NEPHROS INC
Form S-3/A
April 16, 2008

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As filed with the Securities and Exchange Commission on April 16, 2008
Registration No. 333-148200

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Amendment No. 1
to
Form S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**13-3971809**
(State or other jurisdiction of incorporation or organization)	*(IRS employer identification number)*

3960 Broadway
New York, New York 10032
(212) 781-5113
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Norman J. Barta
President and Chief Executive Officer
Nephros, Inc.
3960 Broadway
New York, New York 10032
(212) 781-5113
(Name, address, including zip code, and telephone number, including area code, of agent for service)
Copy to:
David M. Zlotchew, Esq.
Haynes and Boone, LLP
153 East 53rd Street
New York, NY 10022
Telephone: (212) 659-4986
Facsimile: (212) 884-9540

Approximate date of commencement of proposed sale to the public: At such time or other times as may be determined by the selling stockholders following the effectiveness of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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 of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

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

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. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

Indicate by checkmark 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. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company þ
(Do not check if a smaller reporting company)	

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 this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders 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 APRIL 16, 2008

PRELIMINARY PROSPECTUS

36,916,328 Shares of Common Stock

This prospectus relates to the resale or other disposition of up to 36,916,328 shares of our common stock, which shares consist of (i) 25,847,388 presently outstanding shares of our common stock, (ii) 9,112,566 shares of our common stock issuable upon the exercise of our Class D warrants, (iii) 1,756,374 shares of our common stock issuable upon the exercise of our placement agent warrants, and (iv) 200,000 shares of our common stock issuable upon the exercise of our underwriter warrants, that are beneficially owned by the selling stockholders listed on page 21 of this prospectus or their transferees. The selling stockholders may sell any, all or none of the shares of our common stock offered under this prospectus and any supplements to this prospectus from time to time, in one or more transactions.

We are registering the shares of common stock offered under this prospectus as required by the terms of certain registration rights agreements between the selling stockholders and us, as described in the section entitled the Selling Stockholders. We will not receive any proceeds from the sale of shares of our common stock sold by the selling stockholders. However, we may receive up to $10,950,309 of proceeds in connection with the exercise for cash by the selling stockholders of warrants to purchase certain of the shares of our common stock that may be offered and sold under this prospectus.

Our shares of common stock are listed for trading on the American Stock Exchange under the symbol NEP. On March 28, 2008, the last reported sale price of our common stock on the American Stock Exchange was $0.74 per share.

INVESTING IN OUR COMMON STOCK INVOLVES CERTAIN RISKS. AS YOU REVIEW THIS PROSPECTUS, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DESCRIBED IN THE SECTION OF THIS PROSPECTUS TITLED RISK FACTORS BEGINNING ON PAGE 3.

None of the Securities and Exchange Commission, any state securities commission or any other regulatory body 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 April 16, 2008

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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 or incorporated by reference in this prospectus, including the section entitled Risk Factors on page 3 and our financial statements and related notes, which are incorporated by reference. We refer to Nephros, Inc. and its consolidated subsidiary as Nephros , the Company , we , our , and us .

About the Company

Nephros, Inc., headquartered in New York, is a medical device company developing and marketing products designed to improve the quality of life for the End-Stage Renal Disease (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. Nephros believes that its products, particularly its Mid-Dilution Hemodiafiltration therapy, are designed to remove a range of harmful substances more effectively, and more cost-effectively, than existing ESRD treatment methods; particularly with respect to substances known collectively as middle molecules, due to their molecular weight, that 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 products are currently being used in over fifty clinics in Europe, and are currently sold and distributed throughout Europe.

In the course of our extensive development, we have diversified into infection control in the form of our Dual Stage Ultrafilter water filtration products (the DSU). The Company s patented dual stage cold sterilization Ultrafilter has the capability to filter out bacteria and, due to its exceptional filtration levels, filter out many viruses and parasites. The DSU proprietary design provides dual-stage filtration which reduces the risk of filtration failure. With initial focus on health care, the DSU is in a pilot-use program at a major medical center and has been selected for further development by the U.S. Marine Corps. The Company considers the DSU a significant breakthrough in providing affordable and reliable water filtration. The DSU is based on Nephros proprietary water filtration technology originally designed for medical use in its H2H machine, and is a complementary product line to the Company s main focus, the ESRD therapy business.

The Offering

Securities offered by the selling stockholders	36,916,328 shares of common stock of Nephros, par value $0.001 per share, held by the selling stockholders, are being offered by this prospectus.(1)(2)
Shares outstanding before the Offering	38,165,380 shares of common stock(3)
Use of Proceeds	The shares being offered pursuant to this prospectus are being sold by the selling stockholders, and we will not receive any proceeds from the sale of the shares by the selling stockholders. We may receive proceeds in connection with the exercise of the Warrants for cash, the underlying shares of which may be sold by the selling stockholders under this prospectus.

(1)

Includes (i) 9,122,566 shares of our common stock issuable upon conversion of our Class D warrants with an exercise price per share equal to $0.90 per share (the Class D Warrants) issued by us to certain selling stockholders in connection with our September 2007 financing, (ii) 1,756,374 shares of our common stock issuable upon conversion of our placement agent warrants with an exercise price per share equal to $0.706 per share (the Placement Agent Warrants) issued by us to certain selling stockholders in connection with our September 2007 financing and (iii) 200,000 shares of our common stock issuable upon conversion of our underwriter warrants with an exercise price per share equal to $7.50 per share (the Underwriter Warrants , and together with the Class D Warrants and the Placement Agent Warrants, the Warrants) issued by us to certain selling stockholders in connection with our initial public offering.

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(2) (i) The following selling stockholders received our common stock and Class D Warrants, as further described under the section entitled Selling Stockholders , in connection with our September 2007 financing: Lambda Investors LLC, Enso Global Equities Master Partnership LP, GPC 76, LLC, Lewis P. Schneider, Southpaw Credit Opportunity Master Fund LP, 3V Capital Master Fund Ltd., Distressed/High Yield Trading Opportunities Ltd., Kudu Partners, LP and LJHS Company (the 2007 Investors); (ii) the following selling stockholders received Placement Agent Warrants in connection with our September 2007 financing: National Securities Corporation, Mark Goldwasser, Brian Friedman, Christopher Dewey, Malcolm Plett, Ryan Rauch, Matt Portes, Peter Menachem, Michael Compton, Eric Lyon, Tom Holly, Dinosaur Securities LLC, Andrew J. Deniken and David Garrity; and (iii) the following selling stockholders received Underwriter Warrants in connection with our initial public offering: Gary Shemano, William Corbett, Howard Davis, David Weinstein, Doug Kaiser, Frank Salvatore, Michael Bresner, Mark Goldwasser, Brian Friedman, Robert Daskal and National Securities Corporation.

(3) This amount does not include the 11,078,940 shares of common stock issuable upon conversion of the Warrants.

Corporate Information

We are incorporated in Delaware and our principal executive offices are located at 3960 Broadway, New York, New York 10032. Our telephone number is (212) 781-5113 and our website address is *www.nephros.com*. Information contained in, or accessible through, our website does not constitute part of this prospectus.

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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 or incorporated by reference 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

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, 2007, we had an accumulated deficit of approximately $81,612,000 primarily as a result of our research and development expenses and selling, general and administrative expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

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

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2007, 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-KSB expressing doubt as to our ability to continue as a going concern. Our financial statements accompanying the Form 10-KSB have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations, raises substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or to do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

Our short-term investments may not provide us with the liquidity that we intended them to provide. If we are unable to liquidate our short-term investments in a timely manner and on reasonable terms, then we may run out of funds with which to operate our business.

As of December 31, 2007, we held $4.7 million in auction rate securities (ARS) which are classified as short-term investments on our balance sheet. ARS are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction fails and the holders of the ARS are unable to liquidate their investment through such auction. Starting in

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February 2008, the auctions for our ARS have failed. Accordingly, and for so long as such auctions continue to fail, these ARS are no longer functionally short-term.

To the extent that the auctions for our ARS continue to fail and no other markets develop for our ARS, we may be unable to liquidate these assets in a timely manner, on reasonable terms or at all. If we are unable to liquidate our short-term investments in a timely manner and on reasonable terms, then we may run out of funds with which to operate our business. If the current lack of liquidity relating to our ARS investments continues, it may have a material adverse effect on our ability to fund our ongoing operations and growth initiatives.

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

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

On November 14, 2006, we received notice that the AMEX staff had reviewed our plan of compliance to meet the AMEX s continued listing standards and that AMEX would continue our listing while we sought to regain compliance with the continued listing standards during the period ending January 17, 2008. During the plan period, we were required to provide the AMEX staff with updates regarding initiatives set forth in our plan of compliance. On November 14, 2007, all of our Series A 10% Secured Convertible Notes Due 2008 and our Series B 10% Secured Convertible Notes due 2008 (collectively, the Notes), representing an aggregate principal amount of $18 million, were converted into shares of our common stock and warrants, resulting in an increase in our stockholders equity. As a result, and notwithstanding our loss during the fourth quarter of 2007, our stockholders equity, at December 31, 2007, was approximately $8,756,000 and in excess of the $6,000,000 required by the AMEX rules.

On March 5, 2008, we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiencies referenced in the AMEX s letters dated July 17, 2006 and November 14, 2006. However, if we are not able to generate revenues from operations or timely raise equity capital, we are likely to again fail to comply with the AMEX rules regarding minimum shareholders equity. Should this occur within 12 months of January 17, 2009, then, in accordance with Section 1009(h) of the AMEX Company Guide, the AMEX may evaluate the relationship between the two incidents and apply more truncated procedures for compliance or immediately initiate delisting proceedings. Furthermore, there can be no assurance that we will not run afoul of the AMEX s other continued listing standards. If we fail to meet such standards, then our common stock may be delisted from the AMEX.

On September 27, 2007, we received a warning letter from the AMEX stating that the staff of the AMEX Listing Qualifications Department had determined that we were not in compliance with Section 121B(2)(c) of the AMEX Company Guide requiring that at least 50% of the directors of our board of directors are independent directors. This non-compliance was due to the fact that William J. Fox, Judy Slotkin, W. Townsend Ziebold and Howard Davis resigned from our board of directors on September 19, 2007, concurrently with the appointment of Paul Mieyal and Arthur Amron to our board of directors, in accordance with our September 2007 financing. Consequently, our board of directors consisted of five directors, two of whom were independent. The AMEX had given us until December 26, 2007 to regain compliance with the independence requirements. On November 16, 2007, James S. Scibetta was

appointed to serve as an independent director on our board of directors. On December 5, 2007 we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiency identified in their September 27, 2007 letter.

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If our common stock is delisted by the AMEX, trading of our common stock would thereafter likely be conducted on the OTC Bulletin Board. In such case, the market liquidity for our common stock would likely be negatively affected, which may make it more difficult for holders of our common stock to sell their securities in the open market and we could face difficulty raising capital necessary for our continued operation. Investors may find it more difficult to dispose of or obtain accurate quotations as to the market value of our securities. In addition, our common stock, if delisted by the AMEX, may constitute penny stock (as defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934, as amended) if we fail to meet certain criteria set forth in such Rule. Various practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser s written consent to the transactions prior to sale. Consequently, if our common stock were to become penny stock, then the Rule may deter broker-dealers from recommending or selling our common stock, which could further negatively affect the liquidity of our common stock.

Pursuant to the terms of our recently completed financing, if we fail to have the registration statement of which this prospectus is a part declared effective by the SEC in a timely manner as provided in the Registration Rights Agreement, then we may be required to pay liquidated damages to the 2007 Investors.

In connection with our September 2007 financing of an aggregate of approximately $18 million principal amount of Series A and Series B 10% Secured Convertible Notes due 2008 (the New Notes), we entered into a Registration Rights Agreement (the Registration Rights Agreement) with the investors in the Financing (the 2007 Investors) pursuant to which we agreed to file an initial resale registration statement with the SEC no later than 60 days after the filing of a definitive version of an Information Statement on Schedule 14C (the Information Statement). The Information Statement was filed with the SEC on October 24, 2007, and initial resale registration statement was filed on December 20, 2007.

We have agreed to use our commercially reasonable best efforts to have the registration statement of which this prospectus is a part declared effective within 240 days after filing of the Information Statement. In the event such registration statement has not been declared effective within such time period, for each 30-day period thereafter or portion thereof, we will pay each 2007 Investor, as liquidated damages, an amount equal to 1% of the principal and interest amount of such 2007 Investor s New Notes that were automatically converted into shares of our common stock (the Conversion Amount) in respect of the first ten 30-day periods, and 2% of such 2007 Investor s Conversion Amount thereafter. If we fail to pay the liquidated damages when due, then we shall pay interest thereon at a rate of 15% per annum.

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, 2007, one of our customers accounted for 91% of our product sales. Also, this customer represented 98% of our accounts receivable as of December 31, 2007. We believe that the loss of this customer would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

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

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, European Community), for our OLpūr MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage

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Ultrafilter (DSU). We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance. Although we received approval of our IDE 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 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 Cyprus, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom (referred to hereinafter collectively as the Target European Market) and the United States, then we plan to market our ESRD therapy products in several countries outside of our Target European Market and the United States, including Korea and China, Canada and Mexico. Requirements pertaining to the sale of medical devices vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our ESRD therapy products in many of these countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our ESRD therapy products outside of our Target European Market and the United States, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

We have entered into an agreement with Asahi Kasei Medical Co., Ltd. (Asahi) granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpūr MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. If the requisite Japanese regulatory approvals are not timely obtained, our potential license revenues will be limited.

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

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

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these questions. We have obtained approval from Western IRB, Inc., which enables us to proceed with our clinical trial. We began our clinical trials in the United States in the fourth quarter of 2007.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our ESRD therapy products are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our ESRD therapy products may not exhibit the expected medical benefits, may cause harmful side effects, may not be effective in treating dialysis patients or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;

lower than expected retention rates of subjects in a clinical trial;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;

delays in approvals from a study site s review board, or other required approvals;

longer treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the ESRD therapy product;

adverse medical events or side effects in treated subjects;

lack of effectiveness of the ESRD therapy product being tested; and

regulatory changes.

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

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

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

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

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

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

information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;

because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and

if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

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

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

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

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

To obtain product liability insurance; or

To indemnify manufacturers against liabilities resulting from the sale of our products.

For example, our agreement with Medica s.r.l. requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify Medica against certain liabilities arising out of our products that they manufacture, provided they do not arise out of Medica s breach of the agreement, negligence or willful misconduct. If

we are not able to obtain and maintain adequate product liability insurance, then we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

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

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

fines;

injunctions;

civil penalties;

recalls or seizures of our products;

total or partial suspension of the production of our products;

withdrawal of any existing approvals or pre-market clearances of our products;

refusal to approve or clear new applications or notices relating to our products;

recommendations by the FDA that we not be allowed to enter into government contracts; and

criminal prosecution.

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

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

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

Access to the appropriations from the U.S. Department of Defense regarding the development of a dual-stage water ultrafilter could be subject to unanticipated delays which could adversely affect our potential revenues.

Our business strategy with respect to our DSU products depends in part on the successful development of DSU products for use by the military. We have contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters, and Federal appropriations from the U.S. Department of Defense in an aggregate amount of $3 million have been approved for this purpose. If there are unanticipated delays in receiving

the appropriations from the U.S. Department of Defense, our operations and potential revenues may be adversely affected.

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

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

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

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

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

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

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

countries may not adequately protect our trade secrets.

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

Our registered or unregistered trademarks or trade names may be challenged, cancelled, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to

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these trademarks and trade names, which we need to build brand loyalty. Over the long term, if we are unable to establish a brand based on our trademarks and trade names, then we may not be able to compete effectively and our sales and revenues may suffer.

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

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

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

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

Independent manufacturers of medical devices will manufacture all of our products and components. We have contracted Medica s.r.l., a developer and manufacturer of medical products with corporate headquarters located in Italy, to assemble and produce our OLpūr MD190, MD220 and possibly other filters, including our DSU, and have an agreement with Membrana GmbH, a manufacturer of medical and technical membranes for applications like dialysis with corporate headquarters located in Germany, to produce the fiber for the OLpūr MDHDF filter series. As with any independent contractor, these manufacturers will not be employed or otherwise controlled by us and will be generally free to conduct their business at their own discretion. For us to compete successfully, among other things, our products must be manufactured on a timely basis in commercial quantities at costs acceptable to us. If one or more of our independent manufacturers fails to deliver our products in a timely manner, then we may not be able to find a substitute manufacturer. If we are not or if potential customers believe that we are not able to ensure timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.

The loss or interruption of services of any of our manufacturers could slow or stop production of our products, which would limit our ability to generate sales and revenues.

Because we are likely to rely on no more than two contract manufacturers to manufacture each of our products and major components of our products, a stop or significant interruption in the supply of our products or major components by a single manufacturer, for any reason, could have a material adverse effect on us. We expect most of our contract manufacturers will enter into contracts with us to manufacture our products and major components and that these contracts will be terminable by the contractors or us at any time under certain circumstances. We have not made alternative arrangements for the manufacture of our products or major components and we cannot be sure that acceptable alternative arrangements could be made on a timely basis, or at all, if one or more of our manufacturers failed to manufacture our products or major components in accordance with the terms of our arrangements. If any such failure occurs and we are unable to obtain acceptable alternative arrangements for the manufacture of our

products or major components of our products, then the production and sale of our products could slow down or stop and our cash flow would suffer.

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If we are not able to maintain sufficient quality controls, then the approval or clearance of our ESRD therapy products by the European Union, the FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.

Approval or clearance of our ESRD therapy products could be delayed by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our ESRD therapy products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our ESRD therapy products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpūr MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpūr H_2H and OLpūr NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A notified body is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

Even with approval to market our ESRD therapy products in the European Community, the United States and other countries, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our ESRD therapy products, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers, then we may not be able to continue to market the ESRD therapy products manufactured in such facilities and our revenues may be materially adversely affected.

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

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