NEPHROS INC
Form 10-K
April 02, 2010

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, 2009

o 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 Incorporation or Organization)	(I.R.S. Employer 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 ¨ 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, 2009 , was approximately $29,370,000. 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, 2009. 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, 2009.

As of March 30, 2010 there were 41,604,798 shares of the registrant's common stock, $0.001 par value, outstanding.

NEPHROS, INC. AND SUBSIDIARY

TABLE OF CONTENTS

PART I

Item 1. Business

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 new Dual Stage Ultrafilter (the "DSU") water filtration system, which represents 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); to our knowledge, the only filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

- OLpur H2H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

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

We have also developed our OLpur HD 190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpur MD series but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpur HD190 was designed for use with either hemodialysis or hemodiafiltration machines, and received its approval 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 have assumed that the reader understands that these terms are source-indicating. Accordingly, such terms appear throughout the remainder of this Annual Report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as "middle molecules" because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved in 2010, our OLpur H2H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

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. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

In January 2006, we introduced our new Dual Stage Ultrafilter (the "DSU") water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpur H2H and MD Mid-Dilution filter technologies for ESRD therapy provided the foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of November 11, 2009), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

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.

During the twelve months ended December 31, 2009, we were granted four new patents. In the U.S., we were issued patent #7,534,349 for a Dual Stage Ultrafilter with pump mechanism and/or shower feature. In Canada, we were issued patent #2,430,575 for a valve mechanism used in Infusion Fluid systems which is a feature used on our H2H module and patent #2,396,852 for an Ionic Enhanced Dialysis/Diafiltration system which is related to mid-dilution HDF. In China, we were issued patent #200510092067.3 for a Dual Stage Hemodiafiltration cartridge used in its OLpūr MD HDF Filter.

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 $423,000 has been billed to this second project during the four months ended December 31, 2009.

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

Going Concern

The financial statements included in this Annual Report on Form 10-K have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred losses in our operations in each quarter since inception. For the years ended December 31, 2009 and 2008, we have incurred net losses of $2,026,000 and $6,337,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2009 and 2008. 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.

At December 31, 2009, we had $1,004,000 in cash and cash equivalents. There can be no assurance that our cash and cash equivalents will provide the liquidity we need to continue our operations. (See “Certain Risks and Uncertainties”). These operating plans primarily include the continued development and support of our business in the European and Canadian markets, organizational changes necessary to enhance the commercialization of our water filtration business and the completion of current year milestones which are included in the Office of Naval Research appropriation.

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

We continue to investigate additional funding opportunities by talking to various potential investors who could provide financing. However, there can be no assurance that we will be able to obtain further financing, do so on reasonable terms or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we will not be able to continue our operations.

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

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

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

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

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

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

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

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

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

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

Current ESRD Therapy Options

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

replacement therapy in the marketplace today are defined as follows:

- Dialysis

  - Peritoneal Dialysis, or PD, uses the patient's peritoneum, the membrane lining covering the internal abdominal organs, as a filter by introducing injectable-grade dialysate solution into the peritoneal cavity through a surgically implanted catheter. After some period of time, the fluid is drained and replaced. PD is limited in use because the peritoneal cavity is subject to scarring with repeated episodes of inflammation of the peritoneal membrane, reducing the effectiveness of this treatment approach. With time, a PD patient's kidney function continues to deteriorate and peritoneal toxin removal alone may become insufficient to provide adequate treatment. In such case the patient may switch to an extracorporeal renal replacement therapy such as hemodialysis or hemodiafiltration.

  - Hemodialysis uses an artificial kidney machine to remove certain toxins and fluid from the patient's blood while controlling external blood flow and monitoring patient vital signs. Hemodialysis patients are connected to a dialysis machine via a vascular access device. The hemodialysis process occurs in a dialyzer cartridge with a semi-permeable membrane which divides the dialyzer into two chambers: while the blood is circulated through one chamber, a premixed solution known as dialysate circulates through the other chamber. Toxins and excess fluid from the blood cross the membrane into the dialysate solution through a process known as "diffusion."

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

- 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 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 diafiltration; 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 initiated 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. Initial data is 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 November 2006.

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.

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 new 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.

We are currently offering the OLpur MD190 and OLpur MD220 at a price comparable to the existing "high performance" dialyzers sold in the relevant market. We are unable at this time to determine what the market prices will be in the future.

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 have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

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 H2H

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. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

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 provides 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 5,000 registered hospitals in the United States alone, we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration. We hope to gain a foothold at U.S. and European facilities that seek to become centers of excellence in infection control through the use of our DSU products.

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

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

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

Our Strategy

We believe that current mortality and morbidity statistics, in combination with quality of life issues faced by the ESRD patient, has 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. 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 MD190. 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 150,000 treatments to date.

Convert Existing Hemodialysis Machines to Hemodiafiltration: Upon completion of the appropriate documentation for our OLpur H2H technology, we plan to apply for CE marking for our OLpur H2H during 2010. We plan to complete our regulatory approval processes in the United States for both our OLpur MDHDF filter series and our OLpur H2H in 2009. 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 H2H will provide a basis for more MDHDF filter sales. We believe that, if approved in 2010, our OLpur H2H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

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

Develop a Foothold in the Healthcare Arena by Offering our DSU as a Means to Control Environment-Acquired Infections : We believe our DSU offers an effective, and cost-effective, solution in conquering certain infection control issues faced by hospitals, nursing homes, assisted living facilities and other patient environments where chemical or heat alternatives have typically failed to adequately address the problem. The DSU provides for simple implementation without large capital expenses. We have established a goal in 2010 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.

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. 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 intend to manufacture any of our products or components. We have entered into an agreement dated May 12, 2003, with a contract manufacturer ("CM") to assemble and produce our OLpur MD190, MD220 or other filter products at our option. The agreement requires us to utilize this CM to manufacture the OLpur MD190s and MD220s or other filter products that we directly market in Europe, or are marketed by our distributor. In addition, our CM will be given first consideration in good faith for the manufacture of OLpur MD190s, MD220s or other filter products that we do not directly market. No less than semiannually, our CM will provide a report to representatives of both parties to the agreement detailing any technical know-how that they have developed that would permit them to manufacture the filter products less expensively and both parties will jointly determine the actions to be taken with respect to these findings. If the fiber wastage with respect to the filter products manufactured in any given year exceeds 5%, then the CM will reimburse us up to half of the cost of the quantity of fiber represented by excess wastage. The CM will manufacture the OLpur MD190 or other filter products in accordance with the quality standards outlined in the agreement. Upon recall of any OLpur MD190 or other filter product due to manufactured products that fail to conform to the required specifications or having failed to manufacture one or more products in accordance with any applicable laws, the CM will be responsible for the cost of recall. The agreement also requires that we maintain certain minimum product-liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, providing they do not arise out of the CM's breach of the agreement, negligence or willful misconduct. The term of the agreement is through May 12, 2010, with successive automatic one-year renewal terms, until either party gives the other notice that it does not wish to renew at least 90 days prior to the end of the term. The agreement may be terminated prior to the end of the term by either party upon the occurrence of certain insolvency-related events or breaches by the other party. Although we have no separate agreement with respect to such activities, our CM has also been manufacturing our H2H filters and DSU in limited quantities.

We also entered into an agreement in December 2003, and amended in June 2005, with a fiber supplier ("FS"), a manufacturer of medical and technical membranes for applications like dialysis, to continue to produce the fiber for the OLpur MDHDF filter series. Pursuant to the agreement, FS is our exclusive provider of the fiber for the OLpur MDHDF filter series in the European Union as well as certain other territories. On January 18, 2010 the FS notified us that they are exercising their right to terminate the supply agreement. Termination of the supply agreement will be effective on July 18, 2010. The FS noted their desire to negotiate and execute a new supply agreement with us. Negotiations on terms of a new supply agreement have been taking place and we expect to execute a new agreement with the FS, although we cannot assure you that we will be able to do so.

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.

We have established a customer service and financial processing facility in Dublin, Ireland, available to our customer base in our Target European Market. We have also initiated and completed various clinical studies designed to continue our evaluation of effectiveness of the OLpur MDHDF filters when used on ESRD patients in our Target European Market. These studies are intended to provide us, and have provided us, with valuable information regarding the efficacy of our product and an opportunity to introduce OLpur MDHDF filters to medical institutions in our Target European Market. We have engaged a medical advisor to help us in structuring our clinical study protocols and to

support physicians' technical inquiries regarding our products.

We are marketing our ESRD products primarily to healthcare providers such as hospitals, dialysis clinics, managed care organizations, and nephrology physician groups. We ship our products to these customers both directly from our manufacturer, where this is cost-effective, our distributors, and a public warehouse facility in the U.S.

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. 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 $423,000 has been billed to this second project during the four months ended December 31, 2009.

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

Our research and development expenditures were primarily related to development expenses associated with the H2H machine and related salary expense for the years ended December 31, 2009 and 2008 and were $280,000 and $1,977,000, 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 payors.

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, our Target European Market and Canada;
- 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; and
- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities.

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 2009, we have sixteen issued U.S. patents; one issued Eurasian patent; four Mexican patents, four South Korean patents, three Russian patents, five Chinese patents, five French patents, six German patents, four Israeli patents, five Italian patents, two Spanish patents, six United Kingdom patents, eight Japanese patents, two Hong Kong patents, and nine Canadian patents. Our issued U.S. patents expire between 2018 and 2022. In addition, we have four pending U.S. patent applications, ten pending patent applications in Canada, eight pending patent applications in the European Patent Office, five pending patent applications in Brazil, three pending patent applications in China, nine pending patent applications in Japan, three pending patent applications in Mexico, one pending patent application in South Korea, one pending patent application in Hong Kong, two pending patent applications in India, two pending patent applications in Israel and one pending patent application in Australia.. Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal. We also have pending patent applications on our DSU water filtration system and pump/filter applications related to our Office of Naval Research project.

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

Trademarks

As of December 31, 2009, 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, as is the case with our OLpur H2H module and OLpur MD 220 filter, and that it could take several years from the date a Section 515 application is accepted for filing to obtain Section 515 pre-market approval, although it may take longer in both cases.

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

- that we will not need to reevaluate the applicability of the Section 510(k) pre-market notification process to our ESRD therapy and DSU products in the future;

- that the FDA will agree with our determination that we are eligible to use the Section 510(k) pre-market notification process; or

- that the FDA will not in the future require us to submit a Section 515 pre-market approval application, which would be a more costly, lengthy and uncertain approval process.

The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past and may request clinical data to support pre-market clearance. As a result, the FDA could refuse to accept for filing a Section 510(k) notification made by us or request the submission of additional information. The FDA may determine that any one of our proposed ESRD therapy products is not substantially equivalent to a legally marketed device or that additional information is needed before a substantial equivalence determination can be made. A "not substantially

equivalent" determination, or request for additional data, could prevent or delay the market introduction of our products that fall into this category, which in turn could have a material adverse effect on our potential sales and revenues. Moreover, even if the FDA does clear one or all of our products under the Section 510(k) process, it may clear a product for some procedures but not others or for certain classes of patients and not others.

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

If human clinical trials of a device are required in connection with a Section 510(k) notification and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or distributor of the device) will need to file an IDE application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal testing and/or laboratory bench testing. If the IDE application is approved, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as specified in the IDE. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of subjects. We submitted our original IDE application to the FDA for our OLpur H2H hemodiafiltration module and OLpur MD220 filter in May 2006. The FDA answered our application with additional questions in June 2006, and we submitted responses to the FDA questions in December 2006. In January 2007, we received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. We completed the patient treatment phase of our clinical trials during the second quarter of 2008 and filed our 510(k) applications with respect to the OLpur MDHDF filter series and the OLpur H2H module in November 2008. No IDE was required for our DSU product. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. We hope to achieve U.S. regulatory approval of ourl OLpūr H2H module and OLpūr MD 220 filter products during 2010. Following its review of our applications, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

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. We engaged TÜV Rheinland of North America, Inc. ("TÜV Rheinland") as the notified body to assist us in obtaining certification to the International Organization for Standardization, or ISO, 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

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

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

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms with the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. As of the date of filing of this Annual Report, the manufacturing facilities and processes that we are using to manufacture our OLpur MDHDF filter series have been inspected and certified by a notified body.

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

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

Reimbursement

In both domestic markets and markets outside of the United States, sales of our ESRD therapy products will depend in part, on the availability of reimbursement from third-party payors. 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 March 31, 2010, we employed a total of 9 employees, 7 of whom were full time and 2 who are employed on a part-time basis. We also engaged 2 consultants on an ongoing basis. Of the 11 total employees and consultants, 4 were employed in a sales/marketing/customer support capacity, 3 in general and administrative and 4 in research and development. Our President and Chief Executive Officer resigned on March 30, 2010, as reported in our Current Report on Form 8-K filed on March 30, 2010.

Recent Developments

In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. We obtained approval from the IRBs and completed the clinical trial near the end of the second quarter in 2008. The clinical data was complied, analyzed, summarized and submitted with our FDA 510(k) in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

On March 30, 2010, Ernest Elgin, III resigned as our President and Chief Executive Officer and also resigned from our Board of Directors. In connection with Mr. Elgin's resignation, we entered into a separation, release and consulting agreement with him, pursuant to which we will pay Mr. Elgin his current salary through April 16 and pay his applicable COBRA premiums through April 30, 2010, and, during any time that his COBRA coverage is in effect in 2010, reimburse him for out-of-pocket payments made in 2010 under his healthcare coverage up to $5,000, which is the deductible under the healthcare coverage. Mr. Elgin will be available to consult with us for up to 15 hours a week until May 31, 2010, for which we will pay Mr. Elgin at the rate of 50% of his current salary from April 16 to May 31, 2010. We have the right to extend the consulting period for an additional four months during which Mr. Elgin would be available to consult with us for up to 7.5 hours a week and during which we would pay Mr. Elgin 25% of his current salary. We may terminate this consulting arrangement at any time upon 30 days notice.

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 three years commencing December 2008 with a monthly cost of approximately $7,423. We use our facilities to house our corporate headquarters and research facilities.

Our facilities in our Target European Market are currently located at 6 Eaton House, Main Street, Rathcoole, Co. Dublin, Ireland, and consist of approximately 650 square feet of space. The lease agreement was entered into on November 30, 2008. The lease term is 6 months beginning March 1, 2009 and is renewable for 6 month terms with a 3 month notice to discontinue. Our monthly cost is 735 Euro (approximately $1,000).

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

A former employee in France filed a claim in October 2008 stating that the individual is due 30,000 Euro or approximately $42,000 in back wages. The individual left our employment four years ago and signed a Separation Agreement which stated we had no further liability to the individual. A final judgment dated October 15, 2009 was issued by a French court whereby the claimant was awarded 11,707 Euro, approximately $18,000. The award was paid in October 2009.

A former employee in the United States filed a claim in March 2009 against us and our CEO alleging breach of the individual's employment agreement and fraud. The individual was employed with us from April 2008 through January 8, 2009. The claim was settled as of September 30, 2009 for approximately $11,000. The settlement was paid in October 2009.

A third party has brought a claim against us alleging they incurred damages as a result of our cancellation of a transaction in 2008 involving the sale of Auction Rate Securities. The claim has been referred to a Financial Industry Regulatory Authority (FINRA) binding arbitration panel and was scheduled to be heard in March 2010. There was no specific amount of damages identified in the claim. A settlement of this claim was reached and paid in March 2010 in the amount of $20,000. The settlement amount has been accrued as of December 2009.

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

Item 4. Submission of Matters to a Vote of Security Holders

On October 22, 2009 we held our annual meeting of our shareholders at which our shareholders of record as of September 18, 2009 were asked to vote on three proposals.

Of the 41,604,798 shares of common stock eligible to vote at this meeting, a total of approximately 32,373,586 shares of common stock were actually present or represented by proxy. This represents a vote by approximately 77.8% of the total shares eligible to vote.

The first proposal was to elect one director to serve on our Board of Directors for a three-year term. Paul A. Mieyal was re-elected.

The second proposal was to approve the amendment of our Fourth Amended and Restated Certificate of Incorporation to increase the authorized shares of our capital stock from 65,000,000 shares to 95,000,000 shares and increase the authorized shares of our common stock from 60,000,000 shares to 90,000,000 shares. An aggregate of approximately 64% of the total shares outstanding was voted in favor of this proposal.

The third proposal was to ratify the selection of Rothstein Kass & Company, P.C. as our independent auditors for the year ending December 31, 2009. An aggregate of approximately 75.9% of the total shares represented and voting at

the meeting was voted in favor of this proposal.

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.OB”. The following table sets forth the high and low sales prices for our common stock as reported on the AMEX and the high and low bid and ask prices for our common stock as reported on AMEX and the Over the Counter Bulletin Board for each quarter within the years ended December 31, 2008 and 2009.

Quarter Ended	High	Low
March 31, 2008	$ 1.60	$ .33
June 30, 2008	$ .97	$ .50
September 30, 2008	$ .65	$ .24
December 31, 2008	$ .48	$ .05
March 31, 2009	$ .15	$ .04
June 30, 2009	$ 1.77	$ .01
September 30, 2009	$ 2.63	$ .99
December 31, 2009	$ 1.75	$ .70

As of March 29, 2010, there were approximately 35 holders of record and approximately 900 beneficial holders of our common stock.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends on our common stock in the foreseeable future. We expect that any earnings which we may realize will be retained to finance our growth. There can be no assurance that we will ever pay dividends on our common stock. Our dividend policy with respect to the common stock is within the discretion of the Board of Directors and its policy with respect to dividends in the future will depend on numerous factors, including our earnings, financial requirements and general business conditions.

The following table provides information as of December 31, 2009 about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors upon exercise of options or warrants under all of our existing equity compensation plans, and warrants issued to placement agents in connection with our 2007 financing. Our existing equity compensation plans consist of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (together, our “Stock Option Plans”) in which all of our employees and directors are eligible to participate. Our Stock Option Plans and the issuance of the placement agent warrants were approved by our stockholders.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrant and rights	(b) Weighted-average exercise price of outstanding options, warrant and rights	(c) Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by our stockholders:			
Stock Option Plans	1,885,782	$ 0.86	1,543,884
Placement Agent Warrants	129,681	$ 0.70	—
Equity compensation plans not approved by our stockholders:			
None	—		—
All Plans	2,015,463		1,543,884

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

Business Overview

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190 and MD220, which are dialyzers (our "OLpur MDHDF Filter Series"), OLpur H2H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines. We began selling our OLpur MD190 dialyzer in some parts of our Target European Market (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) in March 2004, and have developed units suitable for clinical evaluation for our OLpur H2H product. We are developing our OLpur NS2000 product by modifying an existing HDF platform and incorporating our proprietary H2H technology.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval for our ESRD products, establishing manufacturing and marketing relationships and establishing our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European Market and the United States upon their approval by appropriate regulatory authorities. We submitted to the FDA our 510(k) application in November 2008 for approval of our OLpūr H2H module and OLpūr MD 220 filter. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

We have also applied our filtration technologies to water filtration and in 2006 we introduced our new Dual Stage Ultrafilter (the "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. 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.

In the fourth quarter of 2008, we also filed a 510(k) with the FDA for approval to use our DSU product with reverse osmosis (RO) water systems found within dialysis centers and hospitals. Due the nature of this application our DSU will be categorized as a medical device and therefore requires a 510(k). While waiting for FDA action on both of our ESRD and DSU 510(k) applications we redirected much of our resources to our sales and marketing efforts of our DSU product here in the US in its non-medical device applications. Our goal is to expand distribution to the hospital market and identify other short term applications. Following its review of our DSU 510(k) application, the FDA requested additional information from us. On February 24, 2009, we provided a formal response to the FDA. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

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

Since our inception, we have incurred annual net losses. As of December 31, 2009, we had an accumulated deficit of $89,975,000, and we expect to incur additional losses in the foreseeable future. We recognized net losses of $2,026,000 and $6,337,000 for the years ended December 31, 2009 and 2008, respectively.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through December 31, 2009, we received net offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately $53.3 million in the aggregate. An additional source of finances was our license agreement with Asahi, pursuant to which we received an up front license fee of $1.75 million in March 2005.

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.

NYSE Alternext US LLC (formerly, the American Stock Exchange or "AMEX") Issues

On September 12, 2008, we received a letter from the AMEX notifying us of our noncompliance with certain continued listing standards. The following are the listing standards that we were in noncompliance of:

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

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

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

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

Subsequent to December 31, 2008, on January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan. The AMEX further notified us that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission ("SEC") pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we have decided not to seek an appeal of the AMEX's intention to delist our common stock.

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

Effective February 4, 2009, our common stock is now quoted on the Over the Counter ("OTC") Bulletin Board under the symbol "NEPH.OB".

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

Recently Issued and Adopted Accounting Standards

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

Fair Value Measurements – In September 2006, the FASB issued guidance regarding fair value measurements. This guidance defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, FASB issued a pronouncement, which delayed the effective date of its prior guidance regarding fair value measurements, specifically for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We adopted the guidance for financial assets and liabilities on January 1, 2008. It did not have any impact on our results of operations or financial position and did not result in any additional disclosures and we adopted the guidance for non-financial assets and non-financial liabilities on January 1, 2009, resulting in no impact to our consolidated financial position, results of operations or cash flows.

In April 2009, the FASB issued new accounting guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and identifying transactions that are not orderly. The guidance affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. It provides guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. It applies to all fair value measurements when appropriate. The adoption of this guidance did not have a significant impact on our consolidated financial position, results of operations or cash flows, or related footnotes.

In April 2009, the FASB issued new accounting guidance on interim disclosures about fair value of financial instruments, which is effective for our quarterly period beginning April 1, 2009. The guidance requires an entity to provide the annual disclosures required by a prior pronouncement regarding disclosures about fair value of financial instruments, in its interim financial statements. The application of the guidance did not have a significant impact on our consolidated financial position, results of operations or cash flows, or related footnotes.

In August 2009, the FASB issued an update to provide further guidance on how to measure the fair value of a liability, an area where practitioners have been seeking further guidance. It primarily does three things: 1) sets forth the types of valuation techniques to be used to value a liability when a quoted price in an active market for the identical liability is not available, 2) clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability and 3) clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. This standard is effective beginning the fourth quarter of 2009. The adoption of this standard update is not expected to impact our consolidated financial position, results of operations or cash flows.

Business Combinations – In December 2007, the FASB issued new accounting guidance on business combinations. The pronouncement establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. The pronouncement determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning after December 15, 2008. We adopted the pronouncement on January 1, 2009 resulting in no impact to our consolidated financial position, results of operations or cash flows.

Subsequent Events – On May 28, 2009, the FASB issued guidance regarding subsequent events, which we adopted on a prospective basis beginning April 1, 2009. The guidance is intended to establish general standards of accounting and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date. The application of the pronouncement did not have an impact on our consolidated financial position, results of operations or cash flows.

Recognition and Presentation of Other-Than-Temporary Impairments – In April 2009, the FASB issued an accounting pronouncement, which is effective for our interim and annual reporting periods ending after June 15, 2009, that amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity's management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. We have no debt securities as of December 31, 2009 therefore there is no impact on our December 31, 2009 consolidated financial position, results of operations or cash flows.

New Accounting Pronouncements

In December 2009, the FASB issued ASU No. 2009-17, Consolidations (Topic 810)-Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities (ASU No. 2009-17). ASU No. 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities . This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We are assessing what impact, if any, adoption of this standard will have on our consolidated financial statements.

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 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 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 its 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, 2009 Compared to the Fiscal Year Ended December 31, 2008

Product Revenues

Total product revenues for the year ended December 31, 2009 were $2,661,000 compared to $1,473,000 for the year ended December 31, 2008. The $1,188,000, or 81%, increase is primarily due to $1,093,000 related to revenue generated from the Office of Naval Research project in the United States. The revenue derived from this project was $1,093,000 for the twelve months ended December 31, 2009 compared to $196,000 for the same period in 2008, which was the project's initial period beginning in January 2008. Sales of the OLpūr MD190 and MD220 Dialyzers in Europe were $1,265,000 for the twelve months ended December 31, 2009 compared to $1,228,000 for the same period in 2008. This $37,000 or 3% increase in revenue was impacted by the adverse currency translation of the Euro to the U.S. dollar. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Although the sales price of these units, which is in Euro, remained constant approximately $53,000 was lost due to currency translation. In addition, revenues in the United States from sales of the Dual Stage Ultrafilter (the "DSU") water filter were $303,000 for the twelve months ended December 31, 2009 compared to $49,000 for the same period in 2008. The DSU represents a new and complementary product line introduced in 2008.

Cost of Goods Sold

Cost of goods sold was $1,744,000 for the year ended December 31, 2009 compared to $1,064,000 for the year ended December 31, 2008. The $680,000, or 64%, increase is primarily due to costs related to the Office of Naval Research project in the United States. The cost of goods sold related to the Office of Naval Research project was $692,000 for the twelve months ended December 31, 2009 compared to $141,000 for the same period in 2008, an increase of $551,000. The increased cost is correlated to the higher revenue recognized from this project for the year ended December 31, 2009 compared to the same period in 2008. Cost of goods sold related to the OLpūr MD190 and MD220 Dialyzers sold in Europe for the year ended December 31, 2009 was $969,000 an increase of $46,000, or 5%, over the comparable period in 2008. This increase was due primarily to higher sales volume. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Cost of goods sold related to the DSU water filters sold in the United States were $83,000 for the year ended December 31, 2009. The DSU represents a new and complementary product line introduced in 2008 and there were no cost of goods sold incurred for the year ended December 31, 2008.

Research and Development

Research and development expenses were $280,000 for the year ended December 31, 2009 compared to $1,977,000 for the year ended December 31, 2008, a decrease of $1,697,000 or 86%. This decrease is related to the fact that a clinical trial was conducted in 2008 and there was no clinical trial conducted during 2009. Clinical trial expenses decreased by approximately $964,000 during the twelve months ended December 31, 2009 compared to the same period in 2008. Related reductions in personnel and lab testing resulted in reduced expenses of $491,000 and $226,000 respectively during the twelve months ended December 31, 2009 compared to the same period in 2008. A reduction in travel expenses in the amount of $23,000 was offset by an increase of $13,000 in development expenses related to the DSU water filter during the twelve months ended December 31, 2009 compared to the same period in 2008.

Depreciation and Amortization Expense

Depreciation expense was $231,000, for the year ended December 31, 2009 compared to $447,000 for the year ended December 31, 2008, a decrease of $216,000, or 48.3%. An additional $59,000 of depreciation was recorded in 2008 related to furniture and fixtures and tooling to reflect the assessed utility of these assets as of December 31, 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2,812,000 for the year ended December 31, 2009 compared to $4,702,000 for the year ended December 31, 2008, a decrease of $1,890,000 or 40%. A reduction in personnel and related expenses resulted in a decrease of $1,072,000 for the twelve months ended December 31, 2009 compared to the same period in 2008. Reductions of $246,000 in legal expenses, $232,000 in marketing expenses, $186,000 in recruiting expenses, $70,000 in insurance expenses and $85,000 in facility expenses for the twelve months ended December 31, 2009 compared to the same period in 2008 were also achieved. The legal expense reduction was due to less activity and transition to a new law firm in 2009. Marketing activities related to trade shows were curtailed in 2009. Recruiting fees were incurred for four hires in 2008 and none in 2009. The reduction in facility expenses resulted from both the Ireland and U.S. offices moving to less expensive locations for 2009.

Interest Income

Interest income was $9,000 for the year ended December 31, 2009 compared to $199,000 for the year ended December 31, 2008. The decrease of $190,000, or 95.5%, reflects the impact of having less cash on hand in 2009

compared to 2008 and therefore, fewer investments to generate interest income.

Interest Expense

We incurred approximately $2,000 of interest expense for the year ended December 31, 2009. This interest relates primarily to financing of premiums for product liability insurance. No interest expense was incurred during 2008. We had no outstanding debt during 2009 or 2008.

Impairment of Auction Rate Securities and Gain on sale of investments

During the fiscal year 2008, we had investments in auction rate securities ("ARS") which are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction "fails" and the holders of the ARS are unable to liquidate their investment through such auction. With the liquidity issues experienced in global credit and capital markets, the ARS held by us had experienced multiple failed auctions since February 2008, and as a result, we did not consider these affected ARS liquid in the first quarter of 2008. Accordingly, while we had classified its ARS as current assets as of January 1, 2008, we reclassified them as noncurrent assets at March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, we wrote down ARS with an original par value of $4,400,000 to an estimated fair value of $4,286,000 as of March 31, 2008. We reviewed impairments associated with the above in accordance with ASC Topic 320 to determine the classification of the impairment as "temporary" or "other-than-temporary." We determined the ARS classification to be "other-than-temporary," and charged an impairment loss of $114,000 on the ARS to its results of operations for the three months ended March 31, 2008 and twelve months ended December 31, 2008.

During the three months ended June 30, 2008, $300,000 of principal on our ARS had been paid back by the debtor, resulting in our investment in ARS having decreased from $4,400,000 to $4,100,000 (par value) at June 30, 2008. The net book value of our ARS at June 30, 2008 was $3,986,000 million, due to the approximate $114,000 impairment recorded at March 31, 2008. On July 22, 2008 we sold our ARS to a third party at 100% of par value, for proceeds of $4,100,000. We reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with ASC Topic 320, the ARS, classified as Trading Securities, were valued at their fair value of $4,100,000 at June 30, 2008. The adjustment of the investment's carrying value from $3,986,000 net book value to $4,100,000 fair value resulted in an Unrealized Holding Gain of $114,000 which is included in our Statement of Operations for the three and six months ended June 30, 2008.

We subsequently reversed the Unrealized Holding Gain and recorded in the results of operations for the twelve months ended December 31, 2008, a Realized Gain on Sale of Investments of $114,000 in July 2008 due to the sale transaction being executed.

We had no investments in Auction Rate Securities during the year ended December 31, 2009.

Other Income

Other income in the amount of approximately $373,000 and $181,000 for the years ended December 31, 2009 and December 31, 2008, respectively, resulted primarily from receipt of New York State Qualified Emerging Technology Company ("QETC") tax refunds in each of these periods. Tax credits for the years 2006 and 2007 were received and recognized during the year ended December 31, 2009. The tax credit for the year 2005 was received and recognized during the year ended December 31, 2008.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the periods ended December 31, 2009 and December 31, 2008.

Liquidity and Capital Resources

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

- 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 pre requisite 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.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In the event that our plans change, our assumptions change or prove inaccurate, or if our existing cash resources, together with other funding resources including increased sales of our products, otherwise prove to be insufficient to fund our operations and we are unable to obtain additional financing, we will be required to adopt alternatives, such as curtailing our planned activities or ceasing our operations.

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 $0.90 (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 $0.90.

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 1,345,161 shares of its common stock and warrants to purchase an aggregate of 672,581 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 $0.93. The warrants have an exercise price of $1.12, are exercisable immediately and will terminate on July 24, 2014.

At December 31, 2009, we had an accumulated deficit of $89,975,000, 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 and a private investment in public equity in September 2007 and a private placement in July 2009.

Net cash used in operating activities was $2,612,000 for the year ended December 31, 2009 compared to $5,725,000 for the year ended December 31, 2008.

During 2009, the net cash used in operating activities was $3,113,000 less than the net cash used in operating activities during 2008. The most significant items contributing to the reduction in cash used in operating cash are highlighted below:

- Our net loss in 2009 was $2,026,000 compared to $6,337,000 in 2008. This represents an improvement of $4,311,000 in operating cash in 2009. Noncash adjustments to reconcile net loss to net cash used in operating activities were: stock-based compensation was $108,000 and $155,000 in 2009 and 2008 respectively, a reduction of $47,000, depreciation expense was $231,000 and $447,000 in 2009 and 2008 respectively, a reduction of $216,000 and an increase to the inventory reserve of $18,000 in 2009.

- During 2009, our accounts receivable, other current assets and other assets increased by $193,000. This compares to a decrease of $236,000 in 2008. This represents a $429,000 use of operating cash in 2009.

- During 2009, our inventory decreased by $75,000. This compares to an increase in inventory of $409,000 in 2008. This represents a $484,000 source of operating cash in 2009.

- During 2009, accounts payable and accrued expenses decreased by $807,000. This compares to an increase in accounts payable and accrued expenses of $183,000 during 2008. This represents a $990,000 use of operating cash in 2009.

Net cash used by investing activities was $21,000 for the year ended December 31, 2009 compared to $4,599,000 of net cash provided by investing activities for the year ended December 31, 2008. In 2009, $28,000 was used to purchase equipment and $7,000 was provided by the maturity of a short-term investment. In 2008, $4,693,000 was provided due to the maturity of short-term investments. Approximately $97,000 of funds was used to purchase property, plant and equipment and $3,000 was provided by the sale of equipment.

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. There were no financing activities in 2008.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2009:

		Payments Due in Period		
	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years
Leases	$ 186,000	$ 101,000	$ 85,000	$ —$	—
Employment Contracts	244,000	195,000	49,000		
Total	$ 430,000	$ 296,000	$ 134,000	$ —$	—

Certain Risks and Uncertainties

Certain statements in this Annual Report on Form 10-K, including certain statements contained in “Description of Business” and “Management’s Discussion and Analysis,” constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases “can be,” “may,” “could,” “would,” “expects,” “believes,” “seeks,” “estimates,” “projects” and words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Risks Related to Our Company

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2009, expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this 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, 2009, we had an accumulated deficit of $89,975,000 primarily as a result of our research and development expenses and selling, general and administrative expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of

operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

- the completion and success of additional clinical trials and of our regulatory approval processes for each of our ESRD therapy products in our target territories;

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

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

- our ability to sell our products at competitive prices which exceed our per unit costs; and

- the consolidation of dialysis clinics into larger clinical groups.

We require additional financing in the near future to fund our operations.

At December 31, 2009, we had cash, cash equivalents and short-term investments totaling approximately $1,004,000 and tangible assets of approximately $1,648,000. We estimate that these funds will allow us to keep operating through June 2010. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, our ability to operate will be significantly limited and we might need to cease operations.

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

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

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

For the year ended December 31, 2009, one of our customers accounted for 46% of our product sales. Also, this customer represented 44% of our accounts receivable as of December 31, 2009. We believe that the loss of this customer would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

We cannot sell our ESRD therapy products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. We have not obtained FDA approval for any of our ESRD therapy products, except for our HD190 filter, and cannot sell any of our other ESRD therapy products in the United States unless and until we obtain such approval. If we fail to receive, or experience a significant delay in receiving, such approvals and clearances then we may not be able to get our products to market and enhance our revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpur MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage Ultrafilter (“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 the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

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

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

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, as of March 10, 2010, have been informed that our application is still under their review process.

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 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 2022, assuming they are properly maintained.

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

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

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

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

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

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

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

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

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

We expect to rely on a limited number of independent manufacturers to produce our OLpur MDHDF filter series and our other products, including the DSU. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, if any, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

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

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

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

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

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

Approval or clearance of our ESRD therapy products could be delayed by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our ESRD therapy products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our ESRD therapy products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H2H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or

processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

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

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

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

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

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

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

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

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

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

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

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;
- we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;
- local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;
- political instability could disrupt our operations;

- some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and
- some countries could impose additional taxes or restrict the import of our products.

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

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

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

Risks Related to the ESRD Therapy Industry

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

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

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

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

Some of our competitors, including Fresenius Medical Care AG and Gambro AB, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. In 2005, Gambro AB divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, Inc., whereby DaVita, Inc. will purchase a significant amount of renal products and supplies from Gambro AB Renal Products. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius Medical Care AG Form 20-F annual report for the year ended December 31,

2009, Fresenius Medical Care AG provides treatment in its own dialysis clinics to approximately 195,651 patients in its facilities around the world including facilities located in the North America. According to DaVita, Inc.'s Annual Report for the year ended December 31, 2009, DaVita, Inc. provides treatment in 1,530 outpatient dialysis centers serving approximately 118,000 patients in the United States.

We believe that there is currently a trend among ESRD therapy providers towards greater consolidation. If such consolidation takes the form of our competitors acquiring independent dialysis clinics, rather than such dialysis clinics banding together in independent chains, then more of our potential customers would also be our competitors. If our competitors continue to grow their networks of dialysis clinics, whether organically or through consolidation, and if we cannot successfully market our products to dialysis clinics owned by these competitors or any other competitors and do not acquire clinics ourselves, then our revenues could be adversely affected.

If the size of the potential market for our products is significantly reduced due to pharmacological or technological advances in preventative and alternative treatments for ESRD, then our potential sales and revenues will suffer.

Pharmacological or technological advances in preventative or alternative treatments for ESRD could significantly reduce the number of ESRD patients needing our products. These pharmacological or technological advances may include:

- the development of new medications, or improvements to existing medications, which help to delay the onset or prevent the progression of ESRD in high-risk patients (such as those with diabetes and hypertension);
- the development of new medications, or improvements in existing medications, which reduce the incidence of kidney transplant rejection; and
- developments in the use of kidneys harvested from genetically-engineered animals as a source of transplants.

If these or any other pharmacological or technological advances reduce the number of patients needing treatment for ESRD, then the size of the market for our products may be reduced and our potential sales and revenues will suffer.

If government and other third party reimbursement programs discontinue their coverage of ESRD treatment or reduce reimbursement rates for ESRD products, then we may not be able to sell as many units of our ESRD therapy products as otherwise expected, or we may need to reduce the anticipated prices of such products and, in either case, our potential revenues may be reduced.

Providers of renal replacement therapy are often reimbursed by government programs, such as Medicare or Medicaid in the United States, or other third-party reimbursement programs, such as private medical care plans and insurers. We believe that the amount of reimbursement for renal replacement therapy under these programs has a significant impact on the decisions of nephrologists, dialysis clinics and other health care providers regarding treatment methods and products. Accordingly, changes in the extent of coverage for renal replacement therapy or a reduction in the reimbursement rates under any or all of these programs may cause a decline in recommendations or purchases of our products, which would materially adversely affect the market for our products and reduce our potential sales. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could 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

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, 2009, our common stock has traded at prices ranging from a high of $2.63 to a low of $0.01 per share. Due to the lack of an active market for our common stock, you should expect the prices at which our common stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;
- delays or failures in initiating, completing or analyzing clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our results of operations;

- changes in financial estimates by securities analysts; and
- sales of our common stock.

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

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

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

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

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

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

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

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

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

In April 2002, we entered into a letter agreement with Hermitage Capital Corporation ("Hermitage"), as placement agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, we entered into a settlement agreement with Hermitage pursuant to which, among other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement; and we agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between us and Lancer Offshore, Inc., warrants exercisable until February 2006 to purchase an aggregate of 60,000 shares of common stock for $2.50 per share (or 17,046 shares of our common stock for $8.80 per share, if adjusted for the reverse stock split pursuant to the antidilution provisions of such warrant, as amended). Because Lancer Offshore, Inc. never satisfied the closing conditions and, consequently, a closing has not been held, we have not issued any warrants to Hermitage in connection with our settlement with them. In June 2004, Hermitage threatened to sue us for warrants it claims are due to it under its settlement agreement with us as well as a placement fee and additional warrants it claims are, or will be, owed in connection with our initial public offering completed on September 24, 2004, as compensation for allegedly introducing us to one of the underwriters. We had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. We have not heard from Hermitage since then.

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

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

Our management has broad discretion over the use of our financial resources, including the net proceeds from all of our equity financings. Stockholders may not deem such uses desirable. Our use of our financial resources may vary substantially from our currently planned uses. We cannot assure you that we will apply such proceeds effectively or that we will invest such proceeds in a manner that will yield a favorable return or any return at all.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our common stock.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our common stock could be reduced as a result. These provisions include:

- authorizing our board of directors to issue "blank check" preferred stock without stockholder approval;
- providing for a classified board of directors with staggered, three-year terms;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

stock. As a result, investors in our common stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company's securities. As a result, we may become subject to this type of litigation in the future. Litigation of this type could be extremely expensive and divert management's attention and resources from running our company.

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

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

As of December 31, 2007, management reported a material weakness in our internal control over financial reporting due to an insufficient number of resources in the accounting and finance department that does not allow for a thorough review process. Throughout fiscal year 2008, we implemented the following measures which resulted in the remediation of this material weakness as of December 31, 2008:

- Developed procedures to implement a formal quarterly closing calendar and process and held quarterly meetings to address the quarterly closing process;

- Established a detailed timeline for review and completion of financial reports to be included in our Forms 10-Q and 10-K;

- Enhanced the level of service provided by outside accounting service providers to further support and provide additional resources for internal preparation and review of financial reports and supplemented our internal staff in accounting and related areas; and

- Employed the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-Q and 10-K.

In addition, beginning with our financial statements for the year ending December 31, 2010, we will be subject to the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 that require a report by our independent registered public accounting firm addressing the effectiveness of our internal control over financial reporting. If the auditors were unable to express an 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 principal stockholders control a significant portion of our stock and, if they choose to vote together, could have sufficient voting power to control the vote on substantially all corporate matters.

As of December 31, 2009, our directors, executive officers and principal stockholders beneficially owned approximately 60.8% of our outstanding common stock. As of December 31, 2009, Lambda Investors LLC beneficially owned 44.27% of our outstanding common stock. As of December 31, 2000, Stagg Capital Group LLC beneficially owned 9.03% of our outstanding common stock. As of December 31, 2000, AFS Holdings One LLC beneficially owned 7.6% of our outstanding common stock.

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

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

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

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 10,020,248 shares registered for sale in the public market. Moreover, many of those shares, as well as the 184,250 shares we sold to Asahi, could be sold in the public market without registration once they have been held for one year, subject to the limitations of Rule 144 under the Securities Act. In addition, we entered into a registration rights agreement with the holders of our New Notes pursuant to which we granted the holders certain registration rights with respect to the shares of common stock issuable upon conversion of the New Notes and upon exercise of the Class D Warrants.

39

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, 2009 and 2008, 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, 2009 and 2008, 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 & COMPANY, P.C.

Roseland, New Jersey
March 31, 2010

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share Amounts)

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,004	$ 2,306
Short-term investments	-	7
Accounts receivable, less allowances of $0 and $4, respectively	629	404
Inventory, less allowances of $18 and $0, respectively	653	724
Prepaid expenses and other current assets	135	162
Total current assets	2,421	3,603
Property and equipment, net	210	412
Other assets	21	21
Total assets	$ 2,652	$ 4,036
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 455	$ 986
Accrued expenses	239	411
Accrued severance expense	-	105
Total current liabilities	694	1,502
Total liabilities	694	1,502
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2009 and 2008; no shares issued and outstanding at December 31, 2009 and 2008	-	-
Common stock, $.001 par value; 90,000,000 and 60,000,000 authorized at December 31, 2009 and 2008, respectively; 41,604,798 and 38,165,380 shares issued and outstanding at December 31, 2009 and 2008, respectively.	42	38
Additional paid-in capital	91,815	90,375
Accumulated other comprehensive income	76	70
Accumulated deficit	(89,975)	(87,949)
Total stockholders' equity	1,958	2,534
Total liabilities and stockholders' equity	$ 2,652	$ 4,036

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	
	2009	2008
Product revenue	$ 2,661	$ 1,473
Cost of goods sold	1,744	1,064
Gross margin	917	409
Operating expenses:		
Research and development	280	1,977
Depreciation and amortization	231	447
Selling, general and administrative	2,812	4,702
Total operating expenses	3,323	7,126
Loss from operations	(2,406)	(6,717)
Interest income	9	199
Interest expense	(2)	-
Impairment of auction rate securities	-	(114)
Gain on sale of investments	-	114
Other income	373	181
Net loss	$ (2,026)	$ (6,337)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.17)
Weighted average common shares outstanding, basic and diluted	39,629,346	38,165,380

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 Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Income (Loss)	Accumulated Deficit	Total
Balance, January 1, 2008	38,165,380	$ 38	$ 90,220	$ 110	$ (81,612)	$ 8,756
Comprehensive income:						
Net loss					(6,337)	(6,337)
Net unrealized losses on foreign currency translation				(40)		(40)
Comprehensive loss						(6,377)
Noncash stock-based compensation			155			155
Balance, December 31, 2008	38,165,380	$ 38	$ 90,375	$ 70	$ (87,949)	$ 2,534
Comprehensive income:						
Net loss					(2,026)	(2,026)
Net unrealized gains on foreign currency translation				6		6
Comprehensive loss						(2,020)
Cashless exercise of warrants	1,829,476	2	(2)			-
Private placement sale of common stock	1,345,161	1	1,250			1,251
Exercise of stock options	264,781	1	84			85
Noncash stock-based compensation			108			108
Balance, December 31, 2009	41,604,798	$ 42	$ 91,815	$ 76	$ (89,975)	$ 1,958

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, 2009	2008
Operating activities:		
Net loss	$ (2,026)	$ (6,337)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	231	447
Impairment of auction rate securities	—	114
Noncash stock-based compensation	108	155
Gain on sale of investments	—	(114)
Inventory reserve	18	
(Increase) decrease in operating assets:		
Accounts receivable	(220)	1
Inventory	57	(409)
Prepaid expenses and other current assets	27	227
Other assets	—	8
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(702)	138
Accrued severance expense	(105)	45
Net cash used in operating activities	(2,612)	(5,725)
Investing activities		
Purchase of property and equipment	(28)	(97)
Proceeds from sales of property and equipment	—	3
Maturities of short-term investments	7	4,693
Net cash provided by (used in) investing activities	(21)	4,599
Financing activities		
Proceeds from stock options exercised	85	—
Proceeds from issuance of common stock	1,251	—
Net cash provided by financing activities	1,336	—
Effect of exchange rates on cash	(5)	(17)
Net decrease in cash	(1,302)	(1,143)
Cash, beginning of year	2,306	3,449
Cash, end of year	$ 1,004	$ 2,306
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 2	$ —
Cash paid for taxes	$ 6	$ 1

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

44

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

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 amounts of revenues and expenses, during the reporting period. Actual results could differ 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on the Company's current cash flow projections, it will need to raise additional funds through either the licensing or sale of its technologies or additional public or private offerings of its securities. The Company continues to investigate strategic funding opportunities as they are identified. However, there is no guarantee that the Company will be able to obtain further financing. If it is unable to raise additional funds on a timely basis or at all, the Company would not be

able to continue its operations.

The Company has incurred significant losses in its operations in each quarter since inception. For the years ended December 31, 2009 and 2008, the Company has incurred net losses of approximately $2,026,000 and $6,337,000, respectively. In addition, the Company has not generated positive cash flow from operations for the years ended December 31, 2009 and 2008. 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, the Company's results of operations and financial condition will be materially and adversely affected.

The Company's current operating plans primarily include the continued development and support of the Company's business in the European market, organizational changes necessary to begin the commercialization of the Company's water filtration business and the completion of current year milestones which are included in the Office of Naval Research appropriation.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies – (continued)

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.

The Company continues to investigate additional funding opportunities. However, there can be no assurance that the Company will be able to obtain further financing, do so on reasonable terms or do so on terms that would not substantially dilute the equity interests in the Company. If the Company is unable to raise additional funds on a timely basis, or at all, the Company will not be able to continue its operations.

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.

Short-Term Investments

The Company had no short-term investments at December 31, 2009. The Company had $7,000 of short-term investments consisting of a certificate of deposit at December 31, 2008.

See Note 3 for a further discussion of short-term investments as of December 31, 2009 and December 31, 2008.

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. The allowance for doubtful accounts at December 31, 2009 and 2008 was $0 and $4,000, respectively. There was no allowance for sales returns at December 31, 2009 or 2008. There were no write offs of accounts receivable to bad debt expense during 2009 or 2008.

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, 2009 and December 31, 2008.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies – (continued)

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, 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.

Shipping and Handling Costs

Shipping and handling costs are recorded as cost of goods sold and are approximately $19,000 and $31,000 for the years ended December 31, 2009 and 2008, 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.

Other Income

Other income in the amount of approximately $373,000 and $181,000 for the years ended December 31, 2009 and December 31, 2008, respectively, resulted primarily from receipt of New York State Qualified Emerging Technology Company ("QETC") tax refunds in each of these periods. Tax credits for the years 2006 and 2007 were received and recognized during the year ended December 31, 2009. The tax credit for the year 2005 was received and recognized during the year ended December 31, 2008 and no further tax credits are expected.

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, 2009 and December 31, 2008.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies – (continued)

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 prior to 2006. The adoption of the provisions of ASC 740 did not have a material impact on the Company's consolidated financial statements. During the year ended December 31, 2009 and 2008, 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.

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.

	2009	2008
Stock options	1,885,782	2,696,225
Warrants	8,191,827	11,090,248

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, 2009 and 2008, the comprehensive loss was approximately $2,020,000 and $6,377,000, respectively.

Recent Issued and Adopted Accounting Standards

Fair Value Measurements – In September 2006, the FASB issued guidance regarding fair value measurements. This guidance defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value

measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, FASB issued a pronouncement, which delayed the effective date of its prior guidance regarding fair value measurements, specifically for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The Company adopted the guidance for financial assets and liabilities on January 1, 2008. It did not have any impact on the Company's results of operations or financial position and did not result in any additional disclosures and the Company adopted the guidance for non-financial assets and non-financial liabilities on January 1, 2009, resulting in no impact to the Company's consolidated financial position, results of operations or cash flows.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies – (continued)

In April 2009, the FASB issued new accounting guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and identifying transactions that are not orderly. The guidance affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. It provides guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. It applies to all fair value measurements when appropriate. The adoption of this guidance did not have a significant impact on the Company's consolidated financial position, results of operations or cash flows, or related footnotes.

In April 2009, the FASB issued new accounting guidance on interim disclosures about fair value of financial instruments, which is effective for the Company for the quarterly period beginning April 1, 2009. The guidance requires an entity to provide the annual disclosures required by a prior pronouncement regarding disclosures about fair value of financial instruments, in its interim financial statements. The application of the guidance did not have a significant impact on the Company's consolidated financial position, results of operations or cash flows, or related footnotes.

In August 2009, the FASB issued an update to provide further guidance on how to measure the fair value of a liability, an area where practitioners have been seeking further guidance. It primarily does three things: 1) sets forth the types of valuation techniques to be used to value a liability when a quoted price in an active market for the identical liability is not available, 2) clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability and 3) clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. This standard is effective beginning in the fourth quarter of 2009 for the Company. The adoption of this standard update is not expected to impact the Company's consolidated financial position, results of operations or cash flows.

Business Combinations – In December 2007, the FASB issued new accounting guidance on business combinations. The pronouncement establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. The pronouncement determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning after December 15, 2008. The Company adopted the pronouncement on January 1, 2009 resulting in no impact to the Company's consolidated financial position, results of operations or cash flows.

Subsequent Events – On May 28, 2009, the FASB issued guidance regarding subsequent events, which the Company adopted on a prospective basis beginning April 1, 2009. The guidance is intended to establish general standards of accounting and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date. The application of the pronouncement did not have an impact on the Company's consolidated financial position, results of operations or cash flows.

FASB Accounting Standards Codification – On June 29, 2009, the FASB issued an accounting pronouncement establishing the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities. This pronouncement was effective for financial statements issued for interim and annual periods ending after September 15, 2009, for most entities. On the effective date, all non-SEC accounting and reporting standards will be superseded. The Company adopted this new accounting pronouncement for the quarterly period ended September 30, 2009, as required, and adoption did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

Recognition and Presentation of Other-Than-Temporary Impairments – In April 2009, the FASB issued an accounting pronouncement, which is effective for the Company for interim and annual reporting periods ending after June 15, 2009, that amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity's management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The adoption of this accounting pronouncement did not have an impact on the Company's consolidated financial position, results of operations or cash flows.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies – (continued)

New Accounting Pronouncements

In December 2009, the FASB issued ASU No. 2009-17, Consolidations (Topic 810)-Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. The Company is assessing what impact, if any, adoption of this standard will have on its consolidated financial statements.

Note 3 — Short-Term Investments

ASC Topic 820 provides a framework for measuring fair value under generally accepted accounting principles in the United States and requires expanded disclosures regarding fair value measurements. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs, other than Level 1 prices, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques.

The Company had no financial assets at December 31, 2009.

The following table details the fair value measurements within the fair value hierarchy of the Company’s financial assets at December 31, 2008:

	Total Fair Value at December 31, 2008	Fair Value Measurements at Reporting Date Using Level 1	Level 2	Level 3
Certificates of deposit	$ 7,000	$ 7,000	$ —	$ —

Total	$ 7,000	$ 7,000	$ —	$ —

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 3 — Short-Term Investments (continued)

The following table reflects the activity for the Company's ARS measured at fair value using Level 3 inputs for the year ended December 31, 2008:

	Auction Rate Securities
Balance as of December 31, 2007	$ 4,700,000
Sale of Securities	(4,700,000)
Gain on sale of investments	114,000
Impairment of auction rate securities	(114,000)
Balance as of December 31, 2008	$ —

As of December 31, 2008, the Company had grouped certificates of deposit using a Level 1 valuation because market prices are readily available in active markets.

The Company invested in auction rate securities ("ARS"), which are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction "fails" and the holders of the ARS are unable to liquidate their investment through such auction. With the liquidity issues experienced in global credit and capital markets, the ARS held by the Company experienced multiple failed auctions in the first quarter of fiscal year 2008. As a result of the failed auctions, the Company did not consider the affected ARS liquid and accordingly, the Company classified its ARS as noncurrent assets as of March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, the Company wrote down ARS with an original par value of $4,400,000 to an estimated fair value of $4,286,000 as of March 31, 2008. The Company reviewed impairments associated with the above in accordance with ASC Topic 320 to determine the classification of the impairment as "temporary" or "other-than-temporary." The Company determined the ARS classification to be "other-than-temporary", and charged an impairment loss of $114,000 on the ARS to its results of operations during the three months ended March 31, 2008. Subsequently during the three months ended June 30, 2008, $300,000 of principal on the Company's ARS had been paid back from the debtor. As a result of the payment, the Company's investment decreased from a par value of $4,400,000 to approximately $4,100,000. The net book value of the Company's ARS at June 30, 2008 was $3,986,000. On July 22, 2008, the Company sold its ARS to a third party at 100% of par value, for proceeds of $4,100,000 and as a result, the Company reclassified the ARS from Available-for-Sale to Trading Securities.

In accordance with ASC 320 the ARS, classified as Trading Securities, were valued at their fair value of $4,100,000 at June 30, 2008. The adjustment of the ARS' carrying value from $3,986,000 net book value to $4,100,000 fair value resulted in an Unrealized Holding Gain of $114,000 which was recorded in the Company's Consolidated Statement of Operations for the three and six months ended June 30, 2008. As a result of the sale of investment on July 22, 2008, the Company reclassified the unrealized holding gain of $114,000 to a realized gain on sale of investments.

The Company had no investment in Auction Rate Securities during 2009.

Note 4 — Inventory

The Company’s inventory components as of December 31, 2009 and 2008 were as follows:

	December 31,	
	2009	2008
Raw Materials	$ 257,000	$ 382,000
Finished Goods	414,000	342,000
Total Gross Inventory	671,000	724,000
Less: Inventory reserve	(18,000)	—
Total Inventory	$ 653,000	$ 724,000

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 5 — Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2009 and 2008 were as follows:

	December 31,	
	2009	2008
Prepaid insurance premiums	$ 126,000	$ 88,000
Other	9,000	74,000
Prepaid expenses and other current assets	$ 135,000	$ 162,000

Note 6 — Property and Equipment, Net

Property and equipment as of December 31, 2009 and 2008 was as follows:

		December 31,	
	Life	2009	2008
Manufacturing equipment	3-5 years	$ 2,115,000	$ 2,057,000
Research equipment	5 years	91,000	91,000
Computer equipment	3-4 years	62,000	61,000
Furniture and fixtures	7 years	39,000	39,000
Property and equipment, gross		2,307,000	2,248,000
Less: accumulated depreciation		2,097,000	1,836,000
Property and equipment, net		$ 210,000	$ 412,000

The Company contracts with a contract manufacturer (“CM”) to manufacture the Company’s ESRD therapy products. The Company owns certain manufacturing equipment located at CM’s manufacturing plant.

Depreciation expense for the years ended December 31, 2009 and 2008 was approximately $231,000 and $447,000, respectively, including amortization expense relating to research and development assets.

Note 7 — Accrued Expenses

Accrued expenses as of December 31, 2009 and 2008 were as follows:

	December 31,	
	2009	2008
Accrued Clinical Trial	$ —	