NEPHROS INC
Form 10KSB
April 10, 2007

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, 2006

[ ] 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

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 [**X**] NO [ ]

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, 2006: $793,489

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $8,507,523 computed by reference to the closing price of the common stock on April 9, 2007.

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 April 10, 2007**
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 2006 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 (which we sell in various countries in Europe and currently consists 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 complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpūr H$_2$H 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. The hospital conducted an evaluation of our DSUs by installing them in a sampling of the hospital's patient showers. Upon completion of the first phase, the hospital ordered additional DSU units in December 2006 to continue its evaluation. With over 5,000 registered hospitals, as reported in Fast Facts, October 20, 2006, by the American Hospital Association, 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.

In September 2006, the President of the United States signed the current U.S. Defense Department budget for fiscal 2007, which included an appropriation for the U.S. Marine Corps for development of a dual stage ultra water filter. We are currently working with military laboratories to define the current project scope and objectives in connection with this appropriation. We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology. However, there can be no assurance that our efforts to market the DSU to hospitals or develop the DSU for the military will be successful, or that we will be able to successfully apply the DSU to any other markets.

Liquidity and Going Concern

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

As of April 2, 2007, we had approximately $447,000 in cash and cash equivalents and $900,000 invested in short term securities. We have implemented a strict cash management program to conserve our cash, reduce our expenditures and control our payables. In accordance with this cash management program, we believe that our existing funds will be sufficient to fund our currently planned operations through the second quarter of 2007. If we are unable to successfully implement our cash management program, then we would be unable to fund our currently planned operations through that date.

We will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. 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 can be no assurance that we will be able to obtain further financing, do so on reasonable terms, do so on terms that will satisfy the American Stock Exchange's ("AMEX") continued listing standards or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we will not be able to continue our operations and we may be de-listed from the AMEX.

We do not generate enough revenue through the sale of our products or licensing revenues to meet our expenditure needs. Our ability to make payments on our indebtedness will depend on our ability to generate cash in the future. This, to some extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our indebtedness and to meet our other commitments, we will be required to adopt alternatives, such as seeking to raise additional debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these

actions would enable us to continue to satisfy our capital requirements. For additional information of factors which could affect our ability to meet our obligations, please see the sections titled “Certain Risks and Uncertainties” and “Liquidity and Capital Resources” in Item 6 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, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom (referred to hereafter collectively as our "Target European Market"). There are currently no FDA approved HDF therapies available in the U.S. market. In the first quarter of 2007 we received approval from the FDA to begin human clinical trials in the United States pursuing 510(k) approval of our OLpūr MDHDF filter series and OLpūr H_2**H**. If we can obtain FDA approval of the OLpūr MDHDF filter series and OLpūr H_2H, we could enter the U.S. ESRD market by combining our OLpūr MDHDF filters with our OLpūr H_2H 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, according to an article published by Dr. Zbylut J. Twardowski, entitled Dialyzer Reuse-Part I: Historical Perspective, in Seminars in Dialysis Vol. 19, No. 1 (January-February) 2006, recent available statistics indicate that 60% 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. This does not preclude us from selling to single-use clinics in the United States, or from potentially charging a higher price for reusable filters in the United States.

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 over other dialysis therapies because of better ESRD patient tolerance, superior blood purification of both small and middle molecules, and a substantially improved mortality risk profile.

Current Dialyzer Technology used with HDF Systems

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

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

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

The Nephros Mid-Dilution Diafiltration Process

Our 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,

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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, Italy and Spain to further demonstrate the therapeutic benefits of our OLpūr MDHDF filter series. A multi-center study was started in March 2005. This study encompassed seven centers in France, five centers in Germany and one center in Sweden. Also commencing in 2005 were studies in the United Kingdom and in Italy. A three-month study was conducted in Spain. All enrolled patients in the multi-center and Spain studies completed the studies. Analysis of the samples collected is ongoing. Initial data is very positive, demonstrating improved low-molecular weight protein removal, improvements in appetite, an overall improved distribution of fluids and body composition, and optimal toxin removal and treatment tolerance for patients suffering from limited vascular access. Data was presented at the American Society of Nephrology meeting held in November 2006. A complete manuscript of the entire multi-center study will be submitted for publication in a reputable journal in 2007.

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. In the fourth quarter of 2006 we received CE marking on the DSU.

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, and we have developed marketing material in the relevant local languages. We also attend trade shows where we promote our product to several thousand people from the industry. Our 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. Because of its larger surface area, the OLpūr MD220 may provide greater clearance of certain toxins than the OLpūr MD190, and is suitable for patients of larger body mass.

We are currently offering the OLpūr MD190 and OLpūr MD 220 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 submitted our original Investigational Device Exemption ("IDE") application for our OLpūr H_2H hemodiafiltration module and OLpūr MD220 filter to the FDA in May 2006. The FDA answered our application with additional questions in June 2006. The responses to the FDA questions were submitted in December 2006. In January 2007, we received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpūr H_2H hemodiafiltration module and OLpūr MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We are also required to obtain approval from one or more Institutional Review Boards (IRBs) in order to proceed with our clinical trial. We are in the process of seeking approvals from the relevant IRBs. We expect to have patients using these ESRD products in a human clinical trial in the United States in the second quarter 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. Our design verification of the OLpūr H_2H has progressed to the point where the device is ready for U.S. clinical trials as of the first quarter of 2007, 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 2007 and hope to achieve U.S. regulatory approval of both products during the first half of 2008. We plan to apply for CE marking of our OLpūr H_2H in the second quarter of 2007.

OLpūr NS2000

OLpūr NS2000 is our standalone HDF machine and associated filter technology, which is in the development stage. We are working with an established dialysis machine manufacturer in Italy to develop the OLpūr NS2000 system. 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 the 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 in the European Union 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 H_2H 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 over competitors in the water filtration marketplace:

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

(2) the DSU filters finer 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. The hospital conducted an evaluation of our DSUs by installing them in a sampling of the hospital's patient showers. Upon completion of the first phase, the hospital ordered additional DSU units in December 2006 to continue their evaluation. 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.

In September 2006, the President of the United States signed the current U.S. Defense Department budget for fiscal 2007, which included an appropriation for the U.S. Marine Corps for development of a dual stage ultra water filter. We are currently working with military laboratories to define the current project scope and objectives in connection with this appropriation. We have also introduced the DSU to various government agencies as one of the solutions of providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology. There can be no assurance that our efforts to market the DSU to hospitals or develop the DSU for the military will be successful, or that we will be able to successfully apply the DSU to any other markets. We are pursuing a larger multi-hospital study to demonstrate the efficacy of the DSU. Our goal is to publish this study in 2007 in a relevant publication of substantial distribution.

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 have engaged in a series of clinical trials throughout our Target European Market to demonstrate the superior efficacy of our product. We believe that by demonstrating the effectiveness of our MDHDF filter series we will encourage more customers to purchase our products.

Convert existing hemodialysis machines to hemodiafiltration: Upon completion of the appropriate documentation for our OLpūr H_2H technology, we plan to apply for CE marking for our OLpūr H_2H during the second quarter of 2007. We plan to complete our regulatory approval processes in the United States for both our OLpūr MDHDF filter series and our OLpūr H_2H in the first half of 2008. If successfully 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 a basis for more MDHDF filter sales.

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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 Complementary 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 complementary product line to our existing ESRD therapy business. We believe the Nephros DSU can offer a robust solution to a broad range of contaminated water 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., ("Medica") a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpūr MD190, MD220 or other filter products at our option. The agreement requires us to purchase from Medica the OLpūr MD190s and MD220s or other filter products that we directly market in Europe, or are marketed by our distributor in Italy. In addition, Medica will be given first consideration in good faith for the manufacture of OLpūr MD190s, MD220s 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 having failed to manufacture one or more products 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 ("Membrana"), 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 is our exclusive provider of the fiber for the OLpūr MDHDF filter series in the European Union as well as certain other 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 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. In August 2006, Membrana awarded us temporary pricing concessions until June 2007. We anticipate that these prices will remain in effect

throughout 2007.

Sales and Marketing

We have established our own sales and marketing organization and distributor network to sell products in our Target European Market and, subject to regulatory approval, intend to establish a similar arrangement in 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 also initiated and completed various clinical studies designed to continue our evaluation of effectiveness of the OLpūr MDHDF filters when used on ESRD patients in our Target European Market. These studies are intended to provide us, and have provided us, with valuable information regarding the efficacy of our product and an opportunity to introduce 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 are marketing 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 milestone payments based on the future sales of such products in Japan, which sales are subject to Japanese regulatory approval.

Our New York office oversees sales and marketing activity of our DSU products to major hospitals in the New York City market. We are in discussions with several medical products suppliers to act as non-exclusive distributors of the DSU products to medical institutions. For each prospective market for our DSU products we are pursuing alliance opportunities for joint product development and distribution. Our DSU manufacturer in Europe shares certain intellectual property rights with us for one of our DSU designs and also is engaged in marketing the DSU in Europe.

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 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. In October 2006 we announced that Nephros will be working with the United States Marine Corps Warfighting Laboratory to develop a portable personal water purification system following the approval of a Federal appropriation totaling $1,000,000. The appropriation is part of HR5631, the "Department of Defense Appropriations Act, 2007," signed into law on September 29, 2006.

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, 2006 and 2005 and were $1,844,220 and $1,756,492, respectively.

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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.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis and peritoneal dialysis products include Gambro AB, Baxter International Inc., Asahi Kasei Medical Co. Ltd., Bellco S.p.A., a subsidiary of the Sorin group, B. Braun Melsungen AG, Nipro Corporation Ltd., Nikkiso Co., Ltd., Terumo Corporation and Toray Medical Co., Ltd.

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

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of 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 H2H at a price that does not provide us with significant positive margins in order to encourage adoption of this product and associated demand for our dialyzers; and
- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities.

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

- developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;
- offering unique attributes that illustrate our product reliability, “user-friendliness,” and performance capabilities;

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

Ÿ 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 we may issue on them) will also cover the ultimate commercial embodiment of these products. In addition, technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have applied for patents on our DSU water filtration system.

As of March 2007, we have thirteen issued U.S. patents; one issued Eurasian patent; two Mexican patents, two South Korean patents, two Russian patents, three Chinese patents, five French patents, five German patents, one Israeli patent, four Italian patents, two Spanish patents, and four United Kingdom patents. In addition, we have seven pending U.S. patent applications, fifteen pending patent applications in Canada, eleven pending patent applications in the European Patent Office, four pending patent applications in Brazil, two pending patent applications in China, three pending patent applications in Israel, fifteen pending patent applications in Japan, two pending patent applications in Mexico, one pending patent application in Russia, two pending patent applications in South Korea, and three pending patent applications in Hong Kong. The titles, patent numbers and normal expiration dates (assuming all the U.S. Patent and Trademark Office fees are paid) of our thirteen 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	6,423,231	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

Ionic Enhanced Dialysis/Diafiltration System	7,067,060	April 13, 2021
Method and Apparatus for a Hemodiafiltration Delivery Module	6,916,424	February 7, 2022
Method and Apparatus for Generating a Sterile Infusion Fluid	7,108,790	November 1, 2022
Multistage Hemodiafiltration/Hemofiltration Method and Apparatus	7,074,332	September 29, 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.

Nephros has filed U.S. and International patent applications for a redundant ultra filtration device that was jointly invented by a Nephros employee and an employee of Medica (the manufacturer of certain Nephros products) located in Italy. The companies are negotiating commercial arrangements pertaining to the invention and the patent applications.

Trademarks

As of December 31, 2006, we secured registrations of the trademarks CENTRAPUR, H_2H, OLpūr and the Arrows Logo in the European Union. Applications for these trademarks are pending registration in the United States. We also have applications for registration of a number of other marks pending in the United States Patent and Trademark Office.

Governmental Regulation

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

United States

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

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

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

Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market

- Ÿ 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:

- Ÿ 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;

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

- Ÿ 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 submitted our original IDE application to the FDA for our OLpūr H2H hemodiafiltration module and OLpūr MD220 filter in May 2006. The FDA answered our application with additional questions in June 2006. The responses to the FDA questions were submitted in December 2006. In January 2007, we received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpūr H2H hemodiafiltration module and OLpūr MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We are also required to obtain approval from one or more IRBs in order to proceed with our clinical trial. We are in the process of seeking approvals from the relevant IRBs. We expect to have patients using these ESRD products in a human clinical trial in the United States in the second quarter of 2007. Our design verification of the OLpūr H2H has progressed to the point where the device is ready for U.S. clinical trials as of the first quarter of 2007, 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 H2H in the fourth quarter of 2007 and hope to achieve U.S. regulatory approval of both products during the first half of 2008. We plan to apply for CE marking of our OLpūr H2H in the second quarter 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:

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

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

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

- the design and manufacturing processes be regulated and controlled by the use of written procedures;
- the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;
- any deficiencies in the manufacturing process or in the products produced be investigated;

Ÿ 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 the 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 2007, and regulatory approval in the United States in the first half of 2008.

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, 2006, we employed a total of 20 employees, 18 of whom were full time and two who are employed on a part-time basis. Of the 20 total employees, six were employed in a marketing/clinical support capacity, seven in general and administrative and seven in research and development.

Recent Developments

In January 2007, we received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpūr H_2H hemodiafiltration module and OLpūr MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We are also required to obtain approval from one or more IRBs in order to proceed with our clinical trial. We are in the process of seeking approvals from the relevant IRBs. We expect to begin a human clinical trial of these ESRD therapy products in the second quarter of 2007.

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 2,788 square feet of space. As of September 25, 2006, we renewed our 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 $11,965, including monthly internet access. We use our facilities to house our corporate headquarters and research facilities. Our offices and laboratories are housed in 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 1,610 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 Suite 19, 25-26 Windsor Place, Lower Pembroke St, Dublin 2, Ireland and consist of approximately 500 square feet of space. On August 3, 2006 we entered into a lease for this space with Leeson Business Centres. The term of the lease is for one year with a current monthly cost of 2,000 euro for the first six months (approximately $2,640 as of December 31, 2006) and 3,000 euro per month thereafter ($3,960, approximately). We use our facilities to house our customer service and accounting operations. Windsor Place is a modern office complex in the heart 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 9 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 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, 2006 and 2005.

Quarter Ended	High	Low
March 31, 2005	$5.90	$3.34
June 30, 2005	$4.15	$2.06
September 30, 2005	$3.75	$2.68
December 31, 2005	$3.13	$1.05
March 31, 2006	$3.15	$1.20
June 30, 2006	$2.45	$1.20
September 30, 2006	$1.86	$0.94
December 31, 2006	$1.50	$0.95

As of March 26, 2007, there were approximately 40 holders of record and approximately 931 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.

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 hemodiafiltra-tion, 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 H_2, 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 parts of our Target European Market in March 2004, and have developed prototypes for our OLpūr H_2 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_2 technology. We have also applied our filtration technologies to water filtration and, in 2006, we fulfilled two purchase orders 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

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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, 2006, we had an accumulated deficit of $55,255,794, and we expect to incur additional losses in the foreseeable future. We recognized net losses of $8,012,911 for the year ended December 31, 2006, and $5,468,177 for the year ended December 31, 2005.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through December 31, 2006, 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 $40.3 million in the aggregate.

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. No milestones have been met to date because none of our products have received regulatory approval in Japan.

During January 2006, we received our first purchase order for our DSU from a major hospital in New York City. The hospital conducted an evaluation of our DSUs by installing them in a sampling of the hospital's patient showers. Upon completion of the first phase, the hospital ordered additional DSU units in December 2006, which we fulfilled, to continue its evaluation. We are in discussion with this hospital in connection with their adoption of the DSU as part of their water filtration system. These initial DSU sales did not result in material net revenues. We are pursuing a larger multi-hospital study to demonstrate the efficacy of the DSU. Our goal is to publish this study in 2007 in a relevant publication of substantial distribution.

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.

Regaining Compliance with AMEX's Continued Listing Standards

We have received notices from the staff of the AMEX that we are not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted our failure to comply with Section 1003(a)(i) of the AMEX Company Guide relating to shareholders' equity of less than $2,000,000 and losses from continuing operations and/or net losses in two out of our three most recent fiscal years; Section 1003(a)(ii) of the AMEX Company Guide relating to shareholders' equity of less than $4,000,000 and losses from continuing operations and/or net losses in three of our four most recent fiscal years; and Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in our five most recent fiscal years.

We submitted a plan advising AMEX of the actions we have taken, or will take, that would bring us into compliance with the applicable listing standards. On November 14, 2006, we received notice from the staff of the AMEX that the staff has reviewed our plan of compliance to meet the AMEX's continued listing standards and will continue our listing while we seek to regain compliance with the continued listing standards during the period ending January 17, 2008. During the plan period, we must continue to provide the AMEX staff with updates regarding initiatives set forth in its plan of compliance. We will be subject to periodic review by the AMEX staff during the plan period. If we are not in compliance with the continued listing standards at January 17, 2008 or we do not make progress consistent with the plan during the plan period, then the AMEX may initiate immediate delisting proceedings.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004) "Share-Based Payment" ("SFAS 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. SFAS 123R is effective for small business issuers for the first interim reporting period beginning after December 15, 2005. We have adopted SFAS 123R effective January 1, 2006. SFAS 123R requires the recognition of compensation expense in an amount equal to the fair value of all share-based payments granted to employees.

Effective January 1, 2006, we adopted SFAS No. 154, "Accounting Changes and Error Correction - A replacement of APB Opinion No. 20 and FASB No. 3" ("SFAS 154"). The adoption of SFAS 154 did not have a material impact on our financial position, results of operations or cash flows.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. This interpretation also provides guidance on derecognition, classification, accounting in interim periods, and expanded disclosure requirements. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of adopting FIN 48 on our financial position, cash flows, and results of operations.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. SFAS 157 established a fair value hierarchy that prioritizes the information used to develop the assumption that market participants would use when pricing an asset or liability. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the impact of adopting SFAS 157 on our financial position, cash flows, and results of operations

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements ("SAB 108"). SAB 108

provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities“ (“SFAS 159”), which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for the fiscal years ending after November 15, 2007. We are currently evaluating the impact of adopting SFAS 159 on our financial position, cash flows, and 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. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management’s subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this annual report on Form 10-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 milestone 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 have adopted SFAS 123R, effective January 1, 2006. SFAS 123R requires the recognition of compensation expense in an amount equal to the fair value of all share-based payments granted to employees. We have elected the modified prospective transition method and therefore adjustments to prior periods are not required as a result of adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted after the date of adoption and to any unrecognized expense of awards unvested at the date of adoption based on the grant date fair value. SFAS 123R also amends SFAS No. 95, “Statement of Cash Flows,” to require that excess tax benefits that had been reflected as operating cash flows be reflected as financing cash flows. Deferred compensation of $2,189,511 related to the awards granted in periods prior to January 1, 2006 were reclassified against additional paid-in capital, as required by SFAS 123R.

Prior to our initial public offering, options were granted to employees, non-employees and non-employee directors at exercise prices which were lower than the fair market value of our stock on the date of grant. After the date of our initial public offering, stock options are granted to employees, non-employees and non-employee directors at exercise prices equal to the fair market value of our stock on the date of grant. Stock options granted have a life of 10 years and vest upon a combination of the following: immediate vesting; straight line vesting of two, three, or four years; and upon the achievement of certain milestones.

Inventory Reserves

Our 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, we will make adjustments to its assumptions for inventory reserve 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, 2006 Compared to the Fiscal Year Ended December 31, 2005

Revenues

Total revenues for the fiscal year ended December 31, 2006 were $793,489 compared to $2,424,483 for the fiscal year ended December 31, 2005. Product revenues increased from $674,483 for the fiscal year ended December 31, 2005 to $793,489 for the fiscal year ended December 31, 2006, an increase of 18%. This $119,006 increase in product revenues is primarily due to increased unit sales of our OLpūr MDHDF filter series product in our Target European

Market, which was partially offset by lower average realized prices. The sales of our DSU product, introduced in January 2006, contributed $20,520 to the increase in product revenues. Results for the fiscal year

ended December 31, 2005 included the licensing revenues of $1,750,000 resulting from our agreement with Asahi Kasei Medical Co., Ltd. (“Asahi”).

Cost of Goods Sold

Cost of goods sold increased by $564,264 as cost of sales for the fiscal year ended December 31, 2006 were $943,726 compared to $379,462 for the fiscal year ended December 31, 2005.

The $564,264 increase in cost of goods sold is primarily due to $313,557 in adjustments to inventory, $93,210 increase in cost of goods due to greater sales volumes, $28,890 for the impact of currency translation and other factors, $25,215 in production waste inefficiency and $18,090 related to our sales of the DSU. In 2005, cost of sales was impacted by a reduction of $82,011 relating to manufacturing credits we received as a result of certain products requiring rework by one of our manufacturers. No sales of the DSU were reported during the year ended December 31, 2005.

The aforementioned inventory adjustments of $313,557 relate to a write-off of expired inventory of $154,621, a revaluation of specific inventory lots to reflect the competitive pricing environment in the German market of $141,074 and an adjustment of $17,862 related to the destruction of returns from a 2005 sale to a French clinic.

Research and Development

Research and development expenses increased to $1,844,220 for the fiscal year ended December 31, 2006 from $1,756,492 for the fiscal year ended December 31, 2005. The $87,728 increase is primarily due to expenses associated with the outside testing and clinical trial related to the H_2H.

Depreciation Expense

Depreciation expense increased to $319,164 for the fiscal year ended December 31, 2006 from $305,601 for the fiscal year ended December 31, 2005, an increase of $13,563. The increase primarily relates to currency translation factors. Depreciation expenses were previously classified as selling, general and administrative expenses and have been reclassified to conform to current year presentation.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased to $5,718,037 for the fiscal year ended December 31, 2006 from $6,307,399 for the fiscal year ended December 31, 2005. The decrease of $589,362 reflects a $706,491 decrease in selling expenses and a $287,914 lower severance expense, being offset by a $405,043 increase in general and administrative expenses.

Selling expenses decreased to $1,347,958 for the fiscal year ended December 31, 2006 from $2,054,449 for the fiscal year ended December 31, 2005. The decrease of $706,491 is primarily due to a reduction in European marketing expenses reflecting lower payroll expenses of $401,493, lower sampling expense of $294,884 and a $167,164 decrease in combined U.S. and European based travel related expenses. The decrease in payroll expense is principally due to the 2005 termination of our Senior Vice President of Marketing and Sales.

General and administrative expenses increased to $4,339,743 for the fiscal year ended December 31, 2006 from $3,934,700 for the year ended December 31, 2005. The $405,043 increase is primarily due to expenses associated with fees for professional services associated with investor relations and financial services of approximately $281,765 and increased expenses associated with accounting and audit related services of $188,605. These increases were partially offset by a $51,146 decrease in legal expenses and a decrease in premium expense of $46,492 on directors

and officers insurance due to improved market conditions for this category of insurance.

Interest Income

Interest income decreased to $211,881 for the fiscal year ended December 31, 2006 from $233,207 for the fiscal year ended December 31, 2005. The $21,326 decrease is primarily due to lower average balances of our cash equivalents and short term investments for the twelve months ended December 31, 2006 as compared to the prior year period.

Interest Expense

Interest expense totaled $195,089 for the fiscal year ended December 31, 2006. There was no interest expense for the fiscal year ended December 31, 2005. The current period interest expense primarily represents $183,321 for the accrued interest liability associated with our 6% Secured Convertible Notes due 2012 (“the Notes”), $6,893 associated with the amortization of the debt discount on the Notes and $4,161 for the interest portion of the present value of payments we made to the Receiver of the Lancer Offshore, Inc. pursuant to certain settlement arrangements. For additional information about the Notes, please see the section “Liquidity and Capital Resources” below.

Other Income

Other income of $1,955 in the fiscal year ended December 31, 2006 represents the change in the valuation of the warrants attached to the Notes.

In the fiscal year ended December 31, 2005, the gain of $623,087 was recorded in conjunction with the settlement of the Ancillary Proceeding with Lancer Offshore, Inc. (See “Note 9—Commitments and Contingencies—Settlement Agreements” to the Condensed Consolidated Financial Statements for a description of the settlement).

Off-Balance Sheet Arrangements

The Company did not engage in any off-balance sheet arrangements during the periods ended December 31, 2006.

Liquidity, Going Concern and Capital Resources

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

At December 31, 2006, we had $253,043 in cash and cash equivalents and $2,800,000 in short-term investments. As of April 2, 2007, we had approximately $447,000 in cash and cash equivalents and $900,000 invested in short term securities. We have implemented a strict cash management program to conserve our cash, reduce our expenditures and control our payables. In accordance with this cash management program, we believe that our existing funds will be sufficient to fund our currently planned operations through the second quarter of 2007. If we are unable to successfully implement our cash management program, then we would be unable to fund our currently planned operations through that date.

We will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. 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 can be no assurance that we will be able to obtain further financing, do so on reasonable terms, do so on terms that will satisfy the AMEX's continued listing standards or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we will not be able to continue our operations and we may be de-listed from the AMEX.

We do not generate enough revenue through the sale of our products or licensing revenues to meet our expenditure needs. Our ability to make payments on our indebtedness will depend on our ability to generate cash in the future. This, to some extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our indebtedness and to meet our other commitments, we will be required to adopt alternatives, such as seeking to raise additional debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements. For additional information describing the risks concerning our liquidity, please see "Certain Risks and Uncertainties" below.

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 OLpūr MDHDF filter series, for which the CE mark was obtained in July 2003), or United States regulatory approval;
- the ability to maintain the listing of our common stock on the AMEX;
- 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 and the additional capital we are seeking to raise 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 9—Commitments and Contingencies—Settlement Agreements" to the Condensed Consolidated Financial Statements for a description of the settlement);
- 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 and we are unable to obtain additional financing, we will be required to adopt alternatives, such as curtailing our planned activities or ceasing our operations.

In June 2006, we entered into subscription agreements with certain investors who purchased an aggregate of $5,200,000 principal amount of our 6% Secured Convertible Notes due 2012 (the "Notes") for the face value thereof. We closed on the sale of the first tranche of Notes, in an aggregate principal amount of $5,000,000, on June 1, 2006 (the "First Tranche") and closed on the sale of the second tranche of Notes, in an aggregate principal amount of $200,000, on June 30, 2006 (the "Second Tranche"). The Notes are secured by substantially all of our assets.

The Notes accrue interest at a rate of 6% per annum, compounded annually and payable in arrears at maturity. Subject to certain restrictions, principal and accrued interest on the Notes are convertible at any time at the holder's option into shares of our common stock, at an initial conversion price of $2.10 per share (subject to anti-dilution adjustments upon the occurrence of certain events). There is no cap on any increases to the conversion price. The conversion price may not be adjusted to an amount less than $0.001 per share, the current par value of our common stock. We may cause the Notes to be converted at their then effective conversion price, if the common stock achieves average last sales prices of at least 240% of the then effective conversion price and average daily volume of at least 35,000 shares (subject to adjustment) over a prescribed time period. In the case of an optional conversion by the holder or a compelled conversion by us, we have 15 days from the date of conversion to deliver certificates for the shares of common stock issuable upon such conversion. As further described below, conversion of the Notes is restricted, pending stockholder approval.

We may prepay outstanding principal and interest on the Notes at any time. Any prepayment requires us to pay each holder a premium equal to 15% of the principal amount of the Notes held by such holder receiving the prepayment if such prepayment is made on or before June 1, 2008, and 5% of the principal amount of the Notes held by such holder receiving prepayment in connection with prepayments made thereafter. In addition to the applicable prepayment premium, upon any prepayment of the Notes occurring on or before June 1, 2008, we must issue the holder of such Notes warrants ("Prepayment Warrants") to purchase a quantity of common stock equal to three shares for every $20 principal amount of Notes prepaid at an exercise price of $0.01 per share (subject to adjustment). Upon issuance, the Prepayment Warrants would expire on June 1, 2012.

Unless and until our stockholders approve the issuance of shares of common stock in excess of such amount, the number of shares of common stock issuable upon conversion of the First Tranche of Notes and exercise of the Prepayment Warrants related thereto, in the aggregate, is limited to 2,451,280 shares, which equals approximately 19.9% of the number of shares of common stock outstanding immediately prior to the issuance of the Notes. We will

not issue any shares of common stock upon conversion of the Second Tranche of Notes or exercise of any Prepayment Warrants that may be issued pursuant to such Notes until our stockholders approve the issuance

of shares of common stock upon conversion of the Notes and exercise of the Prepayment Warrants as may be required by the applicable rules and regulations of the AMEX.

In connection with the sale of the Notes, we have entered into a registration rights agreement with the investors pursuant to which we granted the investors two demand registration rights and unlimited piggy-back and short-form registration rights with respect to the shares of common stock issuable upon conversion of the Notes or exercise of Prepayment Warrants, if any.

Subject to terms and conditions set forth in the Notes, the outstanding principal of and accrued interest on the Notes may become immediately due and payable upon the occurrence of any of the following events of default: our failure to pay principal or interest on the Notes when due; certain bankruptcy-related events with respect to us; material breach of any representation, warranty or certification made by us in or pursuant to the Notes, or under the registration rights agreement or the subscription agreements; our incurrence of Senior Debt (as defined in the Notes); the acceleration of certain of our other debt; or the rendering of certain judgments against us.

The Notes contain a prepayment feature that requires us to issue common stock purchase warrants to the Note holders for partial consideration of certain Note prepayments that the Note holders may demand under certain circumstances. Pursuant to the Notes, we must offer the Note holders the option (the "Holder Prepayment Option") of prepayment (subject to applicable premiums) of their Notes, if we complete an asset sale in excess of $250,000 outside the ordinary course of business (a "Major Asset Sale"), to the extent of the net cash proceeds of such Major Asset Sale. Paragraph 12 of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," ("SFAS 133"), provides that an embedded derivative shall be separated from the host contract and accounted for as a derivative instrument if and only if certain criteria are met. In consideration of SFAS 133, we have determined that the Holder Prepayment Option is an embedded derivative to be bifurcated from the Notes and carried at fair value in our financial statements. At December 31, 2006 the value of the embedded derivative was a liability of approximately $69,000. Such valuation decreased by approximately $2,000 during the fiscal year ended December 31, 2006. We reassess the valuation of the Holder Prepayment Option quarterly.

At December 31, 2006, we had an accumulated deficit of $55,255,794, 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 received from Asahi in March 2005.

Net cash used in operating activities was $7,299,597 for the twelve months ended December 31, 2006 compared to $5,103,948 for the twelve months ended December 31, 2005. Included in the prior year amounts is the impact of the Asahi contract revenue of $1,750,000 (the "Asahi Transaction") offset by cash used in operating activities in the twelve months ended December 31, 2005 of approximately $6,853,948.

During 2006, the net cash used in operating activities was approximately $446,000 higher then the net cash used in operating activities (excepting the Asahi Transaction) during 2005. While this difference is primarily due to the fact that the 2006 net loss is approximately $800,000 greater than the net loss (excepting the Asahi Transaction) in 2005, other items also impacted the difference. The most significant items are highlighted below:

• During 2005, we incurred a non-cash gain of $623,087 related to a settlement agreement.

• During 2006, our inventory decreased by approximately $303,000. This compares to an increase in inventory from 2004 to 2005.

• During 2006, we paid severance costs of approximately $249,000. There were no comparable payments during 2005.

• During 2006, we paid amounts due under settlement agreements totaling approximately $346,000 (included with "other liabilities" on the statement of cash flow).

Net cash provided by investing activities was $1,589,837 for the twelve months ended December 31, 2006 compared to net cash provided of $1,102,710 for the twelve months ended December 31, 2005. For the fiscal year ended December 31, 2005, net cash used reflects $397,290 of fixed asset purchases consisting mainly of manufacturing equipment for the production of our OLpūr MDHDF filters. In 2006, $110,163 of fixed assets were purchased primarily related to manufacturing and computer equipment. Net cash provided by investing activities was increased by $1,700,000 in net repayments of short term securities during the twelve months ended December 31, 2006, as compared to net repayments for the twelve months ended December 31, 2005 of $1,500,000.

Net cash provided by financing activities was approximately $5,201,441 for the twelve months ended December 31, 2006 compared to approximately $1,002,761 for the twelve months ended December 31, 2005. The net cash provided in the current period reflects the sale of an aggregate of approximately $5,200,000 of our Notes and $1,441 from the exercise of options to purchase of our common stock. Financing activities in the twelve months ended December 31, 2005 included net proceeds of $955,521 from Asahi from the sale of 184,250 shares of our common stock pursuant to a Subscription Agreement dated March 2, 2005.

Contractual Obligations and Commercial Commitments

The following tables summarize our minimum contractual obligations and commercial commitments as of December 31, 2006:

		Payments Due in Period			
Contractual Obligations	Total	Within 1 Year	Years 1-3	Years 3-5	More than 5 Years
Convertible Notes (1)	$ 7,290,229	$ -	$ -	$ -	$ 7,290,229
Leases	133,612	133,612	-	-	-
Employment Contracts	567,075	424,163	142,912		-
Total	$ 7,990,916	$ 557,775	$ 142,912	$ -	$ 7,290,229

(1) Includes interest of $2,090,229.

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" and words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by 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 do not presently and may not in the future have sufficient cash flows from operating activities and cash on hand to service our indebtedness and meet our anticipated cash needs. We may not be successful in obtaining additional funding in order to continue operations.

As of April 2, 2007, we had approximately $447,000 in cash and cash equivalents and $900,000 invested in short term securities. We have implemented a strict cash management program to conserve our cash, reduce our expenditures and control our payables. In accordance with this cash management program, we believe that our existing funds will be sufficient to fund our currently planned operations through the second quarter of 2007. If we are unable to successfully implement our cash management program, then we would be unable to fund our currently planned operations through that date.

Our ability to make payments on our indebtedness and to meet our anticipated cash needs will depend on our ability to generate cash in the future. We will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. This, to some extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control.

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 can be no assurance that we will be able to obtain further financing, do so on reasonable terms, do so on terms that will satisfy the AMEX's continued listing standards or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we will not be able to continue our operations and we may be de-listed from the AMEX. Even if we obtain such financing, we cannot assure you that our future cash flow will be sufficient to meet our obligations and commitments. If we continue to be unable to generate sufficient cash flow from operations in the future to service our indebtedness and to meet our other commitments, we will be required to adopt alternatives, such as seeking to raise additional debt or equity capital, curtailing our planned activities or ceasing our operations. We cannot assure you that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

Because our capital requirements have been and will continue to be significant, we need to raise additional funds or we will not be able to continue to operate our business or satisfy our debt obligations when they become due. 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, 2006, 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 $40.3 million. We generated an additional approximately $1.7 million in March 2005 from our license agreement with Asahi. There can be no assurance 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 or to satisfy our debt obligations when they become due and payable. 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 and our DSU for which the CE mark was obtained in November 2006), 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

We will require additional capital beyond the cash, if any, generated from our operations, and we are currently seeking additional funding opportunities through the sale of equity securities or otherwise, to achieve our business objectives. There can be no assurance that we will be able to obtain alternative financing on acceptable terms or at all. Our failure to obtain financing would have a material adverse effect on us. Any additional equity financing could substantially dilute your equity interests in our company and any additional debt financing could impose significant financial and operational restrictions on us.

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, 2006, we had an accumulated deficit of approximately $55,255,794 primarily as a result of our research and development expenses and selling, general and administrative expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

- the completion and success of additional clinical trials and of our regulatory approval processes for each of our ESRD therapy products in our target territories;
- the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
- our ability to effectively and efficiently manufacture, market and distribute our products;
- our ability to sell our products at competitive prices which exceed our per unit costs; and

Ÿ 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, 2006, 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 or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or to do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We may not be able to meet the American Stock Exchange's continued listing standards and as a result, we may be delisted from the American Stock Exchange.

During 2006, we received notices from AMEX that we are not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted our failure to comply with Section 1003(a)(i) of the AMEX Company Guide relating to shareholders' equity of less than $2,000,000 and losses from continuing operations and/or net losses in two out of our three most recent fiscal years; Section 1003(a)(ii) of the AMEX Company Guide relating to shareholders' equity of less than $4,000,000 and losses from continuing operations and/or net losses in three out of our four most recent fiscal years; and Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in our five most recent fiscal years. We submitted a plan in August 2006 to advise AMEX of the steps we have taken, and will take, to regain compliance with the applicable listing standards.

On November 14, 2006, we received notice that the AMEX staff had reviewed our plan of compliance to meet the AMEX's continued listing standards and that AMEX will continue our listing while we seek to regain compliance with the continued listing standards during the period ending January 17, 2008. During the plan period, we must continue to provide the AMEX staff with updates regarding initiatives set forth in our plan of compliance. We will be subject to periodic review by the AMEX staff during the plan period.

We may be unable to show progress consistent with our plan of compliance to meet the AMEX continued listing standards or may be otherwise unable to timely regain compliance with the AMEX listing standards. In order to comply with the AMEX's continued listing standards, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. There can be no assurance, however, that we will be able to obtain further financing, do so on reasonable terms or do so on terms that will satisfy the AMEX's continued listing standards. If we are unable to raise additional funds on a timely basis, then we may be delisted from the AMEX.

If our common stock is delisted by the AMEX, trading of our common stock would thereafter likely be conducted on the OTC Bulletin Board. In such case, the market liquidity for our common stock would likely be negatively affected, which may make it more difficult for holders of our common stock to sell their securities in the open market and we could face difficulty raising capital necessary for our continued operation. Investors may find it more difficult to dispose of or obtain accurate quotations as to the market value of our securities. In addition, our common stock, if delisted by the AMEX, may constitute "penny stock" (as defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934, as amended) if we fail to meet certain criteria set forth in such Rule. Various practice

requirements are imposed on broker-dealers who sell “penny stocks” to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser’s written consent to the transactions prior to sale. Consequently, if our common stock were to become “penny stock,” then the Rule may

deter broker-dealers from recommending or selling our common stock, which could further negatively affect the liquidity of our common stock.

Our existing and future debt obligations could impair our liquidity and financial condition.

As of December 31, 2006, we had $5,200,000 aggregate principal amount of secured convertible notes outstanding, which notes have accrued interest in the amount of $183,321. We may incur additional debt in the future to fund all or part of our capital requirements. Our outstanding debt and future debt obligations could impair our liquidity and could:

- make it more difficult for us to satisfy our other obligations;
- require us to dedicate a substantial portion of any cash flow we may generate to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- impede us from obtaining additional financing in the future for working capital, capital expenditures and general corporate purposes; and
- make us more vulnerable in the event of a downturn in our business prospects and limit our flexibility to plan for, or react to, changes in our industry.

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

For the year ended December 31, 2006, one of our customers accounted for 69% of our product sales. Also, this customer represented 71% of our accounts receivable as of December 31, 2006. In addition, in January 2007, we agreed with this customer to assign on an exclusive basis additional territories to it with respect to distribution of our ESRD therapy products, which had previously been assigned to other distributors, thereby further concentrating our activities with this customer. We believe that the loss of this customer would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

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

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpūr MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage Ultrafilter (“DSU”). We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance. Although we received conditional approval of our IDE in January 2007 to begin clinical trials in the United States, 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 United States.

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

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

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpūr H_2H hemodiafiltration module and OLpūr MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We are also required to obtain approval from one or more IRBs in order to proceed with our clinical trial. We are in the process of seeking approvals from the relevant IRBs. We expect to have patients using these ESRD products in a human clinical trial in the United States in the second quarter of 2007.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our ESRD therapy products are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our ESRD therapy products may not exhibit the expected medical benefits, may cause harmful side effects, may not be effective in treating dialysis patients or may

have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

- lower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;
- lower than expected retention rates of subjects in a clinical trial;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's review board, or other required approvals;
- longer treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the ESRD therapy product;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the ESRD therapy product being tested; and
- regulatory changes.

Even if we obtain positive results from clinical studies for our products, we may not achieve the same success in future studies of such products. Data obtained from clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for device approval during the period of product development and FDA regulatory review of each submitted new device application. We may encounter similar delays in foreign countries. Moreover, regulatory approval may entail limitations on the indicated uses of the device. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products. Additionally, we may be unable to complete our clinical trials if we are unable to obtain additional capital.

We may be required to design and conduct additional clinical trials.

We may be required to design and conduct additional clinical trials to further demonstrate the safety and efficacy of our ESRD therapy product, which may result in significant expense and delay. The FDA and foreign regulatory authorities may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials, a possible failure to conduct clinical trials in complete adherence to FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our ESRD therapy products. It is possible that the FDA or foreign regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

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

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

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;
- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and
- if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

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

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

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of $5,000,000 for our dialysis filters outside of the United States and intend to acquire additional product liability insurance upon commercialization of any of our additional products or upon introduction of any products in the United States, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and adversely affect the demand for our products, our ability to generate sales and our profitability.

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

- to obtain product liability insurance; or
- to indemnify manufacturers against liabilities resulting from the sale of our products.

For example, 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:

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

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

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

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

Access to the appropriation included in the fiscal 2007 U.S. Department of Defense budget regarding the development of a dual-stage ultra water filter could be subject to unanticipated delays which could adversely affect our potential revenues.

Our business strategy with respect to our DSU products depends in part on the successful development of DSU products for use by the military. We expect to work with the United States Marine Corps in developing a potable personal water purification system for warfighters, and a Federal appropriation totaling $1 million was recently

approved for this purpose. If funding does not become available to us or if there are delays in obtaining funding we may not be able to adequately pursue our business strategy for the DSU products and our operations and revenues could be materially adversely affected.

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

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 13 granted U.S. patents will expire at various times from 2018 to 2022, assuming they are properly maintained.

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

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

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

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

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

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

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

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

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

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

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

Independent manufacturers of medical devices will manufacture all of our products and components. We have contracted Medica s.r.l., a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpūr MD190, MD220 and possibly other filters, including our DSU, 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.

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

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

- such products will be safe for use;
- such products will be effective;
- such products will be cost-effective;
- we will be able to demonstrate product safety, efficacy and cost-effectiveness;

- there are unexpected side effects, complications or other safety issues associated with such products; and
- government or third party reimbursement for the cost of such products is available at reasonable rates, if at all.

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, we were a defendant in an action captioned Marty Steinberg, Esq. as Receiver for Lancer Offshore, Inc. v. Nephros, Inc., Case No. 04-CV-20547, that was commenced on March 8, 2004. That action is

ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No. 03-CV-80612, which was commenced on July 8, 2003, wherein the court appointed a Receiver to manage Lancer Offshore, Inc. and various related entities. On December 19, 2005 (the "Date of Entry") the United States District Court for the Southern District of Florida issued an order approving the Stipulation of Settlement entered into on November 8, 2005 (the "Settlement") between the Receiver and us. Under the Settlement, we shall pay the Receiver an aggregate of $900,000 under the following payment terms: $100,000 paid no later than 30 days after the Date of Entry; and four payments of $200,000 each at six month intervals thereafter. In addition, any warrants previously issued to Lancer Offshore, Inc. have been cancelled, and we issued to the Receiver warrants to purchase 21,308 shares of our common stock, exercisable for a period of three years at the market price as of the Date of Entry. As of December 31, 2006, $300,000 had been paid to the Receiver and we paid an additional $200,000 in January 2007. The remaining balance to be paid is $400,000. There can be no assurance that we will have sufficient funds to pay the remaining balance of the obligation to the Receiver and our failure to pay could result in further litigation.

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.

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

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

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our reputation and operating results may be harmed. Management identified a material weakness in internal control over financial reporting, due to an insufficient number of resources in the accounting and finance department, resulting in (i) an ineffective review, monitoring and analysis of schedules, reconciliations and financial statement disclosures and (ii) the misapplication of generally accepted accounting principles ("U.S. GAAP") and SEC reporting requirements. Due to the pervasive effect of the lack of resources, including a lack of resources that are appropriately qualified in the areas of U.S. GAAP and SEC reporting, and the potential impact on the financial statements and disclosures and the importance of the annual and interim financial closing and reporting process, in the aggregate, there is more than a remote likelihood that a material misstatement of the annual financial statements would not have been prevented or detected.

Management is in the process of remediating the above-mentioned weakness in our internal control over financial reporting and has designed the following steps to be implemented:

- Develop procedures to implement a formal monthly closing calendar and process and hold monthly meetings to address the monthly closing process;

- Establish a detailed timeline for review and completion of financial reports to be included in our Forms 10-QSB and 10-KSB;

- Enhance the level of service provided by outside accounting service providers to further support and supplement our internal staff in accounting and related areas;

- Seek additional staffing to provide additional resources for internal preparation and review of financial reports; and

- Employ the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-QSB and 10-KSB.

These remediation plans will be implemented during the second and third quarters of fiscal 2007. The material weakness will not be considered remediated until the applicable remedial procedures are tested and management has concluded that the procedures are operating effectively.

The use of our financial resources will be required not only for implementation of these measures, but also for testing their effectiveness. Based on our existing funds, there can be no assurance that such procedures will be implemented on a timely basis, or at all. If we are not able to implement controls to avoid the occurrence of these kinds of problems 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.

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, 2006, 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, 2006, Ronald O. Perelman beneficially owned 28.8% of our outstanding common stock. As of December 31, 2006, 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).

Assuming the holders of our 6% Secured Convertible Notes due 2012 (the “Notes”) converted all of the outstanding principal and accrued interest on their Notes on December 31, 2006, they would have received approximately 2,476,190 shares of our common stock. After conversion, such holders would beneficially own approximately 15.7% of our outstanding common stock (on an as converted basis).

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 such change of control transaction might be desirable to other stockholders.

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

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

Prior to our initial public offering we entered into registration rights agreements with many of our existing security holders that entitled them to have an aggregate of 10,020,248 shares registered for sale in the public market. Moreover, many of those shares, as well as the 184,250 shares we sold to Asahi, could be sold in the public market without registration once they have been held for one year, subject to the limitations of Rule 144 under the Securities Act. In addition, we entered into a registration rights agreement with the holders of our Notes pursuant to which we granted the holders certain demand and piggy-back registration rights with respect to the shares of common stock issuable upon conversion of the Notes.

Risks Related to the ESRD Therapy Industry

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

We expect to compete in the ESRD therapy market with existing suppliers of hemodialysis and peritoneal dialysis devices, supplies and services. Our competitors include Fresenius Medical Care AG and Gambro AB, currently two of the primary machine manufacturers in hemodialysis, as well as B. Braun Biotech International GmbH, and Nikkiso Corporation and other smaller machine manufacturers in hemodialysis. B. Braun, 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. In 2005, Gambro divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, whereby DaVita will purchase a significant amount of renal products and supplies from Gambro Renal Products.

Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius 2006 Form 20-F annual report Fresenius provides treatment in its own dialysis clinics to approximately 163,500 patients in approximately 2,108 facilities around the world of which approximately 1,560 facilities are located in the United States. According to DaVita's 2006 annual report, DaVita provides treatment in its approximately 1,300 owned and/or operated dialysis centers to approximately 103,000 patients in the United States, and DaVita and Fresenius combined treat approximately 65% of the United States dialysis patients.

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

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

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

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

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

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

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

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

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care

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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.

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NEPHROS, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Nephros, Inc.
3960 Broadway
New York, NY 10032

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and subsidiary (the "Company") as of December 31, 2006 and 2005, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the 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, 2006 and 2005, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, as of January 1, 2006, which changed its method of accounting for stock-based compensation.

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

DELOITTE & TOUCHE LLP
Jericho, New York
April 10, 2007

NEPHROS, INC. AND SUBSIDIARY

Consolidated Balance Sheets

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 253,043	$ 746,581
Short-term investments	2,800,000	4,500,000
Accounts receivable, less allowances of $48,368 and $34,687, respectively	227,889	244,100
Inventory, net	511,714	814,548
Prepaid expenses and other current assets	440,294	358,306
Total current assets	4,232,940	6,663,535
Property and equipment, net	910,525	1,143,309
Other assets	23,233	17,731
Total assets	$ 5,166,698	$ 7,824,575
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 567,566	$ 766,158
Accrued expenses	649,074	451,109
Accrued severance expense	94,270	318,250
Note payable - short-term portion	379,701	295,838
Total current liabilities	1,690,611	1,831,355
Convertible notes payable	5,204,938	-
Accrued interest-convertible notes	183,321	-
Note payable - long-term portion	184,025	613,727
Total liabilities	7,262,895	2,445,082
Stockholders' (deficit) equity:		
Common stock, $.001 par value; 25,000,000 shares authorized at December 31, 2006 and December 31, 2005; 12,317,992 and 12,313,494	12,318	12,313

shares issued and outstanding at December 31, 2006 and 2005, respectively.		
Additional paid-in capital	53,135,371	54,848,711
Deferred compensation	-	(2,189,511)
Accumulated other comprehensive income (loss)	11,908	(49,137)
Accumulated deficit	(55,255,794)	(47,242,883)
Total stockholders' (deficit) equity	(2,096,197)	5,379,493
Total liabilities and stockholders' (deficit) equity	$ 5,166,698	$ 7,824,575

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY

Consolidated Statements of Operations

	Twelve Months Ended December 31	
	2006	**2005**
Contract revenues	$ -	$ 1,750,000
Net product revenues	793,489	674,483
Net revenues	793,489	2,424,483
Cost of goods sold	943,726	379,462
Gross (loss) profit	(150,237)	2,045,021
Operating expenses:		
Research and development	1,844,220	1,756,492
Depreciation expense	319,164	305,601
Selling, general and administrative	5,718,037	6,307,399
Total operating expenses	7,881,421	8,369,492
Loss from operations	(8,031,658)	(6,324,471)
Interest income	211,881	233,207
Interest expense	195,089	-
Other income	1,955	623,087
Net loss	$ (8,012,911)	$ (5,468,177)
Basic and diluted net loss per common share	$ (0.65)	$ (0.45)
Shares used in computing basic and diluted net loss per common share	12,317,080	12,269,054

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY

Consolidated Statement of Changes in Stockholders' (Deficit) Equity

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance, December 31, 2004	12,120,248	$ 12,120	$ 53,740,171	$ (2,479,317)	$ 152,373	$ (41,774,706)	$ 9,650,641
Comprehensive loss:							
Net loss	-	-	-	-	-	(5,468,177)	(5,468,177)
Net unrealized losses on foreign currency translation	-	-	-	-	(205,570)	-	(205,570)
Net unrealized gains on available-for-sale securities	-	-	-	-	4,060	-	4,060
Comprehensive loss							(5,669,687)
Amortization of deferred compensation	-	-		378,430	-	-	378,430
Issuance of Noncash stock-based compensation			173,347	(173,347)			
Cancelled stock options due to terminations	-	-	(84,723)	84,723	-	-	-
Exercise of stock options	8,996	9	2,870	-	-	-	2,879
Adjustment to issuance of common stock in connection with initial public offering	-	-	44,361	-	-	-	44,361
Issuance of common stock in connection with private placement	184,250	184	955,337	-	-	-	955,521
Issuance of warrants in connection with settelement of legal proceedings	-	-	17,348	-	-	-	17,348
Balance, December 31, 2005	12,313,494	$ 12,313	$ 54,848,711	$ (2,189,511)	$ (49,137)	$ (47,242,883)	$ 5,379,493
Comprehensive loss:							
Net loss	-	-	-	-	-	(8,012,911)	(8,012,911)

Net unrealized gains on foreign currency translation	-	-	-	-	61,045	-	61,045
Comprehensive loss	-	-	-	-	-	-	(7,951,866)
Reclassification of deferred compensation	-	-	(2,189,511)	2,189,511	-	-	-
Noncash stock-based compensation	-	-	474,735	-	-	-	474,735
Exercise of stock options	4,498	5	1,436	-	-	-	1,441
Balance, December 31, 2006	12,317,992	$ 12,318	$ 53,135,371	$ -	$ 11,908	$ (55,255,794)	$ (2,096,197)

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

	Year ended December 31, 2006	2005
Operating activities:		
Net loss	$ (8,012,911)	$ (5,468,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	319,164	305,601
Amortization of research & development assets	30,318	-
Loss on disposal of equipment	37,881	-
Amortization of debt discount	4,938	-
Noncash stock-based compensation	474,735	374,529
Gain on settlement agreement	-	(623,087)
Provision for returns	9,417	18,697
(Increase) decrease in operating assets:		
Accounts receivable	59,418	(133,066)
Inventory	361,624	(280,613)
Prepaid expenses and other current assets	(53,296)	87,360
Other assets	(5,501)	(13,909)
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(113,807)	660,123
Accrued severance expense	(249,059)	-
Accrued interest-convertible notes	183,321	-
Deferred revenue	-	(64,058)
Other liabilities	(345,839)	32,652
Net cash used in operating activities	(7,299,597)	(5,103,948)
Investing activities		
Purchase of property and equipment	(110,163)	(397,290)
Purchase of short-term investments	(3,000,000)	-
Maturities of short-term investments	4,700,000	1,500,000
Net cash provided by investing activities	1,589,837	1,102,710
Financing activities		
Proceeds from private placement of common stock	-	955,521
Proceeds from private placement of convertible notes	5,200,000	-
Adjustment to proceeds from IPO of common stock	-	44,361
Proceeds from exercise of stock options	1,441	2,879
Net cash provided by financing activities	5,201,441	1,002,761
Effect of exchange rates on cash	14,781	25,877

Net decrease in cash and cash equivalents		(493,538)		(2,972,600)
Cash and cash equivalents, beginning of period		746,581		3,719,181
Cash and cash equivalents, end of period	$	253,043	$	746,581
Supplemental disclosure of cash flow information				
Cash paid for taxes	$	32,283	$	14,240

The accompanying notes are an integral part of these statements.

Note 1 - Organization and Nature of Operations

Nephros, Inc. (“Nephros” or the “Company”) was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease (“ESRD”) therapy technology and products. The Company has three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy for ESRD patients. These are the OLpur™ MDHDF filter series or “dialyzers,” designed expressly for HDF therapy, the OLpur™ H$_2$, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy, and the OLpur™ NS2000 system, a stand-alone hemodiafiltration machine and associated filter technology. In 2006, the Company introduced its Dual Stage Ultrafilter (“DSU”) water filter system, which represents a new and complementary product line to the Company’s existing ESRD therapy business. The DSU incorporates the Company’s unique and proprietary dual stage filter architecture.

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

The consolidated financial statements of the Company include the accounts of Nephros, Inc. and Nephros International Limited, a wholly-owned subsidiary, which was formed in August 2003. Material intercompany items have been eliminated in consolidation.

Note 2 - Basis of Presentation and Significant Accounting Policies

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company’s recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on the Company’s current cash flow projections, it will need to raise additional funds through either the licensing or sale of its technologies or the additional public or private offerings of its securities. The Company is currently investigating additional funding opportunities and it believes that it will be able to secure financing in the near term. However, there is no guarantee that the Company will be able to obtain further financing. If it is unable to raise additional funds on a timely basis or at all, the Company would not be able to continue it’s operations.

AMEX Delisting Issues

During 2006, the Company received notices from AMEX that it is not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted the Company’s failure to comply with Section 1003(a)(i) of the AMEX Company Guide relating to shareholders’ equity of less than $2,000,000 and losses from continuing operations and/or net losses in two out of the Company’s three most recent fiscal years; Section 1003(a)(ii) of the AMEX Company Guide relating to shareholders’ equity of less than $4,000,000 and losses from continuing operations and/or net losses in three out of the Company’s four most recent fiscal years; and Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders’ equity of less than $6,000,000 and losses from continuing operations and/or net losses in the Company’s five most recent fiscal years. The Company submitted a plan in August 2006 to advise AMEX of the steps it has taken, and will take, to regain compliance with the applicable listing standards.

On November 14, 2006, the Company received notice that the AMEX staff had reviewed the Company’s plan of compliance to meet the AMEX’s continued listing standards and that AMEX will continue the Company’s listing while

it seeks to regain compliance with the continued listing standards during the period ending January 17, 2008. During the plan period, the Company must continue to provide the AMEX staff with updates regarding initiatives set forth in its plan of compliance. The Company will be subject to periodic review by the AMEX staff during the plan period.

The Company may be unable to show progress consistent with its plan of compliance to meet the AMEX continued listing standards or may be otherwise unable to timely regain compliance with the AMEX listing standards. In order to comply with the AMEX's continued listing standards, the Company will need to raise additional funds through either the licensing or sale of its technologies or the additional public or private offerings of its securities. There can be no assurance, however, that the Company will be able to obtain further financing, do so on reasonable terms or do so on terms that will satisfy the AMEX's continued listing standards. If the Company is unable to raise additional funds on a timely basis, then it may be delisted from the AMEX.

Use of Estimates in the Preparation of Financial Statements

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

Cash and Cash Equivalents

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

Short-Term Investments

All short-term investments, which are carried at fair market value, primarily represent auction rate debt securities. These securities have been classified as "available-for-sale." Management determines the appropriate classification of its short-term investments at the time of purchase and evaluates such designation as of each balance sheet date. Interest earned on short-term investments is included in interest income. At December 31, 2006, the fair value of the available-for-sale securities was $2,800,000. At December 31, 2005, the fair value of the available-for-sale securities was $4,500,000.

Concentration of Credit Risk

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

For the twelve months ended December 31, 2006 and 2005, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2006	2005
A	69%	41%
B	17%	14%
C	6%	11%

As of December 31, 2006 and 2005, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2006	2005
A	71%	63%
C	14%	8%

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments and accounts payable approximate fair value due to the short-term maturity of these instruments. At December 31, 2006, the fair value of the convertible notes was approximately $5,296,000.

Accounts Receivable

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was $9,558 at December 31, 2006 and $15,990 at December 31, 2005. The allowance for sales returns was $38,810 at December 31, 2006 and was $18,697 at December 31, 2005.

Inventory

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

The Company's inventory, net, as of December 31, 2006 and 2005, was as follows:

	December 31,	
	2006	2005
Raw Materials	$ 53,358	$ 153,299
Finished Goods	458,356	661,249
Total Inventory	$ 511,714	$ 814,548

Patents

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

incurred.

Property and Equipment, net

Property and equipment, net is stated at cost and is being depreciated over the estimated useful lives of the assets, three to seven years, using the straight line method.

Impairment for Long-Lived Assets

The Company periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived assets, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its estimated net realizable market value. There was no impairment or loss incurred during the year.

Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, "*Revenue Recognition"* ("SAB No. 104"). 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.

The Company began sales of its first product in March 2004. Prior to fiscal year 2005, the Company's 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 the Company did not recognize revenue from sales until the rights of return expired (thirty days after the date of shipment). Similarly, the Company deferred cost of goods sold to the extent of amounts billed to customers.

Effective for the fiscal year ended December 31, 2005, the Company started to recognize revenue related to product sales when delivery is confirmed by its external logistics provider and the other criterion of SAB No. 104 were met. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by the Company's customers. Sales made on a returned basis were recorded net of a provision for estimated returns. These estimates are revised as necessary, to reflect actual experience and market conditions. The returns provision is based on historical unit returns levels and valued relative to debtors at the end of each quarter. For the twelve months ended December 31, 2006 returns were less than 5% of annual sales.

During fiscal 2005, the Company received an up front license fee in the amount of $1,750,000 from Asahi Kasei Medical Co., Ltd. ("Asahi"), a business unit of Asahi Kasei Corporation granting Asahi exclusive rights to manufacture and distribute the Company's OLpūr MDHDF hemodiafilter series in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. The Company is entitled to receive additional royalties and milestone 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, the Company recognized $1,750,000 in contract revenue on the effective date of the license agreement.

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Stock Plans

In 2000, the Company adopted the Nephros 2000 Equity Incentive Plan. In January 2003, the Board of Directors adopted an amendment and restatement of the plan and renamed it the Amended and Restated Nephros 2000 Equity Incentive Plan (the "2000 Plan"), under which 2,130,750 shares of common stock have been authorized for issuance upon exercise of options granted and which may be granted by the Company. As of December 31, 2006, 1,316,235 options had been issued to employees and were outstanding. The options expire on various dates between January 24, 2010 and March 15, 2014 and vest upon a combination of the following: immediate vesting; straight line vesting of two, three or four years; and certain milestones.

As of December 31, 2006, 155,261 options had been issued to non-employees under the 2000 Plan and were outstanding. Such options expire at various dates between January 13, 2013 and March 15, 2014 and vest upon a combination of the following: immediate vesting; straight line vesting of two, three or four years; and certain milestones.

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

In 2004, the Board of Directors adopted and the Company's stockholders approved the Nephros, Inc. 2004 Stock Incentive Plan, and, in June 2005, the Company's stockholders approved an amendment to such plan (as amended, the "2004 Plan"), that increased to 800,000 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. As of December 31, 2006, 655,912 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between November 11, 2014 and December 15, 2016, and vest upon a combination of the following: immediate vesting; straight line vesting of two, three or four years; and certain milestones. At December 31, 2006, there were 84,384 shares available for future grants under the 2004 Plan.

As of December 31, 2006, 164,140 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 11, 2014 and December 15, 2016, and vest upon a combination of the following: immediate vesting; straight line vesting of two, three or four years; and certain milestones.

Stock-Based Compensation

The Company has adopted Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004), "*Share-Based Payment"* ("SFAS 123R"), effective January 1, 2006. SFAS 123R requires the recognition of compensation expense in an amount equal to the fair value of all share-based payments granted to employees. The Company has elected the modified prospective transition method and therefore adjustments to prior periods are not required as a result of adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted after the date of adoption and to any unrecognized expense of awards unvested at the date of adoption based on the grant date fair value. SFAS 123R also amends SFAS No. 95, "Statement of Cash Flows," to require that excess tax benefits that had been reflected as operating cash flows be reflected as financing cash flows. Deferred compensation of $2,189,511 related to the awards granted in periods prior to January 1, 2006 were reclassified against additional paid-in capital, as required by SFAS 123R.

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

straight line vesting of two, three, or four years; and upon the achievement of certain milestones.

Expense is recognized, net of expected forfeitures, over the vesting period of the options. For options that vest upon the achievement of certain milestones, expense is recognized when it is probable that the condition will be met. Stock based compensation expense recognized for the twelve months ended December 31, 2006 and 2005 was $474,735 or $0.04 per share and $374,529 or $0.03 per share, respectively.

In 2005, we identified an immaterial adjustment to the amounts and calculations reported in 2004 for deferred compensation. The 2005 non cash stock based compensation reflects a revision to the prior year in the amount of $173,347.

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

	Option Pricing Assumptions	
Grant Year	**2006**	**2005**
Stock Price Volatility	65% to 92%	80%
Risk-Free Interest Rates	4.34% to 4.97%	3.33%
Expected Life (in years)	5.8 to 6.0	7.0

There is no expected dividend yield. Expected volatility is based on historical volatility of the Company's common stock at the time of grant. The risk-free interest rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected life of the options. For the expected life, the Company is using the simplified method as described in the SEC Staff Accounting Bulletin 107. This method assumes that stock option grants will be exercised based on the average of the vesting periods and the grant's life.

Prior to January 1, 2006, stock-based compensation was determined using the intrinsic value method. The following table provides supplemental information for 2005 as if stock-based compensation had been computed under SFAS 123:

	2005
Net loss as reported	$ (5,468,177)
Add back: compensation expense recorded under the intrinsic method	374,529
Deduct: compensation expense under the fair value method	(730,143)
Pro forma net loss using the fair value method	$ (5,819,890)
Net loss per share:	
As reported	$ (0.45)
Pro forma	$ (0.47)

The total fair value of options vested during the fiscal year ended December 31, 2006 was $522,454.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2006:

	Options Outstanding			Options Exerciseable	
Range of exercise price	Number outstanding as of December 31, 2006	Weighted average remaining contractual life in years	Weighted average exercise price	Number exercisable as of December 31, 2006	Weighted average exercise price
$0.32	520,471	3.1	$0.32	520,471	$0.32
$1.36 - $1.49	548,500	9.5	$1.38	145,333	$1.38
$1.76	496,890	6.4	$1.76	397,512	$1.76
$2.32 - $2.64	241,380	7.8	$2.47	100,975	$2.45
$2.77 - $2.78	363,306	6.4	$2.78	173,358	$2.78
$3.40 - $5.45	144,000	8.1	$4.30	105,667	$4.35
	2,314,547			1,443,316	

The number of new options granted in 2006 and 2005 is 665,500 and 65,000, respectively. The weighted-average fair value of options granted in 2006 and 2005 is $1.13 and $2.89, respectively.

The following table summarizes the option activity for the year ended December 31, 2006:

	Shares	Weighted average exercise price
Outstanding at January 1, 2005	1,852,540	$ 1.85
Options granted	65,000	$ 3.49
Options exercised	(8,997)	$ 0.32
Options canceled	(24,006)	$ 2.60
Outstanding at December 31, 2005	1,884,537	$ 1.91
Options granted	665,500	$ 1.59
Options exercised	(4,499)	$ 0.32
Options canceled	(230,991)	$ 2.61
Outstanding at December 31, 2006	2,314,547	$ 1.74

Vested or expected to vest at December 31, 2006	1,982,486	$	2.52
Exerciseable at December 31, 2006	1,443,316	$	1.56

The aggregate intrinsic value of stock options outstanding at December 31, 2006 and the stock options vested or expected to vest is $630,651. The aggregate intrinsic value of stock options currently exercisable at December 31, 2006 is $599,376.

The weighted-average remaining contractual life of options vested or expected to vest is 7.8 years.

The following table summarizes nonvested stock option activity as of December 31, 2006

	Number of options	Weighted-average fair value
Nonvested at January 1, 2006	608,938	$ 3.87
Options granted	423,015	$ 2.60
Options vested	(141,250)	$ 4.70
Options forfeited	(145,161)	$ 1.72
Nonvested at December 31, 2006	745,542	$ 3.41

As of December 31, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to $2,538,973. Of this amount, $1,292,312 will be amortized over the weighted-average remaining requisite service period of 1.4 years and $1,246,661will be recognized upon the attainment of related milestones.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, “Accounting for Income Taxes,” which requires accounting for deferred income taxes under the asset and liability method. Deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable in future years to differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities.

For financial reporting purposes, the Company has incurred a loss in each period since its inception. Based on available objective evidence, including the Company's history of losses, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2006 and December 31, 2005.

Research and Development Costs

Research and development costs are expensed as incurred.

Loss per Common Share

In accordance with SFAS No. 128, “Earnings Per Share,” net loss per common share amounts (“basic EPS”) were computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution (“diluted EPS”) is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. However, because their effect is antidilutive, the Company has excluded stock options and warrants aggregating 2,706,315 and 2,265,092 from the computation of diluted EPS for the years ended December 31, 2006 and 2005, respectively.

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Translation of Foreign Currency

The functional currency of Nephros International Limited is the Euro, and its translation gains and losses are included in accumulated other comprehensive income (loss). The balance sheet is translated at the year-end rate. The statement of operations is translated at the weighted average rate for the year.

Comprehensive Income (Loss)

The Company complies with the provisions of SFAS No. 130, "Reporting Comprehensive Income," which requires companies to report all changes in equity during a period, except those resulting from investment by owners and distributions to owners, for the period in which they are recognized. Comprehensive income (loss) is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)) such as unrealized gains or losses on securities classified as available-for-sale and foreign currency translation adjustments. For the fiscal years ended 2006 and 2005, the comprehensive loss was $(7,951,866) and $(5,669,687), respectively.

Reclassification

Depreciation expenses were previously classified as selling, general and administrative expenses and have been reclassified to conform to current year presentation.

Recent Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (Revised 2004) "Share-Based Payment" ("SFAS 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. SFAS 123R is effective for small business issuers for the first interim reporting period beginning after December 15, 2005. The Company adopted SFAS 123R effective January 1, 2006. SFAS 123R requires the recognition of compensation expense in an amount equal to the fair value of all share-based payments granted to employees.

Effective January 1, 2006, the Company adopted SFAS No. 154, "Accounting Changes and Error Correction - A replacement of APB Opinion No. 20 and FASB No. 3" ("SFAS 154"). The adoption of SFAS 154 did not have a material impact on the Company's financial position, results of operations or cash flows.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. This interpretation also provides guidance on derecognition, classification, accounting in interim periods, and expanded disclosure requirements. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of adopting FIN 48 on its financial position, cash flows, and results of operations.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. SFAS 157 established a fair value hierarchy that prioritizes the information used to develop the assumption that market participants would use when pricing an asset or liability. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the impact of adopting SFAS 157 on the Company's financial position, cash flows, and results of operations

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB 108"). SAB 108

provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities” (“SFAS 159”), which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for the fiscal years ending after November 15, 2007. The Company is currently evaluating the impact of adopting SFAS 159 on its financial position, cash flows, and results of operations.

Note 3 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following:

	December 31,	
	2006	2005
Prepaid insurance premiums	$ 177,336	$ 94,556
Advances on product development services	102,500	96,565
Other	160,458	167,185
Prepaid Expenses and Other Current Assets	$ 440,294	$ 358,306

Note 4 - Property and Equipment, net

Property and equipment is comprised of the following:

		December 31,	
	Life	2006	2005
Manufacturing equipment	5 years	$ 1,808,701	$ 1,742,358
Research equipment	5 years	91,275	34,500
Computer equipment	4 years	122,015	158,169
Furniture and fixtures	7 years	54,123	83,066
Leasehold improvement	1 year	15,000	-
		2,091,114	2,018,093
Less: accumulated depreciation		1,180,589	874,784
Property and Equipment, net		$ 910,525	$ 1,143,309

The Company contracts with Medica s.r.l. to manufacture the Company’s ESRD therapy products. The Company owns certain manufacturing equipment located at Medica's manufacturing plant in Italy. Depreciation expense for the years ended December 31, 2006 and 2005 was $319,164 and $305,601, respectively.

Note 5 - Stockholders' Equity and Redeemable Convertible Preferred Stock

On June 24, 2005, the Company filed its Fourth Amended and Restated Certificate of Incorporation, reducing the number of authorized shares of common stock from 49,000,000 to 25,000,000, and reducing the number of authorized shares of preferred stock from 31,000,000 to 5,000,000.

On March 2, 2005, the Company entered into a Subscription Agreement with Asahi pursuant to which Asahi purchased 184,250 shares of the Company's common stock at an aggregate purchase price of $955,521, the fair market value at the date of issuance.

In connection with its initial public offering, the Company issued to its underwriters (The Shemano Group, Inc. and National Securities Corporation), in exchange for $100, warrants to purchase up to an aggregate of 200,000 shares of its common stock. The Company has reserved an equivalent number of shares of common stock for issuance upon exercise of these warrants. Each warrant represents the right to purchase one share of common stock for a period of four and one-half years commencing six months from September 24, 2004, the effective date of the offering. The exercise price of the warrants is $7.50, and they have a cash-less exercise feature which allows them to be exercised through the surrender of a portion of the warrants (determined based on the market price of the Company's common stock at the time of exercise) in lieu of cash payment of the exercise price. The warrants contain provisions that protect their holders against dilution by adjustment of the exercise price and number of shares issuable upon exercise on the occurrence of specific events, such as stock dividends or other changes in the number of the Company's outstanding shares except for shares issued under certain circumstances, including shares issued under the Company's equity incentive plan and any equity securities for which adequate consideration is received. No holder of these warrants will possess any rights as a stockholder unless the warrant is exercised. The holders of the warrants will be entitled to one demand and customary "piggy-back" registration rights to register the shares underlying the warrants. Such registration rights shall continue for a period of five years from the effective date of the initial public offering.

Warrants Outstanding

Lancer Warrants - These warrants were issued during 2005 as a result of a settlement agreement disclosed in Note 9 to the consolidated financial statements, Commitments and Contingencies. The Company recorded the issuance of the warrants at their fair market value of $17,348 based on a Black-Scholes calculation. During the year ended December 31, 2005, this amount has been reflected as additional paid in capital on the Company's Consolidated Statement of Changes in Stockholders' Equity.

Underwriter Warrants - As disclosed above, these warrants were issued to the Company's underwriters in connection with the initial public offering. These warrants were a non-cash cost of the offering. As an offering cost and an issuance of equity, the impact would be to decrease and increase additional paid in capital by equal offsetting amounts (i.e. the fair value of the warrants). Accordingly, the Company did not value these warrants at the issuance date.

Plexus Warrants - These warrants were issued during 2002 as a result of a settlement agreement disclosed in Note 9 to the consolidated financial statements, Commitments and Contingencies. The Company recorded the issuance of the warrants at their fair market value of $400,000 based on a Black- Scholes calculation. During the year ended December 31, 2002, this amount was reflected as additional paid in capital on the Company's Consolidated Statement of Changes in Stockholders' Equity.

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2006.

Total Outstanding Warrants

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable
Lancer Warrants	1/18/2006	1/18/2009	$ 1.50	21,308
Underwriter Warrants	3/24/2005	9/20/2009	$ 7.50	200,000
Plexus Warrants	6/19/2002	6/19/2007	$ 10.56	170,460

Note 6 - 401(k) Plan

The Company has established a 401(k) deferred contribution retirement plan (the “401(k) Plan”) which covers all employees. The 401(k) Plan provides for voluntary employee contributions of up to 15% of annual earnings, as defined. As of January 1, 2004, the Company began matching 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. The Company contributed and expensed $45,713 and $49,965 in 2006 and 2005, respectively.

Note 7 - Short-Term Investments

The Company’s short-term investments are intended to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to the Company’s Corporate Investment Policy and market conditions.

The following is a summary of available-for-sale securities as of December 31, 2006 and December 31, 2005:

	December 31, 2006		
	Cost	Gross Unrealized Losses	Gross Fair Value
Auction rate securities	$ 2,800,000	$ -	$ 2,800,000
Total securities	$ 2,800,000	$ -	$ 2,800,000

	December 31, 2005		
	Cost	Gross Unrealized Losses	Gross Fair Value
Auction rate securities	$ 4,500,000	$ -	$ 4,500,000
Total securities	$ 4,500,000	$ -	$ 4,500,000

All of the available-for-sale securities held by the Company at December 31, 2006 were due in one year or less. Market values were determined for each individual security in the investment portfolio. Any declines in value of these investments are primarily related to changes in interest rates and are considered to be temporary in nature. Investments are reviewed periodically to identify possible impairment. When evaluating the investments, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the investee, and the Company's ability and intent to hold the investment for a period of time which may be sufficient

for anticipated recovery in market value.

Note 8 - Convertible Notes

In June 2006, the Company entered into subscription agreements with certain investors who purchased an aggregate of $5,200,000 principal amount of 6% Secured Convertible Notes due 2012 (the "Notes") issued by the Company for the face value thereof. The Company closed on the sale of the first tranche of Notes, in an aggregate principal amount of $5,000,000, on June 1, 2006 (the "First Tranche") and closed on the sale of the second tranche of Notes, in an aggregate principal amount of $200,000, on June 30, 2006 (the "Second Tranche"). The Notes are secured by substantially all of the Company's assets.

The Notes accrue interest at a rate of 6% per annum, compounded annually and payable in arrears at maturity. Subject to certain restrictions, principal and accrued interest on the Notes are convertible at any time at the holder's option into shares of the Company's common stock, at an initial conversion price of $2.10 per share (subject to anti-dilution adjustments upon the occurrence of certain events). There is no cap on any increases to the conversion price. The conversion price may not be adjusted to an amount less than $0.001 per share, the current par value of the Company's common stock. The Company may cause the Notes to be converted at their then effective conversion price, if the common stock achieves average last sales prices of at least 240% of the then effective conversion price and average daily volume of at least 35,000 shares (subject to adjustment) over a prescribed time period. In the case of an optional conversion by the holder or a compelled conversion by the Company, the Company has 15 days from the date of conversion to deliver certificates for the shares of common stock issuable upon such conversion. As further described below, conversion of the Notes is restricted, pending stockholder approval.

The Company may prepay outstanding principal and interest on the Notes at any time. Any prepayment requires the Company to pay each holder a premium equal to 15% of the principal amount of the Notes held by such holder receiving the prepayment if such prepayment is made on or before June 1, 2008, and 5% of the principal amount of the Notes held by such holder receiving prepayment in connection with prepayments made thereafter. In addition to the applicable prepayment premium, upon any prepayment of the Notes occurring on or before June 1, 2008, the Company must issue the holder of such Notes warrants ("Prepayment Warrants") to purchase a quantity of common stock equal to three shares for every $20 principal amount of Notes prepaid at an exercise price of $0.01 per share (subject to adjustment). Upon issuance, the Prepayment Warrants would expire on June 1, 2012.

Unless and until its stockholders approve the issuance of shares of common stock in excess of such amount, the number of shares of common stock issuable upon conversion of the First Tranche of Notes and exercise of the Prepayment Warrants related thereto, in the aggregate, is limited to 2,451,280 shares, which equals approximately 19.9% of the number of shares of common stock outstanding immediately prior to the issuance of the Notes. The Company will not issue any shares of common stock upon conversion of the Second Tranche of Notes or exercise of any Prepayment Warrants that may be issued pursuant to such Notes until its stockholders approve the issuance of shares of common stock upon conversion of the Notes and exercise of the Prepayment Warrants as may be required by the applicable rules and regulations of the American Stock Exchange (the "AMEX").

In connection with the sale of the Notes, the Company has entered into a registration rights agreement with the investors pursuant to which the Company granted the investors two demand registration rights and unlimited piggy-back and short-form registration rights with respect to the shares of common stock issuable upon conversion of the Notes or exercise of Prepayment Warrants, if any.

Subject to terms and conditions set forth in the Notes, the outstanding principal of and accrued interest on the Notes may become immediately due and payable upon the occurrence of any of the following events of default: the Company's failure to pay principal or interest on the Notes when due; certain bankruptcy-related events with respect to the Company; material breach of any representation, warranty or certification made by the Company in or pursuant to the Notes, or under the registration rights agreement or the subscription agreements; its incurrence of Senior Debt (as

defined in the Notes); the acceleration of certain of the Company's other debt; or the rendering of certain judgments against the Company.

The Notes contain a prepayment feature that requires the Company to issue common stock purchase warrants to the Note holders for partial consideration of certain Note prepayments that the Note holders may demand under certain circumstances. Pursuant to the Notes, the Company must offer the Note holders the option (the "Holder Prepayment Option") of prepayment (subject to applicable premiums) of their Notes, if the Company completes an asset sale in excess of $250,000 outside the ordinary course of business (a "Major Asset Sale"), to the extent of the net cash proceeds of such Major Asset Sale. Paragraph 12 of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", ("SFAS 133"), provides that an embedded derivative shall be separated from the host contract and accounted for as a derivative instrument if and only if certain criteria are met. In consideration of SFAS 133, the Company has determined that the Holder Prepayment Option is an embedded derivative to be bifurcated from the Notes and carried at fair value in the financial statements. At December 31, 2006, the value of the embedded derivative was a liability of $68,942. The change in value was recorded as other income. Also, the debt discount, of $70,897, created by bifurcating the Holder Prepayment Option, is being amortized over the term of the debt. During the year ended December 31, 2006, the Company recorded interest expense of $6,893.

Note 9 - Commitments and Contingencies

Settlement Agreements

Hermitage Capital Corporation

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. As of December 31, 2006, no loss amount has been accrued because a loss is not considered probable or estimable.

Plexus Services Corp.

In June 2002, the Company entered into a settlement agreement with one of its suppliers, Plexus Services Corp. The Company had an outstanding liability to such supplier in the amount of approximately $1,900,000. Pursuant to this settlement agreement, the Company and the supplier agreed to release each other from any and all claims or liabilities, whether known or unknown, that each had against the other as of the date of the settlement agreement, except for obligations arising out of the settlement agreement itself. The settlement agreement required the Company to grant to the supplier (i) warrants to purchase 170,460 shares of common stock of the Company at an exercise price of approximately $10.56 per share that expire in June 2007 and (ii) cash payments of an aggregate amount of $650,000 in three installments. The warrants were valued at $400,000 using the Black-Scholes model. Accordingly, the Company recorded a gain of approximately $850,000 based on such settlement agreement. On June 19, 2002, the Company issued the warrant to the supplier, and on August 7, 2002, the Company satisfied the first $300,000

installment of the agreement. The second installment of $100,000 was due on February 7, 2003, and the Company paid $75,000 towards the installment. On November 11, 2004, after the successful closing of its initial public offering, the Company paid an additional $25,000 and agreed with the supplier to pay the remaining

$250,000 over time. The outstanding balance at December 31, 2006 was $50,000 and is included in “Accounts Payable” on the Consolidated Balance Sheet.

Lancer Offshore, Inc.

In August 2002, the Company entered into a subscription agreement with Lancer Offshore, Inc. (“Lancer”). The subscription agreement provided, among other things, that Lancer would purchase, in several installments, (1) $3,000,000 principal amount of secured notes due March 15, 2003 convertible into 340,920 shares of the Company’s common stock and (2) warrants to purchase until December 2007 an aggregate of 68,184 shares of the Company’s common stock at an exercise price of approximately $8.80 per share. In accordance with the subscription agreement, the first installment of securities, consisting of $1,500,000 principal amount of the notes and 34,092 of the warrants (which 34,092 warrants had nominal value at such time), were tendered. However, Lancer failed to fund the remaining installments. Following this failure, the Company entered into a settlement agreement with Lancer dated as of January 31, 2003, pursuant to which, (i) the parties terminated the subscription agreement; (ii) Lancer agreed to surrender 12,785 of the original 34,092 warrants issued to it; (iii) the warrants that were not surrendered were amended to provide that the exercise price per share and the number of shares issuable upon exercise thereof would not be adjusted as a result of a 0.2248318-for one reverse stock split of the Company’s common stock that was contemplated at such time but never consummated; and (iv) the secured convertible note in the principal amount of $1,500,000 referred to above was cancelled. Lancer agreed, among other things, to deliver to the Company at or prior to a subsequent closing the cancelled note and warrants and to reaffirm certain representations and warranties and, subject to the satisfaction of these and other conditions, the Company agreed to issue to Lancer at such subsequent closing an unsecured note in the principal amount of $1,500,000 bearing no interest, not convertible into common stock and due on January 31, 2004 or earlier under certain circumstances. Lancer never fulfilled the conditions to the subsequent closing and, accordingly, the Company never issued the $1,500,000 note that the settlement agreement provided would be issued at such closing.

The above transaction resulted in the Company becoming a defendant in an action captioned Marty Steinberg, Esq. as Receiver for Lancer Offshore, Inc. v. Nephros, Inc., Case No. 04-CV-20547, that was commenced on March 8, 2004, in the U.S. District Court for the Southern District of Florida (the “Ancillary Proceeding”). That action was ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No.03-CV-80612, pending in the U.S. District Court for the Southern District of Florida, in which the court had appointed a Receiver to manage Lancer and various related entities (the “Receivership). In the Ancillary Proceeding, the Receiver sought payment of $1,500,000, together with interest, costs and attorneys’ fees, as well as delivery of a warrant evidencing the right to purchase until December 2007 an aggregate of 75,000 shares of the Company’s common stock for $2.50 per share (or 21,308 shares of the Company’s common stock for $8.80 per share, if adjusted for the 0.2841-for-one reverse stock split the Company effected on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended). On or about April 29, 2004, the Company served an answer in which it denied liability for, and asserted numerous defenses to, the Receiver’s claims. In addition, on or about March 30, 2004, the Company asserted claims for damages against Lancer Offshore, Inc. that exceeded the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership.

On December 19, 2005, the U.S. District Court for the Southern District of Florida approved the Stipulation of Settlement with respect to the Ancillary Proceeding dated November 8, 2005 (the “Settlement”). Pursuant to the terms of the Settlement, the Company agreed to pay the Receiver an aggregate of $900,000 under the following payment terms: $100,000 paid on January 5, 2006; and four payments of $200,000 each at six month intervals thereafter. In addition, any warrants previously issued to Lancer were cancelled, and, on January 18, 2006, the Company issued to the Receiver warrants to purchase 21,308 shares of the Company’s common stock at $1.50 per share exercisable until January 18, 2009.

The Company had reserved for the Ancillary Proceeding on its balance sheet as of December 31, 2004 as a $1,500,000 accrued liability. As a result of the above Settlement the Company has adjusted such accrual liability and recorded a note payable to the Receiver to reflect the present value of the above amounts due to the Receiver of $563,726 of which $379,701 is reflected as short-term note payable and $184,025 reflected as a long-term note payable. Additionally, we recorded the issuance of the warrants issued at their fair market value of $17,348 based on a Black-Scholes calculation. Such Settlement resulted in a gain of $623,087 recorded in the fourth quarter of 2005

which is recorded as “Other Income” on the consolidated statements of operations as it was for compensation for damages sustained in the financing transaction.

Manufacturing and Suppliers

The Company does not intend to manufacture any of its products or components. The Company has entered into an agreement dated May 12, 2003, and amended on March 22, 2005 with Medica s.r.l., (“Medica”) a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce the Company’s OLpūr MD190, MD220 or other filter products at the Company’s option. The agreement requires the Company to purchase from Medica the OLpūr MD190s and MD220s or other filter products that the Company directly markets in Europe, or are marketed by our distributor in Italy. In addition, Medica will be given first consideration in good faith for the manufacture of OLpūr MD190s, MD220s or other filter products that the Company does 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 the Company 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 having failed to manufacture one or more products in accordance with any applicable laws, Medica will be responsible for the cost of recall. The agreement also requires that the Company maintain certain minimum product-liability insurance coverage and that the Company indemnify Medica against certain liabilities arising out of the Company’s 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 the Company has no separate agreement with respect to such activities, Medica has also been manufacturing the Company’s DSU in limited quantities.

The Company also entered into an agreement in December 2003, and amended in June 2005, with Membrana GmbH (“Membrana”), 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 is the Company’s exclusive provider of the fiber for the OLpūr MDHDF filter series in the European Union as well as certain other territories through September 2009. Notwithstanding the exclusivity provisions, the Company may purchase membranes from other providers if Membrana is unable to timely satisfy the Company’s orders. If and when the volume-discount pricing provisions of the Company’s agreement with Membrana become applicable, for each period the Company will record inventory and cost of goods sold for the Company’s fiber requirements pursuant to the agreement with Membrana 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 the Company to a greater volume-discount for such calendar year, then the Company will adjust inventory and cumulative cost of goods sold amounts quarterly throughout the calendar year to reflect the greater volume-discount. In August 2006, Membrana awarded the Company temporary pricing concessions until June 2007. The Company anticipates that these prices will remain in effect throughout 2007.

The Company is committed to use one supplier for its production of products for sale in Europe; however no minimum purchase requirements are in effect.

Contractual Obligations

At December 31, 2006, the Company had noncancellable operating leases on real and personal property that expire in 2007 for the rental of its office and research and development facilities and equipment. Rent expense for the years ended December 31, 2006 and 2005 totaled approximately $190,095 and $170,259, respectively. Leases are renewable on the anniversary of their respective commencements.

The following tables summarize our minimum contractual obligations and commercial commitments as of December 31, 2006:

Contractual Obligations	Total	Payments Due in Period Within 1 Year	Years 1-3	Years 3-5	More than 5 Years
Convertible Notes (1)	$ 7,290,229	$ -	$ -	$ -	$ 7,290,229
Leases	133,612	133,612	-	-	-
Employment Contracts	567,075	424,163	142,912	-	-
Total	$ 7,990,916	$ 557,775	$ 142,912	$ -	$ 7,290,229

(1) Includes interest of $2,090,229.

Employee Severance Agreement

During the year ended December 31, 2005, the Company expensed $318,250 for severance costs associated with the termination of the employment of Jan Rehnberg, our former Senior Vice President, Marketing and Sales. These severance expenses were reported within accrued expenses and presented as accrued severance expenses at December 31, 2005. In accordance with the terms and provisions of his employment agreement, the Company paid a lump sum severance payment of $253,856 of the balance to Mr. Rehnberg on April 19, 2006. During September 2006, the Company reversed the $64,394 residual portion of the severance accrual as it was determined during the quarter that this liability was no longer required. In 2006, the Company expensed $93,072 for severance costs associated with the termination of an employee in France.

Note 10 - Income Taxes

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

	2006	2005
U.S. federal statutory rate	35.00%	35.00%
State & local taxes	8.67%	6.13%
Tax on foreign operations	(5.68)%	(10.68)%
Other	0.01%	0.10%
Valuation Allowance	(38.00)%	(30.55)%
Effective tax rate	0.00%	0.00%

Significant components of the Company's deferred tax assets as of December 31, 2006 and 2005 are shown below:

	2006	2005
Deferred tax assets:		
Net operating loss carryforwards	$ 14,926,870	$ 12,077,036
Research and development credits	825,079	745,141
Nonqualified stock option compensation expense	1,367,354	1,130,179
Other Temporary Book - Tax differences	11,562	52,968
Total deferred tax assets	17,130,865	14,005,324
Valuation allowance for deferred tax assets	(17,130,865)	(14,005,324)
Net deferred tax assets	$ —	$ —

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

At December 31, 2006, the Company had Federal, New York State and New York City income tax net operating loss carryforwards of approximately $30 million each and foreign income tax net operating loss carryforwards of approximately $7.5 million. The Company also had Federal research tax credit carryforwards of approximately $745,000 at December 31, 2005 and $825,000 at December 31, 2006. The Federal net operating loss and tax credit carryforwards will expire at various times between 2012 and 2026 unless utilized.

The Company's net operating loss carryforwards and net losses for each jurisdiction as of December 31, 2006 and 2005 are shown below:

	US		IRELAND		Total	
	2006	2005	2006	2005	2006	2005
Net Operating Loss Carryforward	$ 30,017,322	$ 24,579,888	$ 7,510,384	$ 4,836,445	$ 37,527,706	$ 29,416,333
Net Loss	$ 5,998,491	$ 2,872,981	$ 2,014,420	$ 2,595,196	$ 8,012,911	$ 5,468,177

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Note 11 - Related Party Transactions

The Lead Director of the Company's Board is on leave from his position as the Chairman of Columbia University's Department of Surgery. The Company licenses the right to use approximately 2,788 square feet of office space from the Trustees of Columbia University. The term of the license agreement is for one year through September 30, 2007 at a monthly cost of $11,965, including monthly internet access. The Company does not currently have any other material relationship with Columbia University.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 8A. Controls and Procedures.

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the Company's effectiveness of disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-KSB. Management identified a material weakness, due to an insufficient number of resources in the accounting and finance department, resulting in (i) an ineffective review, monitoring and analysis of schedules, reconciliations and financial statement disclosures and (ii) the misapplication of U.S. GAAP and SEC reporting requirements. Due to the pervasive effect of the lack of resources, including a lack of resources that are appropriately qualified in the areas of U.S. GAAP and SEC reporting, and the potential impact on the financial statements and disclosures and the importance of the annual and interim financial closing and reporting process, in the aggregate, there is more than a remote likelihood that a material misstatement of the annual financial statements would not have been prevented or detected. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures have not been operating effectively as of the end of the period covered by this report.

Remediation Plans

Management is also in the process of remediating the above-mentioned weakness in our internal control over financial reporting and has designed the following steps to be implemented:

ŸDevelop procedures to implement a formal monthly closing calendar and process and hold monthly meetings to address the monthly closing process;

ŸEstablish a detailed timeline for review and completion of financial reports to be included in our Forms 10-QSB and 10-KSB;

ŸEnhance the level of service provided by outside accounting service providers to further support and supplement our internal staff in accounting and related areas;

ŸSeek additional staffing to provide additional resources for internal preparation and review of financial reports; and

Ÿ Employ the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-QSB and 10-KSB.

These remediation plans will be implemented during the second and third quarters of fiscal 2007. The material weakness will not be considered remediated until the applicable remedial procedures are tested and management has concluded that the procedures are operating effectively.

Management recognizes that use of our financial resources will be required not only for implementation of these measures, but also for testing their effectiveness. Based on our existing funds, there can be no assurance that such procedures will be implemented on a timely basis, or at all.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 8B. Other Information.

Not applicable.

PART III

Item 9. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance with Section 16(a) of the Exchange Act.

We have adopted a written code of ethics and business conduct that applies to our directors, executive officers and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the American Stock Exchange by filing such amendment or waiver with the Securities and Exchange Commission. This code of ethics and business conduct can be found in the corporate governance section of our website, www.nephros.com.

The other information called for by this item is incorporated by reference to our definitive proxy statement relating to our 2006 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2007, the information called for by this item will be filed as part of an amendment to this Form 10-KSB on or before such date, in accordance with General Instruction E(3).

Item 10. Executive Compensation.

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2006 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2007, the information called for by this item will be filed as part of an amendment to this Form 10-KSB on or before such date, in accordance with General Instruction E(3).

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Equity Compensation Plan Information

The following table provides information as of December 31, 2006 about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors upon exercise of options, warrants or rights under all of our existing equity compensation plans. Our existing equity compensation plans consist of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (together, our "Stock Option Plans") in which all of our employees and directors are eligible to participate.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by stockholders	2,314,548	$ 1.74	84,384
Equity compensation plans not approved by stockholders	-	-	-
All plans	2,314,548	$ 1.74	84,384

The other information called for by this item is incorporated by reference to our definitive proxy statement relating to our 2006 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2007, the information called for by this item will be filed as part of an amendment to this Form 10-KSB on or before such date, in accordance with General Instruction E(3).

Item 12. Certain Relationships and Related Transactions, and Director Independence.

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2006 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2007, the information called for by this item will be filed as part of an amendment to this Form 10-KSB on or before such date, in accordance with General Instruction E(3).

Item 13. Exhibits.

EXHIBIT INDEX

3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant. (5)
3.2	Amended and Restated By-laws of the Registrant. (1)
4.1	Specimen of Common Stock Certificate of the Registrant. (1)
4.2	Form of Underwriter's Warrant. (1)
4.3	Form of Convertible Promissory Note due August 7, 2002. (1)

4.4	Form of Senior Convertible Bridge Notes due 2004. (1)
4.5	Class C Warrant for the Purchase of Shares of Common Stock, dated September 22, 2003, issued to Joseph Giamanco by the Registrant. (1)
4.6	Class C Warrant for the Purchase of Shares of Common Stock, dated September 22, 2003, issued to George Hatsopoulous by the Registrant. (1)
4.7	Stock Purchase Warrant, dated June 19, 2002, issued to Plexus Services Corp. by the Registrant. (1)
4.8	Class A Warrant for the Purchase of Shares of Common Stock, dated August 5, 2002, issued to Lancer Offshore, Inc. (1)
4.9	Warrant for the purchase of shares of common stock dated January 18, 2006, issued to Marty Steinberg, Esq., as Court-appointed Receiver for Lancer Offshore, Inc.
10.1	Amended and Restated 2000 Nephros Equity Incentive Plan. (1) (2)
10.2	2004 Nephros Stock Incentive Plan. (1) (2)
10.3	Form of Subscription Agreement dated as of June 1997 between the Registrant and each Purchaser of Series A Convertible Preferred Stock. (1)
10.4	Amendment and Restatement to Registration Rights Agreement, dated as of May 17, 2000 and amended and restated as of June 26, 2003, between the Registrant and the holders of a majority of Registrable Shares (as defined therein). (1)
10.5	Employment Agreement dated as of November 21, 2002 between Norman J. Barta and the Registrant. (1) (2)
10.6	Amendment to Employment Agreement dated as of March 17, 2003 between Norman J. Barta and the Registrant. (1) (2)
10.7	Amendment to Employment Agreement dated as of May 31, 2004 between Norman J. Barta and the Registrant. (1) (2)
10.8	Form of Employee Patent and Confidential Information Agreement. (1)
10.9	Form of Employee Confidentiality Agreement. (1)
10.10	Settlement Agreement dated June 19, 2002 between Plexus Services Corp. and the Registrant. (1)
10.11	Settlement Agreement dated as of January 31, 2003 between Lancer Offshore, Inc. and the Registrant. (1)
10.12	

	Settlement Agreement dated as of February 13, 2003 between Hermitage Capital Corporation and the Registrant. (1)
10.13	License Agreement dated as of July 1, 2003 between the Trustees of Columbia University in the City of New York and the Registrant. (1)
10.14	Form of Transmittal Letter Agreement, dated as of April 28, 2004, between each holder of convertible promissory notes due August 7, 2002 and the Registrant. (1)

10.15	Commitment Agreement between Ronald Perelman and the Registrant, dated as of May 30, 2003. (1)
10.16	Form of Subscription Agreement between the Registrant and each purchaser of Senior Convertible Bridge Notes due 2004. (1)
10.17	Supply Agreement between Nephros, Inc. and Membrana GmbH, dated as of December 17, 2003. (1) (3)
10.18	Employment Agreement dated as of June 16, 2004 between Marc L. Panoff and the Registrant. (1) (2)
10.19	Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of May 12, 2003. (1) (3)
10.20	License Agreement dated as of July 1, 2005 between the Trustees of Columbia University in the City of New York and the Registrant. (1)
10.21	HDF-Cartridge License Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.22	Subscription Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.23	Amendment No. 1 to 2004 Nephros Stock Incentive Plan. (2) (5)
10.24	Non-employee Director Compensation Summary. (2) (6)
10.25	Named Executive Officer Summary of Changes to Compensation. (2) (6)
10.26	Stipulation of Settlement Agreement between Lancer Offshore, Inc. and Nephros, Inc. approved on December 19, 2005. (8)
10.27	Consulting Agreement, dated as of January 11, 2006, between the Company and Bruce Prashker. (2) (8)
10.28	Summary of Changes to Chief Executive Officer’s Compensation. (2) (8)
10.29	Employment Agreement, dated as of February 28, 2006, between the Company and Mark W. Lerner. (2) (8)
10.30	Amended Supply Agreement between Nephros, Inc. and Membrana GmbH dated as of June 16, 2005. (3) (7)
10.31	Amended Manufacturing and Supply Agreement between Nephros, Inc. and Medica s.r.l., dated as of March 22, 2005. (3) (8)
10.32	Form of 6% Secured Convertible Note due 2012 for June 1, 2006 Investors. (9)

10.33	Form of Prepayment Warrant. (9)
10.34	Form of Subscription Agreement, dated as of June 1, 2006. (9)
10.35	Form of Registration Rights Agreement, dated as of June 1, 2006. (9)

10.36	Form of 6% Secured Convertible Note due 2012 for June 30, 2006 Investors. (10)
10.37	Form of Subscription Agreement, dated as of June 30, 2006. (10)
10.38	Employment Agreement between Nephros, Inc. and William J. Fox, entered into on August 2, 2006. (2) (11)
10.39	Addendum to Commercial Contract between Nephros, Inc. and Bellco S.p.A, effective as of January 1, 2007. (3)
21.1	Subsidiaries of Registrant.
23.1	Consent of Deloitte & Touche LLP, dated as of April 10, 2007.
31.1	Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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(1)	Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1, File No. 333-116162.
(2)	Management contract or compensatory plan arrangement.
(3)	Portions omitted pursuant to a request for confidential treatment.
(4)	Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K Filed with the Securities and Exchange Commission on March 3, 2005.
(5)	Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (No. 333-127264), as filed with the Securities and Exchange Commission on August 5, 2005.
(6)	Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on May 16, 2005.

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

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

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

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

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

Item 14. Principal Accountant Fees and Services.

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2006 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2007, the information called for by this item will be filed as part of an amendment to this Form 10-KSB on or before such date, in accordance with General Instruction E(3).

SIGNATURES

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

NEPHROS INC.

Date: April 10, 2007 By: /s/ Norman J. Barta
Norman J. Barta
President and Chief Executive Officer

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

Signature	**Title**	**Date**
/s/ Norman J Barta Norman J. Barta	President, Chief Executive Officer and Director (Principal Executive Officer)	April 10, 2007
/s/ Mark W. Lerner Mark W. Lerner	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 10, 2007
/s/ William J. Fox William J. Fox	Executive Chairman and Director	April 10, 2007
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Lead Director of the Board of Directors	April 10, 2007
/s/ Lawrence J. Centella Lawrence J. Centella	Director	April 10, 2007
/s/ Donald G. Drapkin Donald G. Drapkin	Director	April 10, 2007
/s/ Howard Davis Howard Davis	Director	April 10, 2007
/s/ Bernard Salick, M.D. Bernard Salick, M.D.	Director	April 10, 2007
/s/ Judy S. Slotkin Judy S. Slotkin	Director	April 10, 2007
/s/ W. Townsend Ziebold, Jr. W. Townsend Ziebold, Jr.	Director	April 10, 2007

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