NEPHROS INC
Form 10-K
March 22, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from to

Commission File Number 001-32288

NEPHROS, INC.

(Exact name of registrant specified in its charter)

Delaware	13-3971809
(State or Other Jurisdiction of	(I.R.S. Employer
Incorporation or Organization)	Identification No.)

41 Grand Avenue

River Edge, NJ 07661

(Address of Principal Executive Offices)

(201) 343-5202

(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

(Title of Class)

Common Stock, $.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information

statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2011, was approximately $4,752,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Over the Counter Bulletin Board on June 30, 2011. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2011.

As of March 13, 2012 there were 10,641,630 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's Proxy Statement (the "2012 Proxy Statement") which will be filed with the SEC in connection with the 2012 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K. The 2012 Proxy Statement will be filed within 120 days of December 31, 2011.

NEPHROS, INC. AND SUBSIDIARY

TABLE OF CONTENTS

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K 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," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. For such statements, we claim the protection of the Private 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 Annual Report on Form 10-K, is set forth in our filings with the SEC, including 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.

3

PART I

Item 1. Business

Reverse Stock Split

On January 10, 2011, our stockholders voted to approve a 1:20 reverse stock split of our common stock. The reverse split became effective on March 11, 2011. All of the share and per share amounts discussed in this Annual Report on Form 10-K have been adjusted to reflect the effect of this reverse split.

Overview

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

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

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); we believe that 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;

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

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

OLpur and H2H are among our trademarks for which U.S. registrations are pending. H2H is a registered European Union trademark.

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. 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. On August 11, 2011, Nephros filed a new 510(k) application with the FDA for clearance of the Company's hemodiafiltration (HDF) system for end-stage renal disease. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. The Company provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. We believe that, if approved, our 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, effective as of 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 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 January 3, 2012), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

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.

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 have filed a special 510(k) application for our SSU and MSU filters 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 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 $1,723,000 of revenue has been recognized on this new project since September 2009 of which approximately $463,000 and $846,000 has been billed to this second project during the years ended December 31, 2011 and 2010, respectively.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, we submitted its 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 its 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 UF40 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 of $40,000 and were 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 completed the remaining milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of $100,000 during 2010, of which approximately $67,000 was recognized in 2010 and approximately $33,000 was recognized in 2011. The remaining milestones, when completed, will result in additional payments of $60,000.

On June 27, 2011, the Company entered into a license agreement, 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.

In exchange for the rights granted to it under the agreement through December 31, 2014, Bellco agreed to pay Nephros installment payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. The first payment was received in July 2011. 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 Nephros 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 the discretion of Nephros, 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.

In the case where Nephros desires to pursue a Change in Control transaction (as defined in the agreement), Bellco will have a 30-day right of first offer with respect to such acquisition, and where either party pursues a change in control transaction, it will require the acquirer to assume such party's obligations under the agreement.

If there is an infringement of any of the patents underlying the Products, Nephros will have the first right to decide whether to act to protect such patents. Where Nephros decides not to act, Bellco, upon the written consent of Nephros, will be allowed to act to protect the patents and Nephros will reimburse Bellco the reasonable expenses sustained by Bellco as a credit against royalties due under the agreement.

The term of the agreement is from July 1, 2011 through December 31, 2016, or until earlier terminated by either party as follows. Either party may terminate immediately after giving notice of a breach of any material obligation or upon the insolvency or bankruptcy of the other party, in each case that remains uncured after the expiration of a 30-day cure period. In addition, in the event the agreement is terminated by Bellco on or prior to December 31, 2014 due to a material breach by Nephros that causes any of the patents underlying the Products to lapse, Nephros will be required to reimburse Bellco any of the Installment Payments paid by Bellco prior to the date of termination. Finally, Nephros may terminate the agreement immediately for the following reasons: Bellco's failure to cure a monetary default within 30 days of being provided notice of such default; in the event any required permit of Bellco expires, is not approved, is not issued, or is terminated, revoked, withdrawn or deactivated; and in respect of any calendar year commencing January 1, 2015, if aggregate royalties payable to Nephros fall below €270,000.The parties are subject to standard indemnification obligations.

On June 27, 2011, Nephros issued a press release announcing its entry into the license agreement. The description of the license agreement set forth above is not complete and is qualified in its entirety by reference to the agreement, which is attached as Exhibit 10.62 to this report and is incorporated by reference.

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 Nephros DSU, MSU, and SSU are FDA cleared devices for the filtration of biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. Within the U.S., there are approximately 4,500 clinics providing over 50million dialysis treatments to 350,000 patients annually. To perform hemodialysis, ultrapure water is crucial to the production of dialysate. Dialysis clinics have water purification systems; however, microbial contaminants can originate from the water treatment system, the water distribution loop, or the dialysate concentrates. Nephros ultrafilters filter out substances down to the 0.005 micron level and address dialysate contamination at crucial points: after the reverse osmosis module and at the dialysis machine entrance from the water distribution loop. Nephros ultrafilters can be used as the last step in the water purification process to ensure that ultrapure water is used for dialysis procedures. Regular use of Nephros ultrafilters offers an affordable safety measure when utilized with modern water treatment systems and optimally maintained hemodialysis machines. Recent data have shown that the Nephros DSU, when used as part of the water purification system for dialysis systems, may reduce the required dosage of erythropoietin stimulating agents, which we believe will provide a unique benefit to patients.

On July 25, 2011, Nephros, Inc. entered into a letter agreement with DHR International, Inc., an international executive search firm, whereby DHR International will conduct a search to recruit a chief executive officer for Nephros. On July 26, 2011, Nephros issued a press release announcing, among other things, its entry into the letter agreement.

Under the agreement, Nephros will pay DHR International a retainer consisting of $100,000 in cash and equity worth $25,000. The cash retainer is due in three equal installments. The first retainer payment was due and paid on execution of the agreement. The second retainer was due and paid when Nephros began the first round of interviews during the third quarter and the third retainer is due upon a candidate's acceptance of an offer from Nephros. The stock portion of the retainer is in the form of an option for 20,000 shares of common stock with an exercise price of $1.25 per share, which was the closing price of our common stock on July 25, 2011 as reported on the Over-the-Counter Bulletin Board. The option is fully vested and has a term of 10 years.

In addition to the payments discussed above, Nephros will reimburse DHR International for indirect out-of-pocket expenses related to the executive search, such as administrative, database management and reproduction costs, which are estimated to run 12% of the aggregate retainer, and are payable in three equal installments to be billed at the same time as the three retainer installments. Nephros also must reimburse DHR International for any direct out-of-pocket expenses, such as travel and lodging, which will be billed monthly as incurred. Nephros has paid DHR for all billed indirect and direct out-of-pocket expenses.

In the event that Nephros hires a candidate provided by DHR International for any position other than chief executive officer, Nephros will be obligated to pay DHR International a fee equal to 33% of the individual's projected first year total cash compensation.

If Nephros hires a candidate presented by DHR International and that individual is terminated, either voluntarily or involuntarily, within two years from the hiring date, DHR International will, at Nephros' request, refill the position for no additional fee.

Nephros may cancel the agreement at any time. DHR International continues the search to recruit a chief executive officer for Nephros at this time.

On July 26, 2011, Nephros issued a press release that reported, among other things, the amount of revenue Nephros has received for the first six months of 2011 from the Office of Naval Research for work related to an advanced water purification system for military field use that Nephros is developing using its proprietary dual stage cold sterilization ultrafilter as the basis of the portable system. Nephros has generated approximately $463,000 and $846,000 of revenue during the years ended December 31, 2011 and 2010, respectively, from its U.S. Defense Department project.

On July 26, 2011, Nephros issued a press release that provided a corporate update on its operations and strategy.

On August 11, 2011 Nephros submitted a new 510(k) application to market its leading-edge hemodiafiltration (HDF) system for end-stage renal disease. The application details Nephros' OLpur MD220 diafilter and Nephros' OLpur H 2 H Hemodiafiltration module. Nephros' OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros' proprietary Mid-Dilution diafiltration technology. Nephros' OLpur H 2 H Hemodiafiltration module enables the most common types of standard dialysis machines to perform HDF therapy. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. The Company provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. We believe that, if approved, our 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.

Going Concern

The accompanying financial statements have been prepared assuming that we will continue as a going concern. 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 condensed consolidated interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred significant losses in operations in each quarter since inception. For the years ended December 31, 2011 and 2010, we incurred net losses of $2,360,000 and $1,933,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 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 was 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. 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 issued to Lambda Investors, LLC, plus $26,650 of accrued interest thereon, 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 were approximately $2.0 million. We issued an aggregate of 4,964,854 shares of common stock and warrants to purchase an aggregate of approximately 4,590,171 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 2,782,577 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.

On June 27, 2011, we entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters. 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. The first two fixed payments have been received. The remaining fixed payment of €600,000 or approximately $778,000, will take place in January 2013. 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 per year in the territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. Anticipated payments from this License Agreement will be a positive source of cash flow to the Company.

There can be no assurance that the Company's future cash flow will be sufficient to meet its obligations and commitments. If the Company is unable to generate sufficient cash flow from operations in the future to service its commitments the Company will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing its planned activities or ceasing its 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 the Company to continue to satisfy its capital requirements.

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
  - o 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."

9

- *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' OLpur MD220 diafilter and Nephros' OLpur H2H Hemodiafiltration module. Nephros' OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros' proprietary Mid-Dilution diafiltration technology. Nephros' OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. The Company provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. 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.

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. The application is subject to the FDA's standard 90-day review period. The application details Nephros' OLpur MD220 diafilter and Nephros' OLpur H2H Hemodiafiltration module. Nephros' OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros' proprietary Mid-Dilution diafiltration technology. Nephros' OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. On November 8, 2011 the Nephros received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. Nephros provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. 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 5,800 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 war fighters. 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 $463,000 and $846,000 has been billed to this project during the years ended December 31, 2011 and 2010, respectively. Approximately $1,732,000 of revenue has been recognized on this $1.8 million project since its beginning in September 2009.

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 of $40,000 and were 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 completed the remaining milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of $100,000 during 2010, of which approximately $67,000 was recognized in 2010 and approximately $33,000 was recognized in 2011. The remaining milestones, when completed, will result in additional payments 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 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 2012. 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 2012, 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 to the market 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. 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.

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 per year 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 per year 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 $463,000 and $846,000 has been billed to this project during the years ended December 31, 2011 and 2010, respectively. Approximately $1,732,000 of revenue has been recognized on this $1.8 million project since its beginning in September 2009.

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 of $40,000 and were 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 completed the remaining milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of $100,000 during 2010, of which approximately $67,000 was recognized in 2010 and approximately $33,000 was recognized in 2011. The remaining milestones, when completed, will result in additional payments 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, 2011 and 2010 and were $451,000 and $362,000, 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 31, 2011, we have sixteen issued U.S. patents; one issued Eurasian patent; five Mexican patents, four South Korean patents, three Russian patents, six Chinese patents, nine French patents, nine German patents, four Israeli patents, seven Italian patents, three Spanish patents, eight United Kingdom patents, eleven Japanese patents, three Hong Kong patents, ten Canadian patents, one Australian patent, and one patent in Brazil. Our issued U.S. patents expire between 2018 and 2026. In addition, we have four pending U.S. patent applications, four pending patent applications in Canada, five pending patent applications in the European Patent Office, four pending patent applications in Brazil, two pending patent applications in China, one pending patent application in Japan, two pending patent applications in Mexico, one pending patent application in South Korea, two pending patent applications in India, and four pending patent applications in Israel. 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 contract manufacturer ("CM"). We and our CM are negotiating commercial arrangements pertaining to the invention and the patent applications.

Trademarks

As of December 31, 2011, 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 our OLpūr H2H module and OLpūr MD 220 filter products during 2012. 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. 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' OLpur MD220 diafilter and Nephros' OLpur H2H Hemodiafiltration module. Nephros' OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros' proprietary Mid-Dilution diafiltration technology. Nephros' OLpur H2H Hemodiafiltration module is designed to enable the most common types of standard dialysis machines to perform HDF therapy. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. The Company provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. The Company 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.

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 to 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 to 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. and expanded our scope to include design and development and production of water filters.

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 and May 2011, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpur MDHDF filter series and our Dual Stage Ultrafilter (DSU), respectively for marketing in Canada. Other than the CE marking and Canadian approval of our OLpur MDHDF filter and DSU 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 December 31, 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 2 consultants on an ongoing basis. Of the 9 total employees and consultants, 2 are 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 December 31, 2011.

Available Information

We make available free of charge on our website (http://www.nephros.com) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. We provide electronic or paper copies of filings free of charge upon request. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC at http://www.sec.gov.

Item 1.A. Risk Factors

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, 2011, 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 Annual Report on Form 10-K 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 the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We 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 December 31, 2011, we had an accumulated deficit of approximately $94,268,000 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 and our future business prospects 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. 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. On August 11, 2011 we submitted a new 510(k) application to market our hemodiafiltration (HDF) system for end-stage renal disease. The application is 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. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. The Company provided answers to the FDA's request in early February 2012 and awaits further communication from the FDA. 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.

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 and our future business prospects 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 sales, and the loss of any of these customers could have a material adverse effect on our sales.

For the year ended December 31, 2011, one of our customers accounted for 50% of our sales and another customer accounted for 21% of our sales. 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.

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. On August 11, 2011 we submitted a new 510(k) application to market our hemodiafiltration (HDF) system for end-stage renal disease and we recently responded to an FDA request for additional information.

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 products, including the 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 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, 2011, our common stock has traded at prices ranging from a high of $2.40 to a low of $0.30 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 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.

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 December 31, 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 Kasei Medical Co. Ltd., 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.

Item 2. 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 one year commencing December 1, 2011 with a monthly cost of approximately $7,813. 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 was renewed on July 1, 2011 and again renewed on January 1, 2012 for a term of 6 months. The lease term 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.

Item 3. Legal Proceedings

There are no 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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 bid and ask prices for our common stock as reported on the Over the Counter Bulletin Board for each quarter listed. All prices have been adjusted to reflect the effect of the reverse split effective March 11, 2011. Such over the counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
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
September 30, 2011	$2.19	$.70
December 31, 2011	$1.90	$.41

As of March 13, 2012, there were approximately 20 holders of record and approximately 1,000 beneficial holders of our common stock.

We have neither paid nor declared dividends on our common stock since our inception. 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.

Recent Sales of Unregistered Securities

Except as previously reported in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, we have not sold any equity security during the three years ended December 31, 2011 which were not registered under the

Securities Act of 1933, as amended.

Issuer Repurchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of 2011.

Item 6. Selected Financial Data

Not required.

Item 7. Management's Discussion and Analysis or Plan of Operation

The following discussion includes forward-looking statements about our business, financial condition, and results of operations, including discussions about management's expectations for our business. These statements represent projections, beliefs and expectations based on current circumstances and conditions and in light of recent events and trends, and you should not construe these statements either as assurances of performances or as promises of a given course of action. Instead, various known and unknown factors are likely to cause our actual performance and management's actions to vary, and the results of these variances may be both material and adverse. A list of the known material factors that may cause our results to vary, or may cause management to deviate from its current plans and expectations, is included in Item 1A "Risk Factors." The following discussion should also be read in conjunction with the consolidated financial statements and notes included herein.

Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this Form 10-K 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.

Business Overview

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.

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. 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 January 3, 2012), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

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

1) receiving regulatory approval for each of our ESRD therapy products and our DSU product in our target territories;

2) the completion and success of additional clinical trials;

3) the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;

4) our ability to effectively and efficiently manufacture, market and distribute our products;

5) our ability to sell our products at competitive prices which exceed our per unit costs;

6) the consolidation of dialysis clinics into larger clinical groups; and

7) the current U.S. healthcare plan is to bundle reimbursement for dialysis treatment which may force dialysis clinics to change therapies due to financial reasons.

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

Recently Adopted Accounting Pronouncements

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 Principles, 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 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.

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.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management’s subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this annual report on Form 10-K, we believe that the following accounting policies require the application of significant judgments and estimates.

Revenue Recognition

Revenue is recognized in accordance with ASC Topic 605. Four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed and determinable; and (iv) 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, 2011 Compared to the Fiscal Year Ended December 31, 2010

Revenues

Total revenues for the year ended December 31, 2011 were approximately $2,214,000 compared to approximately $2,938,000 for the year ended December 31, 2010. Total revenues decreased approximately $724,000. The decrease of approximately 25% is due to decreased revenue of approximately $384,000, or 45%, during the year ended December 31, 2011 over the same period in 2010, related to our contract with the Office of U.S. Naval Research, a $749,000 reduction in direct sales of our MD filters in our Target European Market, and a $73,000 reduction in STERIS project sales. These decreases were partially offset by approximately $117,000 more DSU sales, or 24%, and $365,000 in revenue related to the Bellco license agreement for the year ended December 31, 2011 compared to no Bellco license revenue for the year ended December 31, 2010.

Revenues were not significantly impacted by inflation or changing prices for the years ended December 31, 2010 or 2011.

Cost of Goods Sold

Cost of goods sold was approximately $1,346,000 for the year ended December 31, 2011 compared to approximately $1,816,000 for the year ended December 31, 2010. The decrease of approximately $470,000, or 26%, in cost of goods sold is primarily related to our contract with the Office of U.S. Naval Research, where the cost of goods sold decreased by approximately $180,000, a $513,000 reduction in cost of sales of our MD filters in our Target European Market, and a $83,000 reduction in costs related to the STERIS project. These decreases were partially offset by increased cost of goods sold of approximately $106,000 related to DSU sales for the year ended December 31, 2011 compared to the same period in 2010. Also included in cost of goods sold for the year ended December 31, 2011 is a write-down for obsolete inventory of approximately $200,000. The inventory write-down for the year ended December 31, 2010 was approximately $18,000.

Research and Development

Research and development expenses were approximately $451,000 and $362,000 respectively, for the years ended December 31, 2011 and December 31, 2010. This increase of approximately $89,000 or 25% is primarily due to an increase in research and development personnel related costs of approximately $56,000 and an increase in outside testing costs of approximately $26,000 during the year ended December 31, 2011 compared to the year ended

December 31, 2010.

Depreciation and Amortization Expense

Depreciation expense was approximately $91,000 for the year ended December 31, 2011 compared to approximately $129,000 for the year ended December 31, 2010, a decrease of 29%. The decrease of approximately $38,000 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 year ended December 31, 2011. There was one sale of a fully-depreciated asset during the year ended December 31, 2011, resulting in a gain on the sale of less than $1,000.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $2,636,000 for the year ended December 31, 2011 compared to approximately $2,520,000 for the year ended December 31, 2010, an increase of $116,000 or 5%. The increase is primarily due to $158,000 of bonus expense, an increase in stock compensation expense of $164,000, and $86,000 of recruiting fees during the year ended December 31, 2011 compared to the year ended December 30, 2010. These increases were partially offset by a reduction in U.S. salary expense of $97,000, a reduction in severance expense of $50,000, a reduction in marketing expense of $106,000, a reduction in legal fees of $17,000, and a reduction in U.S. insurance costs of $20,000 during the year ended December 31, 2011 compared to the year ended December 31, 2010.

Interest Income

Interest income was approximately $4,000 for the year ended December 31, 2011 compared to approximately $1,000 for the year ended December 31, 2010. The increase of $3,000 reflects the impact of having more cash on hand in 2011 compared to 2010 and, therefore, more investments to generate interest income.

Interest Expense

Interest expense was approximately $12,000 for the year ended December 31, 2011 compared to $15,000 for the year ended December 31, 2010. For both years, this interest relates to interest accrued on the $500,000 senior secured note issued to Lambda Investors LLC, which was paid in March 2011.

41

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 $40,000 and $50,000 for the years ended December 31, 2011 and 2010, respectively, were associated with the senior secured note issued to Lambda Investors LLC. The note was paid in March 2011 and these capitalized costs were fully amortized by the first quarter of 2011.

Other Income/Expense

Other expense in the amount of approximately $2,000 for the year ended December 31, 2011 was due to foreign currency loss on invoices paid to an international supplier. Other income in the amount of approximately $20,000 for the year ended December 31, 2010 primarily resulted from the reversal of a prior year's accrual determined to no longer be necessary.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the periods ended December 31, 2011 and December 31, 2010.

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 year ended December 31, 2010, $72,000 of cash was also provided by the exercise of stock options. No cash was provided by the exercise of stock options for the year ended December 31, 2011.

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, 2011 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 4,590,171 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 2,782,577 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 were 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, 2011, we had an accumulated deficit of $94,268,000, 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.

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco, as licensee. 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. The first two fixed payments have been received. The remaining fixed payment of €600,000 or approximately $778,000, will take place in January 2013. 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 per year in the Territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. 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 approximately $1,296,000 for the year ended December 31, 2011 compared to approximately $1,292,000 for the year ended December 31, 2010. The most significant items contributing to this net increase of approximately $4,000 in cash used in operating activities during the year ended December 31, 2011 compared to the year ended December 31, 2010 are highlighted below:

- during 2011, our net loss increased by approximately $427,000, compared to 2010;
- during 2011, depreciation expense decreased by approximately $38,000, compared to 2010;
- our accounts receivable increased by approximately $832,000 during 2011 compared to 2010;

- our long-term assets increased by approximately $778,000 during 2011 compared to 2010;
- our accounts payable and accrued expenses decreased by approximately $357,000 in the aggregate during 2011 compared to 2010;
- during 2011, we recorded amortization of debt issuance costs of $40,000, whereas amortization of debt issuance costs in 2010 were $50,000;
- during 2011, we recorded non-cash interest of $12,000, whereas non-cash interest was $15,000 in 2010; and
- our inventory decreased by approximately $295,000 during 2011 compared to an increase of approximately $98,000 during 2010.

Offsetting the above changes are the following items:

- during 2011, our stock-based compensation expense, a non-cash expense, increased by approximately $164,000 compared to 2010;
- during 2011, our deferred revenue increased by approximately $2,061,000 compared to 2010;
- our prepaid expenses and other assets decreased by approximately $76,000 during 2011 compared to 2010; and
- during 2011, we recorded an inventory reserve of $200,000, whereas there was no inventory reserve in 2010.

There was no cash used or provided by investing activities during the year ended December 31, 2011. Net cash used by investing activities was $30,000 for the year ended December 31, 2010, which was for the purchase of equipment.

Net cash provided by financing activities was approximately $2,723,000 for the year ended December 31, 2011, resulting from the issuance of stock and from the exercise of warrants, providing cash of $3,189,000 and $174,000, respectively, 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 $572,000 for the year ended December 31, 2010 resulting from the exercise of stock options of $72,000 and proceeds from short-term borrowings of $500,000.

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.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2011:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years
Leases	$112,000	$92,000	$18,000	$2,000	$ —
Employment Contracts	450,000	200,000	200,000	50,000	—
Total	$562,000	$292,000	$218,000	$52,000	$ —

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Nephros, Inc.

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and Subsidiary (collectively, "the Company") as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nephros, Inc. and Subsidiary as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred negative cash flow from operations and net losses since inception. These conditions, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ ROTHSTEIN KASS

Roseland, New Jersey

March 22, 2012

46

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share Amounts)

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,669	$ 240
Accounts receivable	1,170	326
Inventory, less allowances of $218 and $18 at December 31, 2011 and 2010, respectively	247	726
Prepaid expenses and other current assets	113	190
Total current assets	3,199	1,482
Property and equipment, net	17	108
Long-term receivable	778	-
Total assets	$ 3,994	$ 1,590
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Short-term borrowings	$ -	$ 500
Accounts payable	284	441
Accrued expenses	195	481
Deferred revenue	2,094	33
Total current liabilities	2,573	1,455
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2011 and 2010; no shares issued and outstanding at December 31, 2011 and 2010	-	-
Common stock, $.001 par value; 90,000,000 authorized at December 31, 2011 and 2010; 10,501,477 and 2,090,552 shares issued and outstanding at December 31, 2011 and 2010, respectively	10	2
Additional paid-in capital	95,630	92,019
Accumulated other comprehensive income	49	22
Accumulated deficit	(94,268)	(91,908)
Total stockholders' equity	1,421	135
Total liabilities and stockholders' equity	$ 3,994	$ 1,590

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

(In Thousands, Except Share and Per Share Amounts)

	Years Ended December 31,	
	2011	2010
Product revenues	$ 1,849	$ 2,938
Licensing revenues	365	-
Total net revenues	2,214	2,938
Cost of goods sold	1,346	1,816
Gross margin	868	1,122
Operating expenses:		
Research and development	451	362
Depreciation and amortization	91	129
Selling, general and administrative	2,636	2,520
Total operating expenses	3,178	3,011
Loss from operations	(2,310)	(1,889)
Interest income	4	1
Interest expense	(12)	(15)
Amortization of debt issuance costs	(40)	(50)
Other income (expense)	(2)	20
Net loss	$ (2,360)	$ (1,933)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.93)
Weighted average common shares outstanding, basic and diluted	8,644,962	2,087,068

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

	Common Stock		Additional Paid-in	Accumulated Other	Accumulated	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balance, December 31, 2009	2,080,239	$ 2	$ 91,855	$ 76	$ (89,975)	$ 1,958
Comprehensive income:						
Net loss					(1,933)	(1,933)
Net unrealized losses on foreign currency translation				(54)		(54)
Comprehensive loss						(1,987)
Exercise of stock options	10,313		72			72
Noncash stock-based compensation			92			92
Balance, December 31, 2010	2,090,552	$ 2	$ 92,019	$ 22	$ (91,908)	$ 135
Comprehensive income:						
Net loss					(2,360)	(2,360)
Net unrealized gains on foreign currency translation				27		27
Comprehensive loss						(2,333)
Private placement sale of common stock	3,009,711	3	1,201			1,204
Shareholder rights offering	4,964,854	5	1,980			1,985
Fractional shares not issued	(308)					
Exercise of warrants	436,668		174			174
Noncash stock-based compensation			256			256
Balance, December 31, 2011	10,501,477	$ 10	$ 95,630	$ 49	$ (94,268)	$ 1,421

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In Thousands)

	Years Ended December 31,	
	2011	2010
Operating activities		
Net loss	$ (2,360)	$ (1,933)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	91	129
Non-cash stock-based compensation	256	92
Amortization of debt issuance costs	40	50
Noncash interest	12	15
Inventory reserve	200	-
(Increase) decrease in operating assets:		
Accounts receivable	(832)	283
Inventory	295	(98)
Prepaid expenses and other current assets	76	(55)
Other assets	(778)	21
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(357)	171
Deferred revenue	2,061	33
Net cash used in operating activities	(1,296)	(1,292)
Investing activities		
Purchase of property and equipment	-	(30)
Net cash provided by (used in) investing activities	-	(30)
Financing activities		
Repayment of debt	(500)	-
Payment of financing costs	(140)	-
Proceeds from exercise of warrants	174	-
Proceeds from short-term borrowings	-	500
Proceeds from stock options exercised	-	72
Proceeds from issuance of common stock	3,189	-
Net cash provided by financing activities	2,723	572
Effect of exchange rates on cash and cash equivalents	2	(14)
Net increase (decrease) in cash and cash equivalents	1,429	(764)
Cash and cash equivalents, beginning of year	240	1,004
Cash and cash equivalents, end of year	$ 1,669	$ 240
Supplemental disclosure of cash flow information		
Cash paid for taxes	$ 5	$ 2

The accompanying notes are an integral part of these consolidated financial statements.

50

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Nature of Operations

Nephros, Inc. (“Nephros” or the “Company”) was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease (“ESRD”) therapy technology and products. The Company has three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy for ESRD patients. These are the OLpur TM MDHDF filter series or “dialyzers,” designed expressly for HDF therapy, the OLpur TM H2H TM, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy, and the OLpur TM NS2000 system, a stand-alone hemodiafiltration machine and associated filter technology. In 2006, the Company introduced its Dual Stage Ultrafilter (“DSU”) water filter system, which represents a new and complementary product line to the Company’s existing ESRD therapy business. The DSU incorporates the Company’s unique and proprietary dual stage filter architecture.

On June 4, 2003, Nephros International Limited was incorporated under the laws of Ireland as a wholly-owned subsidiary of the Company. In August 2003, the Company established a European Customer Service and financial operations center in Dublin, Ireland.

Note 2 — Summary of Significant Accounting Policies

On January 10, 2011, the Company’s stockholders voted to implement a 1:20 reverse stock split of the Company’s common stock. The reverse split became effective on March 11, 2011. All of the share and per share amounts discussed in these financial statements on Form 10-K have been adjusted to reflect the effect of this reverse split.

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Nephros International Limited. All intercompany accounts and transactions have been eliminated in consolidation.

These financial statements were approved by management and the Board of Directors and are available for issuance as of the date of the audit opinion. Subsequent events have been evaluated through this date.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amount of revenues and expenses, during the reporting period. Actual results could differ materially from those estimates.

Going Concern and Management's Response

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The Company's condensed consolidated interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has incurred significant losses in operations in each quarter since inception. For the years ended December 31, 2011 and 2010, the Company has incurred net losses of $2,360,000 and $1,933,000, respectively. In addition, the Company has not generated positive cash flow from operations for the years ended December 31, 2011 and 2010. To become profitable, the Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

On October 1, 2010, the Company issued a senior secured note to Lambda Investors LLC, its 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 was due. However, the Company agreed to and did prepay, without penalty, amounts due under the note with the cash proceeds from its rights offering prior to the maturity date. The note was secured by a first priority lien on all of the Company's property, including its intellectual property.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies (continued)

On March 10, 2011 the Company completed its 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 issued to Lambda Investors, LLC, plus $26,650 of accrued interest thereon, 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, the Company's stockholders subscribed for 4,964,854 units in the rights offering and the Company accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of $0.40. Gross proceeds to the Company from the sale of these units in the rights offering were approximately $2.0 million. The Company issued an aggregate of 4,964,854 shares of common stock and warrants to purchase an aggregate of approximately 4,590,171 million shares of its 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 the Company and Lambda Investors. The Company issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,577 shares of common stock. Of the $3.2 million in gross proceeds from the rights offering and the private placement, the Company received approximately $1.2 million in gross proceeds from the sale of units to Lambda Investors.

The Company 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.

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters. 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. The first two fixed payments have been received. The remaining fixed payment of €600,000 or approximately $778,000, will take place in January 2013. 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 per year in the territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. Anticipated payments from this License Agreement will be a positive source of cash flow to the Company.

There can be no assurance that the Company's future cash flow will be sufficient to meet its obligations and commitments. If the Company is unable to generate sufficient cash flow from operations in the future to service its commitments the Company will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing its planned activities or ceasing its 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 the Company to continue to satisfy its capital requirements.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits and money market accounts. The Company considers all highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximate cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

Accounts Receivable

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews 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 management's best estimate of potential losses. There were no allowances for doubtful accounts at December 31, 2011 or 2010. There was no allowance for sales returns at December 31, 2011 or 2010. There were no write offs of accounts receivable to bad debt expense during 2011 or 2010.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies (continued)

Inventory

The Company engages third parties to manufacture and package inventory held for sale, takes title to certain inventory once manufactured, and warehouses such goods until packaged for final distribution and sale. Inventory consists of finished goods and raw materials (fiber) held at the manufacturers' facilities, and are valued at the lower of cost or market using the first-in, first-out method.

Patents

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. All costs and direct expenses incurred in connection with patent applications have been expensed as incurred.

Property and Equipment, net

Property and equipment, net is stated at cost less accumulated depreciation. These assets are depreciated over their estimated useful lives of three to seven years using the straight line method.

Impairment for Long-Lived Assets

The Company adheres to ASC Topic 360 and periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may be recoverable. If such circumstances are

determined to exist, an estimate of undiscounted future cash flows produced by the long-lived assets, or the appropriate grouping of assets, is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its estimated net realizable market value. There were no impairment losses for long-lived assets recorded for the years ended December 31, 2011 and December 31, 2010.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments.

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 or determinable; and (iv) collectability is reasonably assured.

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

Deferred revenue on the accompanying 2011 consolidated balance sheet is approximately $2,094,000 and is related to the License Agreement with Bellco, effective July 1, 2011. The total payments to be received as a result of this agreement approximate $2,459,000 and the Company has recognized approximately $365,000 of revenue related to this license agreement during the year ended December 31, 2011 resulting in $2,094,000 being deferred over the remainder of the fixed payment period. The Company amortizes the deferred revenue monthly over the expected obligation period which ends on December 31, 2014. This will result in expected recognized revenue of approximately $698,000 in each of the three years ended December 31, 2014.

The Company received cash payments before revenue recognition of approximately $709,000 in July 2011. In addition, current trade accounts receivable includes approximately $971,000, which represents a fixed payment received in January 2012 and the final guaranteed fixed payment of approximately $778,000 is due in January 2013 and is included in long-term receivable on the accompanying 2011 consolidated balance sheet.

53

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies (continued)

Shipping and Handling Costs

Shipping and handling costs are recorded as cost of goods sold and are approximately $26,000 and $25,000 for the years ended December 31, 2011 and 2010, respectively.

Research and Development Costs

Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718 by recognizing the fair value of stock-based compensation in the statement of operations. The fair value of the Company's 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 the Company 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-based 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.

Amortization of Debt Issuance Costs

The Company accounts 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 $40,000 and $50,000 for the years ended December 31, 2011 and 2010, respectively, are associated with the senior secured note issued to Lambda Investors LLC. These capitalized costs were fully amortized by the first quarter of 2011.

Other Income

Other expense in the amount of approximately $2,000 for the year ended December 31, 2011 was due to foreign currency loss on invoices paid to an international supplier. Other income in the amount of approximately $20,000 for the year ended December 31, 2010 primarily resulted from the reversal of a prior year's accrual determined to no longer be necessary.

Income Taxes

The Company accounts for income taxes in accordance with ASC Topic 740, which requires accounting for deferred income taxes under the asset and liability method. Deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable in future years to differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities.

For financial reporting purposes, the Company has incurred a loss in each period since its inception. Based on available objective evidence, including the Company's history of losses, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2011 and December 31, 2010.

ASC Topic 740 prescribes, among other things, a recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return. ASC 740 utilizes a two-step approach for evaluating uncertain tax positions. Step one, or recognition, requires a company to determine if the weight of available evidence indicates a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, or measurement, is based on the largest amount of benefit, which is more likely than not to be realized on settlement with the taxing authority. The Company is subject to income tax examinations by major taxing authorities for all tax years subsequent to 2008. The adoption of the provisions of ASC 740 did not have a material impact on the Company's consolidated financial statements. During the years ended December 31, 2011 and 2010, the Company recognized no adjustments for uncertain tax positions. However, management's conclusions regarding this policy may be subject to review and adjustment at a later date based on factors including, but not limited to, on-going analyses of and changes to tax laws, regulation and interpretations, thereof.

54

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies (continued)

Loss per Common Share

In accordance with ACS 260-10, net loss per common share amounts ("basic EPS") are computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution ("diluted EPS") is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. The following securities have been excluded from the dilutive per share computation as they are antidilutive.

	2011	2010
Stock options	747,164	44,664
Warrants	16,452,368	409,591

Foreign Currency Translation

Foreign currency translation is recognized in accordance with ASC Topic 830. The functional currency of Nephros International Limited is the Euro and its translation gains and losses are included in accumulated other comprehensive income. The balance sheet is translated at the year-end rate. The statement of operations is translated at the weighted average rate for the year.

Comprehensive Income (Loss)

Comprehensive income (loss), as defined in ASC 220, is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)) such as unrealized gains or losses on securities classified as available-for-sale and foreign currency translation adjustments. For the years ended December 31, 2011 and 2010, the comprehensive loss was approximately $2,333,000 and $1,987,000, respectively.

New Accounting Pronouncements

In December 2011, the FASB issued an update on comprehensive income, which pertains to the deferral of the effective date for amendments to the presentation of reclassification of items out of accumulated other comprehensive income in a previous accounting standard update that pertained to the presentation of comprehensive income. The update defers the presentation on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods. All other requirements the previous accounting standard on the presentation of comprehensive income, issued in June 2011, are not affected. The previous presentation related comprehensive income standard requires entities to report components of comprehensive income in either a continuous statement of comprehensive income or two separate but consecutive statements. Under the continuous statement approach, the statement would include the components and total of net income, the components and total of other comprehensive income and the total of comprehensive income. Under the two statement approach, the first statement would include the components and total of net income and the second statement would include the components and total of other comprehensive income and the total of comprehensive income. It does not change the items that must be reported in other comprehensive income and it is effective retrospectively for interim and annual periods beginning after December 15, 2011, with early adoption permitted. We have evaluated the guidance and expect it to impact only the presentation and note disclosures in our financial statements.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 3 — Inventory

The Company's inventory components as of December 31, 2011 and 2010 were as follows:

	December 31,	
	2011	2010
Raw Materials	$-	$264,000
Finished Goods	465,000	480,000
Total Gross Inventory	465,000	744,000
Less: Inventory reserve	(218,000)	(18,000)
Total Inventory	$247,000	$726,000

Note 4 — Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2011 and 2010 were as follows:

	December 31,	
	2011	2010
Prepaid insurance premiums	$88,000	$120,000
Deferred debt issuance costs	-	40,000
Security deposit	21,000	21,000
Other	4,000	9,000
Prepaid expenses and other current assets	$113,000	$190,000

Note 5 — Property and Equipment, Net

Property and equipment as of December 31, 2011 and 2010 was as follows:

		December 31,	
	Life	2011	2010
Manufacturing equipment	3-5 years	$1,998,000	$2,029,000
Research equipment	5 years	37,000	91,000
Computer equipment	3-4 years	42,000	60,000
Furniture and fixtures	7 years	39,000	39,000
Property and equipment, gross		2,116,000	2,219,000
Less: accumulated depreciation		2,099,000	2,111,000
Property and equipment, net		$17,000	$108,000

Depreciation expense for the years ended December 31, 2011 and 2010 was approximately $91,000 and $129,000, respectively, including amortization expense relating to research and development assets.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 6 — Accrued Expenses

Accrued expenses as of December 31, 2011 and 2010 were as follows:

	December 31,	
	2011	2010
Accrued Management Bonus	$79,000	$—
Accrued Directors' Compensation	30,000	77,000
Accrued Accounting	15,000	40,000
Accrued Legal	52,000	127,000
Accrued Debt Issuance Costs and Rights Offering fees	—	140,000
Accrued Interest	—	15,000
Accrued Proxy and Annual Report fees	—	42,000
Accrued Other	19,000	40,000
Accrued Expenses	$195,000	$481,000

Note 7 — Income Taxes

A reconciliation of the income tax provision computed at the statutory tax rate to the Company's effective tax rate is as follows:

	2011	2010
U.S. federal statutory rate	35.00 %	35.00 %
State & local taxes	(0.06)%	(0.07)%
Tax on foreign operations	(1.27)%	1.24 %
State research and development credits	1.11 %	1.02 %
Other	(3.07)%	5.05 %
Valuation allowance	(31.71)%	(42.24)%
Effective tax rate	—	—

Significant components of the Company's deferred tax assets as of December 31, 2011 and 2010 are as follows:

	2011	2010
Deferred tax assets:		
Net operating loss carry forwards	$24,714,000	$23,706,000
Research and development credits	1,019,000	994,000
Nonqualified stock option compensation expense	1,586,000	1,566,000
Other temporary book – tax differences	331,000	112,000
Total deferred tax assets	27,650,000	26,378,000
Valuation allowance for deferred tax assets	(27,650,000)	(26,378,000)
Net deferred tax assets	$—	$—

A valuation allowance has been recognized to offset the Company's net deferred tax asset as it is more likely than not that such net asset will not be realized. The Company primarily considered its historical loss and potential Internal Revenue Code Section 382 limitations to arrive at its conclusion that a valuation allowance was required.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7 — Income Taxes (continued)

At December 31, 2011, the Company had Federal and New Jersey income tax net operating loss carryforwards of $76,774,000 and foreign income tax net operating loss carryforwards of $8,135,000. The Company also had Federal research tax credit carryforwards of $1,020,000 at December 31, 2011 and $994,000 at December 31, 2010. The Federal net operating loss and tax credit carryforwards will expire at various times between 2012 and 2026 unless utilized.

Implementation of ASC 740 did not result in a cumulative effect adjustment to the accumulated deficit.

It is the Company's policy to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Note 8 — Stock Plans, Share-Based Payments and Warrants

Stock Plans

In 2000, the Company adopted the Nephros 2000 Equity Incentive Plan. In January 2003, the Board of Directors adopted an amendment and restatement of the plan and renamed it the Amended and Restated Nephros 2000 Equity Incentive Plan (the "2000 Plan"), under which 106,538 shares of common stock had been authorized for issuance upon exercise of options granted.

As of December 31, 2011 and 2010, 2,053 options had been issued to non-employees under the 2000 Plan and were outstanding. Such options expire at various dates through March 15, 2014, all of which are fully vested. As of December 31, 2011 and 2010, 7,230 options had been issued to employees under the 2000 Plan and were outstanding. Such options expire at various dates between January 22, 2013 and March 15, 2014, all of which are fully vested.

The Board retired the 2000 Plan in June 2004, and thereafter no additional awards may be granted under the 2000 Plan.

In 2004, the Board of Directors adopted and the Company's stockholders approved the Nephros, Inc. 2004 Stock Incentive Plan, and, in June 2005, the Company's stockholders approved an amendment to such plan (as amended, the "2004 Plan"), that increased to 40,000 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. In May 2007, the Company's stockholders approved an amendment to the 2004 Plan that increased to 65,000 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. In June 2008, the Company's stockholders approved an amendment to the 2004 Plan that increased to 134,849 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. In January 2011, the Company's stockholders approved an amendment to the 2004 Plan that increased to 1,990,717 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan.

As of December 31, 2010, 22,129 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between January 5, 2016 and December 31, 2019, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2010, there were 82,535 shares available for future grants under the 2004 Plan. As of December 31, 2010, 13,253 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 11, 2014 and January 8, 2020, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

As of December 31, 2011, 443,129 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between March 24, 2014 and December 31, 2019, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2011, there were 1,235,905 shares available for future grants under the 2004 Plan. As of December 31, 2011, 294,753 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 18, 2012 and January 8, 2020, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

Share-Based Payment

Prior to the Company's initial public offering, options were granted to employees, non-employees and non-employee directors at exercise prices which were lower than the fair market value of the Company's stock on the date of grant. After the date of the Company's initial public offering, stock options are granted to employees, non-employees and non-employee directors at exercise prices equal to the fair market value of the Company's stock on the date of grant. Stock options granted have a life of 10 years.

58

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Stock Plans, Share-Based Payments and Warrants (continued)

Unvested options as of December 31, 2011 currently vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

Expense is recognized, net of expected forfeitures, over the vesting period of the options. For options that vest upon the achievement of certain milestones, expense is recognized when it is probable that the condition will be met. Stock based compensation expense recognized for the years ended December 31, 2011 and 2010 was approximately $256,000 or less than $0.03 per share and approximately $92,000 or less than $0.05 per share, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the below assumptions related to risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility.

	Option Pricing Assumptions	
Grant Year	2011	2010
Stock Price Volatility	121.96 – 130.06 %	96 %
Risk-Free Interest Rates	1.08 – 2.42 %	2.85 %
Expected Life (in years)	5.00-5.50	5.75
Expected Dividend Yield	0 %	0 %

Expected volatility is based on historical volatility of the Company’s common stock at the time of grant. The risk-free interest rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected life of the options. For the expected life, the Company is using the simplified method as described in the SEC Staff Accounting Bulletin 107. This method assumes that stock option grants will be exercised based on the average of the vesting periods and the option’s life.

The total fair value of options vested during the fiscal year ended December 31, 2011 was approximately $249,000. The total fair value of options vested during the fiscal year ended December 31, 2010 was approximately $87,000.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2011:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding as of December 31, 2011	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable as of December 31, 2011	Weighted Average Exercise Price
$0.13	1,650	7.02	$ 0.13	825	$ 0.13
$0.41 – $0.51	682,500	9.30	$ 0.51	250,834	$ 0.51
$0.75 – $2.32	50,138	7.80	$ 1.06	42,411	$ 1.10
$2.39 – $4.80	12,876	1.97	$ 2.57	12,876	$ 2.57
Total Outstanding	747,164		$ 0.58	306,946	$ 0.68

The number of new options granted in 2011 and 2010 is 702,500 and 4,125 respectively. The weighted-average fair value of options granted in 2011 and 2010 is $0.45 and $0.73, respectively.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Stock Plans, Share-Based Payments and Warrants (continued)

The following table summarizes the option activity for the years ended December 31, 2011 and 2010:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2010	44,664	$ 27.40
Options granted	702,500	0.53
Options exercised	0	0.00
Options forfeited	0	0.00
Outstanding at December 31, 2011	747,164	0.58
Expected to vest at December 31, 2011	701,631	$ 0.58
Exercisable at December 31, 2011	306,947	$ 0.68

The aggregate intrinsic value of stock options outstanding at December 31, 2011 is $126,000 and the stock options vested or expected to vest is $121,000. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest is 9.1 years.

The aggregate intrinsic value of stock options outstanding at December 31, 2010 and the stock options vested or expected to vest is $0. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest is 6.3 years.

As of December 31, 2011, the total remaining unrecognized compensation cost related to non-vested stock options amounted to $199,000 and will be amortized over the weighted-average remaining requisite service period of 1.7 years.

Warrants

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2011 and 2010:

Total Outstanding Warrants at December 31, 2011

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable	
				2011	2010
Class D Warrants – Lambda	11/14/2007	3/10/2016	$ 0.40	8,806,575	359,541
Class D Warrants – Other	11/14/2007	11/14/2012	$ 0.40	447,197	9,937
Placement Agent Warrants	11/14/2007	11/14/2012	$ 0.40	228,887	6,484
July 2009 Warrants	7/24/2009	7/24/2014	$ 22.40	33,629	33,629
Shareholder Rights Offering Warrants	3/10/2011	3/10/2016	$ 0.40	4,590,171	-
March 2011 Lambda Warrants	3/10/2011	3/10/2016	$ 0.40	2,782,577	-
Warrants Exercised in 2011				(436,668)	
				16,452,368	409,591

The weighted average exercise price of the outstanding warrants was $0.45 and $14.84 for December 31, 2011 and 2010, respectively.

Class D Warrants

The Company issued Class D Warrants in 2007 to purchase an aggregate of 455,628 shares of the Company's common stock to the Investors upon conversion of the purchased notes. The Company recorded the issuance of the Class D Warrants at their approximate fair market value of $3,763,000. The value of the Class D Warrants was computed using the Black-Scholes option pricing model. Our largest stockholder, Lambda Investors LLC, received Class D Warrants in 2007 to purchase 359,541 shares of the Company's common stock and Other Investors received Class D Warrants in 2007 to purchase 96,087 shares of the Company's common stock. A Class D warrant holder elected to

exercise 86,150 of the 455,628 Class D Warrants outstanding as of June 2009 pursuant to the cashless exercise provision of the warrant which is described below. See Issuance of Common Stock due to Class D Warrants' Cashless Exercise Provision.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Stock Plans, Share-Based Payments and Warrants (continued)

Effect of Shareholders' Rights Offering in 2011

The Class D Warrants have full-ratchet anti-dilution provisions that were activated by the Shareholders' Rights Offering in 2011. Following the closing of the rights offering in 2011, and after giving effect to the anti-dilution provisions, Lambda Investors agreed to surrender for cancellation warrants to purchase 7,372,348 shares of our common stock. In addition, following the closing of the rights offering, Lambda Investors' existing warrants to purchase 8,806,575 shares that remain outstanding were amended to expire at the same time as the warrants issued in the rights offering, which is March 10, 2016. The Other Investor's Class D Warrants retain their original expiration date of November 14, 2012.

The following table summarizes the Class D outstanding warrants at December 31, 2011 and 2010:

	Lambda Investors	Other Investors	Total Shares to be issued
As of December 31, 2010	359,541	9,937	369,478
Anti-dilution ratcheting provision	15,819,382	437,260	16,256,642
Surrendered – rights' offering	(7,372,348)	0	(7,372,348)
As of December 31, 2011	8,806,575	447,197	9,253,772

Issuance of Common Stock due to Class D Warrants' Cashless Exercise Provision

The Series D warrants have a cashless exercise provision which states, "If, and only if, at the time of exercise pursuant to this Section 1 there is no effective registration statement registering, or no current prospectus available for, the sale of the Warrant Shares to the Holder or the resale of the Warrant Shares by the Holder and the VWAP (as defined below) is greater than the Per Share Exercise Price at the time of exercise, then this Warrant may also be exercised at such time and with respect to such exercise by means of a "cashless exercise" in which the Holder shall be entitled to receive a certificate for the number of Warrant Shares equal to the quotient obtained by dividing (i) the result of (x) the difference of (A) minus (B), multiplied by (y) (C), by (ii) (A), where:

(A) = the VWAP (as defined below) on the Trading Day (as defined below) immediately preceding the date of such election;

(B) = the Per Share Exercise Price of this Warrant, as adjusted; and

(C) = the number of Warrant Shares issuable upon exercise of this Warrant in accordance with the terms of this Warrant by means of a cash exercise rather than a cashless exercise.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted for trading on the New York Stock Exchange, American Stock Exchange, NASDAQ Capital Market, NASDAQ Global Market, NASDAQ Global Select Market or the OTC Bulletin Board, or any successor to any of the foregoing (a “ Trading Market ”), the daily volume weighted average price of the Common Stock on the Trading Market on which the Common Stock is then listed or quoted for trading as reported by Bloomberg L.P. for such date if such date is a date on which the Trading Market on which the Common Stock is then listed or quoted for trading (a “ Trading Day ”) or the nearest preceding Trading Date (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time); (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the “Pink Sheets” published by Pink Sheets, LLC (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported; or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company.”

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Stock Plans, Share-Based Payments and Warrants (continued)

The Company did not have an effective registration statement or a current prospectus available for the sale of the warrant shares to the holder or the resale of the warrant shares by the holder and the VWAP (as defined above) was greater than the per share exercise price from June 8, 2009 through August 26, 2009.

A Class D warrant holder elected to exercise 86,150 of the 455,628 Class D Warrants outstanding as of June 2009 pursuant to the cashless exercise provision of the warrant. As a result, 54,561 shares of common stock were issued to this Class D warrant holder in August 2009. The number of shares outstanding in the December 31, 2011 balance sheet and the number of shares outstanding used in the earnings per share calculation for the twelve months ended December 31, 2011 include these shares.

Placement Agent Warrants

The Company issued placement agent warrants in 2007 to purchase an aggregate of 87,819 shares of the Company's common stock to the Company's placement agents in connection with their roles in the Company's fall 2007 financing ("the 2007 Financing"). The Company recorded the issuance of the placement agent warrants at their approximate fair market value of $1,047,000. The value of the placement agent warrants was computed using the Black-Scholes option pricing model.

Placement Agents elected to exercise 67,435 of the 87,819 Placement Agent Warrants outstanding in June 2009. All elected the Cashless Exercise provision of their warrants. As a result, 29,725 shares of common stock were issued to the Placement Agents in June 2009.

Placement Agents elected to exercise 13,900 of the 20,384 Placement Agent Warrants outstanding in June 2009. All elected the cashless exercise provision of their warrants. As a result, 7,188 shares of common stock were issued to the Placement Agents.

Effect of Shareholders' Rights Offering in 2011

The Placement Agent Warrants have full-ratchet anti-dilution provisions that were activated by the shareholders' rights offering in 2011. The Placement Agent Warrants retain their original expiration date of November 12, 2012.

As of December 31, 2011 there were Placement Agent Warrants outstanding to issue 228,887 common shares of the Company.

Issuance of Common Stock due to Placement Agent Warrants' Cashless Exercise Provision

National Securities Corporation ("NSC") and Dinosaur Securities, LLC ("Dinosaur" and together with NSC, the "Placement Agents") acted as co-placement agents in connection with the 2007 Financing pursuant to an Engagement Letter, dated June 6, 2007 and a Placement Agent Agreement dated September 18, 2007. The Placement Agents received (i) an aggregate cash fee equal to 8% of the face amount of the notes purchased in the 2007 Financing ("the Purchased Notes") 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 the Company's common stock issued upon conversion of the Purchased Notes with an exercise price per share of the Company's common stock equal to $14.10. The Company issued Placement Agents Warrants to purchase an aggregate of 87,819 shares of the Company's common stock to the Placement Agent in November 2007 in connection with their roles in the 2007 Financing.

The Placement Agent Warrants have a cashless exercise provision identical to that in the Series D Warrants.

The Company did not have an effective registration statement or a current prospectus available for the sale of the warrant shares to the holders or the resale of the warrant shares by the holders and the VWAP (as defined above) was greater than the per share exercise price from June 8 through August 26, 2009. Several Placement Agents elected to exercise the cashless exercise provision of their warrants.

July 2009 Private Placement

On July 24, 2009, the Company raised gross proceeds of $1,251,000 through the private placement to eight accredited investors of an aggregate of 67,258 shares of its 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. The

Company 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. The warrants have no anti-dilution ratcheting provision therefore, they did not increase as a result of the 2011 Shareholders' Rights Offering.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Stock Plans, Share-Based Payments and Warrants (continued)

2011 Shareholders' Rights Offering

On March 10, 2011, Nephros announced the completion of its rights offering and private placement that together resulted in gross proceeds of approximately $3.2 million and estimated net proceeds of approximately $2.3 million to Nephros after deducting the payments to Lambda Investors LLC and after estimated expenses of the rights offering. In the rights offering, Nephros sold 4,964,854 units at $0.40 per unit for gross proceeds of approximately $2.0 million, resulting in the issuance of 4,964,854 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.

On March 10, 2011, based on the completion of the rights offering Lambda Investors LLC, the Company's 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. Net proceeds, after deducting the aggregate of $666,650 in payments due Lambda Investors LLC were approximately $537,000.

Warrants exercised during 2011

Shareholders exercised 472,422 warrants in the fourth quarter of 2011 resulting in 436,668 shares of common stock being issued.

Note 9 — 401(k) Plan

The Company has established a 401(k) deferred contribution retirement plan (the "401(k) Plan") which covers all employees. The 401(k) Plan provides for voluntary employee contributions of up to 15% of annual earnings, as defined. As of January 1, 2004, the Company began matching 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. The Company contributed and expensed $28,000 and $24,000 in 2011 and 2010, respectively.

Note 10 — Commitments and Contingencies

Manufacturing and Suppliers

The Company has not and does not intend in the near future, to manufacture any of its products and components. With regard to the OLpur MD190 and MD220, on June 27, 2011, the Company 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, 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 our written approval, other European countries where the Company does 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 Nephros 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 Nephros a royalty based on the number of units of Products sold per year 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.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 — Commitments and Contingencies (continued)

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

Contractual Obligations

At December 31, 2011, the Company had an operating lease that will expire on November 30, 2012 for the rental of its U.S. office and research and development facilities. The term of the rental agreement is for one year commencing December 1, 2011 with a monthly cost of approximately $7,813.

Rent expense for the years ended December 31, 2011 and 2010 totaled $104,000 and $101,000, respectively.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2011:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years
Leases	$112,000	$92,000	$18,000	$2,000	$ —
Employment Contracts	450,000	200,000	200,000	50,000	
Total	$562,000	$292,000	$218,000	$52,000	$ —

Note 11 — Concentration of Credit Risk

Cash and cash equivalents are financial instruments which potentially subject the Company to concentrations of credit risk. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. To date, the Company has not experienced any impairment losses on its cash and cash equivalents.

Major Customers

For the year ended December 31, 2011 and 2010, two customers accounted for 71% and 79%, respectively, of the Company's sales. In addition, as of December 31, 2011 and 2010, those customers accounted for 85% and 84%, respectively, of the Company's accounts receivable.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes in or disagreements with our accountants during 2011 or 2010.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e),which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our acting Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our acting Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in the fourth quarter of 2011 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes all of our consolidated subsidiaries.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework." Based on this assessment, management believes that, as of December 31, 2011, our internal control over financial reporting was operating effectively.

This annual report does not include an attestation report by our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that require a management assessment in this annual report.

Item 9B. Other Information

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file a definitive proxy statement within one hundred twenty (120) days after the end of the fiscal year pursuant to Regulation 14A (the “2012 Proxy Statement”) for our Annual Meeting of Stockholders currently scheduled for April 23, 2012, and the information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance

The information set forth under the captions "Proposal No. 1 - Election of Directors", "Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2012 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption "Compensation Matters" in the 2012 Proxy Statement is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information set forth under the caption "Stock Ownership of Management and Principal Shareholders" and "Compensation Matters" in the 2012 Proxy Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information set forth under the captions “Corporate Governance” and "Certain Relationships and Related Transactions" in the 2012 Proxy Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information set forth under the caption "Proposal No. 2 - Ratification of Selection of Independent Registered Public Accounting Firm" in the 2012 Proxy Statement is incorporated herein by reference.

Item 15. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant. (5)
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on November 13, 2007. (14)
3.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on October 26, 2009. (23)
3.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 10, 2011. (24)
3.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 11, 2011. (24)
3.8	Second Amended and Restated By-Laws of the Registrant. (16)
4.1	Specimen of Common Stock Certificate of the Registrant. (1)
4.2	Form of Underwriter’s Warrant. (1)
4.3	Warrant for the purchase of shares of common stock dated January 18, 2006, issued to Marty Steinberg, Esq., as Court-appointed Receiver for Lancer Offshore, Inc. (17)
4.4	Form of Series A 10% Secured Convertible Note due 2008 convertible into Common Stock and Warrants. (15)
4.5	Form of Series B 10% Secured Convertible Note due 2008 convertible into Common Stock. (15)
4.6	Form of Class D Warrant. (15)
4.7	Form of Placement Agent Warrant. (15)
4.8	Form of Investor Warrant issued on July 24, 2009. (22)
4.9	Form of Warrant Certificate. (27)
4.10	Form of Warrant Agreement between Nephros, Inc. and Continental Stock Transfer & Trust Company. (27)
4.11	Form of Subscription Rights Certificate. (27)
10.1	Amended and Restated 2000 Nephros Equity Incentive Plan. (1)(2)
10.2	2004 Nephros Stock Incentive Plan. (1)(2)
10.3	Amendment No. 1 to 2004 Nephros Stock Incentive Plan. (2)(5)
10.4	Amendment No. 2 to the Nephros, Inc. 2004 Stock Incentive Plan. (14)
10.5	Form of Subscription Agreement dated as of June 1997 between the Registrant and each Purchaser of Series A Convertible Preferred Stock. (1)
10.6	Amendment and Restatement to Registration Rights Agreement, dated as of May 17, 2000 and amended and restated as of June 26, 2003, between the Registrant and the holders of a majority of Registrable Shares (as defined therein). (1)
10.7	Employment Agreement dated as of November 21, 2002 between Norman J. Barta and the Registrant. (1)(2)
10.8	Amendment to Employment Agreement dated as of March 17, 2003 between Norman J. Barta and the Registrant. (1)(2)

10.9	Amendment to Employment Agreement dated as of May 31, 2004 between Norman J. Barta and the Registrant. (1)(2)
10.10	Employment Agreement effective as of July 1, 2007 between Nephros, Inc. and Norman J. Barta. (14)
10.11	Form of Employee Patent and Confidential Information Agreement. (1)
10.12	Form of Employee Confidentiality Agreement. (1)
10.13	Settlement Agreement and Mutual Release dated June 19, 2002 between Plexus Services Corp. and the Registrant. (1)
10.14	Settlement Agreement dated as of January 31, 2003 between Lancer Offshore, Inc. and the Registrant. (1)
10.15	Settlement Agreement dated as of February 13, 2003 between Hermitage Capital Corporation and the Registrant. (1)
10.16	Supply Agreement between Nephros, Inc. and Membrana GmbH, dated as of December 17, 2003. (1)(3)

Exhibit No.	Description
10.17	Amended Supply Agreement between Nephros, Inc. and Membrana GmbH dated as of June 16, 2005. (3)(7)
10.18	Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of May 12, 2003. (1)(3)
10.19	Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of March 22, 2005. Supersedes prior Agreement dated May 12, 2003. (3)(8)
10.20	HDF-Cartridge License Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.21	Subscription Agreement dated as of

	March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.22	Non-employee Director Compensation Summary. (2)(6)
	Named Executive Officer
10.23	Summary of Changes to Compensation. (2)(6)
	Stipulation of Settlement Agreement between Lancer
10.24	Offshore, Inc. and Nephros, Inc. approved on November 18, 2005. (8)
	Consulting Agreement, dated as of January 11,
10.25	2006, between the Company and Bruce Prashker. (2)(8)
	Summary of Changes to Chief
10.26	Executive Officer’s Compensation. (2)(8)
	Offer of Employment Agreement, dated as of
10.27	February 24, 2006, between the Company and Mark W. Lerner. (2)(8)

10.28	Form of 6% Secured Convertible Note due 2012 for June 1, 2006 Investors. (9)
10.29	Form of Common Stock Purchase Warrant. (9)
10.30	Form of Subscription Agreement, dated as of June 1, 2006. (9)
10.31	Form of Registration Rights Agreement, dated as of June 1, 2006. (9)
10.32	Form of 6% Secured Convertible Note due 2012 for June 30, 2006 Investors. (10)
10.33	Form of Subscription Agreement, dated as of June 30, 2006. (10)
10.34	Employment Agreement between Nephros, Inc. and William J. Fox, entered into on August 2, 2006. (2)(11)
10.35	Addendum to Commercial Contract between Nephros, Inc. and Bellco

	S.p.A, effective as of January 1, 2007. (3)(12)
10.36	Form of Subscription Agreement between Nephros and Subscriber. (15)
10.37	Exchange Agreement, dated as of September 19, 2007, between Nephros and the Holders. (15)
10.38	Registration Rights Agreement, dated as of September 19, 2007, among Nephros and the Holders. (15)
10.39	Investor Rights Agreement, dated as of September 19, 2007, among Nephros and the Covered Holders as defined therein. (15)
10.40	Placement Agent Agreement, dated as of September 18, 2007, among Nephros, NSC and Dinosaur. (15)
10.41	License Agreement, dated October 1, 2007, between the

	Trustees of Columbia University in the City of New York, and Nephros. (17)
10.42	Employment Agreement, dated as of April 1, 2008, between Nephros, Inc. and Gerald Kochanski. (2)(18)
10.43	Separation Agreement and Release, dated as of April 28, 2008, between Nephros, Inc. and Mark W. Lerner. (2)(18)
10.44	Separation Agreement and Release, dated as of September 15, 2008, between Nephros, Inc. and Norman J. Barta. (2) (19)
10.45	Employment Agreement, dated as of September 15, 2008, between Nephros, Inc. and Ernest A. Elgin III. (2)(19)
10.46	Lease Agreement between Nephros, Inc. and 41 Grand Avenue, LLC dated as of November 20, 2008. (20)
10.47	

	Distribution Agreement between Nephros, Inc. and OLS, dated as of November 26, 2008. (21)
10.48	Lease Agreement between Nephros International LTD and Coldwell Banker Penrose & O'Sullivan dated November 30, 2008. (21)
10.49	Distribution Agreement between Nephros, Inc. and Aqua Sciences, Inc., dated as of December 3, 2008. (21)
10.50	Sales Management Agreement between Nephros, Inc. and Steve Adler, dated as of December 16, 2008. (2)(21)
10.51	Amendment No. 3 to the Nephros, Inc. 2004 Stock Incentive Plan. (2)(21)
10.52	Form of Subscription Agreement between Nephros, Inc. and various

	investors , dated July 24, 2009. (22)
10.53	Consulting Agreement between Nephros, Inc. and John Shallman, dated as of January 2, 2009. (25)
10.54	Authorized Representative Services Agreement between Nephros, Inc. and Donawa Lifescience Consulting Srl, dated as of June 1, 2009. (25)
10.55	Consulting Agreement between Nephros, Inc. and Barry A. Solomon, PhD., dated as of December 8, 2009. (25)

10.56	Separation, Release and Consulting Agreement between Nephros, Inc. and Ernest A. Elgin III. (26)
10.57	Senior Secured Note dated October 1, 2010 issued to Lambda Investors LLC. (27)
10.58	Form of Registration Rights Agreement, dated as of September 30, 2010, by and between the Registrant and Lambda Investors LLC. (27)
10.59	Purchase Agreement, dated as of October 1, 2010, by and between the Registrant and Lambda Investors LLC. (28)
10.60	Amendment No. 4 to the Nephros, Inc. 2004 Stock Incentive Plan. (2)(29)
10.61	Employment Agreement between Nephros, Inc. and Gerald J. Kochanski dated April 1, 2011. (2)(30)
10.62	License Agreement, entered into as of July 1, 2011 by and between Nephros, Inc. and Bellco S.r.l. (31)
10.63	Letter Agreement, dated June 27, 2011, between Nephros, Inc. and DHR International, Inc., entered into as of July 25, 2011. (32)
14.1	Code of Ethics and Business Conduct, as amended on April 2, 2007. (33)
21.1	Subsidiaries of Registrant. (12)
24.1	Power of Attorney. (included on the signature page)
31.1	Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101	Interactive Data File. *

*Filed herewith.

(1) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1, File No. 333-116162.

(2) Management contract or compensatory plan arrangement.

(3) Portions omitted pursuant to a request for confidential treatment.

(4) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K Filed with the Securities and Exchange Commission on March 3, 2005.

(5) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (No. 333-127264), as filed with the Securities and Exchange Commission on August 5, 2005.

(6) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on May 16, 2005.

(7) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on August 15, 2005.

(8) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB, filed with the Securities and Exchange Commission on April 20, 2006.

(9) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2006.

(10) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 7, 2006.

(11) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 4, 2006.

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

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

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

(15) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2007.

(16) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2007.

(17) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008.

(18) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the Securities and Exchange Commission on May 15, 2008.

(19) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008, filed with the Securities and Exchange Commission on November 14, 2008.

(20) Incorporated by reference to Nephros, Inc. 's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 20, 2008.

(21) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 31, 2009.

(22) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 14, 2009.

(23) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1 (No. 333-162781), as filed with the Securities and Exchange Commission on October 30, 2009.

(24) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2011.

(25) Incorporated by reference to Nephros, Inc's Annual Report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission April 2, 2010.

(26) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 30, 2010.

(27) Incorporated by reference to Nephros, Inc.'s Registration statement on Form S-1 (No. 333-169728), as filed with the Securities and Exchange Commission on October 1, 2010.

(28) Incorporated by reference to Nephros, Inc.'s Registration statement on Form S-1 (No. 333-169728), as filed with the Securities and Exchange Commission on December 22, 2010.

(29) Incorporated by reference to Nephros, Inc.'s 2011 Proxy Statement (Exhibit A) filed with the Securities and Exchange Commission on December 2, 2010.

(30) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 31, 2011.

(31) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2011.

(32) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2011.

(33) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2007.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEPHROS, INC.

Date: March 22, 2012

By:/s/ Paul A. Mieyal

Name: Paul A. Mieyal
Title: Acting Chief
Executive Officer

POWER OF ATTORNEY

We, the undersigned directors and officers of Nephros, Inc., hereby severally constitute and lawfully appoint Paul A. Mieyal and Gerald J. Kochanski, and each of them singly, our true and lawful attorneys-in-fact with full power to them and each of them to sign for us, in our names in the capacities indicated below, the Annual Report on Form 10-K for the fiscal year ended December 31, 2011 of Nephros, Inc. and any and all amendments thereto, and to file the same with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Paul A. Mieyal Paul A. Mieyal	Acting Chief Executive Officer (Principal Executive Officer)	March 22, 2012
/s/ Gerald J. Kochanski Gerald J. Kochanski	Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2012

/s/ Arthur H. Amron	Director	March 22, 2012
Arthur H. Amron		
/s/ Lawrence J. Centella	Director	March 22, 2012
Lawrence J. Centella		
/s/ Paul A. Mieyal	Director	March 22, 2012
Paul A. Mieyal		
/s/ James S. Scibetta	Director	March 22, 2012
James S. Scibetta		