NEPHROS INC
Form 10KSB
April 20, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

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

For the fiscal year ended December 31, 2005

OR

[ ] 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.
(Name of Small Business Issuer in its Charter)

Delaware	13-3971809
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3960 Broadway
New York, NY 10032

(Address of principal executive offices)

(212) 781-5113

(Issuer's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.001 par value per share	American Stock Exchange

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

Title of Class

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. [ ]

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 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 [ ] NO [X]

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [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]

State issuer's revenues for fiscal year ended December 31, 2005: $2,424,483.

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $11,202,453 computed by reference to the closing price of the common stock on April 13, 2006.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	**Outstanding at March 31, 2006**
Common Stock, $.001 par value	12,317,992

The following documents are incorporated by reference into the Annual Report on Form 10-KSB: Portions of the Registrant's definitive Proxy Statement to be filed for its 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

Transitional Small Business Disclosure Format YES [ ] NO [X]

NEPHROS, INC. AND SUBSIDIARY

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PART I

Item 1. Description of Business.

Overview

We are a Delaware corporation founded in 1997 by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease, or ESRD, therapy technology and products that would address both patient treatment needs and the clinical and financial needs of the treatment provider. We currently have three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy to ESRD patients:

- OLpūr MDHDF filter series (currently consisting of our MD190 and MD220 diafilters) designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

- OLpūr H_2H, 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 OLpūr HD 190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpūr MD series but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpūr HD190 was designed for use with either hemodialysis or hemodiafiltration machines, and received its approval from the U.S. Food and Drug Administration, or the FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act, in June 2005.

OLpūr and H_2H are among our trademarks for which U.S. registrations are pending. H_2H 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 OLpūr 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 OLpūr H_2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profile), and, therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. We believe that the OLpūr MDHDF filter series and the OLpūr H_2H 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 OLpūr NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

In January 2006, we introduced our new Dual Stage Ultrafilter (the “DSU”) water filtration system. Our DSU represents a new and complimentary 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 OLpūr H_2H and 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 problems. 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, anthrax, HIV, Ebola virus, ricin toxin, *legionella*, fungi and *e-coli.* During January 2006, we received our first Purchase Order for our DSU from a major hospital in New York City that will use it initially in the hospital's patient showers. 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 have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology. However, there can be no assurance that our efforts to market the DSU to hospitals will be successful, or that we will be able to successfully apply the DSU to any other markets.

The Company continues to evaluate funding opportunities as we do not generate enough revenue through the sale of our products or licensing revenues to meet our expenditure needs. For additional information of factors which could effect our ability to meet its obligations to please refer to Liquidity and Capital Resources section of this report.

ESRD Industry Background

ESRD is characterized by irreversible loss of kidney function and ESRD is usually the result of years of chronic kidney disease caused by inherited conditions, prolonged medical conditions such as diabetes or high blood pressure, or other events or conditions that harm the kidneys. A healthy kidney removes excess water and various waste products from the blood stream, a process critical to maintaining life. In addition, kidneys play a significant role with hormone levels contributing to healthy bones and red blood cell production. When kidney function drops below certain parameters, treatment is required for patient survival. There are currently only two methods for treating ESRD—renal replacement therapy and kidney transplantation. We believe that, so long as the shortage of suitable kidneys for transplants persists, ESRD patients will continue to need some form of renal replacement therapy and the supplies it requires.

The dialysis filter (also referred to as a dialyzer or an "artificial kidney") is an essential component of extracorporeal ESRD therapy. We are currently competing in the HDF dialyzer market using our OLpūr MDHDF filter series (MD190 and MD220) in part or all of Cyprus, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom (referred to in this Annual Report collectively as our "Target European Market"). There are currently no FDA approved HDF therapies available in the U.S. market. If we can obtain FDA approval of the OLpūr MDHDF filter series and OLpūr$_2$**H**, we could enter the U.S. ESRD market by combining our OLpūr MDHDF filters with our OLpūr$_2$**H** device to enable the HDF process on the most common hemodialysis machines.

There is an important distinction between the dialyzer markets in the United States and those in our Target European Market and Japan. In the United States, a majority of dialysis clinics reuse dialyzers - that is, a single dialyzer is disinfected and reused by the same patient. However, the trend in our Target European Market is towards single use, or not reusing dialyzers, and some countries (such as France, Germany, Italy, the Netherlands and Japan) actually forbid the reuse of dialyzers. As a result, we believe that our Target European Market and Japan provide substantially larger dialyzer markets than the United States on a per patient basis. Assuming patients receive three treatments per week, up to 156 dialyzers per patient per year are used in markets where single use is employed.

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:

- *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.”

- *Hemodiafiltration,* or HDF, in its basic form combines the principles of hemodialysis with hemofiltration. Hemofiltration is a cleansing process without dialysate solution where blood is passed through a semi-permeable membrane, which filters out solute particles. 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 of other dialysis therapies because of better ESRD patient tolerance and superior blood purification of both small and middle molecules.

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 OLpūr 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:

OLpūr MDHDF Filter Series

OLpūr 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 OLpūr 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 OLpūr MD190 as compared to conventional dialyzers in Montpellier, France in 2003. The results from this clinical study support our belief that OLpūr MD190 is superior to post-dilution hemodiafiltration using a standard high-flux dialyzer with respect to ß2-microglobulin clearance. In addition, clearances of urea, creatinine, and phosphate met the design specifications proposed for the OLpūr MD190 device. Furthermore, adverse event data from the study suggest that hemodiafiltration with our OLpūr MD190 device was well tolerated by the patients and safe.

We have initiated clinical studies in the United Kingdom, France, Germany and Italy to further demonstrate the therapeutic benefits of our OLpūr MDHDF filter series. A multi-center study was started in March 2005. This study encompasses 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.

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 OLpūr MD190 (which also covers other dialyzers in our MDHDF filter series), as well as certification of our overall quality system, on July 31, 2003.

We initiated marketing of our OLpūr MD190 in our Target European Market in March 2004, and we have developed our infrastructure both at a clinical and administrative level to support sales. We have established a sales presence in countries throughout our Target European Market, both through direct contact and through a distribution network, developed marketing material in the relevant local languages and attended trade shows where we promoted our product to several thousand people from the industry. Our OLpūr MD220 is a new product that we began selling in our Target European Market in 2006. The OLpūr MD220 employs the same technology as our OLpūr MD190, but contains a larger surface area of fiber.

We are currently offering the OLpūr MD190 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.

We have initiated discussions with the FDA to facilitate the approval process for our OLpūr MDHDF filter series and OLpûr H_2H products. Depending on our discussions with the FDA, we could file 510(k) applications with respect to the OLpūr MDHDF filter series and the OLpūr $_2$**H** in 2006 and would then hope to achieve U.S. regulatory approval of both products during the first half of 2007.

OLpūr HD190

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

In June 2005, we received 510(k) clearance for our OLpūr HD190 high flux filter from the FDA. While we do not expect our OLpūr HD190 high flux filter to offer a substantial sales opportunity in the foreseeable future, we expect this approval to help us streamline the regulatory review and approval process for our OLpūr MDHDF filter series in the United States.

OLpūr H_2H

OLpūr H_2H 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 OLpūr MDHDF filter. We have completed our OLpūr H_2H design and laboratory bench testing, all of which were conducted by members of our research and development staff. We believe that our design verification of the OLpūr H_2H will have progressed to the point where the device will be ready for U.S. clinical trials in the second quarter of 2006, and, provided that such trials are timely and successful, we expect to file 510(k) applications with respect to the OLpūr MDHDF filter series and the OLpūr H_2H in the fourth quarter of 2006 and hope to achieve U.S. regulatory approval of both products during the first half of 2007. We plan to apply for CE marking of our OLpūr H_2H in the second quarter of 2006.

OLpūr NS2000

OLpūr NS2000 is our standalone HDF machine and associated filter technology, which is in the development stage. The OLpūr NS2000 system is currently in development in conjunction with an established dialysis machine manufacturer in Italy. The OLpūr NS2000 will use the basic platform provided by this manufacturer, but will incorporate our H_2H technology including our proprietary substitution fluid systems.

We have also designed and developed proprietary substitution fluid filter cartridges for use with OLpūr 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 OLpūr NS2000 in our Target European Market or the United States. We have targeted a 2007 initial regulatory approval for the OLpūr NS2000 product.

Our Water Filtration Product

In January 2006, we introduced the 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 OLpūr 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 a broad range of contaminated water problems. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including *salmonella*, hepatitis, anthrax, HIV, Ebola virus, ricin toxin, *legionella*, fungi and *e-coli.* We believe our DSU offers four distinct advantages 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 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.

During January 2006, we received our first Purchase Order for our DSU from a major hospital in New York City that will use it initially in the hospital's patient showers. 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 the quality of life of 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 OLpūr MD190. There is an immediate opportunity for sales of the OLpūr MDHDF filters in our Target European Market because there is an established HDF machine base using disposable dialyzers. We believe that by demonstrating the effectiveness of our MDHDF filter series we will encourage more customers to purchase our products.

Convert existing hemodialysis machines to hemodiafiltration: Upon completion of the development of our OLpūr H_2H technology we plan to apply for CE marking for OLpūr H_2H during the second quarter of 2006. We plan to complete our regulatory approval processes in the United States for both our OLpūr MDHDF filter series and our OLpūr $_2$**H** during the first half of 2007. If successfully developed and approved, our OLpūr H_2H product will enable HDF therapy using the most common types of hemodialysis machines together with our OLpūr MDHDF filters. Our goal is to achieve market penetration by offering the OLpūr H_2H for use by healthcare providers inexpensively, thus permitting the providers to use the OLpūr H_2H without a large initial capital outlay. We do not expect to generate any significant positive margins from sales of OLpūr H_2H. We believe H_2H will provide basis for more MDHDF filter sales.

Upgrade dialysis clinics to OLpūr NS2000: We believe the introduction of the OLpūr 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 OLpūr H_2H technology. We believe dialysis clinics will entertain OLpūr NS2000 as an alternative to their current technology at such dialysis clinic's machine replacement point.

Explore Complimentary Product Opportunities: Where appropriate, we are also seeking to leverage our technologies and expertise by applying them to new markets. Our DSU represents a new and complimentary 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 problems.

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, and amended on March 22, 2005 with Medica s.r.l., a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpūr MD190, or other filter products at our option. The agreement requires us to purchase from Medica the OLpūr MD190s or other filter products that we directly

market in Europe, or marketed by our distributor in Italy. In addition, Medica will be given first consideration in good faith for the manufacture of OLpūr MD190s or other filter products that we do not directly market. No less than semiannually, Medica will provide a report to representatives of both parties to the agreement detailing any technical know-how that Medica has 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 Medica will reimburse us up to half of the cost of the quantity of fiber represented by excess wastage. Medica will manufacture the OLpūr MD190 or other filter products in accordance with the quality standards outlined in the agreement. Upon recall of any OLpūr MD190 or other filter product due to Medica's having manufactured one or more products that fail to conform to the required specifications or were not manufactured in accordance with any applicable laws, Medica 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 Medica against certain liabilities arising out of our products that they manufacture, providing they do not arise out of Medica's breach of the agreement, negligence or willful misconduct. The term of the

agreement is through May 12, 2009, 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, Medica has also been manufacturing our DSU in limited quantities.

We also entered into an agreement in December 2003 and amended in June 2005, with Membrana GmbH, a manufacturer of medical and technical membranes for applications like dialysis with corporate headquarters located in Germany, to continue to produce the fiber for the OLpūr MDHDF filter series. Pursuant to the agreement, Membrana will be our exclusive provider of the fiber for the OLpūr MDHDF filter series in the European Union as well as other certain territories through September 2009. Notwithstanding the exclusivity provisions, we may purchase membranes from other providers if Membrana is unable to timely satisfy our orders. If and when the volume-discount pricing provisions of our agreement with Membrana become applicable, for each period we will record inventory and cost of goods sold for our fiber requirements pursuant to our agreement with Membrana GmbH based on the volume-discounted price level applicable to the actual year-to-date cumulative orders at the end of such period. If, at the end of any subsequent period in the same calendar year, actual year-to-date cumulative orders entitle us to a greater volume-discount for such calendar year, then we will adjust inventory and cumulative cost of goods sold amounts quarterly throughout the calendar year to reflect the greater volume-discount.

Sales and Marketing

We have established and are seeking to expand our own sales and marketing organization to sell products in our Target European Market and, subject to regulatory approval, the United States. Our sales and marketing staff has experience in both these geographic areas.

We have established a multi-lingual customer service and financial processing facility in Dublin, Ireland, with multi-lingual customer support available to our customer base in our Target European Market. We have engaged a full time Director of Clinical Services who has a background in nephrology nursing, administration and education who provides customer training and support. We have also initiated four studies designed to continue our evaluation of effectiveness of the OLpūr MDHDF filters when used on ESRD patients in our Target European Market. We intend for these studies to provide us with valuable information regarding the efficacy of our product and an opportunity to introduce OLpūr MDHDF filters to medical institutions in our Target European Market. We have engaged a medical advisor to help us in structuring our clinical study protocols, and to support physicians' technical inquiries regarding our products.

We intend to market our 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, and through a warehouse facility in the Netherlands. We have engaged, and are in discussions with product distributors in our Target European Market, and major medical device manufacturers/providers in our Target European Market and Japan regarding license and/or distribution opportunities for our technology.

On March 2, 2005, we entered into a license agreement with Asahi Kasei Medical Co., Ltd. ("Asahi"), a business unit of Asahi Kasei Corporation, granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpūr MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, we received an up front license fee in the amount of $1.75 million, and we are entitled to receive additional royalties and payments based on the future sales of such products in Japan, which sales are subject to Japanese regulatory approval which is an obligation of Asahi.

Research and Development

Our research and development efforts continue on several fronts directly related to our current product lines. In particular, in the ESRD therapy domain we are examining ways to enhance further the removal of toxins from the blood by modifying certain blood characteristics. We have applied, and will continue to apply, if and when available, for U.S. Government grants in relation to this research, and will apply for further grants as appropriate. We received a U.S. Government grant in the amount of $99,837 beginning in the third quarter of 2003 to pursue some of this research. According to the terms of the grant, we seek reimbursement from the U.S. Government for expenses incurred with respect to this research. As of December 31, 2005, we have submitted claims of $46,992 for expenses related to the grant and have received reimbursements for such claims. We are also working on additional machine devices, next-generation user interface enhancements and other product enhancements. In the area of water filtration, we are finalizing our initial water filtration product line and developing refinements and enhancements to ensure our water filtration products meet customer needs for various applications. To date, we have not engaged any outside engineering, hired any additional personnel or otherwise incurred any material separate research and development expenses specifically allocated to water filtration product development. Our research and development expenditures were primarily related to development expenses associated with the H_2H machine and salary expense for the fiscal years ended December 31, 2005 and 2004 and were $1,756,492 and $2,352,604, respectively.

Competition

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

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

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

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

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

· displaying our products and providing associated literature at major industry trade shows in the United States, our Target European Market and Asia;

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

· offering the OLpūr H_2H at a price that does not provide us with significant positive margins in order to encourage adoption of this product and associated demand for our dialyzers; and

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

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

· developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;

· offering unique attributes that illustrate our product reliability, “user-friendliness,” and performance capabilities;

· selling products to specific customer groups where our unique product attributes are mission-critical; and

· pursuing alliance opportunities for joint product development and distribution.

Intellectual Property

Patents

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

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus

for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge," have claims that cover the OLpūr MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Although there are pending applications with claims to the present embodiments of the OLpūr H_2H and the OLpūr NS2000 products, these products are still in the development stage and we cannot determine if the applications (or the patents that may issue on them) will also cover the ultimate commercial embodiment of these products. In addition, technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have applied for patents on our DSU water filtration system.

As of March 30, 2006, we have ten issued U.S. patents; one issued Eurasian patent; and two issued Chinese patents. In addition, we have eight pending U.S. patent applications, thirteen pending patent applications in each of the European Patent Office, Japan and Canada, four pending patent applications in each of Brazil, Israel, South Korea and Mexico, three pending patent applications in Russia and three pending patent applications in China and Hong Kong. The titles, patent numbers and normal expiration dates (assuming all the U.S. Patent and Trademark Office fees are paid) of our ten issued U.S. patents are set forth in the chart below.

	Patent Number	**Expiration Date**
Method and Apparatus for Efficient Hemodiafiltration . . .	6,303,036	July 30, 2019
Two Stage Diafiltration Method and Apparatus	6,406,631	July 30, 2019
Non-Isosmotic Diafiltration System	6,423,23	October 29, 2019
Dual Stage Hemodiafiltration Cartridge	6,315,895	December 30, 2019
Sterile Fluid Filtration Cartridge and Method for Using Same	6,635,179	December 30, 2019
Method for High Efficiency Hemofiltration	6,620,120	May 22, 2018
Thermally Enhanced Dialysis/Diafiltration System	6,716,356	May 29, 2021
Dual-Stage Filtration Cartridge	6,719,907	January 26, 2022
Ionic Enhanced Dialysis/Diafiltration System.	6,821,431	June 3, 2021
Method and Apparatus for a Hemodiafiltration Delivery Module	6,916,424	February 7, 2022

Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal. We also have pending patent applications on our DSU water filtration system.

Trademarks

As of December 31, 2005, we do not have any registered trademarks. Centrapur, OLpūr, and our stylized "N" logo are among our non-registered trademarks, for which trademark registration applications are pending in both the U.S. Patent and Trademark Office and the European Union Office for Harmonisation in the Internal Market. H_2H is a trademark of ours which is registered in the European Union and for which we have a registration application pending in the U.S.

Governmental Regulation

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

United States

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

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

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

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

Before a new medical device can be introduced to the market, FDA clearance of a pre-market notification under Section 510(k) of the FDC Act or FDA clearance of a pre-market approval, or PMA, application under Section 515 of the FDC Act must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process. We understand that it generally takes four to 12 months from the date a Section 510(k) notification is accepted for filing to obtain Section 510(k) pre-market clearance and that it could take several years from the date a Section 515 application is accepted for filing to obtain Section 515 pre-market approval, although it may take longer in both cases. On March 8, 2005 we submitted a filing to the FDA, a Pre-market Notification under section 510(k), for approval of our OLpūr HD190 high flux filter and in June 2005 we received 510(K) clearance of the device. This filing is designed to help us streamline the regulatory review and approval process, and may provide us with a useful predicate device as we move forward on our OLpūr MDHDF filter series products in the United States.

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

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

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

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

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

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

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

If human clinical trials of a device are required in connection with a Section 510(k) notification and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or distributor of the device) will need to file an Investigational

Device Exemption, or IDE, application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal testing and/or laboratory bench testing. If the IDE application is approved, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as specified in the IDE. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of subjects. We intend to file IDEs with respect to the OLpūr MDHDF filter series, the OLpūr H_2H and the OLpūr NS2000. We have initiated discussions with the FDA to facilitate the 510(k) approval process. As a result of such discussions, we believe that a separate U.S. clinical study would be to our advantage. We believe that our design verification of the OLpūr H_2H will have progressed to the point where the device will be ready for U.S. clinical trials in the second quarter of 2006 and, provided that such trials are successful, we expect to file 510(k) applications with respect to the OLpūr MDHDF filter series and the OLpūr H_2H in the second half of 2006 and hope to achieve U.S. regulatory approval of both products during the first half of 2007.

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

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

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

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

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

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

and sell our products.

Before the FDA approves a Section 510(k) pre-market notification, the FDA is likely to inspect the relevant manufacturing facilities and processes to ensure their continued compliance with QSR. Although some of the manufacturing facilities and processes that we expect to use to manufacture our OLpūr MDHDF filters and OLpūr NS2000 have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not all been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpūr H_2H have been inspected by the FDA, they have not all been inspected by any notified body. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. Even after the FDA has cleared a Section 510(k) submission, it will periodically inspect the manufacturing facilities and processes for compliance with QSR. In addition, in the event that additional manufacturing sites are added or manufacturing processes are changed, such new facilities and processes are also subject to FDA inspection for compliance with QSR. The manufacturing facilities and processes that will be used to manufacture our

products have not yet been inspected by the FDA for compliance with QSR. We cannot assure you that the facilities and processes used by us will be found to comply with QSR and there is a risk that clearance or approval will, therefore, be delayed by the FDA until such compliance is achieved.

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

- all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;

- information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur; and

- certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

European Union

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

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

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

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

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

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

We also plan to sell our ESRD therapy products in foreign markets outside the United States which are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to

export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. Other than the CE marking of our OLpūr MDHDF filter products, we have not obtained any regulatory approvals to sell any of our products and there is no assurance that any such clearance or certification will be issued. We anticipate obtaining CE marking of our OLpūr H_2H product during the second half of 2006, and regulatory approval in the United States in the first half of 2007.

Reimbursement

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

Product Liability and Insurance

The production, marketing and sale of kidney dialysis products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our OLpūr MDHDF filter products in the amount of $5 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.

Some of our existing and potential agreements with manufacturers of our products and components of our products do or may require us (1) to obtain product liability insurance or (2) to indemnify manufacturers against liabilities resulting from the sale of our products. If we are not able to maintain adequate product liability insurance, we will be in breach of these agreements, which could materially adversely affect our ability to produce our products. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

Employees

As of December 31, 2005, we employed a total of 22 employees, 21 of whom were full time and one who was employed on a consulting basis or part-time.

Recent Developments: Late Filing of Annual Report

This Annual Report on Form 10-KSB was not timely filed.

On April 19, 2006, we received notice (the "Amex Notice") from the American Stock Exchange (the "Amex") regarding our failure to timely file our annual report on Form 10-KSB for the year ended December 31, 2005. According to the Amex Notice, our failure to timely file our annual report resulted in a violation of Sections 134 and 1101 of the Amex Company Guide and our listing agreement with the Amex. The Amex Notice further stated that, pursuant to Section 1003(d) of the Amex Company Guide, the Amex is authorized to suspend and, unless prompt corrective action is taken, remove our securities from the Amex. We believe that the filing of this annual report on Form 10-KSB would likely constitute such corrective action.

As a result of our failure to timely file our annual report on Form 10-KSB, we have breached the Registration Rights Agreement, dated as of May 17, 2000 and amended and restated as of June 26, 2003, between us and the Investors (as defined therein). Specifically, our delay in filing this Form 10-KSB constitutes a breach of our covenant in the Registration Rights Agreement to comply with all reporting requirements under the Exchange Act. We anticipate obtaining a waiver of this breach from the Investors. However, there can be no assurance that we will succeed in obtaining such waivers and, if these waivers are not obtained, then the Investors may have claims against us for damages that they incur as a result of such breach.

Item 2. Description of Property

Our U.S. facilities are located at 3960 Broadway, 4th Floor, New York, New York 10032 and consist of approximately 2,678 square feet of space. On July 1, 2005, we entered into a rental agreement for the use of this space with the Trustees of Columbia University in the City of New York. The term of the rental agreement is for one year with a monthly cost of $10,184, including monthly internet access. We use our facilities to house our corporate headquarters and research facilities. Our offices and laboratories are housed in the Mary Woodard Lasker Building, a part of the Audubon Business and Technology Center administered by Columbia University, which is equipped to accommodate biotechnology and medical product development companies. Of the space we license, approximately 1,500 square feet is dedicated laboratory space, which is equipped with laboratory equipment, such as benches, fume hoods, gas, air and water systems, and the remaining 1,178 square feet is dedicated office space.

Our facilities in our Target European Market are located at 1st Floor, Suite 5, The Avenue, Beacon Court, Sandyford, Dublin 18, Ireland and consist of approximately 700 square feet of space. On August 1, 2003 we entered into a lease for this space with Mohan & Company, an accounting firm wholly-owned by our Director of Finance, Europe, Cormac Mohan. The term of the lease is for three years with a current monthly cost of 3,500 Euro (approximately $4,200 as of December 31, 2005). We use our facilities to house our customer service and accounting operations. The Avenue, Beacon Court is a new office complex within approximately 10 miles of downtown Dublin. We believe this space is currently adequate to meet our needs.

We do not own any real property for use in our operations or otherwise.

Item 3. Legal Proceedings

There is no currently pending legal proceeding and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject. Please refer to the "Risks Related to Our Company" section of this report for a discussion of certain threatened litigation and please refer to "Note 10 to the Condensed Consolidated Financial Statements" for a discussion of certain settlement arrangements.

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

There were no matters submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this Report.

PART II

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

Our common stock began trading on the American Stock Exchange ("AMEX") on September 21, 2004 under the symbol NEP. The following table sets forth the high and low sales prices for our common stock as reported on the AMEX for each quarter within the years ended December 31, 2005 and 2004.

Quarter Ended	High	Low
September 30, 2004	$6.27	$4.76
December 31, 2004	$5.70	$3.90
March 31, 2005	$5.72	$3.34
June 30, 2005	$4.04	$2.08
September 30, 2005	$3.55	$2.80
December 31, 2005	$2.95	$1.35

As of April 12, 2006, there were approximately 46 holders of record and approximately 993 beneficial holders of our common stock.

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

The initial public offering of our common stock, par value $.001 (the "Offering"), was effected through a Registration Statement on Form S-1 (File No. 333-116162) that was declared effective by the Securities and Exchange Commission on September 20, 2004. From September 20, 2004 through December 31, 2005, of the net $10.8 million of proceeds from the Offering, we had used: approximately $2.950 million for the marketing and sales of our products; approximately $1.550 million on product engineering; approximately $530,000 for capital expenditures; approximately $350,000 on payments of preferred stock dividends; and approximately $2.2 million for working capital and other purposes. As of December 31, 2005, we held approximately $2.8 million of the remaining proceeds from the Offering in short term investments and $420,000 in cash and cash equivalents.

Item 6. Management's Discussion and Analysis or Plan of Operation

Business Overview

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpūr MD190 and MD220, which are dialyzers, OLpūr $_2$**H**, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines, and the OLpūr NS2000 system, a stand-alone HDF machine with associated filter technology. We began selling our OLpūr MD190 dialyzer in some or all of our Target European Market in March 2004, and have developed prototypes for our OLpūr H_2H product. We are developing our OLpūr NS2000 product in conjunction with an established machine manufacturer in Italy. We are working with this manufacturer to modify an existing HDF platform they currently offer for sale in parts of our Target European Market, incorporating our proprietary H_2H technology. We have also applied our filtration technologies to water filtration and, in January 2006, we received the first purchase order for our DSU.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval and establishing manufacturing and marketing relationships and our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European Market and the United States upon their approval by appropriate regulatory authorities.

Since our inception, we have incurred annual net losses. As of December 31, 2005, we had an accumulated deficit of $47.2 million, and we expect to incur additional losses in the foreseeable future. We recognized net losses of $5.5 million for the year ended December 31, 2005, and $7.6 million for the year ended December 31, 2004.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through December 31, 2005, we received net offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately $35.1 million in the aggregate. We have devoted substantially all of our capital resources to the research and development and the marketing of our products.

On March 2, 2005, we entered into a Subscription Agreement with Asahi, pursuant to which Asahi purchased 184,250 shares of our common stock for an aggregate of 100 million Japanese Yen ($955,521 or $5.19 per share). The Subscription Agreement contains certain transfer restrictions with respect to the shares purchased thereunder.

Also on March 2, 2005, we entered into a license agreement with Asahi granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpūr MDHDF filter series hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, we received an up front license fee in the amount of $1.75 million, and we are entitled to receive additional royalties and milestone payments based on the future sales of such products in Japan, which sales are subject to Japanese regulatory approval.

In January 2006, we received our first Purchase Order from a major hospital in New York City for our new water filtration device. The hospital has placed an initial order for our new Dual Stage Ultrafilter, or DSU, a water filtration system that will be used initially in the hospital's patient showers. This first Purchase Order will not, by itself, result in material net revenues.

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

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

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

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

(4) our ability to sell our products at competitive prices which exceed our per unit costs; and

(5) the consolidation of dialysis clinics into larger clinical groups.

To the extent we are unable to succeed in accomplishing (1) through (4), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (5), the impact could either be positive, in the case where dialysis clinics consolidate into independent chains, or negative, in the case where competitors acquire these dialysis clinics and use their own products, as competitors have historically tended to use their own products in clinics they have acquired.

New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board ("FASB") issued SFAS No. 154, "Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3". SFAS No. 154 replaces APB Opinion No. 20, "Accounting Changes" (APB 20) and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements," and changes the requirements for the accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements for voluntary changes in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made subsequent to January 1, 2006. The impact of SFAS No. 154 will depend on the accounting change, if any, in a future period.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations* (FIN 47). FIN 47 clarifies that an entity must record a liability for a conditional asset retirement obligation if the fair value of the obligation can be reasonably estimated. Asset retirement obligations covered by FIN 47 are those for which an entity has a legal obligation to perform an asset retirement activity, even if the timing and method of settling the obligation are conditional on a future event that may or may not be within the control of the entity. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective no later than the end of fiscal years ending after December 15, 2005. The adoption of this accounting pronouncement did not have a material effect on the Company's consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment," which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. SFAS No. 123R is effective for small business issuers the first interim reporting period beginning after December 15, 2005. Accordingly, we have adopted SFAS No. 123R for the quarter ending March 31, 2006. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods are either a prospective method or a retroactive method. Under the retroactive method, prior periods may be revised either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period revised. We will use the prospective method of transition in our adoption of SFAS No. 123R. We expect the impact in future periods to be consistent with the company's current pro-forma disclosure under SFAS No 123. We expect the adoption of 123R to have a material impact on the Company's consolidated results of operations.

In December 2004, the FASB issued SFAS 153 "Exchange of Non-monetary assets." This statement was a result of a joint effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. One such difference was the exception from fair value measurement in APB Opinion No. 29, "Accounting for Non-Monetary Transactions," for non-monetary exchanges of similar productive assets. SFAS 153 replaces this exception with a general exception from fair value measurement for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. This statement is effective for non-monetary assets exchanges occurring in fiscal periods beginning after June 15, 2005.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs." SFAS 151 amends Accounting Research Bulletin ("ARB") No. 43, Chapter 4. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS 151 is the result of a broader effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not expect the adoption of SFAS 151 to have a material impact on our consolidated results of operations.

Critical Accounting Policies and Estimates

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

Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104 Revenue Recognition. SAB No. 104 requires that four basic criteria must be met before revenue can be

recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed and determinable; and (iv) collectibility is reasonably assured.

We began sales of our first product in March 2004. Prior to fiscal 2005, our sales history did not provide a basis from which to reasonably estimate rates of product return. Consequently, for the fiscal year ended December 31, 2004 we did not recognize revenue from sales until the rights of return expired (thirty days after the date of shipment). Similarly, we deferred cost of goods sold to the extent of amounts billed to customers. Starting October 1 2005 sales were recorded net of provisions for estimated returns as we have a more reliable returns history. These estimates are revised as necessary, to reflect actual experience and market conditions.

During 2005, we entered into an agreement with Asahi, a business unit of Asahi Kasei Corporation, granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpūr MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, we received an up front license fee in the amount of $1,750,000, and we are entitled to receive additional royalties and payments based on the future sales of products in Japan, which sales are subject to Japanese regulatory approval. Because (i) the license agreement requires no continuing involvement in the manufacture and delivery of the licensed product in the covered territory of Japan; (ii) the criteria of SAB No. 104 have been met; and (iii) the license fee received is non-refundable, we recognized $1,750,000 in contract revenue on the effective date of the license agreement.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves identifying services which have been performed on our behalf, and the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for the preclinical development of our products, the manufacturing of clinical materials, and clinical trials, as well as legal and accounting services provided by professional organizations. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-Based Compensation

We accounted for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued in accordance with the EITF 96-18 “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services.”

We account for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to Employees,” and disclose the effect of the differences which would result had we applied the fair-value-based method of accounting on a pro forma basis, as required by Statement of Financial Accounting Standards (“SFAS”) No. 123, “Accounting for Stock-Based Compensation.”

We have elected to follow APB Opinion No. 25 and related interpretations in accounting for our employee stock options because the alternative fair value accounting provided for under SFAS No. 123, Accounting for Stock-Based Compensation, or SFAS No. 123, as amended by SFAS No. 148, requires use of option valuation models that were not developed for use in valuing employee stock options. Employee stock compensation expense, which is a non-cash charge, is measured as the excess, if any, of the fair value of our underlying common stock at the date of grant over the amount an employee must pay to acquire such stock. This compensation cost is either amortized over the related vesting periods, or expensed upon the reaching of certain milestones.

During December 2004, the FASB issued Statement No. 123R, “Share-Based Payment” (“SFAS No. 123R”), which requires companies to measure and recognize compensation expense for all stock-based payments at fair value.

Stock-based payments include stock option grants to our employees and directors. We grant options to purchase common stock to our employees and directors under various plans at prices equal to the market value of the stock on the dates the options were granted. SFAS No. 123R is effective for small business issuers the first interim reporting period beginning after December 15, 2005. Accordingly, we will adopt SFAS No. 123R as of January 1, 2006.

Inventory Reserves

The Company's inventory reserve requirements are based on factors including the products' expiration date and estimates for the future sales of product. If estimated sales levels do not materialize the Company will make adjustments to its assumptions for inventory reserves requirements.

Results of Operations

Fluctuations in Operating Results

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

The Fiscal Year Ended December 31, 2005 Compared to the Fiscal Year Ended December 31, 2004

Revenues

Revenues increased to $2,450,275 for the fiscal year ended December 31, 2005 from $138,406 for the fiscal year ended December 31, 2004. Revenues for the fiscal year ended December 31, 2005 represented licensing revenues of $1,750,000 resulting from our agreement with Asahi and shipments of our OLpūr MD190 product to customers in our Target European Market - which commenced in March 2004. Sales in 2005 reflect a full twelve months of sales and increased penetration of our target markets.

Cost of Goods Sold

Cost of goods sold increased to $379,462 for the fiscal year ended December 31, 2005 from $211,942 for the fiscal year ended December 31, 2004. Cost of goods sold represented the cost of our OLpūr MD190 product shipped to customers in our Target European Market in both fiscal years ended December 31, 2005 and December 31, 2004 as well as obsolete inventory written-off, in the amount of $123,159, in fiscal year ended December 31, 2004 due to the incorporation of improved fiber into our dialyzers. Cost of goods sold as a percentage of revenues, excluding the obsolete inventory write-off, decreased to 57.5% in fiscal year ended December 31, 2005 from 64.2% in fiscal year ended December 31, 2004 as a result of the improvement in purchasing efficiencies realized during fiscal 2005.

Research and Development

Research and development expenses decreased to $1,756,493 for the fiscal year ended December 31, 2005 from $2,352,604 for the fiscal year ended December 31, 2004. The $596,111 decrease was primarily due to a decrease in development expenses related to our OLpūr H_2H product due to a reduced number of hours required to be spent on the project by our outside developers, as a result of our H_2H engineering approaching completion, in the fiscal year ended December 31, 2005. Substantially all of our research and development expense has related to the development of the H_2H product. To date, we have not engaged any outside engineering, hired any additional personnel or otherwise incurred any material separate research and development expenses specifically allocated to water filtration product development.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $6,294,639 for the fiscal year ended December 31, 2005 from $5,220,250 for the fiscal year ended December 31, 2004. This $1,074,389 increase was primarily due to an increase in sales and marketing costs in our Target European Market, consisting principally of increased product sampling of our OLpūr MD190 product, costs associated with clinical trials being conducted in Europe, and increased personnel costs due to the hiring of sales and sales support personnel in the region.

In addition we have provided for the severance costs associated with the termination of the employment of Jan Rehnberg, our Senior Vice President, Marketing and Sales. In accordance with the terms and provisions of an employment agreement we are required to pay a one-time lump sum severance payment of approximately $318,250 to Mr. Rehnberg during the second quarter of 2006.

In addition, we experienced increased costs associated with being a public company, including legal fees, accounting fees, insurance premiums, stock market listing fees and investor relations expenses. Such increases were partially offset by a decrease in non-cash compensation in connection with options granted to employees.

Other Income, net

Other income, net increased to $856,294 for the fiscal year ended December 31, 2005 from $49,910 for the fiscal year ended December 31, 2004. This $806,384 increase is due to the gain of $623,087 recorded in conjunction with the settlement of the Ancillary Proceeding with Lancer Offshore, Inc. (See “Note 10—Commitments and Contingencies—Settlement Agreements” to the Condensed Consolidated Financial Statements for a description of the settlement), plus an increase in interest income for the fiscal year ended December 31, 2005 versus the fiscal year ended December 31, 2004 of $183,297. This increase represents increased interest income earned on cash deposits and short-term investments as a result of higher average balances of our cash and cash equivalents and short-term investments during the period ended December 31, 2005 versus December 31, 2004, combined with higher average interest rates in 2005 versus 2004.

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock decreased to $0 for the fiscal year ended December 31, 2005 from $11,734,533 for the fiscal year ended December 31, 2004. This decrease is because the conversion of our redeemable convertible preferred stock into common stock occurred in connection with our initial public offering in September 2004.

Off-Balance Sheet Arrangements

The Company did not engage in any off-balance sheet arrangements during the periods ended December 31, 2005.

Liquidity and Capital Resources

At December 31, 2005, we had an accumulated deficit of $47.2 million, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering in September 2004 and from licensing revenue of $1.75 million received from Asahi in March 2005 pursuant to a license agreement granting Asahi exclusive rights to manufacture and distribute filter products based on our OLp ur ™MD190 hemodiafilter in Japan.

At December 31, 2005, we had $0.7 million in cash and cash equivalents and approximately $4.5 million in short-term investments. We believe that these funds and our anticipated cash flows will be sufficient to fund our currently planned operations though the end of the third quarter of 2006. This time frame estimate includes the costs associated with our clinical trials in the United States for our OLpur MDHDF filters and H2H Module. Based on our current cash flow projections, we will need to raise additional funds through either the licensing of our technologies or the additional public or private offerings of our securities. We are currently investigating additional funding opportunities, talking to various potential investors who could provide financing and we believe that we will be able to secure financing in the near term. However, there is no guarantee that we will be able to obtain further financing.

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

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

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

- for the marketing and sales of our products;
- to complete certain clinical studies, obtain appropriate regulatory approvals and expand our research and development with respect to our ESRD therapy products;
- to continue our ESRD therapy product engineering;
- to pursue business opportunities with respect to our DSU water-filtration product;
- to pay the Receiver of Lancer Offshore, Inc. amounts due under the settlement with respect to the Ancillary Proceeding between us and the Receiver (See “Note 10—
- Commitments and Contingencies—Settlement Agreements” to the Condensed Consolidated Financial Statements for a description of the settlement);
- to pay severance to our former Senior Vice President, Marketing and Sales;
- to pay a former supplier, Plexus Services Corp., amounts due under our settlement agreement; and
- for working capital purposes and for additional professional fees and expenses and other operating costs.

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

Net cash used in operating activities was $5.1 million for the fiscal year ended December 31, 2005 compared to $7.8 million for the fiscal year ended December 31, 2004. The $2.7 million decrease in net cash used in operating activities during the fiscal year ended December 31, 2005 was primarily due to a smaller net loss from operations of $2.1 million in fiscal 2005 versus fiscal 2004. Additionally, the change in cash used in operating activities included reconciling items for a non-cash gain on the settlement of litigation and a decrease in non-cash stock based compensation. In addition, significant changes in balance sheet accounts that effected operating cash flows included an increase in inventory of $170,774 and an increase of $1,083,753 in accounts payable and accrued expenses due to the timing of expenses and factors related to the growth of the business.

Net cash provided by investing activities was $1.1 million for the fiscal year ended December 31, 2005 compared to a use of $6.9 million for the fiscal year ended December 31, 2004. This $8.0 million increase was due to redemptions of short-term investments being offset by a decreased amount of short-term investment purchases and fixed asset purchases, mainly manufacturing equipment for the production of our OLp r MD190 product in the fiscal year ended December 31, 2005 as compared to the fiscal year ended December 31, 2004. The short-term investment purchases in the 2004 period were made with proceeds from our initial public offering.

Net cash provided by financing activities was $1.0 million for the fiscal year ended December 31, 2005 compared to $14.3 million for the fiscal year ended December 31, 2004. The net cash provided by financing activities in the fiscal year ended December 31, 2005 was primarily due to the net proceeds of $955,521 from our sale of 184,250 shares of our common stock to Asahi pursuant to a Subscription Agreement dated March 2, 2005. The net cash provided by financing activities for the fiscal year ended December 31, 2004 was primarily due to the approximately $10.8 million in net proceeds raised from the initial public offering in September 2004 as well as the approximately $3.8 million in net proceeds raised from the issuance of Series D convertible preferred stock in March 2004.

Contractual Obligations and Commercial Commitments

The following tables summarize our minimum contractual obligations and commercial commitments as of December 31, 2005:

		Payments Due in Period		
Contractual Obligations	Total	Within 1 Year	Years 1 - 3	Years 3 - 5
Open Purchase Orders	$ 52,306	$ 52,306		
Leases	$ 90,504	$ 90,504	$ -	$ -
Employment Contracts	$ 427,500	$ 285,000	$ 142,500	$ -
Total	$ 570,310	$ 427,810	$ 142,500	$ -

Certain Risks and Uncertainties

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

Risks Related to Our Company

We have a history of operating losses and a significant accumulated deficit, and we may not achieve or maintain profitability in the future.

We have not been profitable since our inception in 1997. As of December 31, 2005, we had an accumulated deficit of approximately $ 47.2 million primarily as a result of our research and development expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

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

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

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

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

- the consolidation of dialysis clinics into larger clinical groups.

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2005, expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this Annual Report on Form 10-KSB expressing doubt as to our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations, raises substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or to do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be adversely affected.

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

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpūr MDHDF filter series product on July 31, 2003. We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance. Until we complete the requisite U.S. human clinical trials and submit pre-market notification to the FDA pursuant to Section 510(k) of the FDC Act or otherwise comply with FDA requirements for a 510(k) approval, we will not be eligible for FDA approval for any of our products, except for our HD190 filter.

In addition to the pre-market notification required pursuant to Section 510(k) of the FDC Act, the FDA could require us to obtain pre-market approval of our ESRD therapy products under Section 515 of the FDC Act, either because of legislative or regulatory changes or because the FDA does not agree with our determination that we are eligible to use the Section 510(k) pre-market notification process. The Section 515 pre-market approval process is a significantly more costly, lengthy and uncertain approval process and could materially delay our products coming to market. If we do obtain clearance for marketing of any of our devices under Section 510(k) of the FDC Act, then any changes we

wish to make to such device that could significantly affect safety and effectiveness will require clearance of a notification pursuant to Section 510(k), and we may need to submit clinical and manufacturing comparability data to obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the U.S.

The clearance and/or approval processes in the European Community and in the United States can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or any FDA approval for any of our ESRD therapy products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals with respect to the European Community or the United States would prevent us from selling our affected products in these regions. If we cannot sell some of our products in these regions, or if we are delayed in selling while awaiting the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

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

We have entered into an agreement with Asahi granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpūr MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. If the requisite Japanese regulatory approvals are not timely obtained, our potential license revenues will be limited.

We cannot assure you that our ESRD therapy products will be safe and we are required under applicable law to report any product-related deaths or serious injuries or product malfunctions that could result in deaths or serious injuries, and such reports could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.

We cannot assure you that our ESRD therapy products will be safe. Under the FDC Act, we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and product malfunctions that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;

- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and

- if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to gain market acceptance of our ESRD therapy products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our ESRD therapy products.

Product liability associated with the production, marketing and sale of our products, and/or the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our goodwill.

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of $5 million for our dialysis filters outside of the U.S. and intend to acquire additional product liability insurance upon commercialization of any of our additional products or upon introduction of any products in the U.S., we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and goodwill and adversely affect the demand for our products, our ability to generate sales and our profitability.

Some of the agreements that we may enter into with manufacturers of our products and components of our products may require us:

- to obtain product liability insurance; or

- to indemnify manufacturers against liabilities resulting from the sale of our products.

For example, our agreement with Medica s.r.l. requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify Medica against certain liabilities arising out of our products that they manufacture, provided they do not arise out of Medica’s breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, we could be in breach of these

agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our ESRD therapy products. If we violate the FDC Act or other regulatory requirements at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including:

- fines;
- injunctions;
- civil penalties;
- recalls or seizures of our products;
- total or partial suspension of the production of our products;
- withdrawal of any existing approvals or pre-market clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations by the FDA that we not be allowed to enter into government contracts; and
- criminal prosecution.

Any of the above could have a material adverse effect on our business, financial condition and results of operations.

Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales and revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. Any future laws, regulations, interpretations, applications or enforcements could delay or prevent regulatory approval or clearance of our products and our ability to market our products. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

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

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 10 granted U.S. patents will expire at various times from 2018 to 2022, assuming they are properly maintained.

The protection provided by our patents, and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. Numerous publications may have been disclosed by, and numerous patents may have been issued to, our competitors and others relating to methods and devices for dialysis of which we are not aware and additional patents relating to methods and devices for dialysis may

be issued to our competitors and others in the future. If any of those publications or patents conflict with our patent rights, or cover our products, then any or all of our patent applications could be rejected and any or all of our granted patents could be invalidated, either of which could materially adversely affect our competitive position.

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

If we file patent applications or obtain patents in foreign countries, we will be subject to laws and procedures that differ from those in the United States. Such differences could create additional uncertainty about the level and extent of our patent protection. Moreover, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be as favorable

to us. Many non-U.S. jurisdictions, for example, prohibit patent claims covering methods of medical treatment of humans, although this prohibition may not include devices used for such treatment.

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

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

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

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

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

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

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

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

Independent manufacturers of medical devices will manufacture all of our products and components. We have contracted Medica s.r.l., a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpūr MD190 and possibly other filters, and have an agreement with Membrana GmbH, a manufacturer of medical and technical membranes for applications like dialysis with corporate headquarters located in Germany, to produce the fiber for the OLpūr MDHDF filter series. As with any independent contractor, these manufacturers will not be employed or otherwise controlled by us and will be generally free to conduct their business at their own discretion. For us to compete successfully, among other things, our products must be manufactured on a

timely basis in commercial quantities at costs acceptable to us. If one or more of our independent manufacturers fails to deliver our products in a timely manner, then we may not be able to find a substitute manufacturer. If we are not or if potential customers believe that we are not able to ensure timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.

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

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

of our manufacturers failed to manufacture our products or major components in accordance with the terms of our arrangements. If any such failure occurs and we are unable to obtain acceptable alternative arrangements for the manufacture of our products or major components of our products, then the production and sale of our products could slow down or stop, and our cash flow would suffer.

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

Approval or clearance of our ESRD therapy products could be delayed by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our ESRD therapy products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our ESRD therapy products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpūr MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpūr H_2H and OLpūr NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

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

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

Our products are, or will be, new to the market, and we do not yet have an established market or customer base for our products. Acceptance of our ESRD therapy products in the marketplace by both potential users, including ESRD patients, and potential purchasers, including nephrologists, dialysis clinics and other health care providers, is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform dialysis patients and nephrologists, dialysis clinics and other health care providers of the benefits of using our ESRD therapy products. We may encounter significant clinical and market resistance to our products and our products may never achieve market acceptance. Factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace include whether:

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

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance will limit our ability to generate revenue and be profitable. Many of the same factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace will also apply to our water filtration products, except for those related to side effects, clinical trials and third party reimbursement.

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

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

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

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

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

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

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

Our success depends upon the skills, experience and efforts of our management and other key personnel, including our chief executive officer, certain members of our scientific and engineering staff and our marketing executives. As a relatively new company, much of our corporate, scientific and technical knowledge is concentrated in the hands of these few individuals. We do not maintain key-man life insurance on any of our management or other key personnel other than Norman Barta, on whom we obtained a $1 million key-man life insurance policy. The loss of the services of one or more of our present management or other key personnel could significantly delay the development and/or launch of our products as there could be a learning curve of several months or more for any replacement personnel. Furthermore, competition for the type of highly skilled individuals we require is intense and we may not be able to attract and retain new employees of the caliber needed to achieve our objectives. Failure to replace key personnel could have a material adverse effect on our business, financial condition and operations.

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

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

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

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

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

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

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

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

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

- authorizing our board of directors to issue "blank check" preferred stock without stockholder approval;
- providing for a classified board of directors with staggered, three-year terms;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;

· prohibiting stockholder action by written consent unless the written consent is signed by all stockholders entitled to vote on the action;

· limiting the persons who may call special meetings of stockholders; and

· establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

Prior to our initial public offering completed on September 24, 2004, there was no public market for our common stock. Unlike many companies with publicly traded securities, we have little or no name recognition in the investment community. We are a relatively new company and very few investors are familiar with either our company or our products. As we will not be marketing our products directly to the public, it may be difficult for us to generate the kind of interest in our stock that other companies experience after an initial public offering. We do not have an active trading market in our common stock, and one might never develop, or if it does develop, might not continue.

Additionally, the market price of our common stock may fluctuate significantly in response to many factors, many of which are beyond our control. Risks and uncertainties, including those described elsewhere in this "Certain Risks and Uncertainties" section could impair our business operations or otherwise cause our operating results or prospects to be below expectations of investors and market analysts, which could adversely affect the market price of our common stock. As a result, investors in our common stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against the company. We may become involved in this type of litigation in the future. Litigation of this type could be extremely expensive and divert management's attention and resources from running our company.

We have identified a material weakness in our internal control over financial reporting with respect to our financial closing and review and analysis process. We cannot guarantee that we will be able implement controls to avoid the occurrence of this kind of problem in the future.

In connection with the audit of our financial statements, our auditors identified a material adjustment to accrued severence expense for the recognition of employee severance relating to the closing process with respect to the termination of one of our employees and a number of other adjustments relating to the closing process that were immaterial. We promptly recorded such adjustments, pursuant to which we accrued severance costs in the fourth quarter of 2005 associated with the termination of the employment of Jan Rehnberg, our Senior Vice President, Marketing and Sales, arising from our requirement to make a one-time lump sum severance payment of approximately $318,360 to Mr. Rehnberg during the second quarter of 2006. Our management concluded that our failure to book these severance and other adjustments prior to our auditors bringing them to our attention evidenced a material weakness in our internal control over financial reporting with respect to our financial closing and review and analysis process. The Audit Committee of our Board of Directors is continuing its review of our internal controls to determine how this material weakness occurred and how to implement controls designed to avoid the occurrence of this kind of problem in the future. If we are not able to implement controls to avoid the occurrence of this kind of problem in the future, we might report results that are not consistent with our actual results and we may need to restate results that will have been previously reported.

Because our capital requirements have been and will continue to be significant, we may need to raise additional funds or we will not be able to continue to operate our business. If our business fails, investors in our common stock could lose their entire investment.

Our capital requirements have been and will continue to be significant. Through December 31, 2005, we have been dependent primarily on the net proceeds of our initial public offering and private placements of our equity and debt securities, aggregating approximately $35.1 million. We generated an additional approximately $1.7 million in March 2005 from our license agreement with Asahi We are currently investigating additional funding opportunities. We cannot assure you that our existing capital resources, together with the net proceeds from future operating cash flows, if any, will be sufficient to fund our future operations. Our capital requirements will depend on numerous factors, including:

- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;

- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;

- the timing and costs associated with obtaining the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpūr MDHDF filter series, for which the CE mark was obtained in July 2003), or United States regulatory approval;

- the continued progress in and the costs of clinical studies and other research and development programs;

- the costs associated with manufacturing scale-up;

- the costs involved in filing and enforcing patent claims and the status of competitive products; and

- the cost of litigation, including potential patent litigation and actual, current and threatened litigation

If we require additional capital beyond the cash, if any, generated from our operations, we would need to seek other forms of financing, through the sale of equity securities or otherwise, to achieve our business objectives. We are currently investigating additional funding opportunities. We cannot assure you that we will be able to obtain alternative financing on acceptable terms or at all. Our failure to obtain financing when needed could have a material adverse effect on us. Any additional equity financing could substantially dilute your equity interests in our company and any debt financing could impose significant financial and operational restrictions on us.

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

As of December 31, 2005, our directors, executive officers and principal stockholders beneficially owned approximately 58.4% of our outstanding common stock. Should they act as a group, they will have the power to elect all of our directors and to control the vote

on substantially all other corporate matters without the approval of other stockholders. As of December 31, 2005, Ronald O. Perelman beneficially owned 28.8% of our outstanding common stock. WPPN, LP, Wasserstein SBIC Ventures II L.P., WV II Employee Partners, LLC, and BW Employee Holdings, LLC, entities that may be deemed to be controlled by Bruce Wasserstein (collectively, the "Wasserstein Entities"), beneficially owned an aggregate of 15.7% of our outstanding common stock, although Mr. Wasserstein himself disclaims beneficial ownership of the shares held by the Wasserstein Entities except to the extent of his pecuniary interest therein (which is less than 1% of our outstanding common stock). Our principal stockholders may have significant influence over our policies and affairs, including the election of directors. Furthermore, such concentration of voting power could enable those stockholders to delay or prevent another party from taking control of our company even where you might find such change of control transaction desirable.

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

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

Prior to our initial public offering we entered into registration rights agreements with many of our existing security holders that entitled them to have an aggregate of 10,020,248 shares registered for sale in the public market. Moreover, many of those shares, as well as the 184,250 shares we sold to Asahi, could be sold in the public market without registration once they have been held for one year, subject to the limitations of Rule 144 under the Securities Act.

Risks Related to Our ESRD Therapy Industry

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

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

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

Some of our competitors own or could acquire dialysis clinics throughout the United States, our Target European Market and other regions of the world. We may not be able to successfully market our products to the dialysis

clinics under their ownership. If our potential market is materially reduced in this manner, then our potential sales and revenues could be materially reduced.

Some of our competitors, including Fresenius and Gambro, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to Gambro's annual report for 2005: (1) Fresenius treated in its own dialysis clinics approximately 26% of the dialysis patients in the United States, 9% of the dialysis patients in Europe, and 2% of the dialysis patients in Asia and the rest of the world; and (2) Gambro treated in its own dialysis clinics approximately 3% of the dialysis patients in Europe and 0.5% of the dialysis patients in Asia and the rest of the world. In 2005, Gambro divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, supplier arrangement with DaVita, whereby Gambro will be the preferred, but not exclusive, supplier of renal products to DaVita. According to Gambro's annual report for 2005, DaVita treated in its own dialysis clinics approximately 28% of the dialysis patients in the United States,

We believe that there is currently a trend among ESRD therapy providers towards greater consolidation. If such consolidation takes the form of our competitors acquiring independent dialysis clinics, rather than such dialysis clinics banding together in independent

chains, then more of our potential customers would also be our competitors. If our competitors continue to grow their networks of dialysis clinics, whether organically or through consolidation, and if we cannot successfully market our products to dialysis clinics owned by these competitors or any other competitors and do not acquire clinics ourselves, then our revenues could be adversely affected.

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

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

- the development of new medications, or improvements to existing medications, which help to delay the onset or prevent the progression of ESRD in high-risk patients (such as those with diabetes and hypertension);

- the development of new medications, or improvements in existing medications, which reduce the incidence of kidney transplant rejection; and

- developments in the use of kidneys harvested from genetically-engineered animals as a source of transplants.

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

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

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

As the number of managed health care plans increases in the United States, amounts paid for our ESRD therapy products by non-governmental programs may decrease and we may not generate sufficient revenues to be profitable.

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our ESRD

therapy products or sell fewer units, and, in either case, our potential revenues would suffer.

If HDF does not become a preferred therapy for ESRD, then the market for our ESRD therapy products may be limited and we may not be profitable.

A significant portion of our success is dependent on the acceptance and implementation of HDF as a preferred therapy for ESRD. There are several treatment options currently available and others may be developed. HDF may not increase in acceptance as a preferred therapy for ESRD. If it does not, then the market for our ESRD therapy products may be limited and we may not be able to sell a sufficient quantity of our products to be profitable.

If the per-treatment costs for dialysis clinics using our ESRD therapy products are higher than the costs of clinics providing hemodialysis treatment, then we may not achieve market acceptance of our ESRD therapy products in the United States and our potential sales and revenues will suffer.

If the cost of our ESRD therapy products results in an increased cost to the dialysis clinic over hemodialysis therapies and such cost is not separately reimbursable by governmental programs or private medical care plans and insurers outside of the per-treatment fee, then we may not gain market acceptance for such products in the United States unless HDF therapy becomes the standard treatment method for ESRD. If we do not gain market acceptance for our ESRD therapy products in the United States, then the size of our market and our anticipated sales and revenues will be reduced.

Proposals to modify the health care system in the United States or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, then our margins and our profitability will be adversely affected.

A substantial portion of the cost of treatment for ESRD in the United States is currently reimbursed by the Medicare program at prescribed rates. Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reform proposals. We cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in the Medicare program could affect the pricing of our ESRD therapy products. As we are not yet established in our business and it will take some time for us to begin to recoup our research and development costs, our profit margins are likely initially to be lower than those of our competitors and we may be more vulnerable to small decreases in price than many of our competitors.

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

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

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

In the United States, a majority of dialysis clinics reuse dialyzers - that is, a single dialyzer is disinfected and reused by the same patient. However, the trend in our Target European Market is towards not reusing dialyzers, and some countries (such as France, Germany, Italy and the Netherlands) actually forbid the reuse of dialyzers. As a result, each patient in our Target European Market can generally be expected to purchase more dialyzers than each United States patient. The laws forbidding reuse could be repealed and it may become generally accepted to reuse dialyzers in our Target European Market, just as it currently is in the United States. If reuse of dialyzers were to become more common among patients in our Target European Market, then there would be demand for fewer dialyzer units and our potential product sales could be materially adversely affected.

Item 7. Financial Statements.

INDEX TO FINANCIAL STATEMENTS

Nephros, Inc. and Subsidiary

NEPHROS, INC. AND SUBSIDIARY

Report Of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Nephros, Inc

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and subsidiary (the "Company") as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements for the year ended December 31, 2005 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the Company's consolidated financial statements, the Company's recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations, raises substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/S/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
April 19, 2006

NEPHROS, INC. AND SUBSIDIARY

Consolidated Balance Sheets

	December 31, 2005	December 31, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 746,581	$ 3,719,181
Short-term investments	4,500,000	5,995,940
Accounts receivable, less allowances: 2005: $18,697; 2004: $0	244,100	174,797
Inventory	814,548	653,351
Prepaid expenses and other current assets	358,306	468,355
Total current assets	6,663,535	11,011,624
Property and equipment, net	1,143,309	1,191,856
Other assets	17,731	3,822
Total assets	$ 7,824,575	$ 12,207,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 766,158	$ 629,814
Accrued expenses	769,359	362,789
Deferred revenue	-	64,058
Note Payable - short-term portion	295,838	-
Total current liabilities	1,831,355	1,056,661
Notes Payable-long-term portion	613,727	1,500,000
Total Liabilities	2,445,082	2,556,661
Stockholders' equity		
Preferred stock, $.001 par value; 5,000,000 and 31,000,000 shares authorized at December 31, 2005 and 2004, respectively; no shares issued and outstanding at December 31, 2005 and 2004	-	-
Common stock, $.001 par value; 25,000,000 and 49,000,000 shares authorized at December 31, 2005 and December 31, 2004, respectively; 12,313,494 and 12,120,248 shares issued and outstanding at December 31, 2005 and 2004, respectively	12,313	12,120
Additional paid-in capital	54,848,711	53,740,171
Deferred compensation	(2,189,511)	(2,479,317)
Accumulated other comprehensive income (loss)	(49,137)	152,373
Accumulated deficit	(47,242,883)	(41,774,706)
Total stockholders' equity	5,379,493	9,650,641

Total liabilities and stockholders' equity	$	7,824,575	$	12,207,302

The accompanying notes are an integral part of these statements

NEPHROS, INC. AND SUBSIDIARY

Consolidated Statements of Operations

	Year Ended December 31	
	2005	**2004**
Contract revenues	$ 1,750,000	$ -
Net product revenues	674,483	138,406
Net revenues	2,424,483	138,406
Cost of product revenue	379,462	211,942
Gross profit (loss)	2,045,021	(73,536)
Operating expenses:		
Research and development	1,756,493	2,352,604
Selling, general and administrative	6,294,639	5,220,250
Severance expense	318,360	-
Total operating expenses	8,369,492	7,572,854
Loss from operations	(6,324,471)	(7,646,390)
Other income, net:		
Interest income	233,207	49,910
Gain on settlement agreement	623,087	-
Total other income, net	856,294	49,910
Net loss	(5,468,177)	(7,596,480)
Dividends and accretion to redemption value of redeemable convertible preferred stock	-	(11,734,533)
Net loss attributable to common stockholders	(5,468,177)	(19,331,013)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.45)	$ (4.38)
Shares used in computing basic and diluted net loss	12,269,054	4,412,254

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY

Consolidated Statement of Changes in Stockholders' Equity

Accumulated