NEPHROS INC
Form S-1/A
January 21, 2010

As filed with the Securities and Exchange Commission on January 21, 2010
Registration No. 333-162781

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

Pre-Effective
Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

NEPHROS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	3841	13-3971809
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I. R. S. Employer Identification No.)

41 Grand Avenue
River Edge, New Jersey 07661
(201) 343-5202
(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

Ernest Elgin III
President and Chief Executive Officer
Nephros, Inc.
41 Grand Avenue
River Edge, New Jersey 07661
(201) 343-5202
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:

Alexander M. Donaldson, Esq.
W. David Mannheim, Esq.
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4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607
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Approximate date of commencement of proposed sale to the public: As promptly as practicable after this registration statement becomes effective and the satisfaction or waiver of certain other conditions described herein.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if smaller reporting company) Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum aggregate offering price per unit(2)	Proposed maximum aggregate offering price	Amount of registration fee(3)
Common stock, $0.001 par value per share	2,352,941	$ 0.765	$ 1,800,000	$ 100

(1) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transaction.

(2) Estimated solely for the purpose of calculating the registration fee, based upon the average of the bid and asked prices of our common stock on the Over-the-Counter Bulletin Board on December 22, 2009, in accordance with Rule 457.

(3) Paid previously.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation or sale is not permitted.

SUBJECT TO COMPLETION — DATED January 21, 2010

PROSPECTUS

2,352,941 Shares
Common Stock

We are offering 2,352,941 shares of our common stock, $0.001 par value, at a fixed price per share equal to $___. We will conduct one closing for the sale of our common stock. Proceeds that we receive from the offering of shares will not be placed into escrow.

There is no minimum number of shares that we must sell in this offering. As a result, the actual amount of gross proceeds from the sale of shares, if any, might not be sufficient to cover the expenses of the offering.

The offering will run for 15 business days from the date of this prospectus.

We are offering the shares on our own. There will be no underwriter, sales agent or other third party involved in the sale of the shares. We will offer the shares through our officers and directors who will not be paid any commission for such sales. We will pay all expenses incurred in this offering.

Our shares of common stock are quoted on the Over-the-Counter Bulletin Board under the symbol “NEPH.OB.” On January 20, 2010, the last reported sale price of our common stock on the Over-the-Counter Bulletin Board was $0.91 per share.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under “Risk Factors” beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is [ ], 2010.

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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 prospectus without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

Unless the context otherwise requires, "Nephros," "the company," "we," "us," "our" and similar names refer to Nephros, Inc. a our subsidiary, Nephros International Limited.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. You should carefully read the more detailed information contained in this prospectus, including the section entitled "Risk Factors" beginning on page 5 and our financial statements for the years ended December 31, 2007 and 2008, and the quarter ended September 30, 2009, and related notes, included herein. We refer to Nephros, Inc. and its consolidated subsidiary as "Nephros", the "Company", "we", "our", and "us".

About the Company

We are a medical device company developing and marketing filtration products for therapeutic applications, infection control, and water purification.

Our hemodiafiltration, or HDF, system is designed to improve the quality of life for the End-Stage Renal Disease, or ESRD, patient while addressing the critical financial and clinical needs of the care provider. ESRD is a disease state characterized by the irreversible loss of kidney function. The Nephros HDF system removes a range of harmful substances more effectively, and with greater capacity, than existing ESRD treatment methods, particularly with respect to substances known collectively as "middle molecules." These molecules have been found to contribute to such conditions as dialysis-related amyloidosis, carpal tunnel syndrome, degenerative bone disease and, ultimately, mortality in the ESRD patient. Nephros ESRD products are sold and distributed throughout Europe and are currently being used in over 50 clinics in Europe.

We currently have three HDF products in various stages of development to deliver improved therapy to ESRD patients:

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters), which is, to our knowledge, the only filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

- OLpur H2H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and

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

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

We believe that products in our OLpur 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 OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved in 2009, our OLpur H2H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

We submitted a 501(k) application for our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter to the FDA in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Per FDA guidelines, the FDA generally reviews additional information within 90 days. As of the date of this prospectus, we have not received a response from the FDA.

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 profiles), and therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. In addition, independent studies in Europe have indicated that, when compared with dialysis as it is currently offered in the United States, HDF can reduce the patient's mortality risk by up to 35%. We believe that the OLpur MDHDF filter series 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.

In January 2006, we introduced our new Dual Stage Ultrafilter, or DSU, water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpur H2H and MD Mid-Dilution filter technologies for ESRD therapy provided the foundation 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 and disease prevention issues. 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, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,000 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of October 20, 2006), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

Due to the ongoing concerns of maintaining water quality, on October 7, 2008, we filed a 510(k) application for approval to market our DSU to dialysis clinics for in-line purification of dialysate water. On July 1, 2009, the FDA approved the DSU to be used to filter biological contaminants from water and dialysate concentrate used in hemodialysis procedures.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we are developing a personal potable water purification system for use by soldiers. Work on this project commenced in January 2008 and we billed $196,000 during the year ended December 31, 2008. In December 2007, the U.S. Department of Defense Appropriations Act appropriated an additional $2 million to continue the development of a dual stage ultra reliable personal water filtration system. In August 2009, we were awarded a new $2 million research contract from the Office of Naval Research, or ONR, for development of a potable dual-stage military water purifying filter. The research contract was an expansion of our current ONR contract which is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of the Nephros ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded ONR contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We believe that the military product development efforts will have broad consumer applications as well and have begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

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Recent Developments

On July 24, 2009, we raised gross proceeds of $1,251,000 through the private placement to eight accredited investors of an aggregate of 1,345,161 shares of our common stock and warrants to purchase an aggregate of 672,581 shares of our common stock, representing 50% of the shares of common stock purchased by each investor. We sold the shares to investors at a price per share equal to $0.93. The warrants have an exercise price of $1.12, are exercisable immediately and will terminate on July 24, 2014. Each investor agreed that it will not sell, pledge, sell short or otherwise dispose of any of the purchased shares until January 31, 2010. The proceeds from the private placement are being used for ongoing operations and other general corporate purposes, including the launch of our recently FDA-approved Dual Stage Ultrafilters and, if approved by the FDA, the preparation to launch our OLpur MD220 Dialyzers and H2H Hemodiafiltration Module in the United States.

Corporate Information

We are incorporated in Delaware and our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey 07661. Our telephone number is (201) 343-5202 and our website address is www.nephros.com. Information contained in, or accessible through, our website does not constitute part of this prospectus.

The Offering

Securities Offered:	We are offering 2,352,941 shares of our common stock, $0.001 par value.
Offering Price:	The offering price per share is $___.
Use of Proceeds:	We intend to use the net proceeds from this offering for general corporate purposes, including further development of our product candidates, clinical trials, research and development expenses, and administrative expenses. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities.
Manner of offering:	We are offering the shares on our own. There will be no underwriter, sales agent or other third party involved in the sale of the shares. We will offer the shares through our officers and directors who will not be paid any commission for such sales. We will conduct one closing for the sale of our common stock. We estimate the expenses of the offering to be $55,000. There is no minimum number of shares that we must sell in this offering. As a result, the actual amount of gross proceeds from the sale of shares, if any, might not be sufficient to cover the expenses of the offering. The offering price will be negotiated by us with prospective purchasers. Each purchaser will pay the same price to purchase stock in this offering. The offering will run for 15 business days from the date of this prospectus.
Over-the-Counter Bulletin Board stock symbol:	NEPH.OB
Risk Factors:	This investment involves a high degree of risk. See “Risk Factors” beginning on page 5 of this prospectus.
Number of shares outstanding before the offering:	41,604,798 shares. Does not include 1,506,712 shares issuable upon the exercise of stock options or 8,191,827 shares issuable upon the exercise of warrants outstanding on September 30, 2009 (which number will increase to 8,626,334 shares after giving effect to this offering due to anti-dilution provisions applicable to certain warrants in the event that the offering price is less than $0.90).
Number of shares outstanding after the offering:	43,957,739 shares, assuming all shares are sold.
Proceeds to us from this offering:	$_____, without deducting any offering expenses.

Where you can find more information: If you have any questions relating to this prospectus, you should contact:

Ernest Elgin
President and Chief Executive Officer
Nephros, Inc.
41 Grand Avenue
River Edge, New Jersey 07661
(201) 343-5202

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus, before you decide whether to buy our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Company

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2008, expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in our Annual Report on Form 10-K for the period ended December 31, 2008, expressing doubt as to our ability to continue as a going concern. The financial statements included in our Form 10-K were prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations, raises substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We might require additional financing to fund operations or potential acquisitions. If financing is not available, we might not be able to grow as we plan.

At September 30, 2009, we had cash, cash equivalents and short-term investments totaling approximately $1,795,000 and tangible assets of approximately $3,279,000. In the future, we might be required to seek additional financing to fund operations or potential acquisition opportunities. Despite our recent private placement from which we raised gross proceeds of $1,251,000, as described above under “Prospectus Summary - Recent Developments,” the recent downturn in the capital markets and the general economic slowdown could prevent us from raising additional capital or obtaining additional financing on favorable terms, if at all. If we cannot raise sufficient capital, our ability to operate and to grow through acquisitions or otherwise respond to competitive pressures would be significantly limited.

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 September 30, 2009, we had an accumulated deficit of $89,492,000 primarily as a result of our research and development expenses and selling, general and administrative expenses and non-cash expenses related to converted bonds in 2007. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

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

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

- our ability to effectively and efficiently manufacture, market and distribute our products;
- our ability to sell our products at competitive prices which exceed our per unit costs; and
- the consolidation of dialysis clinics into larger clinical groups.

We have limited experience selling our DSU water filtration system to dialysis clinics, and we might be unsuccessful in increasing our sales.

Our business strategy depends in part on our ability to sell our DSU water filtration system to hospitals and other healthcare facilities that include dialysis clinics. On July 1, 2009, we received approval from the FDA to market our DSU to dialysis clinics. If we are unsuccessful at manufacturing, marketing and selling our DSU, our operations and potential revenues might be adversely affected.

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

For the year ended December 31, 2008, one of our customers accounted for 78% of our product sales. Also, this customer represented 66% of our accounts receivable as of December 31, 2008. We believe that the loss of this customer would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

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

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpur MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage Ultrafilter, or DSU. We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance. Although we received approval of our Investigational Device Exemption in March 2007 to begin clinical trials in the United States, until we complete the requisite U.S. human clinical trials and submit pre-market notification to the FDA pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or FDC Act, or otherwise comply with FDA requirements for a 510(k) approval, we will not be eligible for FDA approval for any of our products, except for our HD190 filter.

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

obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the United States.

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

If we are successful in our initial marketing efforts in some or all of our Target European Market (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) and the United States, then we plan to market our ESRD therapy products in several countries outside of our Target European Market and the United States, including Korea, China, Canada and Mexico. Requirements pertaining to the sale of medical devices vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our ESRD therapy products in many of these countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our ESRD therapy products outside of our Target European Market and the United States, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

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

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H2H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We obtained approval from Western IRB, Inc., whic