NEPHROS INC
Form 10KSB
April 20, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from_____to_____

Commission file number 001-32288

NEPHROS, INC.
(Name of Small Business Issuer in its Charter)

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

3960 Broadway
New York, NY 10032

(Address of principal executive offices)

(212) 781-5113

(Issuer's telephone number, including area code)

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

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

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

Title of Class

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

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES [ ] NO [X]

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act. YES [ ] NO [X]

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

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

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

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

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

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

NEPHROS, INC. AND SUBSIDIARY

Table of Contents

PART I

Item 1. Description of Business.

Overview

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

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

- OLpūr H_2H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

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

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

OLpūr and H_2H are among our trademarks for which U.S. registrations are pending. H_2H is a registered European Union trademark. We have assumed that the reader understands that these terms are source-indicating. Accordingly, such terms appear throughout the remainder of this Annual Report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpūr MDHDF filter series are more effective than any products currently available for ESRD therapy, because they are better at removing certain larger toxins (known in the industry as “middle molecules” because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpūr H_2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profile), and, therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. We believe that the OLpūr MDHDF filter series and the OLpūr H_2H will provide these benefits to ESRD patients at competitive costs and without the need for ESRD treatment providers to make significant capital expenditures in order to use our products. We also believe that the OLpūr NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

In January 2006, we introduced our new Dual Stage Ultrafilter (the “DSU”) water filtration system. Our DSU represents a new and complimentary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpūr H_2H and Mid-Dilution filter technologies for ESRD therapy provided the foundations for a proprietary

multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water problems. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including *salmonella*, hepatitis, anthrax, HIV, Ebola virus, ricin toxin, *legionella*, fungi and *e-coli.* During January 2006, we received our first Purchase Order for our DSU from a major hospital in New York City that will use it initially in the hospital's patient showers. With over 5,000 registered hospitals in the United States alone, we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology. However, there can be no assurance that our efforts to market the DSU to hospitals will be successful, or that we will be able to successfully apply the DSU to any other markets.

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

ESRD Industry Background

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

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

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

Current ESRD Therapy Options

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

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

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

from the blood cross the membrane into the dialysate solution through a process known as “diffusion.”

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

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

Current Dialyzer Technology used with HDF Systems

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

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

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

The Nephros Mid-Dilution Diafiltration Process

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

Our ESRD Therapy Products

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

OLpūr MDHDF Filter Series

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

Laboratory bench studies have been conducted on our OLpūr MD190 by members of our research and development staff and by a third party. We completed our initial clinical studies to evaluate the efficacy of our OLpūr MD190 as compared to conventional dialyzers in Montpellier, France in 2003. The results from this clinical study support our belief that OLpūr MD190 is superior to post-dilution hemodiafiltration using a standard high-flux dialyzer with respect to ß2-microglobulin clearance. In addition, clearances of urea, creatinine, and phosphate met the design specifications proposed for the OLpūr MD190 device. Furthermore, adverse event data from the study suggest that hemodiafiltration with our OLpūr MD190 device was well tolerated by the patients and safe.

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

We contracted with TÜV Rheinland of North America, Inc., a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, to assist us in obtaining the Conformité Européene, or CE mark, a mark which demonstrates compliance with relevant European Union requirements. We received CE marking on the OLpūr MD190 (which also covers other dialyzers in our MDHDF filter series), as well as certification of our overall quality system, on July 31, 2003.

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

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

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

OLpūr HD190

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

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

OLpūr H_2H

OLpūr H_2H is our add-on module that converts the most common types of hemodialysis machines—that is, those with volumetric ultrafiltration control—into HDF-capable machines allowing them to use our OLpūr MDHDF filter. We have completed our OLpūr H_2H design and laboratory bench testing, all of which were conducted by members of our research and development staff. We believe that our design verification of the OLpūr H_2H will have progressed to the point where the device will be ready for U.S. clinical trials in the second quarter of 2006, and, provided that such trials are timely and successful, we expect to file 510(k) applications with respect to the OLpūr MDHDF filter series and the OLpūr H_2H in the fourth quarter of 2006 and hope to achieve U.S. regulatory approval of both products during the first half of 2007. We plan to apply for CE marking of our OLpūr H_2H in the second quarter of 2006.

OLpūr NS2000

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

We have also designed and developed proprietary substitution fluid filter cartridges for use with OLpūr NS2000, which have been subjected to pre-manufacturing testing. We will need to obtain the relevant regulatory clearances prior to any market introduction of our OLpūr NS2000 in our Target European Market or the United States. We have targeted a 2007 initial regulatory approval for the OLpūr NS2000 product.

Our Water Filtration Product

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

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

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

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

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

During January 2006, we received our first Purchase Order for our DSU from a major hospital in New York City that will use it initially in the hospital's patient showers. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

Our Strategy

We believe that current mortality and morbidity statistics, in combination with the quality of life of the ESRD patient, has generated demand for improved ESRD therapies. We also believe that our products and patented technology offer the ability to remove toxins more effectively than current dialysis therapy, in a cost framework competitive with currently available, less-effective therapies. The following are some highlights of our current strategy:

Showcase product efficacy in our Target European Market: As of March 2004, we initiated marketing in our Target European Market for the OLpūr MD190. There is an immediate opportunity for sales of the OLpūr MDHDF filters in our Target European Market because there is an established HDF machine base using disposable dialyzers. We believe that by demonstrating the effectiveness of our MDHDF filter series we will encourage more customers to purchase our products.

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

Upgrade dialysis clinics to OLp