporation and Toray Medical Co., Ltd.

Other competitive considerations include pharmacological and technological advances in preventing the progression of ESRD in high-risk patients such as those with diabetes and hypertension, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants.

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of competing in the ESRD marketplace to include:

- continuing our efforts to develop, have manufactured and sell products which, when compared to existing products, perform more efficiently and are available at prices that are acceptable to the market;

- displaying our products and providing associated literature at major industry trade shows in the United States;

- initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;

- offering the OLpur H2H at a price that does not provide us with significant positive margins in order to encourage adoption of this product and associated demand for our dialyzers;

- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities; and

- entering into license agreements similar to the Bellco S.r.l. agreement to expand market share.

With respect to the water filtration market, we expect to compete with companies that are well entrenched in the water filtration domain. These companies include Pall Corporation, which manufactures end-point water filtration systems, as well as CUNO (a 3M Company) and US Filter (a Siemens business). Our methods of competition in the water filtration domain include:

- developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;
- offering unique attributes that illustrate our product reliability, "user-friendliness," and performance capabilities;
- selling products to specific customer groups where our unique product attributes are mission-critical; and
- pursuing alliance opportunities for joint product development and distribution.

Intellectual Property

Patents

We protect our technology and products through patents and patent applications. In addition to the United States, we also applied for patents in other jurisdictions, such as the European Patent Office, Canada and Japan, to the extent we deem appropriate. We have built a portfolio of patents and applications covering our products, including their hardware design and methods of hemodiafiltration.

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge," have claims that cover the OLpur MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Although there are pending applications with claims to the present embodiments of the OLpur H2H and the OLpur NS2000 products, these products are still in the development stage and we cannot determine if the applications (or the patents that we may issue on them) will also cover the ultimate commercial embodiment of these products. In addition, technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have applied for patents on our DSU water filtration products to cover various applications in residential, commercial, and remote environments.

As of December 2010, we have sixteen issued U.S. patents; one issued Eurasian patent; four Mexican patents, four South Korean patents, three Russian patents, five Chinese patents, seven French patents, seven German patents, four Israeli patents, six Italian patents, three Spanish patents, six United Kingdom patents, nine Japanese patents, three Hong Kong patents, and ten Canadian patents. Our issued U.S. patents expire between 2018 and 2026. In addition, we have five pending U.S. patent applications, five pending patent applications in Canada, eight pending patent applications in the European Patent Office, five pending patent applications in Brazil, two pending patent applications in China, four pending patent applications in Japan, three pending patent applications in Mexico, one pending patent application in South Korea, two pending patent applications in India, three pending patent applications in Israel and one pending patent application in Australia. Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal. We also have pending patent applications on our DSU water filtration system, pump/filter applications related to our Office of Naval Research project, and means to test filter integrity as part of a liquid purification system.

We have filed U.S. and International patent applications for a redundant ultra filtration device that was jointly invented by one of our employees and an employee of our CM. We and our CM are negotiating commercial arrangements pertaining to the invention and the patent applications.

Trademarks

As of December 31, 2010, we secured registrations of the trademarks CENTRAPUR, H2H, OLpur and the Arrows Logo in the European Union. Applications for these trademarks are pending registration in the United States. We also have applications for registration of a number of other marks pending in the United States Patent and Trademark Office.

Governmental Regulation

The research and development, manufacturing, promotion, marketing and distribution of our ESRD therapy products in the United States, our Target European Market and other regions of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and analogous agencies.

United States

The FDA regulates the manufacture and distribution of medical devices in the United States pursuant to the FDC Act. All of our ESRD therapy products are regulated in the United States as medical devices by the FDA under the FDC Act. Under the FDC Act, medical devices are classified in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

- Class I devices are medical devices for which general controls are deemed sufficient to ensure their safety and effectiveness. General controls include provisions related to (1) labeling, (2) producer registration, (3) defect notification, (4) records and reports and (5) quality service requirements, or QSR.

- Class II devices are medical devices for which the general controls for the Class I devices are deemed not sufficient to ensure their safety and effectiveness and require special controls in addition to the general controls. Special controls include provisions related to (1) performance and design standards, (2) post-market surveillance, (3) patient registries and (4) the use of FDA guidelines.

- Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before a new medical device can be introduced to the market, FDA clearance of a pre-market notification under Section 510(k) of the FDC Act or FDA clearance of a pre-market approval, or PMA, application under Section 515 of the FDC Act must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process. We understand that it generally takes four to 12 months from the date a Section 510(k) notification is accepted for filing to obtain Section 510(k) pre-market clearance, (but has taken much longer in the case of our OLpur H2H module and OLpur MD 220 filter) and that it could take several years from the date a Section 515 application is accepted for filing to obtain Section 515 pre-market approval, although it may take longer in both cases.

We expect that all of our ESRD therapy products and our DSU will be categorized as Class II devices and that these products will not require clearance of pre-market approval applications under Section 515 of the FDC Act, but will be eligible for marketing clearance through the pre-market notification process under Section 510(k). We have determined that we are eligible to utilize the Section 510(k) pre-market notification process based upon our ESRD therapy and DSU products' substantial equivalence to previously legally marketed devices in the United States. However, we cannot assure you:

- that we will not need to reevaluate the applicability of the Section 510(k) pre-market notification process to our ESRD therapy and DSU products in the future;
- that the FDA will agree with our determination that we are eligible to use the Section 510(k) pre-market notification process; or
- that the FDA will not in the future require us to submit a Section 515 pre-market approval application, which would be a more costly, lengthy and uncertain approval process.

The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past and may request clinical data to support pre-market clearance. As a result, the FDA could refuse to accept for filing a Section 510(k) notification made by us or request the submission of additional information. The FDA may determine that any one of our proposed ESRD therapy products is not substantially equivalent to a legally marketed device or that additional information is needed before a substantial equivalence determination can be made. A "not substantially equivalent" determination, or request for additional data, could prevent or delay the market introduction of our products that fall into this category, which in turn could have a material adverse effect on our potential sales and revenues. Moreover, even if the FDA does clear one or all of our products under the Section 510(k) process, it may clear a product for some procedures but not others or for certain classes of patients and not others.

For any devices cleared through the Section 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require a new Section 510(k) pre-market notification submission. Accordingly, if we do obtain Section 510(k) pre-market clearance for any of our ESRD therapy and DSU products, we will need to submit another Section 510(k) pre-market notification if we significantly affect that product's safety or effectiveness through subsequent modifications or enhancements.

If human clinical trials of a device are required in connection with a Section 510(k) notification and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or distributor of the device) will need to file an IDE application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal testing and/or laboratory bench testing. If the IDE application is approved, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as specified in the IDE. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of subjects. We submitted our original IDE application to the FDA for our OLpur H2H hemodiafiltration module and OLpur MD220 filter in May 2006. The FDA answered our application with additional questions in June 2006, and we submitted responses to the FDA questions in December 2006. In January 2007, 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. In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. We completed the patient treatment phase of our clinical trials during the second quarter of 2008 and filed our 510(k) applications with respect to the OLpur MDHDF filter series and the OLpur H2H module in November 2008. No IDE was required for our DSU product. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. We hope to achieve U.S. regulatory approval of ourl OLpūr H2H module and OLpūr MD 220 filter products during 2011. Following its review of our OLpur MDHDF filter series and the OLpur H2H module applications, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. On August 11, 2011 Nephros submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. Another in-person meeting with the FDA took place on April 20, 2011 to discuss a proposal for submission of a new 510(k) application for its on-line HDF system. The application is subject to the FDA's standard 90-day review period. The application details Nephros's OLpur MD220 diafilter and Nephros's OLpur H2H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution diafiltration technology. Nephros's OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if approved, its technology would be the first approved on-line HDF therapy available in the U.S. The prior decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

The Section 510(k) pre-market clearance process can be lengthy and uncertain. It will require substantial commitments of our financial resources and management's time and effort. Significant delays in this process could occur as a result of factors including:

- our inability to timely raise sufficient funds;
- the FDA's failure to schedule advisory review panels;
- changes in established review guidelines;
- changes in regulations or administrative interpretations; or
- determinations by the FDA that clinical data collected is insufficient to support the safety and effectiveness of one or more of our products for their intended uses or that the data warrants the continuation of clinical studies.

Delays in obtaining, or failure to obtain, requisite regulatory approvals or clearances in the United States for any of our products would prevent us from selling those products in the United States and would impair our ability to generate funds from sales of those products in the United States, which in turn could have a material adverse effect on our business, financial condition, and results of operations.

The FDC Act requires that medical devices be manufactured in accordance with the FDA's current QSR regulations which require, among other things, that:

- the design and manufacturing processes be regulated and controlled by the use of written procedures;
- the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;
- any deficiencies in the manufacturing process or in the products produced be investigated;
- detailed records be kept and a corrective and preventative action plan be in place; and
- manufacturing facilities be subject to FDA inspection on a periodic basis to monitor compliance with QSR regulations.

If violations of the applicable QSR regulations are noted during FDA inspections of our manufacturing facilities or the manufacturing facilities of our contract manufacturers, there may be a material adverse effect on our ability to produce and sell our products.

Before the FDA approves a Section 510(k) pre-market notification, the FDA is likely to inspect the relevant manufacturing facilities and processes to ensure their continued compliance with QSR. Although some of the manufacturing facilities and processes that we expect to use to manufacture our ESRD and DSU filters 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 all been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H2H have been inspected by the FDA, they have not all 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. Even after the FDA has cleared a Section 510(k) submission, it will periodically inspect the manufacturing facilities and processes for compliance with QSR. In addition, in the event that additional manufacturing sites are added or manufacturing processes are changed, such new facilities and processes are also subject to FDA inspection for compliance with QSR. The manufacturing facilities and processes that will be used to manufacture our products have not yet been inspected by the FDA for compliance with QSR. We cannot assure you that the facilities and processes used by us will be found to comply with QSR and there is a risk that clearance or approval will, therefore, be delayed by the FDA until such compliance is achieved.

In addition to the requirements described above, the FDC Act requires that:

- all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;
- information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur; and
- certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive 93/42/EEC. The European Union directive applies to both the manufacturer's quality assurance system and the product's technical design and discusses the various ways to obtain approval of a device (dependent on device classification), how to properly CE Mark a device and how to place a device on the market. We have subjected our entire business in our Target European Market to the most comprehensive procedural approach in order to demonstrate the quality standards and performance of our operations, which we believe is also the fastest way to launch a new product in the European Community.

The regulatory approach necessary to demonstrate to the European Union that the organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices requires the certification of a full quality management system by a notified body. Initially, we engaged TÜV Rheinland of North America, Inc. ("TÜV Rheinland") as the notified body to assist us in obtaining certification to the International Organization for Standardization, or ISO, 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

European Union requirements for products are set forth in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. A company demonstrates conformity to these requirements, with respect to a product, by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

Once a manufacturer's full quality management system is determined to be in compliance with ISO 13485/2003 and other statutory requirements, and the manufacturer's products conform with harmonized European standards, the notified body will recommend and document such conformity. The manufacturer will receive a CE marking and ISO certifications, and then may place a CE mark on the relevant products. The CE mark, which stands for Conformité Européenne, demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported to, or sold or distributed within, the European Union.

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms with the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. In April 2010, we changed our notified body from TÜV Rheinland to BSI America, Inc.

With regard to the OLpur MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, with Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the

Products. Under the agreement, we granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where we do not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by us, Bellco will be required to sell the Products to our distributors in the Territory.

Regulatory Authorities in Regions Outside of the United States and the European Union

We also plan to sell our ESRD therapy products in foreign markets outside the United States which are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. In November 2007, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpur MDHDF filter series for marketing in Canada. Other than the CE marking and Canadian approval of our OLpur MDHDF filter products, we have not obtained any regulatory approvals to sell any of our products and there is no assurance that any such clearance or certification will be issued.

Reimbursement

In both domestic markets and markets outside of the United States, sales of our ESRD therapy products will depend in part, on the availability of reimbursement from third-party payers. In the United States, ESRD providers are reimbursed through Medicare, Medicaid and private insurers. In countries other than the United States, ESRD providers are also reimbursed through governmental and private insurers. In countries other than the United States, the pricing and profitability of our products generally will be subject to government controls. Despite the continually expanding influence of the European Union, national healthcare systems in its member nations, reimbursement decision-making included, are neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government.

Product Liability and Insurance

The production, marketing and sale of kidney dialysis products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our products in the amount of $5 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.
Some of our existing and potential agreements with manufacturers of our products and components of our products do or may require us (1) to obtain product liability insurance or (2) to indemnify manufacturers against liabilities resulting from the sale of our products. If we are not able to maintain adequate product liability insurance, we will be in breach of these agreements, which could materially adversely affect our ability to produce our products. 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.

Employees

As of June 30, 2011, we employed a total of 7 employees, 6 of whom were full time and 1 who is employed on a part-time basis. We also have engaged 1 consultant on an ongoing basis. Of the 8 total employees and consultants, 1 was employed in a sales/marketing/customer support capacity, 3 in general and administrative and 4 in research and development.

Gerald Kochanski, the Company’s Chief Financial Officer, served as the acting Chief Executive Officer from March 30, 2010 until April 5, 2010. Since April 6, 2010, Paul A. Mieyal, a member of the Board of Directors, has served as the acting Chief Executive Officer following the resignation of our former President and Chief Executive Officer on March 30, 2010. Dr. Mieyal is a Vice President of Wexford Capital LP, the managing member of Lambda Investors LLC, which is the beneficial owner of approximately 56% of the Company’s outstanding stock based on common stock and warrants held at September 22, 2011.

Properties

Our U.S. facilities are located at 41 Grand Avenue, River Edge, New Jersey, 07661 and consist of approximately 4,688 square feet of space. The term of the rental agreement is for three years commencing December 2008 with a monthly cost of approximately $7,423. We use our facilities to house our corporate headquarters and research facilities.

Our facilities in our Target European Market are currently located at A5 Clonlara Avenue, Baldonnell Business Park, Dublin, Ireland, and consist of approximately 500 square feet of space. The lease agreement was entered into on July

1, 2010. The lease term is 6 months beginning July 1, 2010 and is renewable for 6 month terms with a 2 month notice to discontinue. Our monthly cost is 500 Euro (approximately $700).

We use our facilities to house our accounting, operations and customer service departments. We believe this space will be adequate to meet our needs. We do not own any real property for use in our operations or otherwise.

Legal Proceedings

There are no other currently pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject.

MANAGEMENT

Board of Directors

Our board of directors is divided into three classes, each class as nearly equal in number as practicable. Each year, one class is elected to serve for three years. The business address for each director for matters regarding our company is 41 Grand Avenue, River Edge, New Jersey 07661.

Our Board of Directors is currently composed of four directors. Although our common stock is no longer listed on the AMEX but is traded on Over-the-Counter Bulletin Board, our Board of Directors has determined to apply AMEX's test for director independence to all of our directors. Using that test, the Board has determined that all of our directors are independent under AMEX's rules, as of the date of this report. As part of such determination of independence, our Board has affirmatively determined that none of our directors has a relationship with our company that would interfere with the exercise of independent judgment in carrying out his responsibility as a director.

As of April 6, 2010, Paul A. Mieyal, a member of the Board of Directors, has served as the acting Chief Executive Officer. Dr. Mieyal is a Vice President of Wexford Capital LP, the managing member of Lambda Investors LLC, which is the beneficial owner of approximately 56% of the our outstanding stock based on common stock and warrants held at September 22, 2011. Dr. Mieyal receives no compensation for his services, except in his capacity as a director of our company, which compensation is disclosed below. Since Dr. Mieyal is not an employee of the Company and does not receive any employee compensation from the Company, our Board has determined that his service as acting Chief Executive Officer would not interfere with the exercise of independent judgment in carrying out his responsibility as a director.

Class I Directors — Term Expiring 2011

Name	Age (as of 12/31/10)	Director Since	Business Experience For Last Five Years
Arthur H. Amron	53	2007	Arthur H. Amron has served as a director of our company since September 2007. Mr. Amron is a Partner of Wexford Capital LP and serves as its General Counsel. Mr. Amron also actively participates in various private equity transactions, particularly in the bankruptcy and restructuring areas, and has served on the boards and creditors' committees of a number of public and private companies in which Wexford has held investments. From 1991 to 1994, Mr. Amron was an Associate at Schulte Roth & Zabel LLP, specializing in corporate and bankruptcy law, and from 1984 to 1991, Mr. Amron was an Associate at Debevoise & Plimpton LLP specializing in corporate litigation and bankruptcy law. Mr. Amron holds a JD from Harvard University, a BA in Political Theory from Colgate University and is a member of the New York Bar. Among other experience, qualifications, attributes and skills, Mr. Amron's legal training and experience in the capital markets, as well as his experience serving on boards of directors of other public companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

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Name	Age (as of 12/31/10)	Director Since	Business Experience For Last Five Years
James S. Scibetta	45	2007	James S. Scibetta has served as a director of our company since November 2007 and as Chairman of our Board since September 2008. Since August 2008, Mr. Scibetta has been the Chief Financial Officer of Pacira Pharmaceuticals, Inc. Prior to that, Mr. Scibetta was Chief Financial Officer of Bioenvision, Inc. from December 2006 until its acquisition by Genzyme, Inc. in October 2007. From September 2001 to November 2006, Mr. Scibetta was Executive Vice President and Chief Financial Officer of Merrimack Pharmaceuticals, Inc., and he was a member of the Board of Directors of Merrimack from April 1998 to March 2004. Mr. Scibetta formerly served as a senior investment banker at Shattuck Hammond Partners, LLC and PaineWebber Inc., providing capital acquisition, mergers and acquisitions, and strategic advisory services to healthcare companies. Mr. Scibetta holds a B.S. in Physics from Wake Forest University, and an M.B.A. in Finance from the University of Michigan. He completed executive education studies in the Harvard Business School Leadership & Strategy in Pharmaceuticals and Biotechnology program. Among other experience, qualifications, attributes and skills, Mr. Scibetta's extensive management experience in the pharmaceutical industry, as well as his investment banking experience, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Class II Director — Term Expiring 2012

Name	Age (as of 12/31/10)	Director Since	Business Experience For Last Five Years
Paul A. Mieyal	41	2007	Paul A. Mieyal has served as a director of our company since September 2007. Dr. Mieyal has been a Vice President of Wexford Capital LP since October 2006. From January 2000 through September 2006, he was Vice President in charge of healthcare investments for Wechsler & Co., Inc., a private investment firm and registered broker-dealer. Dr. Mieyal is also a director of Nile Therapeutics, Inc., which is a publicly traded company. Dr. Mieyal received his Ph.D. in pharmacology from New York Medical College, a B.A. in Chemistry and Psychology from Case Western Reserve University, and is a Chartered Financial Analyst. Since April 6, 2010, Mr. Mieyal has served as our acting Chief Executive Officer. Among other experience, qualifications, attributes and skills, Dr. Mieyal's pharmacology and chemistry education, his experience in investment banking in the healthcare industry, as well as his experience serving on boards of directors of other public companies, led to the

conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Class III Directors — Term Expiring 2013

Name	Age (as of 12/31/10)	Director Since	Business Experience For Last Five Years
Lawrence J. Centella	69	2001	Lawrence J. Centella has served as a director of our company since January 2001. Mr. Centella serves as President of Renal Patient Services, LLC, a company that owns and operates dialysis centers, and has served in such capacity since June 1998. From 1997 to 1998, Mr. Centella served as Executive Vice President and Chief Operating Officer of Gambro Healthcare, Inc., an integrated dialysis company that manufactured dialysis equipment, supplied dialysis equipment and operated dialysis clinics. From 1993 to 1997, Mr. Centella served as President and Chief Executive Officer of Gambro Healthcare Patient Services, Inc. (formerly REN Corporation). Prior to that, Mr. Centella served as President of COBE Renal Care, Inc., Gambro Hospal, Inc., LADA International, Inc. and Gambro, Inc. Mr. Centella is also the founder of LADA International, Inc. Mr. Centella received a B.S. from DePaul University. Among other experience, qualifications, attributes and skills, Mr. Centella's extensive experience in managing companies engaged in the business of dialysis centers and equipment, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Selection of Nominees for the Board of Directors

The entire Board is responsible for nominating members for election to the Board and for filling vacancies on the Board that might occur between annual meetings of the stockholders. The Nominating and Corporate Governance Committee is responsible for identifying, screening, and recommending candidates to the entire Board for prospective Board membership. When formulating its Board membership recommendations, the Nominating and Corporate Governance Committee also considers any qualified candidate for an open board position timely submitted by our stockholders in accordance with our established procedures.

Audit Committee

The Audit Committee is composed of James S. Scibetta (Chairman) and Lawrence J. Centella, neither of whom is our employee and each of whom has been determined by the Board of Directors to be independent under the NYSE Alternext US LLC, formerly the American Stock Exchange, or AMEX, listing standards. Although our common stock was delisted from the NYSE Alternext in January 2009, our Board has chosen to apply the NYSE Alternext definition of independence. The purpose of the Audit Committee is to (i) oversee accounting, auditing, and financial reporting processes; (ii) assess the integrity of our financial statements; (iii) ensure that our internal controls and procedures are designed to promote compliance with accounting standards and applicable laws and regulations; and (iv) appoint and evaluate the qualifications and independence of our independent registered public accounting firm.

The Board of Directors has determined that all Audit Committee members are financially literate under the current listing standards of the NYSE Alternext. The Board also determined that Mr. Scibetta qualifies as an "audit committee financial expert" as defined by the SEC rules adopted pursuant to the Sarbanes-Oxley Act of 2002.

Code of Business Conduct and Code of Ethics

During the fiscal year ended December 31, 2004, we adopted a Code of Ethics and Business Conduct, which was amended and restated on April 2, 2007, for our employees, officers and directors that complies with Securities and Exchange Commission, or SEC, regulations. The Code of Ethics is available free of charge on our website at www.nephros.com, by clicking on the Investor Relations link, then the Corporate Governance link. We intend to timely disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC.

Executive Officers

The following table sets forth certain information concerning our non-director executive officer:

Name	Age (as of 12/31/10)	Position with Nephros and Business Experience for Last Five Years
Gerald J. Kochanski	57	Gerald J. Kochanski has served as our Chief Financial Officer since April 2008 and served as our acting Chief Executive Officer from March 31 through April 5, 2010. Prior to joining us, Mr. Kochanski served as the Financial Services Director of Lordi Consulting LLC, a national consulting firm, from February 2007 through February 2008. From October 2004 until December 2006, Mr. Kochanski was the Chief Financial Officer of American Water Enterprises, Inc., a business unit of a privately owned company in the water and wastewater treatment industry. From November 1998 through September 2004, Mr. Kochanski was the Chief Financial Officer of Scanvec Amiable Ltd., a publicly traded provider of software to the signmaking, digital printing and engraving industries. Mr. Kochanski is a Certified Public Accountant and received his B.S. in Accounting and his M.B.A. in Finance from La Salle University, where he has also been an adjunct accounting department faculty member since 1986.

Gerald J. Kochanski, the Company’s Chief Financial Officer, served as the acting Chief Executive Officer from March 30, 2010 until April 5, 2010. Since April 6, 2010, Paul A. Mieyal, a member of the Board of Directors, has served as the acting Chief Executive Officer. Dr. Mieyal is a Vice President of Wexford Capital LP, the managing member of Lambda Investors LLC, which is the beneficial owner of approximately 56% of our outstanding stock based on common stock and warrants held at September 22, 2011.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth all compensation earned in the fiscal years ended December 31, 2010 and 2009 by our Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus(1) ($)	Option Awards (2) ($)	All Other Compensation (3) ($)	Total
Paul A. Mieyal Acting Chief Executive Officer (4)	2010	—	—	$ 14,956	$ 14,800	$ 29,396
Ernest A. Elgin III(5)						
President and Chief	2010	$ 66,250	—	—	$ 53,507	$ 119,757
Executive Officer	2009	$ 240,000	—	$ 160,048	$ 23,876	$ 423,924
Gerald J. Kochanski	2010	$ 192,143	—	—	$ 13,079	$ 205,222
Chief Financial Officer	2009	$ 190,550	—	$ 48,614	$ 32,059	$ 271,223

(1) The amounts in this column reflect decisions approved by our Compensation Committee and are based on an analysis of the executive's contribution to Nephros during fiscal 2009 and 2010.

(2) The amount reported is the aggregate grant date fair value of the options granted, computed in accordance with FASB ASC Topic 718.

(3) See table below for details on "All Other Compensation."

(4) Dr. Mieyal began serving as our acting Chief Executive Officer on April 6, 2010 and receives no compensation for his services, except in his capacity as a director of our company, which compensation is disclosed in the columns titled "Option Awards," and "All Other Compensation" included in this table.

(5) Mr. Elgin became our President and Chief Executive Officer on September 15, 2008 and resigned on March 30, 2010.

All Other Compensation

Name	Year	Matching 401K Plan Contribution	Health Insurance Paid by Company	Life Insurance Paid by the Company	Consulting Fees	Director Fees	Company Paid Transportation Expense	Total Other Compensation
Paul A. Mieyal	2010	—	—	—	—	$ 14,800	—	$ 14,800
Ernest A. Elgin III	2010	—	$ 3,404	$ 416	$ 49,687	—	—	$ 53,507
	2009	—	$ 23,208	$ 668	—	—	—	$ 23,876

Gerald J. Kochanski	2010	$ 7,126	$ 7,926	$ 5,153	—	—	—	$ 20,205
	2009	$ 4,846	$ 16,407	$ 806	—	—	$ 10,000	$ 32,059

Option Holdings and Fiscal Year-End Option Values

The following table shows information concerning unexercised options outstanding as of December 31, 2010 for our named executive officers (after giving effect to the 1:20 reverse stock split effected on March 11, 2011).

Outstanding Equity Awards at Fiscal Year-End 2010

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Paul A. Mieyal	3,750	-0-	$ 16.00	11/30/17
Paul A. Mieyal	333	667	$ 19.00	1/8/20
Gerald J. Kochanski	6,250	6,250	$ 15.00	4/1/18
Gerald J. Kochanski	313	938	$ 2.60	1/6/19
Gerald J. Kochanski	945	2,834	$ 15.40	12/31/19

Employment and Change in Control Agreements

We have used employment agreements as a means to attract and retain executive officers. These are more fully discussed below. We believe that these agreements provide our executive officers with the assurance that their employment is a long-term arrangement and provide us with the assurance that the officers' services will be available to us for the foreseeable future.

Agreement with Mr. Ernest A. Elgin III

We entered into an employment agreement with Mr. Elgin, dated as of September 15, 2008, having a term of three years. Mr. Elgin resigned on March 30, 2010. As part of his resignation, Mr. Elgin and we mutually agreed to terminate his employment agreement effective March 30, 2010. In connection with Mr. Elgin's resignation, we entered into a separation, release and consulting agreement with him, pursuant to which we paid Mr. Elgin his current salary through April 16, paid his applicable COBRA premiums through April 30, 2010 and, during any time that his COBRA coverage was in effect in 2010, were obligated to reimburse him for out-of-pocket payments made in 2010 under his healthcare coverage up to $5,000, which is the deductible under the healthcare coverage. Mr. Elgin was available to consult with us for up to 15 hours a week until May 31, 2010, for which we paid Mr. Elgin at the rate of 50% of his current salary from April 16 to May 31, 2010. We had the right to extend the consulting period for an additional four months, which we did, during which Mr. Elgin was available to consult with us for up to 7.5 hours a week and during which we paid Mr. Elgin 25% of his current salary. We could terminate this consulting arrangement at any time upon 30 days notice. The agreement terminated pursuant to its terms on September 30, 2010. For his consulting services we paid Mr. Elgin an aggregate of $49,687.

Agreement with Mr. Gerald J. Kochanski

Mr. Kochanski began serving as our chief financial officer on April 28, 2008, pursuant to an employment agreement dated as of April 1, 2008. Mr. Kochanski's initial annual base salary is $185,000. For the first year of Mr. Kochanski's employment, we will pay him a non-accountable commuting allowance of $10,000. In addition, we agreed to pay up to $10,000 of Mr. Kochanski's moving costs. Mr. Kochanski may be awarded a bonus based on performance. Pursuant

to the employment agreement, we granted Mr. Kochanski an option to purchase 12,500 shares of our common stock under our 2004 Equity Incentive Plan. The option vests in four equal annual installments of 3,125 shares on each of March 31, 2009, March 31, 2010, March 31, 2011 and March 31, 2012 provided that he remains employed by us at such time, and provided further that such options shall become exercisable in full immediately upon the occurrence of a change in control (as defined in our 2004 Stock Incentive Plan).

Mr. Kochanski's agreement provides that upon termination by us for cause or disability (as such terms are defined in the agreement) or by Mr. Kochanski for any reason other than his exercise of the change of control termination option (as defined in the agreement), then we shall pay him only his accrued but unpaid base salary and bonuses for services rendered through the date of termination, his unvested options shall immediately be cancelled and forfeited and his vested options shall remain exercisable for 90 days after such termination. If Mr. Kochanski's employment is terminated by his death or by his voluntary resignation or retirement other than upon his exercise of the change of control termination option, then we shall pay him his accrued but unpaid base salary for services rendered through the date of termination and any bonuses due and payable through such date of termination and those that become due and payable within 90 days after such date. If we terminate Mr. Kochanski's employment for any other reason, then, provided he continues to abide by certain confidentiality and non-compete provisions of his agreement and executes a release, he shall be entitled to: (1) any accrued but unpaid base salary for services rendered through the date of termination; and (2) the continued payment of his base salary, in the amount as of the date of termination, for a period of either three months or, if he has been employed under the agreement for at least one year, six months subsequent to the termination date or until the end of the remaining term of the agreement if sooner.

Upon any sale of all or substantially all of our business or assets, whether direct or indirect, by purchase, merger, consolidation or otherwise, Mr. Kochanski shall have a period of time in which to discuss, negotiate and confer with any successor entity regarding the terms and conditions of his continued employment. If Mr. Kochanski, acting reasonably, is unable to timely reach an agreement through good faith negotiations with such successor, then he may elect to terminate his employment with us and receive the payments and bonuses described above with respect to such a termination. This is the same change in control termination option found in the Elgin employment agreement.

The agreement defines “cause” as (1) conviction of any crime (whether or not involving us) constituting a felony in the jurisdiction involved; (2) engaging in any act which, in each case, subjects, or if generally known would subject, us to public ridicule or embarrassment; (3) gross neglect or misconduct in the performance of the employee’s duties under the agreement; or (4) material breach of any provision of the agreement by the employee; provided, however, that with respect to clauses (3) or (4), the employee must have received written notice from us setting forth the alleged act or failure to act constituting "cause", and the employee shall not have cured such act or refusal to act within 10 business days of his actual receipt of notice.

The agreement defines “disability” as our determination that, because of the employee’s incapacity due to physical or mental illness, the employee has failed to perform his duties under the agreement on a full time basis for either (1) 120 days within any 365-day period, or (2) 90 consecutive days.

On March 28, 2011, we entered into an employment agreement, to be effective on April 1, 2011, with Mr. Kochanski. The new employment agreement replaces the current agreement and is substantially similar to the prior agreement with the following material changes: Mr. Kochanski’s base annual salary will be increased to $200,192, an increase of $15,192; and in the event that Mr. Kochanski’s employment is either terminated by us for other than “cause” (as defined in the agreement), then (i) all of his unvested stock options that would have vested during the shorter of (a) the subsequent six months or (b) the remainder of the term, shall immediately become vested.

Change in Control Payments

If the change in control payments called for in the agreements for Mr. Kochanski had been triggered on December 31, 2010, we would have been obligated to make the following payments:

Name	Cash Payment Per Month (# of months paid)	Number of Options that Would Vest (Market Value) (1)
Gerald J. Kochanski	$ 97,180 (6 mos.)	10,021 (-0-)

(1) The market value equals the difference between $0.10, the fair market value of the shares that could be acquired based on the closing sale price per share of our common stock on the Over-the-Counter Bulletin Board on December 31, 2010 and the exercise prices for the underlying stock options. All options have an exercise price in excess of $0.10.

2004 Equity Incentive Plan

The 2004 Plan provides that if there is a change in control, unless the agreement granting an award provides otherwise, all awards under the 2004 Plan will become vested and exercisable as of the effective date of the change in control. As defined in the 2004 Plan, a change in control means the occurrence of any of the following events: (i) any “person,” including a “group,” as such terms are defined in sections 13(d) and 14(d) of the Exchange Act and the rules promulgated thereunder, becomes the beneficial owner, directly or indirectly, whether by purchase or acquisition or

agreement to act in concert or otherwise, of more than 50% of the outstanding shares of our common stock; (ii) our complete liquidation; (iii) the sale of all or substantially all of our assets; or (iv) a majority of the members of our Board of Directors are elected to the Board without having previously been nominated and approved by a majority of the members of the Board incumbent on the day immediately preceding such election.

The following table provides information as of December 31, 2010 (adjusted to give effect to the reverse stock split effected on March 11, 2011) about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors upon exercise of options or warrants under all of our existing equity compensation plans, and warrants issued to placement agents in connection with our 2007 financing. Our existing equity compensation plans consist of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (together, our "Stock Option Plans") in which all of our employees and directors are eligible to participate. Our Stock Option Plans and the issuance of the placement agent warrants were approved by our stockholders.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrant and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrant and Rights	(c) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our stockholders:			
Stock Option Plans	44,664	$ 27.4	82,535
Placement Agent Warrants	6,484	$ 18.00	—
Equity compensation plans not approved by our stockholders:			
None	—		—
All Plans	51,148		82,535

Director Compensation

In fiscal 2010, our directors received a $10,000 annual retainer, $1,200 per meeting for each quarterly Board meeting attended and reimbursement for expenses incurred in connection with serving on our Board of Directors. The Chairman of the Board receives an annual retainer of $20,000 and $1,500 per meeting for each quarterly Board meeting attended. The chairperson of our Audit Committee is paid a $5,000 annual retainer and $500 per meeting for meetings of the Audit Committee, with a maximum of eight meetings per year.

We grant each non-employee director who first joins our Board, immediately upon such director's joining our Board, options to purchase 1,000 shares of our common stock in respect of such first year of service at an exercise price per share equal to the fair market value price per share of our common stock on the date of grant. We also grant annually to each non-employee director options to purchase 500 shares of our common stock (625 shares to the Chairman of the Board, effective in 2009) at an exercise price per share equal to the fair market value price per share of our common stock on the grant date, although inadvertently we did not grant these options in 2008 and 2009, and subsequently granted them in January 2010 with an exercise price of $19.00 per share. These non-employee director options vest in three equal installments on each of the date of grant and the first and second anniversaries thereof. Our executive officers do not receive additional compensation for service as directors if any of them so serve.

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2010.

Non-Employee Director Compensation in Fiscal 2010

Name	Fees Earned or Paid in Cash	Option Awards(1) (2)	Total ($)
Arthur H. Amron	$ 14,800	$ 14,596	$ 29,396
Lawrence J. Centella	$ 14,800	$ 14,596	$ 29,396
Paul A. Mieyal	$ 14,800	$ 14,596	$ 29,396
James S. Scibetta	$ 32,700	$ 16,420	$ 49,120

(1) The amount reported is the aggregate grant date fair value of the options granted, computed in accordance with FASB ASC Topic 718.

(2) Unless otherwise indicated below, option awards included in this table vest in three equal installments on each of the date of grant and the first and second anniversaries thereof. This table gives effect to the 1:20 reverse stock split effected on March 11, 2011.

Compensation Committee Interlocks and Insider Participation

Lawrence J. Centella and Paul Mieyal served as members of our Compensation Committee during all of 2010. Neither of these individuals was at any time during 2010 or at any other time an officer or employee of our company. Dr. Mieyal serves as our acting Chief Executive Officer, but he receives no employee compensation or employee benefits from Nephros. No interlocking relationship exists between any member of our Compensation Committee and any member of any other company's board of directors or compensation committee.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On October 1, 2010, Lambda Investors loaned us $500,000 pursuant to a secured promissory note. The note bore interest at the rate of 12% per annum and was to mature on April 1, 2011. Lambda Investors also committed to purchase, through a private placement evidenced by a purchase agreement, 3,009,711 units, which amount equals the number of units that would otherwise be available for purchase by Lambda Investors pursuant to the exercise of its basic subscription privilege, at the rights offering subscription price of $0.40 per unit, so long as certain conditions are met, including that stockholders not affiliated with Lambda Investors subscribe for at least 4,375,000 of the units offered in the rights offering. In addition, under the purchase agreement, Lambda Investors has the right to purchase, at the rights offering subscription price, that number of units that would otherwise be available for purchase by Lambda Investors pursuant to its over-subscription privilege in the event our other stockholders do not exercise their basic subscription privileges in full and Lambda Investors purchases 3,009,711 units under the purchase agreement. Lambda Investors did not receive any compensation for its purchase commitment. Following the closing of the rights offering, and after giving effect to anti-dilution provisions in existing warrants to purchase shares of our common stock that the rights offering triggered, Lambda Investors surrendered for cancellation warrants to purchase a number of shares equal to the total number of shares underlying warrants issued as part of the units sold in the rights offering and under the purchase agreement with Lambda Investors. The term of the remaining Lambda Investors warrants was extended so that the warrants expire at the same time as the warrants issued in the rights offering, which have a five-year term. We used proceeds from the rights offering to repay the $500,000 principal due under the note, plus pay all accrued interest thereon, as well as an 8% sourcing/transaction fee ($40,000) in respect of the note and an aggregate of $100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering. Lambda Investors our largest stockholder and as of February 14, 2011 beneficially owned approximately 71% of our outstanding common stock, including warrants to purchase an aggregate of 11,589,151 shares of our common stock. Lambda Investors is controlled by Wexford Capital LP. Arthur H. Amron, one of our directors, is a Partner and General Counsel of Wexford Capital LP. Paul A. Mieyal, our acting Chief Executive Officer and one of our directors, is a Vice President of Wexford Capital LP.

In connection with the rights offering, we have agreed to enter into a registration rights agreement with Lambda Investors pursuant to which we will file a registration statement on Form S-1 (or other appropriate form if we are not then eligible to use Form S-3) covering the resale by Lambda Investors of the common stock (including shares issuable upon the exercise of warrants) underlying Units sold under the purchase agreement with Lambda Investors, the existing Lambda Investors' warrants that will remain outstanding following the closing of the rights offering and shares of common stock issuable to Lambda Investors upon the exercise of such remaining warrants and warrants issued in the rights offering. Under this registration rights agreement, we will pay all of the expenses, including reasonable legal fees, of Lambda Investors in connection with such registration statement and resale of shares by Lambda Investors under such registration statement, which may be in an underwritten public offering. We will be obligated to use our reasonable best efforts to keep such registration statement continuously effective until such time as all the securities registered on such registration statement have been sold or are eligible for sale without restriction under the applicable securities laws.

In connection with our September 2007 financing, we entered into the registration rights agreement with certain parties, including Lambda Investors, pursuant to which we filed a resale registration statement registering common stock and shares of common stock issuable upon exercise of warrants held by such investors. We agreed to pay all expenses of such investors in connection with such registration statement and the resale of shares thereunder.

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 Investors (i) to nominate two individuals having reasonably appropriate experience and background to our board to serve as directors until their respective successor(s) are elected and qualified, (ii) to nominate each successor to the Lambda Investors 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 of directors at least once every three months. If we fail to do so, a Lambda Investors director will be empowered to convene such meeting.

The investor rights agreement also provides that, except as Lambda Investors may otherwise agree in writing, Lambda Investors 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 Investors nor any officer, director, partner, manager, employee or affiliate of Lambda Investors, which is referred to as a Lambda Investors person, will be liable to us or our stockholders for breach of any fiduciary duty by reason of any such activities of Lambda Investors or of such Lambda Investors person's participation therein. A Lambda Investors 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 Investors or any Lambda Investors person acquires knowledge of a potential transaction or matter that may be a corporate opportunity for both Lambda Investors and us other than in the case of a "director-related opportunity" (as defined below), Lambda Investors and such Lambda Investors person will have no duty to communicate or present such corporate opportunity to us. In addition, in the event that a Lambda Investors director acquires knowledge of a potential transaction or matter that may be a corporate opportunity for both us and Lambda Investors, such corporate opportunity will belong to Lambda Investors, 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 Investors where knowledge of such corporate opportunity is made known to a Lambda Investors person who is serving as our director as a result of his serving as our director prior to (x) Lambda Investors or any other Lambda Investors person acquiring knowledge of such corporate opportunity, or (y) such Lambda Investors person acquiring knowledge of such corporate opportunity other than as a result of such Lambda Investors person's serving as a director.

Dr. Eric A. Rose was a director until his resignation in June 2009. During his service, Dr. Rose was on leave from his position as the Chairman of Columbia University's Department of Surgery. Until November 30, 2008, we licensed the right to use approximately 2,788 square feet of office space from the Trustees of Columbia University. The term of the lease agreement was for one year through September 30, 2008 at a monthly cost of $13,359.55. Pursuant to this agreement, we could access the internet through the Columbia University Network at a monthly fee of $328.50. The lease terminated on November 30, 2008, and we do not currently have any other material relationship with Columbia University.

All share amounts and related prices have been adjusted to give effect to the 1:20 reverse stock split effected on March 11, 2011.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the beneficial ownership of our common stock as of September 22, 2011, 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' filings with the SEC as of that date; (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)	15,317,924	56.3	%
Southpaw Asset Management LP(3)	925,923	3.4%	%
Arthur H. Amron(4)	14,217	*	

Lawrence J. Centella(5)	41,684	*
Gerald J. Kochanski(6)	110,944	*
Paul A. Mieyal(7)	14,217	*
James S. Scibetta(8)	26,750	*
All executive officers and directors as a group(4) – (8)	207,812	*

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

(1) Applicable percentage ownership is based on 10,064,809 shares of common stock outstanding as of September 22, 2011, after giving effect to the 1:20 reverse stock split effected March 11, 2011, together with applicable options and warrants for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors including voting and investment power with respect to shares. Common stock subject to options and warrants exercisable on or within 60 days after September 22, 2011 are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options or warrants, but not for computing the percentage ownership of any other person.

(2) Based in part on information provided in Schedule 13D/A filed on March 21, 2011. The shares beneficially owned by Lambda Investors may be deemed beneficially owned by Wexford Capital LP, which is the managing member of Lambda Investors, Wexford GP LLC, which is the General Partner of Wexford Capital, by Charles E. Davidson in his capacity as Chairman and managing member of Wexford Capital LP and by Joseph M. Jacobs in his capacity as President and managing member of Wexford Capital LP. The address of each of Lambda Investors LLC, Wexford Capital LP, Mr. Davidson and Mr. Jacobs is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. Each of Wexford Capital LP, Wexford GP LLC, Mr. Davidson and Mr. Jacobs disclaims beneficial ownership of the shares of Common Stock owned by Lambda Investors except, in the case of Mr. Davidson and Mr. Jacobs, to the extent of their respective interests in each member of Lambda Investors. Includes 11,589,132 shares issuable upon exercise of warrants held by Lambda Investors having an exercise price of $0.40 per share. Lambda Investors is controlled by Wexford Capital LP. Arthur H. Amron, one of our directors, is a Partner and General Counsel of Wexford Capital LP. Paul A. Mieyal, our acting Chief Executive Officer and one of our directors, is a Vice President of Wexford Capital LP.

(3) Includes 442,669 shares issuable upon exercise of warrants having an exercise price of $0.40. Based in part on information provided in Schedule 13D/A filed on March 24, 2011 and May 25, 2011. The shares beneficially owned by Southpaw Asset Management LP may be deemed beneficially owned by Southpaw Holdings LLC, which is the General Partner of Southpaw Asset Management LP, and by each of Kevin Wyman and Howard Golden, who are principals of Southpaw Holdings LLC, and Southpaw Credit Opportunity Master Fund LP, of which Southpaw Asset Management LP is the investment manager. The address of each of Southpaw Asset Management LP, Southpaw Holdings LLC, Kevin Wyman, Howard Golden, and Southpaw Credit Opportunity Master Fund LP, is 2 Greenwich Office Park, Greenwich, CT 06831. Each of Southpaw Asset Management LP, Southpaw Holdings LLC, Kevin Wyman and Howard Golden disclaims beneficial ownership of 41,825 shares of common stock and 38,312 shares issuable upon the exercise of warrants beneficially owned by Southpaw Credit Opportunity Master Fund LP.

(4) Mr. Amron's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Amron consist of 14,217 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 19,533 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 22, 2011.

(5) Mr. Centella's address is the Company address. The shares identified as being beneficially owned by Mr. Centella include 26,417 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 36,375 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 22, 2011.

(6) Mr. Kochanski's address is the Company address. The shares identified as being beneficially owned by Mr. Kochanski consist of 110,944 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 156,584 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 22, 2011.

(7) Mr. Mieyal's address is c/o Wexford Capital LP, 411 West Putnam Avenue, Greenwich, CT 06830. The shares identified as being beneficially owned by Mr. Mieyal consist of 14,217 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 19,533 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 22, 2011.

(8) Mr. Scibetta's address is the Company address. The shares identified as being beneficially owned by Mr. Scibetta consist of 26,750 shares issuable upon exercise of options granted under the 2004 Plan. Does not include 36,375 shares issuable upon the exercise of options which have been granted under our Stock Option Plans but will not vest within 60 days of September 22, 2011.

DESCRIPTION OF COMMON STOCK

Our authorized capital stock consists of 90,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. As of September 22, 2011, there were 10,064,809 shares of common stock outstanding and no shares of preferred stock outstanding. All amounts are reported on a post reverse stock split basis.

To effect the rights offering we needed to increase the number of authorized shares of our common stock. Accordingly, we sought and received the approval of our stockholders at our annual meeting of stockholders held on January 10, 2011, to amend our certificate of incorporation to increase the authorized shares of our capital stock from 95,000,000 to 905,000,000 shares and the authorized shares of our common stock from 90,000,000 to 900,000,000 shares. We filed a certificate of amendment to our certificate of incorporation providing for such share increase

immediately prior to the closing of the rights offering. Immediately after completion of the rights offering, we effected a 1-for-20 reverse stock split of our outstanding shares of common stock and decrease the authorized shares of our capital stock from 905,000,000 to 95,000,000 shares and the authorized shares of our common stock from 900,000,000 to 90,000,000 shares. We received stockholder approval of such amendment at our annual meeting of stockholders held on January 10, 2011.

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.

DESCRIPTION OF WARRANTS

This prospectus relates to the shares of our common stock issuable upon the exercise, if any, of the warrants issued to the investors in this offering.

The warrants have an exercise price of $0.40 per share of our common stock and are exercisable at the option of the holder at any time after the closing date of this offering, through and including the date that is the five year anniversary of the initial exercise date. Notwithstanding the foregoing, no warrants will be exercisable and we will not be obligated to issue any shares issuable upon the exercise of such warrants unless (i) at the time the holder thereof seeks to exercise such warrant, we have a registration statement under the Securities Act in effect covering the shares issuable upon the exercise of such warrant and a current prospectus relating to our common stock, and (ii) the shares issuable upon such exercise have been registered or qualified or deemed to be exempt from registration under the securities laws of the state of residence of the holder of the warrant. The warrants may be exercised only for full shares of common stock, and may not be exercised on a “cashless” basis. We will not issue fractional shares of common stock or cash in lieu of fractional shares of common stock. Warrant holders do not have any voting or other rights as a stockholder of our company.

If we (i) pay a dividend or make a distribution on our common stock in shares of common stock, other securities, cash or any other property, (ii) subdivide our outstanding shares of common stock into a greater number of shares, (iii) combine or reverse-split our outstanding shares of common stock into a smaller number of shares, or (iv) engage in certain pro-rata repurchases of common stock, then the per share warrant price and the number of warrant shares will be proportionately decreased and increased, respectively, in the case of a subdivision, distribution or stock dividend, or proportionately increased and decreased, respectively, in the case of a combination or reverse stock split. The aggregate warrant price payable for the then total number of warrant shares available for exercise under the warrant will remain the same.

If we effect any capital reorganization or reclassification, or any consolidation or merger, or any sale, transfer or other disposition of all or substantially all of our property, assets or shares to which we are a party, the holder of the warrant will have the right to receive on the exercise of the warrant the kind and amount of securities, cash or other property which the holder would have owned or have been entitled to receive immediately after such reorganization, reclassification, consolidation, merger or reorganization had the warrant been exercised immediately prior to the effective date of such transaction. Our consummation of any such transaction in which we are not the surviving entity will be contingent upon the assumption of the warrants by the surviving party to such transaction.

No market exists for the warrants. We do not intend to list the warrants offered hereby on any securities exchange or automated quotation system.

In the rights offering, Nephros sold 4,964,864 units at $0.40 per unit for gross proceeds of approximately $2.0 million, resulting in the issuance of 4.964,864 shares of common stock and warrants to purchase an aggregate of 4,590,171 shares of common stock. The warrants expire on March 10, 2016 and have an exercise price of $0.40 per share. All amounts are reported on a post reverse stock split basis.

On March 10, 2011, based on the completion of the rights offering Lambda Investors LLC, Nephros’ largest stockholder, purchased in a private placement 3,009,711 units at a per unit purchase price of $0.40 for aggregate gross proceeds of approximately $1.2 million, pursuant to a purchase agreement between Nephros and Lambda Investors LLC. Each unit consisted of one share of common stock and a warrant to purchase 0.924532845 shares of common stock at an exercise price of $0.40 per share for a period of five years following the issue date of the warrant, resulting in Lambda Investors LLC acquiring 3,009,711 shares of common stock and a warrant to purchase 2,782,577 shares of common stock. All amounts are reported on a post reverse stock split basis.

As of the rights offering record date, warrants to purchase 409,591 shares of our common stock were outstanding. Upon completion of the rights offering, warrants to purchase 375,961 shares had full-ratchet anti-dilution provisions and they became exercisable for an aggregate of 9,482,659 shares at an exercise price of $0.40 per share. After giving effect to these anti-dilution provisions, Lambda Investors' surrendered for cancellation warrants to purchase 808,966 shares of our common stock, which equaled the number of shares underlying warrants issued as part of the Units in the Rights Offering. The remaining 33,630 warrants have no full-ratchet anti-dilution provision and they are exercisable at $22.40 per share. All amounts are reported on a post reverse stock split basis.

As of September 22, 2011, there are warrants to purchase 16,855,406 shares at an exercise price of $0.40 with expiration dates in 2016 and warrants to purchase 33,630 shares at an exercise price of $22.40 that expire in 2014.

See "Certain Relationships and Related Transactions" for a description of registration rights with respect to shares of common stock issuable upon exercise of Lambda Investors warrants.

LEGAL MATTERS

The legality of the securities offered hereby have been 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, 2010 and 2009 included in this prospectus have been audited by Rothstein Kass & Company P.C., an independent registered public accounting firm, as stated in their report, 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.

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.

FINANCIAL STATEMENTS