NEPHROS INC
Form 10-K
March 29, 2011

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, 2010

¨ 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, 2010, was approximately $9,860,000. 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, 2010. 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, 2010.

As of March 28, 2011 there were 10,065,117 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

Reverse Stock Split

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

Overview

Founded in 1997, we are a Delaware corporation that has been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. In January 2006, we introduced our 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:

- OLpūr™ 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;

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

- OLpūr 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 2011, 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. Prior to March 2010, the FDA did not provide us with any additional requests for information or render a decision on our application. After we made additional inquiries to the FDA about the status of our application, the FDA informed us on March 10, 2010 that our application was still under their review process.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. Based upon the meeting with the FDA reviewers and ongoing communication, we are evaluating the appropriate course of future action, which could include filing a new 510(k) application or pursuing dispute resolution related to the current application. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. We also intend to utilize the FDA's Ombudsman process, as applicable. We have a meeting scheduled with the FDA for April 20, 2011 to discuss a proposal for submission of a new 510(k) application. Depending on the results of that meeting, we currently anticipate proceeding with the submission of a new 510(k) application for approval of our hemodiafiltration system in the U.S. by the third quarter of 2011 which would be subject to the FDA's standard 90-day review period. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

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 nearly 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of December 10, 2010), 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.

During the twelve months ended December 31, 2010, we were granted six new patents. In the U.S., we were issued patent #7,775,375 for our Dual Stage Ultrafilter (DSU). In Canada, we were issued patents #2,431,431 for a Multistage Hemodiafiltration/Hemofiltration Method and Apparatus which forms the basis of our mid-dilution technology and patent #2,437,090 for a Method and Apparatus for a Hemodiafiltration Delivery Module which covers our H2H Hemodiafiltration device. In Japan, we were issued patents #4623909 and #4436569 for a Sterile Fluid Filtration Cartridge and a Non-Isomotic Diafiltration Sytem and Method, respectively. And in Europe, European patent #134787821 was granted for our OLpūr MD HDF Filter under the title, Dual Stage Hemodiafiltration cartridge, and whereby individual patents were granted in the countries of Germany, France, Italy, Spain, United Kingdom,

Netherlands, Sweden, and Hong Kong.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $846,000 and $423,000 has been billed to this second project during the year ended December 31, 2010 and the four months ended December 31, 2009, respectively. Approximately $1,269,000 of revenue has been recognized on this second project since its beginning in September 2009.

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

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

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. Nephros received an initial payment upon entering into the agreement and is eligible to receive additional payments upon successful completion of product development milestones.

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, 2010 and 2009, we have incurred net losses of $1,933,000 and $2,026,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2010 and 2009. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

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

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

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

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

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

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

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.

Current ESRD Therapy Options

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

- Dialysis

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

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

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

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

Hemodialysis is the most common form of extracorporeal renal replacement therapy and is generally used in the United States. Hemodialysis fails, in our opinion, to address satisfactorily the long-term health or overall quality of

life of the ESRD patient. We believe that the HDF process, which is currently available in our Target European Market and Japan, offers improvement over other dialysis therapies because of better ESRD patient tolerance, superior blood purification of both small and middle molecules, and a substantially improved mortality risk profile.

Current Dialyzer Technology used with HDF Systems

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

- With pre-dilution, substitution fluid is added to the blood before the blood enters the dialyzer cartridge. In this process, the blood can be over-diluted, and therefore more fluid can be drawn across the membrane. This enhances removal of toxins by convection. However, because the blood is diluted before entering the device, it actually reduces the rate of removal by diffusion; the overall rate of removal, therefore, is reduced for small molecular weight toxins (such as urea) that rely primarily on diffusive transport.

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

The Nephros Mid-Dilution Diafiltration Process

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

Our ESRD Therapy Products

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

OLpur MDHDF Filter Series

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

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

We have 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. During 2010, we replaced TÜV with BSI America, Inc. as our notified body.

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

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

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

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. Based upon the meeting with the FDA reviewers and ongoing communication, we are evaluating the appropriate course of future action, which could include filing a new 510(k) application or pursuing dispute resolution related to the current application. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. We also intend to utilize the FDA's Ombudsman process, as applicable. We intend to use some of the proceeds from our recently completed rights offering to resume our analysis of the best course of action. We have a meeting scheduled with the FDA for April 20, 2011 to discuss a proposal for submission of a new 510(k) application. Depending on the results of that meeting, we currently anticipate proceeding with the submission of a new 510(k) application for approval of our hemodiafiltration system in the U.S. by the third quarter of 2011 which would be subject to the FDA's standard 90-day review period. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

OLpur HD190

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

OLpur 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.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. An in-person meeting with the FDA took place on September 10, 2010, where the issues raised in the current FDA letter were discussed as well as the process for moving forward. Based upon the meeting with the FDA reviewers and ongoing communication, we are evaluating the appropriate course of future action, which could include filing a new 510(k) application or pursuing dispute resolution related to the current application. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. We also intend to utilize the FDA's Ombudsman process, as applicable. We intend to use some of the proceeds from our recently completed rights offering to resume our analysis of the best course of action. We have a meeting scheduled with the FDA for April 20, 2011 to discuss a proposal for submission of a new 510(k) application. Depending on the results of that meeting, we currently anticipate proceeding with the submission of a new 510(k) application for approval of our hemodiafiltration system in the U.S. by the third quarter of 2011 which would be subject to the FDA's standard 90-day review period. The current decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

OLpur NS2000

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

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

Our Water Filtration Product

In January 2006, we introduced our Dual Stage Ultrafilter, or DSU, water filtration system. The DSU incorporates our unique and proprietary dual stage filter architecture. Our research and development work on the OLpur H2H and MD filter technologies for ESRD therapy provided the foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to various contaminated water and infection control issues. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. We believe our DSU offers four distinct advantages over competitors in the water filtration marketplace:

1) the DSU is, to our knowledge, the only water filter that has the potential to provide the user with a simple sight verification that the filter is properly performing its cleansing function due to our unique dual-stage architecture;

2) the DSU filters finer biological contaminants than other filters of which we are aware in the water filtration marketplace;

3) the DSU filters relatively large volumes of water before requiring replacement; and

4) the DSU continues to protect the user even if the flow is reduced by contaminant volumes, because contaminants do not cross the filtration medium.

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

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

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately $900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new $1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop

them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately $846,000 and $423,000 has been billed to this second project during the year ended December 31, 2010 and the four months ended December 31, 2009, respectively.

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

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. Nephros received an initial payment upon entering into the agreement and is eligible to receive additional payments upon successful completion of product development milestones.

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

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

Our Strategy

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

Showcase Product Efficacy in our Target European Market: As of March 2004, we initiated marketing in our Target European Market for the OLpur 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 200,000 treatments to date.

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

Convert Existing Hemodialysis Machines to Hemodiafiltration: Upon completion of the appropriate documentation for our OLpur H2H technology, we plan to apply for Conformité Européene, or CE, marking in Europe for our OLpur H2H during 2011. 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 2011, our OLpur H2H and MDHDF filters will be the first and only HDF therapy available in the United States at that time.

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

Develop a Foothold in the Healthcare Arena by Offering our DSU as a Means to Control Environment-Acquired Infections : We believe our DSU offers an effective, and cost-effective, solution in conquering certain infection control issues faced by hospitals, nursing homes, assisted living facilities and other patient environments where chemical or heat alternatives have typically failed to adequately address the problem. The DSU provides for simple implementation without large capital expenses. We have established a goal in 2011 to gain a foothold at U.S. 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, such as currently being done under a development contract with STERIS Corporation. Our H2H has potential applications in acute patient care and controlled provision of ultrapure fluids in the field. Our DSU represents a new and complementary product line to our existing ESRD therapy business; we believe the Nephros DSU can offer a robust solution to a broad range of contaminated water and infection control issues.

Manufacturing and Suppliers

We do not 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 current 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.

The Company entered into an agreement in December 2003, as amended in June 2005, with a fiber supplier ("FS"), a manufacturer of medical and technical membranes for applications such as dialysis, to continue to produce the fiber for the OLpur MDHDF filter series. Pursuant to the agreement, the FS is the Company's 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 the Company that it is exercising its right to terminate the supply agreement. Termination of the supply agreement was effective on July 18, 2010. The FS has continued to sell fiber to the Company while negotiations on terms of a new supply agreement have continued. With proceeds from our recently completed rights offering, we intend to resume contract negotiations, which had been put on hold due to our cash needs in 2010.

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 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. In July 2010, we announced a distribution agreement with AmeriWater Corporation and that AmeriWater had adopted the Nephros DSU as a standard component of its MRO portable reverse osmosis water treatment systems for dialysis. Our DSU manufacturer in Europe shares certain intellectual property rights with us for one of our DSU designs.

During 2011, we plan to increase our sales and marketing activities in an effort to significantly expand our market presence in the dialysis and infection control arenas. To this end, in March 2011, we engaged Zwolinski Management Consulting to facilitate and reinforce our sales and marketing efforts.

Research and Development

Our research and development efforts c