

NEPHROS INC
Form 10-K
April 02, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2009

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
(State or Other Jurisdiction of
Incorporation or Organization)

13-3971809
(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

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

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

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 Smaller reporting company
(Do not check if a smaller reporting company)

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

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

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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 OLpur 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:

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- Dialysis
 - o 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.
 - o 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 β_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. Pur