NEPHROS INC
Form 10KSB
March 31, 2005

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, 2004

OR

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

For the transition period from_____ to_____

Commission file number 001-32288

NEPHROS, INC.

(Name of Small Business Issuer in its Charter)

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

3960 Broadway
New York, NY 10032

(Address of principal executive offices)

(212) 781-5113

(Issuer's telephone number, including area code)

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

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

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

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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. []

State issuer's revenues for fiscal year ended December 31, 2004: $138,406

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant: $22,872,589.88 determined by reference to the closing price of the common stock on March 17, 2005.

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

Class	Outstanding at March 17, 2005
Common Stock, $.001 par value	12,120,248

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 2004 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
(A Development Stage Company)

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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. Although the Chairman of our Board is the Chairman of Columbia University's Department of Surgery and we license the right to use office space from Columbia University, we do not currently have any other material relationship with Columbia University.

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

We currently have three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy to ESRD patients:

- OLpurTM MD190, our filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

- OLpurTM H2HTM, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

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

We are also developing our OLpurTM HD190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpurTM MD190 but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpurTM HD190 was designed for use with either hemodialysis or hemodiafiltration machines.

OLpur and H2H are among our trademarks for which U.S. registrations are pending. H2H is a registered European Union trademark. We have assumed that the reader understands that these terms are source-indicating. Accordingly, such terms appear throughout the remainder of this Annual Report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that our OLpur MD190 is more effective than any products currently available for ESRD therapy, because our dialyzer is better at removing certain larger toxins (known in the industry as "middle molecules" because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

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 OLpur MD190 and the OLpur H2H will provide these benefits to ESRD patients at competitive costs and without the need for ESRD treatment providers to make significant capital expenditures in order to use our products. We also believe that the OLpur NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

We began sales of our first product in March 2004. Accordingly, our sales history does not yet provide a basis from which to reasonably estimate rates of product return, if any. Consequently, and until we can estimate rates of product return, if any, more effectively, we will not recognize revenue from these sales until the rights of return have expired. We have incurred losses since our inception primarily as a result of our research and development efforts.

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.

Based on our review of industry publications, we believe that there were approximately 486,000 ESRD patients in the United States and 1.5 million worldwide at year end 2001, with an expected worldwide ESRD population of approximately 2.5 million by the end of 2010. See S. Moeller et al., ESRD patients in 2001: global overview of patients, treatment modalities and development trends, Nephrol. Dial. Transplant., 2002; 17:2071- 2076, and see "10 Important Facts About Kidney Disease," from The American Society of Nephrology's website. We believe the worldwide distribution of the population of dialysis patients at year end 2001 was approximately as follows:

Territory	2001 Dialysis Patients (1)
United States of America	288,000
Japan	220,000
Germany	54,000
Brazil	54,000
Italy	42,000
The rest of the World	483,000
Total	1,141,000

(1) See S. Moeller et al., ESRD patients in 2001: global overview of patients, treatment modalities and development trends, Nephrol. Dial. Transplant., 2002; 17:2071-2076.

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 OLpur MD190 in part or all of Cyprus, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom (referred to in this Annual Report collectively as our "Target European Market"). There are currently no FDA approved HDF therapies available in the U.S. market. If we can obtain FDA approval of OLpur MD190 and OLpur H2H, we will enter the U.S. hemodialysis dialyzer market by combining our OLpur MD190 filter with our OLpur H2H device which enables 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. According to certain industry publications, there is a high penetration of reuse practices in North America, as opposed to a low penetration of reuse practices in Europe and Japan. See S. Moeller et al., ESRD patients in 2001: global overview of patients, treatment modalities and development trends, Nephrol. Dial. Transplant., 2002; 17:2071-2076. 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 reuse is not employed.

Current ESRD Therapy Options

Current renal replacement therapy technologies include (1) two types of dialysis, peritoneal dialysis and hemodialysis, (2) hemofiltration and (3) hemodiafiltration, a combination of hemodialysis and hemofiltration. Dialysis can be broadly defined as the process that involves movement of molecules across a semipermeable membrane. In hemodialysis, hemofiltration or hemodiafiltration, the blood is exposed to an artificial membrane outside of the body. During

Peritoneal Dialysis (PD), the exchange of molecules occurs across the membrane lining of the patient's peritoneal cavity. While there are variations in each approach, in general, the three major categories of renal replacement therapy in the marketplace today are defined as follows:

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

- Hemodialysis uses an artificial kidney machine to remove certain toxins and fluid from the patient's blood while controlling external blood flow and monitoring patient vital signs. Hemodialysis patients are connected to a dialysis machine via a vascular access device. The hemodialysis process occurs in a dialyzer cartridge with a semi-

permeable membrane which divides the dialyzer into two chambers: while the blood is circulated through one chamber, a premixed solution known as dialysate circulates through the other chamber. Toxins and excess fluid from the blood cross the membrane into the dialysate solution through a process known as "diffusion."

- Hemodiafiltration, or HDF, in its basic form combines the principles of hemodialysis with hemofiltration. Hemofiltration is a cleansing process without dialysate solution where blood is passed through a semi-permeable membrane, which filters out solute particles. HDF uses dialysate solution with a negative pressure (similar to a vacuum effect) applied to the dialysate solution to draw additional toxins from the blood and across the membrane. This process is known as "convection." HDF thus combines diffusion with convection, offering efficient removal of small solutes by diffusion, with improved removal of larger substances (i.e., middle molecules) by convection.

Hemodialysis is the most common form of extracorporeal renal replacement therapy and is generally used in the United States. Hemodialysis fails, in our opinion, to address satisfactorily the long-term health or overall quality of life of the ESRD patient. We believe that the HDF process, which is currently available in our Target European Market and Japan, offers improvement of other dialysis therapies because of better ESRD patient tolerance and superior blood purification of both small and middle molecules.

Current Dialyzer Technology used with HDF Systems

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

blood's proper fluid volume. With the current dialyzer technology, fluid is replaced in one of two ways: pre-dilution or post-dilution.

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

- With post-dilution, substitution fluid is added to blood after the blood has exited the dialyzer cartridge. This is the currently preferred method because the concentration gradient is maintained at a higher level, thus not impairing the rate of removal of small toxins by diffusion. The disadvantage of this method, however, is that there is a limit in the amount of plasma water that can be filtered from the blood before the blood becomes too viscous, or thick. This limit is approximately 25% to 30% of the blood flow rate. This limit restricts the amount of convection, and therefore limits the removal of middle and larger molecules.

The Nephros Mid-Dilution Diafiltration Process

Our OLpur MD190 filter 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; it is then overdiluted with sterile infusion fluid before entering a second stage, where it is filtered once again against a dialysate solution. We believe that the MDF process provides improved toxin removal in HDF treatments, with a resulting improvement in patient health.

Our Products

Our products currently available or in development include:

OLpur MD190

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

Laboratory bench studies have been conducted on our OLpur MD190 by members of our research and development staff and by a third party. In laboratory bench studies conducted by members of our research and development staff, OLpur MD190 offered small molecule removal comparable to existing HDF standards and an improvement of over 80% in removing middle molecules. In a third-party study which was performed between April 2001 and June 2001 by the University of Kentucky in concert with Baxter Renal

Division, a division of Baxter Healthcare Corporation, each of two prototypes of the OLpur MD190 offered urea (a small molecule) removal comparable to a leading

HDF dialyzer in common use at the time (which was used as a control device) and an improvement of over 122% in removing the protein known as (beta)2-microglobulin (a middle molecule), when compared to such existing HDF dialyzer. The control device used in this study is still one of the leading HDF dialyzers in common use today.

We completed our initial clinical studies to evaluate the efficacy of our OLpur MD190 as compared to conventional dialyzers in Montpellier, France in 2003, under the supervision of Bernard Canaud, M.D., in Dr. Canaud's capacity as president of L'institut de Recherche et de Formation en Dialyse, a research institute located in Montpellier, France. Dr. Canaud is a nephrologist associated with the Hospal Lapeyronie in Montepellier, France. The results from this clinical study support our belief that OLpur MD190 is superior to post-dilution hemodiafiltration using a standard high-flux dialyzer with respect to B2-microglobulin clearance. In addition, clearances of urea, creatinine, and phosphate met the design specifications proposed for the OLpur MD190 device. Furthermore, adverse event data from the study suggest that hemodiafiltration with our OLpur MD190 device was well tolerated by the patients and safe. A manuscript describing the results of this study has been published in Kidney International, Vol. 67 (2005), pp. 349-356.

We have initiated clinical studies in the United Kingdom, France, Germany and Italy to further demonstrate the therapeutic benefits of our OLpur MD190. A multi-center study under the direction of Dr. Canaud (Principal Investigator) was started in March 2005. This study will encompass six centers in France and four centers in Germany. Also commencing in the first quarter of 2005 were studies by Dr. Magdi Yaqoob in the United Kingdom and Dr. Antonio Santoro in Italy.

We contracted with TUV 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 Conformite Europeene, or CE mark, a mark which demonstrates compliance with relevant European Union requirements. We received CE marking on the MD190, as well as certification of our overall quality system, on July 31, 2003.

We initiated sales of OLpur MD190 in our Target European Market in March 2004, and we have developed our infrastructure both at a clinical and administrative level to support sales. We have established a sales presence in countries throughout our Target European Market, both through direct contact and through a distribution network, developed marketing material in the relevant local languages and attended trade shows where we promoted our product to several thousand people from the industry.

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

We have filed a pre-IDE application with respect to the OLpur MD190 and have initiated discussions with the FDA to facilitate the 510(k) approval process. At this point, the onus is on us to take the initiative in pushing forward on the application. We met with the FDA in February 2005 to discuss potential strategies and the appropriate next steps. As a result of such meeting, we believe that a separate U.S. clinical study would be to our advantage. Provided that such trials are timely and successful, we expect to file 510(k) applications with respect to the OLpur MD190 and the OLpur H2H in the first half of 2006 and hope to achieve U.S. regulatory approval of both products by the end of 2006.

OLpur HD190

OLpur HD190 is our high-flux dialyzer cartridge, designed for use with either hemodialysis or hemodiafiltration machines. The OLpur HD190 incorporates the same materials as our OLpur MD190, but has the architecture similar to other dialyzer cartridges currently marketed for hemodialysis and hemodiafiltration therapy.

We do not expect our OLpur HD190 high flux filter to offer a substantial sales opportunity in the foreseeable future. On March 8, 2005, we submitted a 510(k) application for approval of our OLpur HD190 high flux filter. 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 OLpur MD190 hemodiafilter product in the United States.

OLpur H2H

OLpur H2H is our add-on module that converts the most common types of hemodialysis machines into HDF-capable machines allowing them to use the OLpur MD190. Ausus Technologies, Inc., a provider of repair service for dialysis machine circuit boards and modules, which promotes itself as the largest independent service provider in the United States, has indicated that at least 85% of the circuit cards it had sold or repaired in 2002 were used in machines with volumetric ultrafiltration control. Based on this information, we estimate that in 2003, approximately 85% of the dialysis machines in use by independent dialysis clinics in the United States will feature volumetric ultrafiltration control, which is the mechanism required to use our H2H technology.

We have completed our OLpur H2H design and laboratory bench testing, all of which were conducted by members of our research and development staff. We believe that our design verification of the OLpur H2H will have progressed to the point where the device will be ready for U.S. clinical trials in the second half of 2005, and, provided that such trials are timely and successful, we expect to file 510(k) applications with respect to the OLpur MD190 and the OLpur H2H in the first half of 2006 and hope to achieve U.S. regulatory approval of both products by the end of 2006. We plan to apply for CE marking of our OLpur H2H in the first quarter of 2006.

OLpur NS2000

OLpur NS2000 is our standalone HDF machine and associated filter technology, which is in the development stage. The OLpur NS2000 system is currently in development in conjunction with an established dialysis machine manufacturer in Italy. The OLpur NS2000 will use the basic platform provided by this manufacturer, but will incorporate our H2H technology including our proprietary substitution fluid systems.

We anticipate having OLpur NS2000 units available for clinical testing by the third quarter of 2005. We have also designed and developed proprietary substitution fluid filter cartridges for use with OLpur NS2000, which have been subjected to pre-manufacturing testing. OLpur NS2000 is currently targeted for market introduction in our Target European Market and the United States no earlier than 2006. In any event, we will need to obtain the relevant regulatory clearances prior to any market introduction of our OLpur NS2000 in our Target European Market or the United States. We are currently in the design verification stage of development with respect to the NS2000 and anticipate filing our pre-IDE and beginning our clinical studies in 2006. Depending on results, we anticipate filing for regulatory approval (including a 510(k)

application) in 2006 and ultimately receiving CE marking and regulatory approval in the United States in the second half 2006.

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 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. Our objective is to capitalize on the demand for improved therapy and to generate market acceptance and market share for our products through a three stage approach:

Showcase product efficacy in our Target European Market:

As of March 2004, we initiated sales in our Target European Market for the OLpur MD190. There is an immediate opportunity for sales of the OLpur MD190 in our Target European Market because there is an established HDF machine base using disposable dialyzers. Assuming a three-times-per-week treatment schedule using disposable dialyzers, each ESRD patient will use approximately 156 dialyzers a year. Consequently, we believe that this presents a substantial sales opportunity.

We are marketing our OLpur MD190 directly to major dialysis centers in our Target European Market, including prominent practitioners in ESRD therapy. We believe that an endorsement of our product by early adopters will encourage others to follow. In addition, we have engaged, and are engaging, distributors in several regions of our Target European Market to accelerate our product sales. Each of our current and prospective distributors with which we are currently seeking relationships has over two decades of experience in its respective ESRD therapy markets.

Convert existing hemodialysis machines to hemodiafiltration:

We are seeking to complete development of our OLpur H2H technology, will pursue comprehensive clinical trials to validate OLpur H2H in 2005, and plan to apply for CE marking for OLpur H2H in the first quarter of 2006. We also plan to complete our regulatory approval processes in the United States for both OLpur MD190 and OLpur H2H in 2006. If successfully developed and approved, our OLpur H2H product will enable HDF therapy using the most common types of hemodialysis machines together with our OLpur MD190 filters. We intend to use the OLpur H2H to introduce HDF technology to the U.S. dialysis market.

Upgrade dialysis clinics to OLpur NS2000:

We believe the introduction of the OLpur NS2000, targeted for 2006, will represent a further upgrade in performance for dialysis clinics by offering a cost-effective stand-alone HDF solution that incorporates the benefits of our OLpur H2H technology. We believe dialysis clinics will entertain OLpur NS2000 as an alternative to their current technology at such dialysis clinic's machine replacement point.

Manufacturing and Suppliers

We do not intend to manufacture any of our products or components. We have entered into an agreement dated May 12, 2003, with Medica s.r.l., a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpur MD190. The agreement requires us to purchase from Medica a specified percentage of the OLpur MD190's that we directly market, where such percentage is reduced over the course of the agreement and provides for certain volume discounts. In addition, Medica will be given first consideration in good faith for the manufacture of OLpur MD190s 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 OLpur MD190 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 OLpur MD190s 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 OLpur MD190 in accordance with the quality standards outlined in the agreement. Upon recall of any OLpur MD190 due to Medica's having manufactured one or more products that fail to conform to the required specifications or were not manufactured in accordance with any applicable laws, Medica will be responsible for the cost of recall. The agreement also requires that we maintain certain minimum product-liability insurance coverage and that we indemnify Medica against certain liabilities arising out of our products that they manufacture, providing they do not arise out of Medica's breach of the agreement, negligence or willful misconduct. The agreement provides for an initial term of three years, 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.

We have also entered into an agreement dated December 17, 2003, with Membrana GmbH, a manufacturer of medical and technical membranes for applications like dialysis with corporate headquarters located in Germany, to continue to produce the fiber for the OLpur MD190. Pursuant to the agreement, Membrana was our exclusive provider of the fiber for the OLpur MD190 for calendar year 2004. The agreement provides that Membrana's exclusivity may be extended to each successive calendar year of the term of the agreement if Membrana and we agree to product pricing to be applicable to such year during the prior year. Although Membrana and we did not reach an agreement as to exclusivity for calendar year 2005 during the prescribed period, we are currently in negotiations with Membrana that may result in such exclusivity, among other things. Pursuant to the agreement, after initial purchases at a fixed price, the purchase price for the fiber will be calculated on a volume discounted basis. Pursuant to such agreement, in each year of the term, Membrana and we will agree upon an estimate of the annual amount of fiber we expect to order in the following calendar year, and the purchase price of that fiber will be estimated and invoiced on the basis of the volume-discount applicable to such estimated volume. If the total amount of fiber purchased during any calendar year exceeds the amount used to set the invoice price for that year, then Membrana will refund to us the excess funds that we paid over the expenditure that would have occurred if the price for the actual volume had been invoiced all year. Conversely, if we purchase less fiber than the quantity used to set the invoice price during a calendar year, then we will pay Membrana the amount that we would have paid had the price for the actual volume been invoiced all year. In either case, the payments will be made by January 31 of the following year. The term of the agreement is perpetual, however, it may be terminated by either party, upon certain insolvency events or breaches by the other party or, after December 17, 2007, for any or no reason.

Sales and Marketing

We have established and are seeking to expand our own sales and marketing

organization to sell products in our Target European Market and, subject to regulatory approval, the United States. Our marketing staff has experience in both these areas. Our Senior Vice President, Marketing and Sales was formerly the Managing Director for Gambro Healthcare Europe, one of our major competitors. During his tenure with Gambro, he successfully initiated and developed the marketing of vertically-integrated dialysis products and services in France, Spain and the Middle East. We also have a Director of Sales who was a Territory Manager for Cobe Laboratories/Gambro, another of our major competitors, and was formerly Vice President of Renal Ventures Management, a corporation that developed dialysis clinics in the United States on a joint venture basis.

Our marketing strategy involves the marketing of our OLpur MD190 and OLpur H2H within the ESRD therapy market in the following two phases:

Phase I: In the first phase, which we have already begun, we are marketing the OLpur MD190 to healthcare providers such as hospitals, dialysis clinics, managed care organizations and nephrology physician groups, which already own the equipment necessary to use the OLpur MD190 and/or understand hemodiafiltration therapy. We expect that we will be able to demonstrate the toxin removal advantages of the OLpur MD190 to those healthcare providers who have a working knowledge of hemodiafiltration therapy. We have begun marketing the OLpur MD190 in our Target European Market, and plan to begin marketing OLpur MD190 in the United States together with the OLpur H2H as soon as we obtain the requisite approvals.

Phase II: In the second phase, we intend to introduce the OLpur H2H to healthcare providers within the ESRD therapy market. Our goal is to achieve market penetration by offering the OLpur H2H for use by healthcare providers

inexpensively, thus permitting the providers to use the OLpur H2H without a large initial capital outlay. We believe that this will allow healthcare providers to upgrade their therapeutic performance profile and generate demand for our dialyzers with at most a very small cost increase on a per treatment basis, and without replacing their existing machines. We do not expect to generate any significant positive margins from sales of OLpur H2H. We plan to begin marketing the OLpur H2H in our Target European Market and the United States as soon as we obtain the respective requisite approvals.

As part of our marketing strategy, we also intend to introduce the OLpur NS2000 if and when we obtain the requisite regulatory approvals. We have targeted the OLpur NS2000 for market introduction in 2006.

We have established a multi-lingual customer service and financial processing facility in Dublin, Ireland, with telephone-toll-free multi-lingual customer support available to our customer base in our Target European Market. We have engaged a full time Director of Clinical Services who has a background in nephrology nursing, administration and education who provides customer training and support. We have also initiated four studies designed to continue our evaluation of effectiveness of the OLpur MD190 when used on ESRD patients in our Target European Market. We intend for these studies to provide us with valuable information regarding the efficacy of our product and an opportunity to introduce the OLpur MD190 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.

As discussed above, we intend to market our products primarily to healthcare providers such as hospitals, dialysis clinics, managed care organizations, and nephrology physician groups. We intend to ship our products to these potential customers with the assistance of the manufacturers of our products. We have engaged, and are in discussions with product distributors in our Target European Market, and major medical device manufacturers/ providers in Korea, China, and South America, regarding license and/or distribution opportunities for our technology.

We have entered into two non-exclusive distribution agreements with respect to the distribution of our products in certain territories within our Target European Market. To date, we have had only preliminary meetings with major medical device manufacturers/providers in Korea, China and South America.

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 OLpur 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.

In addition, we entered into a Subscription Agreement with Asahi dated March 2, 2005, pursuant to which Asahi purchased 184,250 shares of our common stock for an aggregate of 100 million Japanese Yen (approximately $956,000). The Subscription Agreement contains certain transfer restrictions with respect to the shares purchased thereunder.

Research and Development

Our research and development efforts continue on several fronts directly related to our current product line. In particular, we are examining ways to enhance further the removal of toxins from the blood by modifying certain blood characteristics. We have applied, and will continue to apply, if and when available, for U.S. Government grants in relation to this research, and will apply for further grants as appropriate. We received a U.S. Government grant in the amount of $99,837 beginning in the third quarter of 2003 to pursue some of this research. According to the terms of the grant, we seek reimbursement from the U.S. Government for expenses incurred with respect to this research. As of December 31, 2004, we have submitted claims of $46,992 for expenses related to the grant and have received reimbursements for such claims. We are also working on additional machine devices, next-generation user interface enhancements and other product enhancements. Our research and development expenditures were $2,352,604 and $1,320,556 for the fiscal years ended December 31, 2004 and 2003, respectively.

Competition

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

We expect to compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG, The Gambro Company and Baxter International Inc., currently three of the primary machine manufacturers in hemodialysis. At present, Fresenius, Gambro and Baxter also manufacture HDF machines.

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

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. Barriers to entry in our industry include:

- a large investment in research and development;
- costly and time-consuming regulatory hurdles to overcome before any products can be marketed and sold;
- high costs for marketing and for building an effective distribution network, both of which are particularly difficult in a market already dominated by a few well-established key players; and
- the ability to obtain financing during the entire start up period.

We believe that in order to become competitive, 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 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 OLpur H2H at a price that does not provide us with significant positive margins in order to encourage adoption of this product and associated demand for our dialyzers; and
- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities.

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 OLpur MD190 product and the method of hemodiafiltration employed in the operation of the product. Although there are pending applications with claims to the present embodiments of the OLpur H2H and the OLpur NS2000 products, these products are still in the development stage and we cannot determine if the applications (or the patents that 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.

As of December 31, 2004, we have nine issued U.S. patents and one issued Eurasian patent. In addition, we have eight pending U.S. patent applications, 13 pending patent applications in each of the European Patent Office, Japan and Canada, four pending patent applications in each of Brazil, China, Israel, South Korea and Mexico, three pending patent applications in Russia and two 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 nine issued U.S. patents are set forth in the chart below.

Title	Patent Number	Expiratio
Method and Apparatus for Efficient Hemodiafiltration	6,303,036	July 30,
Two Stage Diafiltration Method and Apparatus	6,406,631	July 30,
Non-Isosmotic Diafiltration System	6,423,231	October
Dual Stage Hemodiafiltration Cartridge	6,315,895	December
Sterile Fluid Filtration Cartridge and Method for Using Same . .	6,635,179	December
Method for High Efficiency Hemofiltration	6,620,120	May 22,
Thermally Enhanced Dialysis/Diafiltration System	6,716,356	May 29,
Dual-Stage Filtration Cartridge	6,719,907	January
Ionic Enhanced Dialysis/Diafiltration System.	6,821,431	June 3,

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.

Trademarks

As of December 31, 2004, we do not have any registered trademarks. Centrapur, OLpur, and our stylized "N" logo are among our non-registered trademarks, for which trademark registration applications are pending in both the U.S. Patent and Trademark Office and the European Union Office for Harmonisation in the Internal Market. H2H is a trademark of ours which is registered in the European Union and for which we have a registration application pending in the U.S.

Governmental Regulation

The research and development, manufacturing, promotion, marketing and distribution of our 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 U.S. Food and Drug Administration, or 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 Food, Drug and Cosmetic Act, or the FDC Act. All of our 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 medical devices generally limited to life-sustaining, life-supporting or implantable devices or new devices which have been found not to be substantially equivalent to legally marketed devices, that the FDA deems to require the most restrictive controls to ensure their safety and effectiveness.

Before a new medical device can be introduced to the market, FDA clearance of a premarket notification under Section 510(k) of the FDC Act or FDA clearance of a premarket 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

premarket approval under Section 515. The Section 510(k) premarket clearance process is generally faster and simpler than the Section 515 premarket 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) premarket clearance and that it may take several years from the date a Section 515 application is accepted for filing to obtain Section 515 premarket approval, although it may take longer in both cases. On March 8, 2005 we submitted a

filing to the FDA, a Premarket Notification under section 510(k), for approval of our OLpur HD190 high flux filter. 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 OLpur MD190 hemodiafilter product in the United States.

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

- that we will not need to reevaluate the applicability of the Section 510(k) premarket notification process to our products in the future;
- that the FDA will agree with our determination that we are eligible to use the Section 510(k) premarket notification process; or
- that the FDA will not in the future require us to submit a Section 515 premarket 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 premarket 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 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) premarket notification submission. Accordingly, if we do obtain Section 510(k) premarket clearance for any of our products, we will need to submit another Section 510(k) premarket notification if we significantly affect that product's safety or effectiveness through subsequent modifications or enhancements.

If human clinical trials of a device are required in connection with a Section 510(k) notification and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or distributor of the device) will need to file an Investigational Device Exemption, or IDE, application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal testing and/or laboratory bench testing. If the IDE application is approved, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as specified in the IDE. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its

scientific soundness or the rights, safety or welfare of subjects. We intend to file IDEs with respect to the OLpur MD190,, the OLpur H2H and the OLpur NS2000. We have filed a pre-IDE application with respect to the OLpur MD190 and have initiated discussions with the FDA to facilitate the 510(k) approval process. As a result of such discussions, we believe that a separate U.S. clinical study would be to our advantage. We believe that our design verification of the OLpur H2H will have progressed to the point where the device will be ready for U.S. clinical trials in the second half of 2005 and, provided that such trials are successful, we expect to file 510(k) applications with respect to the OLpur MD190 and the OLpur H2H in the first half of 2006 and hope to achieve U.S. regulatory approval of both products by the end of 2006.

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

- the FDA's failure to schedule advisory review panels;
- changes in established review guidelines;

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

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

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

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

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

Before the FDA approves a Section 510(k) premarket 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 OLpur MD190 and OLpur 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 OLpur H2H have been inspected by the FDA, they have not all been inspected by any notified body. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. Even after the FDA has cleared a Section 510(k) submission, it will periodically inspect the manufacturing facilities and processes for compliance with QSR. In addition, in the event that additional manufacturing sites are added or manufacturing processes are changed, such new facilities and processes are also subject to FDA inspection for compliance with QSR. The manufacturing facilities and processes that will be used to manufacture our products have not yet been inspected by the FDA for compliance with QSR. We cannot assure you that the facilities and processes used by us will be found to comply with QSR and there is a risk that clearance or approval will, therefore, be delayed by the FDA until such compliance is achieved.

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

- all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;
- information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur; and
- certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive. The European Union directive applies to both the manufacturer's

quality assurance system and the product's technical design. Depending on the class of medical devices, a manufacturer may choose alternative regulatory approaches to demonstrate compliance with European Union provisions. 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 we chose to demonstrate compliance with European Union provisions requires the certification of a full quality management system by a notified body. We engaged TUV Rheinland of North America, Inc. ("TUV Rheinland") as the notified body to assist us in obtaining certification to International

Standards Organization ("ISO") 13485, which demonstrates compliance with the European Medical Device Directive for our quality management system.

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 the European Medical Device Directive 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 Conformite Europeenne, 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 TUV Rheinland that our quality management system conforms with the requirements of the European Community. At the same time, TUV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. As of the date of filing of this Annual Report, the manufacturing facilities and processes that we are using to manufacture our OLpur MD190 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 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 OLpur MD190 product, 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 OLpur H2H product by the first quarter of 2006, and regulatory approval in the United States in the second half of 2006. We anticipate obtaining CE marking of the NS2000 as well as regulatory approval in the United States in 2006.

Reimbursement

In both domestic markets and markets outside of the United States, sales of our 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. The following reflects the current reimbursement landscape in the United States.

Medicare Reimbursement

Medicare generally provides health insurance coverage for persons who are age 65 or older and for persons who are completely disabled. Medicare also provides coverage for other eligible patients, regardless of age, who have been medically determined to have ESRD. For patients eligible for Medicare based solely on ESRD (generally patients under age 65), Medicare eligibility begins three months after the month in which the patient begins dialysis. During this three-month waiting period, Medicaid, private insurance or

the patient is responsible for payment for dialysis services. This waiting period is waived for individuals who participate in a self-care dialysis-training program.

For ESRD patients under age 65 who have any employer group health insurance coverage (regardless of the size of the employer or the individual's employment status), Medicare coverage is generally secondary to the employer coverage during a 30-month coordination period that follows the establishment of Medicare eligibility or entitlement based on ESRD. During the coordination period, an employer group health plan is responsible for paying primary benefits at the rate specified in the plan, which may be a negotiated rate or the healthcare provider's usual and customary rate. As the secondary payer during this coordination period, Medicare will make payments up to the applicable composite rate for dialysis services to supplement any primary payments by the employer group health plan if the plan covers the services but pays only a portion of the charge for the services.

Medicare generally is the primary payer for ESRD patients after the 30-month coordination period. Under current rules, Medicare is also the primary payer for ESRD patients during the 30-month coordination period if, before becoming eligible for Medicare on the basis of ESRD, the patient was already age 65 or over (or eligible for Medicare based on disability) unless covered by an employer group health plan (other than a "small" employer plan) because of current employment. This rule eliminates for many dual-eligible beneficiaries the 30-month coordination period during which the employer plan would serve as primary payer and reimburse health care providers at a rate that we believe may be higher than the Medicare composite rate. The rule regarding entitlement to primary Medicare coverage when the patient is eligible for Medicare on the basis of both age (or disability) and ESRD has been the subject of frequent legislative and regulatory change in recent years and there can be no assurance that the rule will remain unchanged in the future.

When Medicare is the primary payer, it reimburses 80% of the composite rate set by the Medicare prospective reimbursement system for each dialysis treatment. The beneficiary is responsible for the remaining 20%, as well as any unmet Medicare deductible amount, although an approved Medicare supplement insurance policy, other private health insurance or Medicaid may pay on the beneficiary's behalf. The composite payment rates, effective January 1, 2002, for urban renal facilities published in February 2001 by the Department of Health and Human Services for outpatient dialysis services ranged from $121.24 to $144.05 per treatment depending on the location of the renal facility. We have confirmed with the Department of Health and Human Services that these composite payment rates currently remain in effect as of December 31, 2004. Reimbursement rates are subject to periodic adjustment based on certain factors,

including legislation and executive and congressional budget reduction and control processes, inflation and costs incurred in rendering the services, but in the past have had little relationship to the cost of conducting business.

We are unable to predict what, if any, future changes may occur in the Medicare composite reimbursement rate or in any other reimbursement program. Any reductions in the Medicare composite reimbursement rate or in any other reimbursement program could have a material adverse effect on our revenues and net earnings. In addition, there have been various legislative proposals for the reform of numerous aspects of Medicare, including extension of the coordination period and expanded enrollment of Medicare beneficiaries in managed care programs.

Private Reimbursement

Some ESRD patients have private insurance that covers dialysis services. As discussed above, health care providers receive reimbursement for ESRD treatments from the patient or private insurance during a "waiting period" of up to three months before the patient becomes eligible for Medicare. In addition, if the private payer is an employer group health plan, it is generally required to continue to make primary payments for dialysis services during the 30-month period following eligibility or entitlement to Medicare. In general, employers may not reduce coverage or otherwise discriminate against ESRD patients by taking into account the patient's eligibility or entitlement to Medicare benefits.

We believe that before Medicare primary coverage is established, private payers may reimburse dialysis expenses at rates significantly higher than compensation under the Medicare composite rate on a per-treatment basis. When Medicare becomes a patient's primary payer, private insurance often covers the per-treatment 20% coinsurance that Medicare does not pay.

Medicaid

Reimbursement Medicaid programs are state-administered programs partially funded by the federal government. These programs are intended to provide coverage for patients whose income and assets fall below state defined levels and who are otherwise uninsured. The programs may also serve as supplemental insurance programs for the Medicare co-insurance portion and provide certain coverages (e.g., oral medications) that are not covered by Medicare. Some Medicaid programs require Medicare recipients to pay a share of the cost of services based upon the recipient's level of income or assets, but other programs provide for coverage without coinsurance amounts.

Potential Health Care Legislation

Because the Medicare program represents a substantial portion of the federal budget, Congress takes action in almost every legislative session to modify the Medicare program for the purpose of reducing the amounts otherwise payable by the program to health care providers in order to achieve deficit reduction targets or meet other political goals. Legislation and/or regulations may be enacted in the future that may significantly modify the Medicare ESRD program or substantially affect reimbursement for dialysis services. Such legislation or regulations may materially adversely affect our potential revenues from the United States market.

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 OLpur MD190 product 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, 2004, we employed a total of 21 employees, 20 of whom were full time and one who was employed on a consulting basis or part-time.

Item 2. Description of Property

Our U.S. facilities are located at 3960 Broadway, 3rd and 4th Floors, New York, New York 10032 and consist of approximately 2,678 square feet of space. On July 1, 2004, we entered into a license agreement for the use of this space with the Trustees of Columbia University in the City of New York. The term of the license agreement is for one year with a monthly cost of $8,839, including monthly internet access. We use our facilities to house our corporate headquarters and research facilities. Our offices and laboratories are housed in the Mary Woodard Lasker Building, a part of the Audubon Business and Technology Center administered by Columbia University, which is equipped to accommodate biotechnology and medical product development companies. Of the space we license, 1,500 square feet is dedicated laboratory space, which is equipped with laboratory equipment, such as benches, fume hoods, gas, air and water systems, and the remaining 1,178 square feet is dedicated office space.

Our facilities in our Target European Market are located at 1st Floor, Suite 5, The Avenue, Beacon Court, Sandyford, Dublin 18, Ireland and consist of approximately 700 square feet of space. On August 1, 2003 we entered into a lease for this space with Mohan & Company, an accounting firm wholly-owned by our Director of Finance, Europe, Cormac Mohan. The term of the lease is for three years. The lease was modified on December 1, 2004 and was increased from 1,000 Euro (approximately $1,360 as of December 31, 2004) to 3,500 Euro (approximately $4,800 as of December 31, 2004) as part of a space increase and additional services provided to our Dublin offices. We use our facilities to house our customer service and accounting operations. The Avenue, Beacon Court is a new office complex within approximately 10 miles of downtown Dublin. We believe this space is currently adequate to meet our needs.

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

Item 3. Legal Proceedings

We are the 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, and is pending in the U.S. District Court for the Southern District of Florida (the "Ancillary Proceeding"). 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, and is also pending in the U.S. District Court for the Southern District of Florida, wherein the court has appointed a Receiver to manage Lancer Offshore, Inc. and various related entities (the "Receivership").

In April 2002, we engaged Hermitage Capital Corporation ("Hermitage") as our placement agent in connection with a proposed private placement of our securities. Thereafter, Hermitage introduced Lancer Offshore, Inc. to us as a potential investor in such proposed financing. In August 2002, we entered into a subscription agreement with Lancer Offshore, Inc. The subscription agreement

provided, among other things, that Lancer Offshore, Inc. would purchase, in three installments, (1) $3,000,000 principal amount of secured notes due March 15, 2003 convertible into 340,920 shares of our common stock and (2) warrants to purchase until December 2007 an aggregate of 68,184 shares of our 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, was sold. However, Lancer Offshore, Inc. 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 our 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.

In the Ancillary Proceeding, the Receiver for Lancer Offshore, Inc. alleges that, in consideration for Lancer Offshore, Inc.'s agreement to enter into the settlement agreement, we were required to deliver a note in the principal amount of $1,500,000 and an instrument evidencing the portion of warrants previously issued to Lancer Offshore, Inc. that were not surrendered by Lancer Offshore, Inc. pursuant to the settlement agreement, and the Receiver seeks 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 our common stock for $2.50 per share (or 21,308 shares of our common stock for $8.80 per share, if adjusted for the 0.2841-for-one reverse stock split we effected on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended).

On or about April 29, 2004, we served an answer in which we denied liability for, and asserted numerous defenses to, the Receiver's claims. We believe that we have valid defenses to the Receiver's claims and the prospective claims mentioned above, and we intend to continue to contest them vigorously. In

addition, on or about March 30, 2004, we asserted claims for damages against Lancer Offshore, Inc. that exceed the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership. We have discussed the potential settlement of all claims with the Receiver, however, at this time discovery for the Ancillary Proceeding is ongoing. There can be no assurance that we will settle or that the outcome of any of these proceedings will be successful.

Lancer Offshore, Inc. may contend that the 75,000 shares and $2.50 per share exercise terms of their warrant are not subject to adjustment as a result of the 0.2841-for-one reverse stock split we effected on September 10, 2004. Furthermore, Lancer Offshore, Inc. may claim that the number of shares issuable upon exercise of the warrant should actually be increased to 94,771 and the exercise price proportionally decreased to $1.98 per share, due to our September 10, 2004 reverse stock split to adjust for the difference between the split contemplated in the warrants (0.2248318-for-one) and our September 10, 2004 split (0.2841-for-one). We believe that the plain language of the amended warrant only excepts from adjustment the specific reverse stock split referred to in our registration statement that had been filed with the SEC at such time and was later withdrawn. In addition to the plain language of the amendment, we believe certain equitable considerations support our position that the warrant was subject to adjustment for our 0.2841-for-one reverse stock split.

We have currently reserved for the Ancillary Proceeding on our balance sheets as of December 31, 2004 as a $1,500,000 accrued liability. Such balance sheets do not include any adjustment for the possibility of a settlement of the Ancillary Proceeding or otherwise reflect our claims against the Receivership. Nonetheless, if and to the extent that our expenses related to defending against the Receiver's claims in the Ancillary Proceeding and/or pursuing our claims in the Receivership become significant or if we are found to have significant liability under the warrant or for costs and fees, 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.

Except for the matters described above, 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.

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

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

PART II

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

Our common stock began trading on the American Stock Exchange ("AMEX") on September 21, 2004 under the symbol NEP. The following table sets forth the high and low sales prices for our common stock as reported on the AMEX for each of the quarters ended September 30, 2004 and December 31, 2004.

Quarter	Common

Ended	Stock	
	High	Low
September 30, 2004	$6.27	$4.76
(September 21, 2004 - September 30, 2004)		
December 31, 2004	$5.70	$3.90

As of February 28, 2005, there were approximately 51 holders of record and approximately 779 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.

Nephros Equity Incentive Plan Information
As of December 31, 2004

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,852,540	$1.85	257,471
Equity compensation plans not approved by security holders	--	N/A	--
Total	1,852,540	$1.85	257,471

On September 20, 2004, the Securities and Exchange Commission declared effective our Registration Statement on Form S-1 (File No. 333-116162) with respect to the Company's initial public offering. Through December 31, 2004, of the $10.7 million of proceeds from the offering the Company had used: approximately $350,000 for the payment of accrued dividends with respect to our series B, series C and series D convertible preferred stocks; approximately $350,000 for product engineering towards the completion of our clinical grade OLpur H2H; and approximately 183,000 on sales and marketing expenses. The remaining proceeds are currently invested in short term, investment grade

securities.

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

Business Overview

Since our inception in April 1997, we have been engaged in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190, a dialyzer, OLpur H2H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines, and the OLpur NS2000 system, a stand-alone HDF machine with associated filter technology. We began selling our OLpur MD190 dialyzer in some or all of our Target European Market in March 2004, and have developed prototypes for our OLpur H2H product. We are developing our OLpur 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 H2H technology.

To date, we have devoted substantially all of our efforts to research, clinical development, seeking regulatory approval and establishing manufacturing and marketing relationships and our own marketing and sales support staff for the development, production and sale of our 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, 2004, we had an accumulated deficit of $41.8 million, and we expect to incur additional losses in the foreseeable future. We recognized net losses of $7.6 million for the year ended December 31, 2004, and $5.6 million for the year ended December 31, 2003.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through December 31, 2004, 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 $34.2 million in the aggregate. We have devoted substantially all of our capital resources to the research and development and the marketing of our products.

On March 2, 2005, we entered into a license agreement with Asahi granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpur 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.

In addition, we entered into a Subscription Agreement with Asahi dated March 2, 2005, pursuant to which Asahi purchased 184,250 shares of our common stock for an aggregate of 100 million Japanese Yen (approximately $956,000). The Subscription Agreement contains certain transfer restrictions with respect to the shares purchased thereunder.

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 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.

Financial Operations Overview

Revenue

We began sales of our first product in March 2004. Accordingly, our sales history does not yet provide a basis from which to reasonably estimate rates of product return, if any. Consequently, and until we are able to estimate rates of return, if any, more effectively, we do not recognize revenue from these sales until the rights of return have expired. Similarly, we are deferring cost of goods sold to the extent of amounts billed to customers.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees of our scientific and engineering consultants and related costs, clinical studies, machine and product parts and software and product testing. We expense research and development costs as incurred.

Selling, General and Administrative

Selling, General and Administrative expenses consist primarily of personnel and related costs for general corporate functions, including finance, accounting, legal, human resources, facilities and information systems expense.

We expect our expense from sales, marketing and customer service activities, including costs of distributing samples and expenses related to marketing clinical trials, to increase in future periods. These increases are a result of our plan to seek greater market penetration with our OLpur MD190 within our Target European Market and to enter additional markets and introduce additional products once we obtain the requisite regulatory approvals. We also anticipate increases in general and administrative expenses for insurance, professional services, investor relations and other activities associated with operating as a publicly-traded company.

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. Accordingly, our sales history does not yet provide a basis from which to reasonably estimate rates of product return, if any. Consequently, and until we can estimate rates of return, if any, more effectively, we do not recognize revenue from these sales until the rights of return have expired.

Accrued Expenses

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

Stock-Based Compensation

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

During December 2004, the FASB issued Statement No. 123R, "Share-Based

Payment" ("SFAS No. 123R"), which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. We grant options to purchase common stock to our employees and directors under various plans at prices equal to the market value of the stock on the dates the options were granted. SFAS No. 123R is effective for small business issuers the first interim reporting period beginning after December 15, 2005. Accordingly, we will adopt SFAS No. 123R commencing with the quarter ending March 31, 2006.

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

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

Plan of Operation

Based on our cash flow projections, we expect that our existing cash resources will be sufficient to satisfy our cash needs, with no further financing required, to obtain positive cash flow. However, if our sales do not meet our projections or our expenses exceed our expectations, then we may need to raise additional funds through additional public or private offerings of our securities. In such event, if we are unable to raise additional funds on a timely basis or at all, any progress with respect to our products, and, therefore, our potential revenues, would be adversely affected. Even if we generate no revenues, we believe our existing cash resources will be sufficient to satisfy our cash needs, with no further financing required through the second quarter of 2006.

We intend to focus our research and development efforts during the next 12 months on:

- advancing our OLpur H2H product development in order to eventually apply for regulatory approval for the OLpur H2H product in the European Community which we have targeted for the first quarter of 2006;
- advancing our OLpur H2H product development in order to eventually apply for regulatory approval for the OLpur H2H and the OLpur MD190 in the United States which we have targeted for the second half of 2006; and
- advancing our OLpur NS2000 product development in conjunction with our dialysis machine manufacturer in order to eventually obtain regulatory approval in the European Community and in the United

States in 2006.

We intend to focus our sales and marketing efforts over the next 12 months primarily on expanding our marketing of OLpur MD190 in our Target European Market, and on continuing our clinical studies on the OLpur MD190 to provide definitive demonstration of the OLpur MD190's efficacy, including four such studies we have already initiated in our Target European Market. Furthermore, we anticipate initiating marketing of OLpur H2H in our Target European Market once we obtain the requisite regulatory approvals.

Over the next 12 months, we currently expect to spend approximately: $700,000 to continue our product engineering to complete our clinical grade OLpur H2H product; $1.5 million for the marketing and sales of our OLpur MD190 product, including marketing clinical studies, product sampling and exhibiting at trade shows; $500,000 to complete clinical studies and pursue regulatory approvals with respect to our OLpur H2H product in Europe; $600,000 in costs associated with operating as a publicly traded company, such as professional and insurance fees; and $800,000 to conduct clinical studies and pursue U.S. regulatory approvals with respect to both our OLpur MD190 and our OLpur H2H products, unless we make arrangements whereby collaborative partners finance such activities.

Once the volume-discount pricing provisions of our agreement with our fiber supplier, Membrana GmbH, become applicable, for each period we will record inventory and cost of goods sold for our fiber orders pursuant to our agreement with Membrana GmbH based on the volume-discounted price level applicable to the actual year-to-date cumulative orders at the end of such period. If, at the end of any subsequent period in the same calendar year, actual year-to-date cumulative orders entitle us to a deeper 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 deeper volume-discount.

In August 2003, we established a European customer service and financial operations center in Dublin, Ireland. Our sales staffs are based in various parts of our Target European Market. We have a clinical services staff that provides customer support and training. We intend to add one to three members to our sales staff as well as one to two members to our administrative or our clinical services staff in our Target European Market. We intend to make these staff additions as we expand our presence in our Target European Market, and such expansion is currently in process.

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, and marketing expenses related to product launches. 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, 2004 Compared to the Fiscal Year Ended December 31, 2003

Revenues

Revenues increased to $138,406 for the fiscal year ended December 31, 2004 from $0 for the fiscal year ended December 31, 2003. Revenues represented shipments of our OLpur MD190 product to customers in our Target European Market where the rights of return have expired. Our revenues increased because we began shipping our OLpur MD190 product in the fiscal year ended December 31, 2004 and rights of return expired in that period with regard to certain shipments.

Cost of Goods Sold

Cost of goods sold increased to $211,942 for the fiscal year ended December 31, 2004 from $0 for the fiscal year ended December 31, 2003. Cost of goods sold represented the cost of our OLpur MD190 product shipped to customers in our Target European Market where the rights of return have expired as well as obsolete inventory written-off due to the incorporation of improved fiber into our dialyzers. Cost of goods sold increased because we wrote off $123,159 in obsolete inventory and because we began shipping our OLpur MD190 product in the fiscal year ended December 31, 2004.

Research and Development

Research and development expenses increased to $2,352,604 for the fiscal year ended December 31, 2004 from $1,320,556 for the fiscal year ended December 31, 2003. This $1,032,048 increase was primarily due to an increase in development expenses related to our OLpur H2H product of approximately $1,266,000 as well as development expenses related to our OLpur NS2000 diafiltration machine of approximately $120,000. Such increase was partially offset by a decrease in development expenses related to our OLpur MD190 dialyzer of approximately $214,000 and by a decrease in deferred compensation of approximately $179,000 in connection with options granted to employees. We anticipate increases to research and development expenses in future periods as we plan to complete the development of our OLpur H2H and OLpur NS2000 products, make them available for clinical testing and obtain regulatory approval for introduction in our Target European Market and the United States.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $5,220,250 for the fiscal year ended December 31, 2004 from $3,673,902 for the fiscal year ended December 31, 2003. This $1,546,348 increase was primarily due to an increase of approximately $918,000 in marketing expenses related to the launch of our OLpur MD190 in our Target European Market; an increase of approximately $749,000 in general and administrative costs associated with the expansion of support staff and facilities at our Irish subsidiary; an increase in U.S. personnel expenses of approximately $743,000; and approximately $270,000 in increased travel and entertainment expenses due to U.S. personnel traveling overseas to assist in the expansion of our European operations. Such increases were partially offset by an approximately $1.1 million decrease in non-cash compensation in connection with options granted to employees. We anticipate increases to selling, general and administrative expenses in future periods as we plan to seek greater market penetration with our OLpur MD190 within our Target European Market and to enter additional markets and introduce additional products once we obtain the requisite regulatory approvals. We also expect to incur additional costs for insurance and professional fees associated with operating as a public company.

Other Income (Expense), net

Our other income (expense), net increased to income of $49,910 for the fiscal year ended December 31, 2004 from expense of $641,542 for the fiscal year ended December 31, 2003. This $691,452 increase is due to the amortization of a debt discount in the fiscal year ended December 31, 2003 of approximately $641,000, plus an increase in interest income for the fiscal year ended December 31, 2004 of approximately $50,000.

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock increased to $11,734,533 for the fiscal year ended December 31, 2004 from $1,791,000 for the fiscal year ended December 31, 2003. This $9.9 million increase is due primarily to the accelerated accretion of the beneficial conversion feature ("BCF") associated with our issuance of series D convertible preferred stock of approximately $9.4 million. Accretion of this BCF was accelerated as a result of the automatic conversion of all of our then-outstanding shares of preferred stock in connection with our initial public offering.

Off-Balance Sheet Arrangements

The Company did not engage in any off-balance sheet arrangements during fiscal year 2004.

Liquidity and Capital Resources

At December 31, 2004, we had a deficit accumulated of $41.8 million, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we manufacture and market our products profitably. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering. From our inception through December 31, 2004, we have received net proceeds of $34.2 million from private sales of our equity and debt securities and our initial public offering.

On March 2, 2005, we received $1.75 million pursuant to a license agreement entered into with Asahi, granting Asahi exclusive rights to manufacture and distribute filter products based on the our OLpur (TM) MD190 hemodiafilter in Japan. We are entitled to receive additional royalties and milestone payments based on the future sales of the product in Japan, which sales are subject to Japanese regulatory approvals.

In addition, we received 100 million Japanese Yen (approximately $956,000) from Asahi in exchange for 184,250 shares of our common stock pursuant to a Subscription Agreement dated March 2, 2005.

At December 31, 2004, we had $3.7 million in cash and cash equivalents. Net cash used in operating activities was $7.8 million for the fiscal year ended December 31, 2004 compared to $3.4 million for the fiscal year ended December 31, 2003. The $4.4 million increase in net cash used in operations during the fiscal year ended December 31, 2004 was primarily due to a larger net loss of approximately $2.0 million in fiscal 2004 over fiscal 2003, a net decrease in the adjustment to net income for noncash stock-based compensation and for depreciation and amortization of approximately $1.0 million, an adjustment to net income of $0.6 million for amortization of debt discount in fiscal 2003, and an increase in the adjustments in operating assets and a decrease in the adjustments in operating liabilities of approximately $0.9 million in the aggregate.

Net cash used in investing activities was $6.9 million for the fiscal year ended December 31, 2004 compared to $0.5 million for the fiscal year ended December 31, 2003. $6 million of the cash used in the fiscal year ended December 31, 2004 was for the purchase of short-term investments. The remainder of the cash used in 2004 and all of the cash used in 2003 was for the purchase of fixed assets, mainly manufacturing equipment for the production of our OLpur MD190 product.

Net cash provided by financing activities was $14.3 million for the fiscal year ended December 31, 2004 compared to $7.6 million for the fiscal year ended December 31, 2003. The net cash provided by financing activities in the fiscal year ended December 31, 2004 was primarily due to the net proceeds of approximately $10.7 million raised in our initial public offering, and approximately $3.9 million raised from private sales of equity and debt securities and from the exercise of warrants, which was offset by $0.3 million for payment of preferred dividends. The net cash provided by financing activities in the fiscal year ended December 31, 2003 was primarily due to net proceeds of $7.8 million from the issuance of bridge notes that were subsequently converted into Series D convertible preferred stock and the issuance of additional Series D convertible preferred stock, which were offset against $0.2 million net repayment of short term loans.

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

- for the marketing and sales of our products;

- to complete certain clinical studies, obtain appropriate regulatory approvals and expand our research and development with respect to our products;
- to continue our product engineering;
- to pay a former supplier, Plexus Services Corp., amounts due under our settlement agreement; and
- for working capital purposes, including for additional salaries and wages as our organization grows and as we expand our presence in our Target European Market and establish operations in the United States and other markets, and for additional professional fees and expenses and other operating costs.

We have consumed substantial amounts of capital since our inception. We currently expect our long-term future liquidity source to be gross margins generated from sales of our products. Nonetheless, we believe our existing resources would be sufficient to fund our currently planned operations through the first half of 2006, even if we were not to generate any gross revenues from sales of our products. 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 timing and costs associated with obtaining the Conformite Europeene, 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 (for products

other than our OLpur MD190, for which the CE mark was obtained in July of 2003), or United States regulatory approval;

- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs associated with manufacturing scale-up;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and actual, current and threatened litigation.

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 anticipated sales of our products, otherwise prove to be insufficient to fund our operations, we could be required to seek additional financing. We have no current arrangements with respect to sources of additional financing.

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 or Plan of Operation," 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 similar 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 and we caution you that any forward-looking information provided by or on behalf of us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Risks Related to Our Company

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

We have not been profitable since our inception in 1997. As of December 31, 2004, we had an accumulated deficit of approximately $41.8 million primarily as a result of our research and development expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may

never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

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

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

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

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

- the consolidation of dialysis clinics into larger clinical groups.

We cannot sell our 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 products and cannot sell any of our 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 Conformite Europeene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, "European Community"), for our OLpur MD190 product on July 31, 2003. We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our products in the United States until we receive U.S. Federal Drug Administration, or FDA, clearance. Until we complete the requisite U.S. human clinical trials and submit premarket notification to the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDC Act, we will not be eligible for FDA approval for any of our products.

In addition to the premarket notification required pursuant to Section 510(k) of the FDC Act, the FDA could require us to obtain premarket approval of our 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) premarket notification process. The Section 515 premarket approval process is a significantly more costly, lengthy and uncertain approval process and could materially delay our products coming to market. If we do obtain clearance for marketing of any of our devices under Section 510(k) of the FDC Act, then any changes we wish to make to such device that could significantly affect safety and effectiveness will require clearance of a notification pursuant to Section 510(k), and we may need to submit clinical and manufacturing comparability data to obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the U.S.

The clearance and/or approval processes in the European Community and in the United States can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or any FDA approval for any of our 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 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 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 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 OLpur MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. If the requisite Japanese regulatory approvals are not timely obtained, our potential license revenues will be limited.

We cannot assure you that our 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 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 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 products.

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

impair our goodwill.

The production, marketing and sale of kidney dialysis products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of $5 million for our OLpur MD190 product and intend to acquire additional product liability insurance upon commercialization of any of our additional products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and goodwill and adversely affect the demand for our products, our ability to generate sales and our profitability.

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

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

For example, our agreement with Medica s.r.l. requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify Medica against certain liabilities arising out of our products that they manufacture, provided they do not arise out of Medica's breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

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

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

- fines;
- injunctions;
- civil penalties;
- recalls or seizures of our products;
- total or partial suspension of the production of our products;

- withdrawal of any existing approvals or premarket clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations by the FDA that we not be allowed to enter into government contracts; and
- criminal prosecution.

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

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

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

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

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

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

Litigation and other proceedings relating to patent matters, whether initiated by us or a third party, can be expensive and time-consuming, regardless of whether the outcome is favorable to us, and may require the diversion of

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

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

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

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

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

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

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

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

We expect to rely on a limited number of independent manufacturers to produce the OLpur MD190 and our other products for us. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to

achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner.

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 OLpur MD190, 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 OLpur MD190. 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 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 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 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 products and from marketing our products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MD190 have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H2H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

Even with approval to market our products in the European Community, the United States and other countries, manufacturers of our products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our 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 products manufactured in such facilities and our revenues may be materially adversely affected.

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

Our products are, or will be, new to the market, and we do not yet have an established market or customer base for our products. Acceptance of our 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 products. We may encounter significant clinical and market resistance to our products and our products may never achieve market acceptance. Factors that may affect our ability to achieve acceptance of our products in the market place include whether:

- our products will be safe for use;
- our products will be effective;
- our 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 our products; and

- government or third party reimbursement for the cost of our products is available at reasonable rates, if at all.

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

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

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

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

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;

- we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;

- local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;

- political instability could disrupt our operations;

- some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and

- some countries could impose additional taxes or restrict the import of our products.

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

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

Our success depends upon the skills, experience and efforts of our management

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

If a non-competition clause in an employee's employment agreement with his former employer is enforceable and such employer successfully seeks enforcement thereof, then we may be liable for damages, which could impair our potential profitability.

At the time we entered into an employment agreement with one of our employees, he was subject to an employment agreement with his former employer that included a non-competition clause. The former employer may seek to enforce such non-competition clause that purports to impose a fine upon us, in our capacity as our employee's employer, and if a court of competent jurisdiction finds us liable for damages, such liability could impair our potential profitability.

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

Our certificate of incorporation provides, with specific exceptions required by Delaware law, that our directors are not personally liable to us or our stockholders for monetary damages for any action or failure to take any action. In addition, we have agreed to, and our certificate of incorporation and bylaws provide for, mandatory indemnification of directors and officers to the fullest extent

permitted by Delaware law. These provisions may discourage stockholders from bringing suit against a director for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against any of our directors.

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

We are the defendant in an action captioned Marty Steinberg, Esq. as Receiver for Lancer Offshore, Inc. v. Nephros, Inc., Case No. 04-CV-20547, pending in the U.S. District Court for the Southern District of Florida (the "Ancillary Proceeding"). That action is ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No. 03-CV-80612, also pending in the U.S. District Court for the Southern District of Florida, in which the court has appointed a Receiver to manage Lancer Offshore, Inc. and various related entities (the "Receivership").

In the Ancillary Proceeding, the Receiver for Lancer Offshore, Inc. alleges that, in consideration for Lancer Offshore, Inc.'s agreement to enter into a

settlement agreement in January 2003, we were required to deliver a note in the principal amount of $1,500,000 and an instrument evidencing the portion of warrants previously issued to Lancer Offshore, Inc. that were not surrendered by Lancer Offshore, Inc. pursuant to the settlement agreement, and the Receiver seeks 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 our common stock for $2.50 per share (without giving effect to any adjustment from the reverse stock split we effected on September 10, 2004, pursuant to the antidilution provisions of such warrant, as amended). Pursuant to our January 2003 settlement agreement with Lancer Offshore, Inc., such warrants 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 our common stock that was contemplated at such time but never consummated. Lancer Offshore, Inc. may contend that the 75,000 shares and $2.50 per share exercise terms of their warrant are not subject to adjustment as a result of our recently completed 0.2841-for-one reverse stock split. Furthermore, Lancer Offshore, Inc. may claim that the number of shares issuable upon exercise of the warrant should actually be increased to 94,771 and the exercise price proportionally decreased to $1.98 per share, upon consummation of the recently completed split to adjust for the difference between the split contemplated in the warrants (0.2248318-for-one) and our recently completed split (0.2841-for-one). We have asserted claims for damages against Lancer Offshore, Inc. that exceed the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership, and we have discussed the potential settlement of all claims with the Receiver. However, there can be no assurance that we will settle or that the outcome of any of these proceedings will be successful.

In April 2002, the Company 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, the Company 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 the Company agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between the Company 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 have commenced discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims. However such discussions may prove unsuccessful.

The form of warrants that would have been issuable to Hermitage pursuant to the settlement agreement, if the closing of the transactions contemplated by our settlement agreement with Lancer Offshore, Inc. had occurred, contained the same antidilution provisions as were added to Lancer Offshore, Inc.'s warrant pursuant to our settlement agreement with Lancer Offshore, Inc. Accordingly, Hermitage may contend that the 60,000 shares and $2.50 per share exercise terms of the warrant described in the settlement agreement would not be subject to adjustment as a result of our recently completed 0.2841-for-one reverse stock split. Furthermore, Hermitage may claim that the number of shares issuable upon exercise of the warrant should actually be increased to 75,817 and the exercise price proportionally decreased to $1.98 per share, upon consummation of the

recently completed split to adjust for the difference between the split contemplated in the warrants (0.2248318-for-one) and our recently completed split (0.2841-for-one).

If and to the extent we are found to have significant liability to Lancer Offshore, Inc. or Hermitage, or our expenses related to defending against the Receiver's claims in the Ancillary Proceeding, any lawsuit Hermitage may bring against us and/or pursuing our claims in the Receivership become significant, then our liquidity could be materially adversely affected and/or our stockholders could experience dilution in their investment in us and the value of our stockholders' interests in us could be impaired.

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

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

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

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

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

As a relatively new company with little or no name recognition and with several risks and uncertainties that could impair our business operations, we are not

likely to generate widespread interest in our common stock. Without widespread interest in our common stock, our common stock price may be highly volatile and an investment in our common stock could decline in value.

Prior to our initial public offering completed on September 24, 2004, there was no public market for our common stock. Unlike many companies with publicly traded securities, we have little or no name recognition outside the nephrology community. We are a relatively new company and very few investors are familiar with either our company or our products. As we will not be marketing our products directly to the public, it may be difficult for us to generate the kind of interest in our stock that other companies experience after an initial public offering. An active trading market in our common stock might not develop, or if it does develop, might not continue.

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

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

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

Our capital requirements have been and will continue to be significant. Through December 31, 2004, 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 $34.2 million. We generated an additional approximately $2.7 million in March 2005 from our license agreement with, and private placement of common stock to, Asahi. We currently have no committed sources of, or other arrangements with respect to, additional financing. We cannot assure you that our existing capital resources, together with the net proceeds from future operating cash flows, if any, will be sufficient to fund our future operations. Our capital requirements will depend on numerous factors, including:

- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the timing and costs associated with obtaining the Conformite Europeene, 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, or United States regulatory approval;
- the continued progress in and the costs of clinical studies and

other research and development programs;

- the costs associated with manufacturing scale-up;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and actual, current and threatened litigation.

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

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

As of December 31, 2004, our directors, executive officers and principal stockholders beneficially owned approximately 58% 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, 2004, Ronald O. Perelman beneficially owned 29.2% of our outstanding common stock. WPPN, LP, Wasserstein SBIC Ventures II L.P., WV II Employee Partners, LLC, and BW Employee Holdings, LLC, entities that may be deemed to be controlled by Bruce Wasserstein (collectively, the "Wasserstein Entities"), beneficially owned an aggregate of 15.9% of our outstanding common stock, although Mr. Wasserstein himself disclaims beneficial ownership of the shares held by the Wasserstein Entities except to the extent of his pecuniary interest therein (which is less than 1% of our outstanding common stock). Our principal stockholders may have significant influence over our policies and affairs, including the election of directors. Furthermore, such concentration of voting power could enable those stockholders to delay or prevent another party from taking control of our company even where you might find such change of control transaction desirable.

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

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

We have entered into registration rights agreements with many of our existing securityholders that entitle them to have an aggregate of 10,040,681 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 and certain contractual "lock-up" provisions.

Risks Related to Our 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 kidney dialysis market with existing suppliers of hemodialysis and peritoneal dialysis devices, supplies and services. Our competitors include Fresenius Medical Care AG, The Gambro Company and Baxter International Inc., currently three of the primary machine manufacturers in hemodialysis, as well as B. Braun Biotech International GmbH, Nipro Medical Corporation, Asahi Kasei Corporation and other smaller machine manufacturers in hemodialysis. Fresenius and Gambro 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 an established customer base and may encounter a high degree of competition in 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 other regions of the world. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. Based on the annual reports for each company as of December 2003: (1) Fresenius treated in its own dialysis clinics approximately 26% of the dialysis patients in the United States, 7% of the dialysis patients in Fresenius's European market, including the Czech Republic, France, Germany, Hungary, Italy, Portugal, Poland, Slovakia, Slovenia, Spain, Turkey and the United Kingdom, and 9% of the dialysis patients worldwide; and (2) Gambro treated in its own dialysis clinics approximately 14% of the dialysis patients in the United States, 3% of the dialysis patients in Europe and 4% of the dialysis patients worldwide.

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, 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 products as otherwise expected, or we may need to reduce the anticipated prices of our products and, in either case, our potential revenues may be reduced.

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

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

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

require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our 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 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, the market for our 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 products are higher than the costs of clinics providing hemodialysis treatment, then we may not achieve market acceptance of our products in the United States and our potential sales and revenues will suffer.

If the cost of our 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 our products in the United States unless HDF therapy becomes the standard treatment method for ESRD. If we do not gain market acceptance for our 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 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 products. If we are not able to charge a sufficient amount for our products, then our margins and our

profitability will be adversely affected.

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

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

Item 7. Financial Statements.

INDEX TO FINANCIAL STATEMENTS

Nephros, Inc. and Subsidiary
(A Development Stage Company)

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Nephros, Inc.
New York, New York
March 28, 2005

We have audited the accompanying consolidated balance sheet of Nephros, Inc. and Subsidiary (the "Company") (a Delaware corporation in the development stage) as of December 31, 2004, and the related consolidated statements of operations, changes in stockholders' equity (deficiency), and cash flows for the year then ended, and for the period from April 3, 1997 (date of inception) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The Company's consolidated financial statements as of and for the year ended December 31, 2003 and for the period April 3, 1997 (date of inception) through December 31, 2003 were audited by other auditors whose report, dated April 28, 2004, expressed an unqualified opinion and included an explanatory paragraph referring to an uncertainty as to the entity's ability to continue as a going concern on those statements. The consolidated financial statements for the period from April 3, 1997 (date of inception) through December 31, 2003 reflect total revenues and net loss of $300,000 and $19,804,693, respectively, of the related totals. The other auditors' report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such prior period, is based solely on the report of such other auditors.

We conducted our audit 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 audit 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 audit provides a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2004, and the results of its operations and its cash flows for the year then ended, and for the period from April 3, 1997 (date of inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
Nephros, Inc.

We have audited the accompanying consolidated balance sheets of Nephros, Inc. (a Delaware corporation in a development stage) and Subsidiary as of December 31, 2003, and the related consolidated statements of operations, changes in stockholders equity (deficit) and cash flows for the year then ended and the consolidated statements of changes in stockholders equity (deficit) for the period from inception (April 3, 1997) to December 31, 2003. We have also audited consolidated statements of operations and cash flow for the period from inception (April 3, 1997) to December 31, 2003, not presented separately herein. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform 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 audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nephros, Inc. and Subsidiary as of December 31, 2003, and the consolidated results of their operations and their cash flows for the year then ended and for the period from inception (April 3, 1997) to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

New York, New York
April 28, 2004 (except with respect to the reverse stock split discussed in Note 5, as to which the date is September 10, 2004).

/s/ GRANT THORNTON LLP

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Consolidated Balance Sheets

	Decembe
	2004

ASSETS

Current assets:

Cash and cash equivalents	$ 3,719,181
Short-term investments	5,995,940
Accounts receivable	174,797
Inventory	653,351
Prepaid expenses and other current assets	430,361
Deferred cost of goods sold	37,994
Total current assets	11,011,624
Property and equipment, at cost less accumulated depreciation of $584,130 and $384,889 at December 31, 2004 and December 31, 2003, respectively	1,191,856
Other assets	3,822
Total assets	$ 12,207,302
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	
Current liabilities:	
Accounts payable	$ 629,814
Accrued expenses	362,789
Deferred revenue	64,058
Short-term convertible note payable	--
Accrued liabilities	1,500,000
Total current liabilities	2,556,661
Mandatorily Redeemable Convertible Preferred Stock	
Series B preferred stock, $.001 par value; no shares and 2,333,333 shares authorized at December 31, 2004 and December 31, 2003, respectively; no shares and 2,333,333 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	--
Series C preferred stock, $.001 par value; no shares and 3,387,500 shares authorized at December 31, 2004 and December 31, 2003, respectively; no shares and 3,137,550 shares issued and outstanding at December 31, 2004, and December 31, 2003, respectively	--
Series D preferred stock, $.001 par value; no shares and 20,000,000 shares authorized at December 31, 2004 and December 31, 2003, respectively; no shares and 8,006,450 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	--
	--
Stockholders' equity (deficiency):	
Series A preferred stock, $.001 par value, no shares and 4,500,000 shares authorized at December 31, 2004 and December 31, 2003, respectively; no shares and 4,000,000 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	--

Common stock, $.001 par value; 49,000,000 shares authorized at December 31, 2004 and December 31, 2003; 12,120,248 and 1,593,659 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	12,120
Additional paid-in capital	53,740,171
Deferred compensation	(2,479,317)
Accumulated other comprehensive income - foreign currency translation	156,433
Accumulated other comprehensive loss - unrealized losses on available-for-sale securities	(4,060)
Deficit accumulated during the development stage	(41,774,706)
Total stockholders' equity (deficiency)	9,650,641
Total liabilities and stockholders' equity (deficiency)	$ 12,207,302

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Consolidated Statements of Operations

	Period from April 3, 1997 (date of inception) to December 31, 2004	Years 2004
Net revenues	$ 438,406	$ 138
Cost of goods sold	211,942	211
Gross profit (loss)	226,464	(75
Operating expenses:		
Research and development	13,628,806	2,352
Selling, general and administrative	13,254,209	5,220
Total operating expenses	26,883,015	7,572
Loss from operations	(26,656,551)	(7,646

Other income (expense):		
Other income	6,113	
Interest income	223,007	49
Interest expense and amortization of debt discount	(1,837,542)	
Gain on disposal of assets	30,007	
Forgiveness of indebtedness	833,793	
Total other income (expense)	(744,622)	49
Net loss	(27,401,173)	(7,596
Dividends and accretion to redemption value of redeemable convertible preferred stock	(14,373,533)	(11,734
Net loss attributable to common stockholders	$ (41,774,706)	$ (19,331
Basic and diluted net loss attributable to common stockholders per common share		$ (
Shares used in computing basic and diluted net loss attributable to common stockholders per common share		4,412

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Statement of Changes in Stockholders' Equity (Deficiency)

	Series A Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount
Issuance of common stock upon inception (at a purchase price of $0.0035 per share)	--	$ --	1,562,550	$ 1,563
Issuance of preferred stock (at a purchase price $1.25 per share)	4,000,000	4,000	--	--
Net loss	--	--	--	--
Balance, December 31, 1997	4,000,000	4,000	1,562,550	1,563
Net loss	--	--	--	--
Balance, December 31, 1998	4,000,000	4,000	1,562,550	1,563

Noncash stock-based compensation (at a price of $0.37 per share)	--	--	2,699	3
Collection of stock subscription receivable	--	--	--	--
Net loss	--	--	--	--
Balance, December 31, 1999	4,000,000	4,000	1,565,249	1,566
Noncash stock-based compensation	--	--	--	--
Cumulative preferred dividend and accretion	--	--	--	--
Net loss	--	--	--	--
Balance, December 31, 2000	4,000,000	4,000	1,565,249	1,566
Noncash stock-based compensation (at a price of $2.11 per share)	--	--	28,410	28
Cumulative preferred dividend and accretion	--	--	--	--
Net loss	--	--	--	--
Balance, December 31, 2001	4,000,000	4,000	1,593,659	1,594
Issue of warrants	--	--	--	--
Noncash stock-based compensation	--	--	--	--
Beneficial conversion and warrants issued in connection with convertible note payable	--	--	--	--
Cumulative preferred dividend and accretion	--	--	--	--
Net loss	--	--	--	--
Balance, December 31, 2002	4,000,000	4,000	1,593,659	1,594
Comprehensive loss:				
Net loss	--	--	--	--
Net unrealized gains on foreign currency translation	--	--	--	--
Comprehensive loss				
Issue of warrants	--	--	--	--

Noncash stock-based compensation	--	--	--	--
Beneficial conversion recognized in connection with issuance of preferred stock	--	--	--	--
Amortization of deferred compensation	--	--	--	--
Cumulative preferred dividend and accretion	--	--	--	--
Balance, December 31, 2003	4,000,000	4,000	1,593,659	1,594
Comprehensive loss:				
Net loss	--	--	--	--
Net unrealized gains on foreign currency translation	--	--	--	--
Net unrealized losses on available-for-sale securities	--	--	--	--
Comprehensive loss				

	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Loss From Inception
Issuance of common stock upon inception (at a purchase price of $0.0035 per share)	$ 3,937	$ --	$ --
Issuance of preferred stock (at a purchase price $1.25 per share)	4,996,000	--	--
Net loss	--	--	(453,001)
Balance, December 31, 1997	4,999,937	--	(453,001)
Net loss	--	--	(1,146,061)
Balance, December 31, 1998	4,999,937	--	(1,599,062)
Noncash stock-based			

compensation (at a price of $0.37 per share)	997	--	--
Collection of stock subscription receivable	--	--	--
Net loss	--	--	(3,484,817)
Balance, December 31, 1999	5,000,934	--	(5,083,879)
Noncash stock-based compensation	5,000	--	--
Cumulative preferred dividend and accretion	--	--	(169,000)
Net loss	--	--	(5,582,583)
Balance, December 31, 2000	5,005,934	--	(10,835,462)
Noncash stock-based compensation (at a price of $2.11 per share)	59,972	--	--
Cumulative preferred dividend and accretion	--	--	(314,000)
Net loss	--	--	(1,085,189)
Balance, December 31, 2001	5,065,906	--	(12,234,651)
Issue of warrants	430,000	--	--
Noncash stock-based compensation	20,000	--	--
Beneficial conversion and warrants issued in connection with convertible note payable	1,500,000	--	--
Cumulative preferred dividend and accretion	--	--	(365,000)
Net loss	--	--	(2,417,042)
Balance, December 31, 2002	7,015,906	--	(15,016,693)
Comprehensive loss:			
Net loss	--	--	(5,636,000)
Net unrealized gains on foreign currency translation	--	100,337	--

Comprehensive loss			
Issue of warrants	19,000	--	--
Noncash stock-based compensation	3,964,000	--	--
Beneficial conversion recognized in connection with issuance of preferred stock	8,006,450	--	--
Amortization of deferred compensation	--	--	--
Cumulative preferred dividend and accretion	--	--	(1,791,000)
Balance, December 31, 2003	19,005,356	100,337	(22,443,693)
Comprehensive loss:			
Net loss	--	--	(7,596,480)
Net unrealized gains on foreign currency translation	--	56,096	--
Net unrealized losses on available-for-sale securities	--	(4,060)	--
Comprehensive loss			

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Statement of Changes in Stockholders' Equity (Deficiency)

	Series A Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount
Noncash stock-based compensation	--	--	--	--
Beneficial conversion recognized in connection with issuance of preferred stock	--	--	--	--

Amortization of deferred compensation	--	--	--	--
Cumulative preferred dividend and accretion	--	--	--	--
Exercise of warrants	87,500	88	--	--
Issuance of common stock in connection with initial public offering (at a purchase price of $6.00 per share)	--	--	2,100,000	2,100
Conversion of preferred stock into common stock upon initial public offering (at an average price of $2.24 per share)	(4,087,500)	(4,088)	8,426,589	8,426
Balance, December 31, 2004	$ --	$ --	12,120,248	$ 12,120

	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Loss From Inception
Noncash stock-based compensation	1,223,133	--	--
Beneficial conversion recognized in connection with issuance of preferred stock	3,811,538	--	--
Amortization of deferred compensation	--	--	--
Cumulative preferred dividend and accretion	--	--	(11,734,533)
Exercise of warrants	87,412	--	--
Issuance of common stock in connection with initial public offering (at a purchase price of $6.00 per share)	10,732,486	--	--
Conversion of preferred stock into common stock upon initial public offering (at an average price of $2.24 per share)	18,880,246	--	--

Balance, December 31, 2004	$ 53,740,171	$ 152,373	$(41,774,706)

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Consolidated Statements of Cash Flows

	Period from April 3, 1997 (date of inception) to December 31, 2004	Y - 2 -
Operating activities		
Net loss	$(27,401,173)	$ (7,
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	614,137	
Forgiveness of indebtedness	(833,793)	
Noncash stock-based compensation	2,793,817	
Amortization of debt discount	1,798,000	
Deferred IPO costs	30,000	
Gain on disposal of assets	(30,007)	
(Increase) decrease in operating assets		
Accounts receivable	(174,797)	(
Prepaid expenses and other current assets	(430,361)	(
Inventory	(653,351)	(
Other assets	(3,822)	
Deferred cost of goods sold	(37,994)	
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	1,725,846	(
Deferred revenue	64,058	
Net cash used in operating activities	(22,539,440)	(7,
Investing activities		
Purchase of property and equipment	(1,859,339)	(
Purchase of short-term investments	(6,000,000)	(6,
Proceeds from disposal of property and equipment	83,352	
Net cash used in investing activities	(7,775,987)	(6,
Financing activities		
Proceeds from issuance of preferred stock, net	19,675,538	3,
Proceeds from issuance of common stock prior to the initial public offering	5,500	
Loan from related party, net	185,000	
Payment of preferred dividends	(349,949)	(

Payments from issuance of short term loan, net	--	
Proceeds from issuance of convertible notes payable, net	3,540,000	
Proceeds from initial public offering of common stock	10,734,586	10,
Proceeds from exercise of warrants	87,500	
Net cash provided by financing activities	33,878,175	14,
Effect of exchange rates on cash	156,433	
Net increase (decrease) in cash and cash equivalents	3,719,181	(
Cash and cash equivalents, beginning of period	--	4,
Cash and cash equivalents, end of period	$ 3,719,181	$ 3,
Supplemental disclosure of cash flow information		
Cash paid for Interest	$ 21,842	$
Cash paid for Taxes	5,383	

The accompanying notes are an integral part of these statements.

NEPHROS, INC. AND SUBSIDIARY
(A Development Stage Company)
Notes to Consolidated Financial Statements

Note 1 - Organization and Nature of Operations

Nephros, Inc. ("Nephros" or the "Company") was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease ("ESRD") therapy technology and products. Although the Chairman of the Company's Board is the Chairman of Columbia University's Department of Surgery and the Company license's the right to use office space from Columbia University, the Company does not currently have any other material relationship with Columbia University. The Company has three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy for ESRD patients. These are the OLpur(TM) MD190, a filter, or "dialyzer," designed expressly for HDF therapy, the OLpur(TM) H2H(TM), an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy, and the OLpur(TM) NS2000 system, a stand-alone hemodiafiltration machine and associated filter technology.

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 Company is a development stage company, as defined by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," as it continues to devote substantially all of its efforts to establishing its business, and the Company has recognized

$138,406 in revenues from such operations as of December 31, 2004. All other revenues earned by the Company to date are primarily related to consulting services rendered to third parties outside of the planned principal operations.

Note 2 - Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

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.

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 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. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on short-term investments is included in interest income. At December 31, 2004, the cost of the available-for-sale securities was $6 million.

Concentration of 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.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, accounts payable and debt approximate fair value due to the short-term maturity of these instruments.

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 losses. Factors considered include economic conditions and each customer's payment 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. No allowance for doubtful accounts was considered necessary at December 31, 2004 and 2003.

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 as of December 31, 2004 and 2003 was as follows:

	December 31,	
	2004	2003
Raw Materials	$467,655	$149,481
Finished Goods	185,696	52,483
Total Inventory	$653,351	$201,964

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

Property and equipment are stated at cost and are being depreciated over the estimated useful lives of the assets, which range between three and five years. Research and computer equipment are being depreciated using an accelerated method of 200% declining balance. Furniture and fixtures as well as other equipment is being depreciated using the straight-line method.

Accounting for Long-lived Assets

In August 2001, the Financial Accounting Services Board ("FASB") issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," which was adopted by the Company effective January 1, 2002. SFAS No. 144 addresses

financial

accounting and reporting for the impairment of long-lived assets (excluding goodwill) or assets to be disposed of. Management has performed a review of all long-lived assets and has determined that no impairment of the carrying values of its long-lived assets exists as of December 31, 2004 and 2003.

Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin ("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.

The Company's sales history does not yet provide a basis from which to reasonably estimate rates of product return, and therefore revenues from certain shipments during the fiscal year ended December 31, 2004 were deferred. Product sales are recognized thirty days after the date of shipment. In addition, cost of revenue to the extent of amount billed was deferred and will be recognized when the revenue is recognized.

Advertising

The Company has incurred minimal advertising costs to date, and all advertising costs have been expensed as incurred.

Shipping and Handling

The Company is responsible for all shipping and handling costs for the distribution of its product to its customers, and such costs are recorded as a selling expense on its financial statements.

Stock-based Compensation

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

The Company accounted for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and discloses the effect of the differences which would result had the Company applied the fair-value-based method of accounting on a pro forma basis, as required by SFAS No. 123, "Accounting for Stock-Based Compensation." Had compensation expense for stock options granted under the Nephros 2000 Equity Incentive Plan (the "2000 Plan") and the 2004 Stock Incentive Plan (the "2004 Plan") been determined based on fair value at the grant dates, the Company's net loss and net loss per share for the years ended December 31, 2004 and 2003 would have been as follows:

Years Ended December 31,

	2004	2003
Net loss attributable to common stockholders:		
As reported	$(19,331,013)	$ (7,427,000)
Less - compensation recognized under the intrinsic-value method	793,756	1,914,060
Add - compensation under the fair value method	(667,831)	(2,592,869)
Pro forma	$(19,205,088)	$ (8,105,809)
Net loss per share:		
As reported	$ (4.38)	$ (4.66)
Pro forma	$ (4.35)	$ (5.08)

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.

Research and Development Costs

Research and development costs are expensed as incurred.

Income (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 2,249,857 and 7,844,257 from the computation of diluted EPS for the years ended December 31, 2004 and 2003, respectively.

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.

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, foreign currency translation adjustments and minimum pension liability adjustments. For the fiscal years ended 2004 and 2003, the comprehensive loss was $7,544,444 and $5,535,663, respectively.

New Accounting Pronouncements

During December 2004, the FASB issued Statement No. 123R, "Share-Based Payment" ("SFAS No. 123R"), which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. The Company grants options to purchase common stock to its employees and directors under various plans at prices equal to the market value of the stock on the dates the options were granted. SFAS No. 123R is effective for small business issuers the first interim reporting period beginning after December 15, 2005. Accordingly, the Company will adopt SFAS No. 123R commencing with the quarter ending March 31, 2006. If the Company had included the fair value of employee stock options in its financial statements, the Company's net loss for the years ended December 31, 2004 and 2003 would have been as disclosed in this Note 2, under the caption "Stock-based Compensation," above. Accordingly, the adoption of SFAS No. 123R is expected to have a material effect on the Company's consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." This Statement requires that certain instruments that were previously classified as equity on a company's balance sheets now be classified as liabilities. The Statement is effective for financial instruments entered into or modified after May 31, 2003, and to all other instruments that exist as of the beginning of the first interim financial reporting period beginning after June 15, 2003. The Company has no instruments impacted by the adoption of this statement and, therefore, the adoption of SFAS No. 150 did not have any effect on the Company's consolidated financial statements.

Note 3 - Prepaid Expenses and Other Current Assets

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

	December 31,	
	2004	2003
Prepaid insurance premiums	$181,500	$ 6,915
Advances on product development services	130,000	130,000
Other	118,861	81,698

Total	$430,361	$218,613

Note 4 - Property and Equipment

Property and equipment are comprised of the following:

	December 31,	
	2004	2003
Manufacturing equipment	$1,103,186	$333,632
Research equipment	465,206	365,269
Computer equipment	155,591	122,206
Furniture and fixtures	52,003	52,008
	1,775,986	873,115
Less: accumulated depreciation	(584,130)	(384,889)
	$1,191,856	$488,226

Depreciation expense for the years ended December 31, 2004 and 2003 was $199,241 and $42,531, respectively.

Note 5 - Stockholders' Equity and Redeemable Convertible Preferred Stock

On September 24, 2004, the Company completed the initial public offering of its common stock. The initial public offering consisted of the sale of 2,100,000 shares of common stock at a price of $6.00 per share. Net proceeds from the initial public offering after deducting underwriters' discounts, commissions and expenses, and offering expenses, were approximately $10.7 million.

Upon the closing of the Company's initial public offering on September 24, 2004:

- Each outstanding share of the Company's series A convertible preferred stock was converted into 0.2841 shares of its common stock resulting in the issuance of 1,161,256 shares of common stock;
- Each outstanding share of series B convertible preferred stock was converted into 0.2841 shares of common stock, and all accrued and unpaid dividends through May 31, 2004 on each such share was converted into common stock at a conversion price of approximately $3.03 per share resulting in the issuance of 845,287 shares of common stock;
- Each outstanding share of series C convertible preferred stock was converted into 0.2841 shares of common stock, and all accrued and unpaid dividends through May 31, 2004 on each such share was converted into common stock at a conversion price of approximately $3.52 per share resulting in the issuance of 1,170,397 shares of common stock; and
- Each outstanding share of series D convertible preferred stock was converted into 0.4310 shares of common stock, and all accrued and unpaid dividends through May 31, 2004 on each such share was converted into common stock at a conversion price of approximately $2.32 per share resulting in the issuance of 5,249,649 shares of common stock.

Dividends accrued after May 31, 2004 on the shares of preferred stock that were converted into common stock upon the closing of the Company's initial public offering were paid in cash in the fourth quarter of 2004 in the amount of $349,949.

On September 10, 2004, the Company effected a reverse stock split pursuant to which each share of its common stock then outstanding was converted into 0.2841 of one share of its common stock. All share and per share amounts for all periods presented preceding September 10, 2004 have been retroactively restated to give effect to this reverse stock split.

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.

Note 6 - Stock-Based Compensation

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, 2004, 1,571,358 options had been issued to employees and were outstanding. The options expire on various dates between December 31, 2009 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, 2004, 52,416 options had been issued to non-employees under the 2000 Plan and were outstanding. Such options expire at various dates between December 31, 2006 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.

In 2004, the Board of Directors adopted and the Company's stockholders

approved the Nephros, Inc. 2004 Stock Incentive Plan (the "2004 Plan"), under which 486,237 shares of the Company's common stock have been authorized for issuance upon exercise of options granted and which may be granted by the Company. As of December 31, 2004, 214,626 options had been issued to employees and were outstanding. The options expire on various dates between November 11, 2014 and December 14, 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, 2004, 14,140 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 14, 2014, and vest upon a combination of the following: immediate vesting; straight line vesting of two, three or four years; and certain milestones.

Option activity for the years ended December 31, 2004 and 2003 is summarized as follows:

	Shares	Weighted -average exercise price
Outstanding at January 1, 2003	536,807	.32
Options granted	1,010,260	2.27
Options canceled	(108,242)	2.78
Outstanding at December 31, 2003	1,438,825	1.51
Options granted	434,454	3.04
Options canceled	(20,739)	2.62
Outstanding at December 31, 2004	1,852,540	1.85
Exercisable at December 31, 2004	1,049,696	1.27

The Board retired the 2000 Plan in June 2004, and thereafter no additional awards may be granted under the 2000 Plan. At December 31, 2004, there were 257,471 shares available for future grants under the 2004 Plan.

The portion of stock options granted to employees which is time vested is accounted for as a fixed award. For options issued prior to 2003, no compensation has been recorded on such portion as it had no intrinsic value at the date of grant. For options issued in 2003 and 2004, the value of an option's underlying shares at the date of grant in excess of the option price is recognized as compensation over the period of vesting.

The portion of stock options granted to employees which was based on performance achievement is accounted for as a variable award. As vesting depends upon discrete events, the measurement date and the expense recognition will occur when such targets are achieved.

The weighted-average fair value of options granted in 2004 and 2003 is $5.39 and

$6.09, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: risk-free interest rate of 3.33%; no expected dividend yield; expected lives of ten years; and expected stock price volatility of 80% for 2004 and 2003.

The following table summarizes information about stock options outstanding at December 31, 2004:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding as of December 31, 2004	Weighted-average remaining contractual life in years	Weighted average exercise price	Number exercisable as of December 31, 2004	Weighted average exe price
$.32	533,966	5.06	$ .32	533,966	$ .32
$1.76	499,732	8.39	1.76	300,975	1.76
$2.32 to 2.39	322,613	9.44	2.39	46,424	2.39
$2.64 to 2.78	387,228	8.10	2.77	142,831	2.78
$4.80 to 5.45	109,000	9.93	4.98	25,500	4.80
	1,852,540			1,049,696	

Note 7 - 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 compensation, as defined. As of January 1, 2004, the Company began matching 100% of the first 3% and 50% of the next 2% of employee contributions to the 401(k) Plan. The Company contributed and expensed $37,691 and $0 in 2004 and 2003, respectively.

Note 8 - Leases

At December 31, 2004, the Company had noncancellable operating leases on real and personal property that expire in 2006 for the rental of its office and research and development facilities and equipment. Rent expense for the years ended December 31, 2004 and 2003 totaled approximately $105,000 and $87,000, respectively.

As of December 31, 2004, future net minimum rental payments required under operating leases are as follows:

Year ending December 31,	
2005	$108,370
2006	33,428
	$141,798

Note 9 - 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, 2004:

	December 31, 2004			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Gross Fair Value
Auction rate securities	$5,000,000	$ --	$ --	$5,000,000
Other debt securities	1,000,000	--	4,060	995,940
Total securities	$6,000,000	$ --	$ 4,060	$5,995,940

The Company held no short-term investments as of December 31, 2003.

During the years ended December 31, 2004 and 2003, there were no sales of available-for-sale securities. The net adjustment to unrealized gains / (losses) during 2004 and 2003 on available-for-sale securities included in stockholders' equity totaled $(4,060) and $0, respectively. All of the available-for-sale securities held by the Company at December 31, 2004 were due in one year or less. The cost and estimated fair value of these available-for-sale securities at December 31, 2004, were $6,000,000 and $5,995,940, respectively.

Market values were determined for each individual security in the investment portfolio. The 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 10 - Commitments and Contingencies

Settlement Agreements

In June 2002, the Company entered into a settlement agreement with one of its suppliers. 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 has agreed with the supplier to pay the remaining $250,000 over time.

In April 2002, the Company entered into a letter agreement with a placement agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, the Company entered into a settlement agreement with such placement agent pursuant to which, among other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement; and the Company agreed to issue such placement agent or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between the Company and Lancer Offshore, Inc. ("Lancer"), 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 the Company's common stock for $8.80 per share, if adjusted for the reverse stock split effected by the Company on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended). Because Lancer never satisfied the closing conditions and, consequently, a closing has not been held, the Company has not issued any warrants to the placement agent in connection with its settlement with them. In June 2004, the placement agent threatened to sue the Company for warrants it claims are due to it under its settlement agreement with the Company as well as a placement fee and additional warrants it claims are, or will be, owed in connection with the Company's initial public offering completed on September 24, 2004, as compensation for allegedly introducing the Company to one of the underwriters. The Company has commenced discussions with the placement agent in the hopes of reaching an amicable resolution of any potential claims. However such discussions may prove unsuccessful.

Fee Abatement

The Company settled outstanding liabilities arising out of certain professional services rendered to it. The Company had booked liabilities for such services of approximately $1,400,000. The gains on these transactions were recorded in the fourth quarter of 2003.

Litigation

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 three 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, consisting of $1,500,000 principal amount of the notes and 34,092 of the warrants, was 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, pending in the U.S. District Court for the Southern District of Florida (the "Ancillary Proceeding"). That action is ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No.03-CV-80612, also pending in the U.S. District Court for the Southern District of Florida, in which the court has appointed a Receiver to manage Lancer and various related entities (the "Receivership"). In the Ancillary Proceeding, the Receiver seeks 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 effected by the Company on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended), that the Receiver alleges are due as a result of the Company's settlement agreement with Lancer. The Company believes that it has valid defenses to the Receiver's claims, and it intends to continue to contest them vigorously. Additionally, the Company has asserted claims for damages against Lancer that exceed the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership. The Company has discussed the potential settlement of all claims with the Receiver, however, at this time, discovery for the Ancillary Proceeding is ongoing. There can be no assurance that the Company will settle or that the outcome of any of these proceedings will be successful.

Suppliers

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.

Note 11 - 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:

	2004	2003
U.S. federal statutory rate	35.00%	35.00%

State & local taxes	8.14%	9.72%
Tax on foreign operations	(6.19)%	(1.46)%
Other	(0.81)%	(3.34)%
Valuation Allowance	(36.14)%	(39.91)%
Effective tax rate	0.00%	0.00%

Significant components of the Company's deferred tax assets as of December 31, 2004 and 2003 are shown below:

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 10,584,348	$ 8,079,698
Research and development credits	651,498	547,638
Nonqualified stock option compensation expense	969,779	679,939
Total deferred tax assets	12,205,625	9,307,275
Valuation allowance for deferred tax assets	(12,199,589)	(9,301,239)
Net deferred tax assets	$ 6,036	$ 6,036
Deferred Tax Liabilities:		
Other Liabilities	(6,036)	(6,036)
Total deferred tax liabilities	$ (6,036)	$ (6,036)
Net deferred tax assets/(liabilities)	$ --	$ --

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, 2004, the Company had Federal, New York State and New York City income tax net operating loss carryforwards of approximately $22 million each and foreign income tax net operating loss carryforwards of approximately $2 million. The Company also had Federal and New York State research tax credit carryforwards of approximately $650,000 each at December 31, 2004. The Federal net operating loss and tax credit carryforwards will expire at various times between 2012 and 2024 unless utilized.

Note 12 - Related Party Transactions

a. In April 2002, the Company issued convertible notes in the aggregate principal amount of $250,000, pursuant to which the Company agreed to pay to the holder the principal amount due under each holder's convertible note, together with interest on the unpaid principal amount at the rate of 6% per annum, compounded semi-annually, from the date of the convertible note.

These notes were convertible, into 250,000 shares of the Company's series A convertible preferred stock or 250,000 shares of the Company's series C convertible preferred stock at the Company's election. In addition, the Company had agreed to issue warrants to these note holders to purchase through April 2004, an additional 125,000 shares of its series A convertible preferred stock or such common shares as would be issuable upon conversion of the preferred stock.

In April of 2004, the Company and holders of these notes agreed to convert the entire principal amount of these notes (except for $50, which the Company repaid) into an aggregate of 249,950 shares of series C convertible preferred stock, and the Company paid accrued interest on such convertible notes amounting to $5,000 in the aggregate. In connection with the warrant rights related to these convertible notes, in April 2004, the Company sold an aggregate of 87,500 shares of series A convertible preferred stock to the holders of such notes for $1.00 per share.

b. In May 2003, the Company entered into a Commitment Agreement with a holder of more than 5% of the Company's stock, pursuant to which, the Company agreed to sell convertible bridge notes in the aggregate principal amount of $1,000,000 at face value. The outstanding principal amount of such convertible bridge notes, together with interest at the rate of 6% per annum, would become due and payable on January 26, 2004. Pursuant to the Commitment Agreement, the Company offered the holders of its then outstanding capital stock and convertible notes the opportunity to invest in a portion of the bridge notes pro rata, in accordance with the number of shares issuable upon conversion of the capital stock and convertible notes then held by them. Under the Commitment Agreement, such 5% holder had agreed to purchase additional bridge notes, if and to the extent that the other security holders elected not to purchase their respective pro rata shares of the bridge notes, thus ensuring that the Company would sell exactly $1,000,000 in aggregate principal amount of bridge notes. In June 2003, the Company sold the convertible bridge notes to twenty-three of the Company's security holders. Pursuant to the Commitment Agreement, the 5% holder had the right to elect whether he and the other holders would have the option to convert the bridge notes and purchase additional shares of series D convertible preferred stock at any time prior to the earlier of (i) 10 days after the Company notified such 5% holder that the Company obtained a CE mark on the initial product and (ii) January 15, 2004. The Company received such CE mark on July 31, 2003 and promptly notified such 5% holder thereof. On August 1, 2003, the 5% holder elected to proceed with the conversion and purchase. As of September 11, 2003, each of the holders converted its bridge note into shares of series D convertible preferred

stock at a conversion price equal to the liquidation preference of the series D convertible preferred stock, in accordance with the terms thereof.

Pursuant to the terms of the bridge notes, in order to convert each holder's bridge note, such holder was required to commit to purchase, for the aggregate liquidation preference thereof, a number of additional shares of series D convertible preferred stock having an aggregate liquidation preference equal to any amount, at such holder's option, between 9 and 11 times the principal amount of the bridge note being converted. The purchase of the additional shares of series D convertible preferred stock occurred in three installments, with 3,993,793 shares purchased at the time of conversion on September 11, 2003, another 3,000,000 shares purchased as of December 1, 2003, and the remaining 3,811,538 shares purchased as of March 3, 2004.

c. During 2001, 2002 and 2003, the Chairman of the Board of Directors of the Company made non-interest bearing demand loans to the Company in the aggregate principal amount of $160,000. On September 11, 2003, the Chairman assigned all of his right, title and interest in the loans to a holder of more than 5% of the Company's stock in exchange for 160,000 shares of the Company's series D convertible preferred stock due to such 5% stockholder at the first closing. Such 5% stockholder instructed the Company to issue the 160,000 shares directly to the Chairman and the $160,000 outstanding under the loans was applied to the purchase price of the series D convertible preferred stock to be purchased by such 5% stockholder.

d. During 2003, a Director made non-interest bearing demand loans to the Company in the aggregate principal amount of $50,000. On September 11, 2003, the Director assigned all of his right, title and interest in (i) the loans, (ii) his note, convertible into series D convertible preferred stock, in the principal amount of $72,189, and (iii) $80,000, to a holder of more than 5% of the Company's stock in exchange for 203,102 shares of series D convertible preferred stock due to such 5% stockholder at the first closing. Such 5% stockholder instructed the Company to issue the 203,102 shares directly to said Director and the $50,000 outstanding under the loans was applied to the purchase price of the series D convertible preferred stock to be purchased by such 5% stockholder.

Note 13 - Debt

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 three installments, (1) $3,000,000 principal amount of secured notes due March 15, 2003, convertible into 340,920 shares of common stock of the Company, and (2) warrants to purchase until December 2007, an aggregate of 68,184 shares of the common stock of the Company, at an exercise price of approximately $8.80 per share. In accordance with the subscription agreement, the first installment, consisting of $1,500,000 principal amount of the notes and 34,092 of the warrants, was sold. The $1,500,000 note issued in August 2002, contained a beneficial conversion of $1,110,000, which was recorded as a debt discount and was amortized over the term of the debt (7.5 months). In connection with the issuance of such note, the Company incurred issuance costs of approximately $224,000. Such costs are recorded as debt issuance costs and were amortized over the term of the debt

(7.5 months). The notes were originally to bear interest at the rate of 8% per annum, and be convertible at any time into shares of common stock at a price of approximately $8.80 per share. The warrants were valued at $390,000 using the Black-Scholes model, and were recorded as a debt discount, which was amortized over the term of the debt (7.5 months).

Lancer failed to fund the remaining installments under the subscription agreement. Following such 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.

In December 2002, the Company issued promissory notes in the aggregate principal amount of $250,000 to two lenders. Each of these loans was payable on the earlier to occur of (i) 30 days after the consummation of the Company's initial public offering and (ii) December 26, 2003. Each of these loans accrued interest, calculated quarterly in arrears, at a rate of 7% per annum from December 26, 2002 to March 31, 2003, 10% per annum from April 1, 2003 to April 30, 2003, and 15% per annum from May 1, 2003 to December 26, 2003. In connection with these loans, the Company issued the holders thereof warrants to purchase an aggregate of 5,549 shares of

Common Stock at an exercise price of approximately $8.80 per share, and paid Hermitage Capital Corporation, as placement agent, an aggregate amount of $25,000. The warrants were valued at $19,000 using Black-Scholes model, and were recorded as interest expense. On September 22, 2003, the Company prepaid the outstanding principal of, and all $21,842 of accrued interest on, these promissory notes in full.

Note 14 - Subsequent Events

On March 2, 2005, the Company entered into an 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 the Company's OLpur MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, the Company received an up front license fee in the amount of $1.75 million, and 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.

In addition, the Company and Asahi entered into a Subscription Agreement dated March 2, 2005, pursuant to which Asahi purchased 184,250 shares of the Company's common stock at an aggregate of 100 million Japanese Yen (approximately $956,000). The Subscription Agreement contains certain transfer restrictions with respect to the shares purchased thereunder.

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

On December 21, 2004, the Audit Committee of the Board of Directors dismissed Grant Thornton, LLP ("Grant Thornton") as our registered independent public accounting firm and approved the engagement of Deloitte & Touche LLP ("Deloitte & Touche") as our independent public accountants to audit our financial statements for the fiscal year ending December 31, 2004. During the fiscal years ended December 31, 2003 and 2002 and through December 21, 2004, we had no disagreement with Grant Thornton on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Grant Thornton, would have caused it to make reference to the subject matter thereof in connection with its reports. During the years ended December 31, 2003 and 2002 and through December 21, 2004, there have been no events reportable pursuant to Item 304(a)(1)(iv)(B) of Regulation S-B.

Item 8A. Controls and Procedures.

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic Securities and Exchange Commission reports. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. In addition, we reviewed our internal controls over financial reporting, and there have been no changes in our internal controls or in other factors in the last fiscal quarter that has materially affected or is 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 and Control Persons; Compliance with Section 16(a) of the Exchange Act.

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors" and "Directors, Director Nominees and Executive Officers" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. If such proxy statement is not filed on or before May 2, 2005, 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).

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.

Item 10. Executive Compensation.

The discussion under the heading "Executive Compensation" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. If such proxy statement is not filed on or before May 2, 2005, 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.

The discussion under the heading "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. If such proxy statement is not filed on or before May 2, 2005, 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.

The discussion under the heading "Certain Relationships and Related Transactions" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. If such proxy statement is not filed on or before May 2, 2005, 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 Third Amended and Restated Certificate of Incorporation of the Registrant. (1)

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)

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, 2004 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)

21.1 Subsidiaries of Registrant.

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 Report on Form 8-K Filed with the Securities and Exchange Commission on March 3, 2005.

Item 14. Principal Accountant Fees and Services.

The discussion under the heading "Auditor Services and Fees" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. If such proxy statement is not filed on or before May 2, 2005, 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).

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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 INCORPORATED

Date: March 31, 2005

By /s/ Norman J. Barta

Norman J. Barta
President and Chief Executive Officer (Principal 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	March 31, 2005
/s/ Marc L. Panoff Marc L. Panoff	Chief Financial Officer and Principal Accounting Officer	March 31, 2005
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Chairman of the Board of Directors and Director	March 31, 2005
/s/ Lawrence J. Centella Lawrence J. Centella	Director	March 31, 2005
/s/ Donald G. Drapkin Donald G. Drapkin	Director	March 31, 2005
/s/ Howard Davis Howard Davis	Director	March 31, 2005
/s/ William J. Fox		

William J. Fox	Director	March 31, 2005
/s/ W. Townsend Ziebold, Jr.		
W. Townsend Ziebold, Jr.	Director	March 31, 2005

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