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 o