

NEPHROS INC  
Form S-1/A  
June 18, 2010

As filed with the Securities and Exchange Commission on June 18, 2010

**Registration No. 333-167022**

**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549**

**Pre-Effective Amendment No. 1  
to  
Registration Statement  
on  
FORM S-1  
UNDER THE SECURITIES ACT OF 1933**

**NEPHROS, INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

Delaware  
*(State or Other Jurisdiction of  
Incorporation or Organization)*

3841  
*(Primary Standard Industrial  
Classification Code Number)*

13-3971809  
*(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)*

**Paul A. Mieyal**  
**Acting 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:*

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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.  x

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.  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

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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

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Title of each class of securities to be registered	Amount to be registered	Proposed maximum aggregate offering price per unit	Proposed maximum aggregate offering price <sup>(1)</sup>	Amount of registration fee <sup>(1)</sup>
500,000 units, each unit consisting of 25 shares of common stock, \$0.001 par value per share, and warrants to purchase 25 shares of common stock		\$	\$	\$
Common stock included in the units	12,500,000	\$ 0.525	\$ 6,562,500	\$ 468
Common stock warrants included in the units <sup>(2)</sup>	12,500,000	\$	\$	\$
Common stock underlying the warrants included in the units	12,500,000	\$ 0.525	\$ 6,562,500	\$ 468
Warrants issued to placement agent <sup>(2)</sup>	625,000	\$	\$	\$
Common stock underlying placement agent warrants	625,000	\$ 0.525	\$ 328,125	\$ 23
Total	38,750,000	\$ 0.525	\$ 13,453,125	\$ 959 <sup>(3)</sup>

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) and Rule 457(g) under the Securities Act of 1933, as amended.

Pursuant to Rule 457(g) under the Securities Act, no separate registration fee is required for the warrants because the registrant is registering these securities in the same registration statement as the underlying common stock to be offered pursuant thereto. Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(3) The registrant previously paid \$357.00 of the registration fee in connection with the filing of its Registration Statement on Form S-1 with the Securities and Exchange Commission on May 21, 2010.

**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.**

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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.

**PRELIMINARY PROSPECTUS**

**SUBJECT TO COMPLETION DATED JUNE 18, 2010**

500,000 UNITS, EACH CONSISTING OF 25 SHARES OF COMMON STOCK AND 25 WARRANTS

We are offering up to 500,000 units, each unit consisting of 25 shares of our common stock and warrants to purchase an additional 25 shares of our common stock. The warrants are exercisable at any time after the closing date of this offering and on or before the five year anniversary of their initial exercise date at an exercise price of \$ per share. Units will not be issued or certificated. The units will separate immediately and the common stock and warrants will be issued separately and the common stock and warrants will trade separately. The units are being offered and sold at a price of \$ per unit.

This is a reasonable best efforts offering by us, with Dawson James Securities, Inc. acting as our exclusive placement agent. We have entered into a letter agreement with the placement agent, relating to the units offered by this prospectus. The placement agent is not purchasing or selling any securities pursuant to this prospectus, nor is it required to sell any specific number or dollar amount of the securities offered hereby, but will use its best efforts to arrange for the sale of the securities being offered. The placement agent will receive compensation for sales of the securities offered hereby at a fixed commission rate of 7% of the gross proceeds of the offering and warrants to purchase shares of common stock equal to 5% of the aggregate number of shares included in the units sold in this offering with a term of five years from the effective date of this offering and an exercise price of \$. See the section entitled Plan of Distribution beginning on page 24 of this prospectus for more information regarding these arrangements.

At the election of us and Dawson James Securities, Inc., we may increase the aggregate offering amount in this offering by up to 20%.

In connection with this offering, we will establish a non-interest-bearing escrow account with Signature Bank, which we refer to as the escrow account. On the closing of this offering, each purchaser will deliver funds equal to the purchase price directly to the escrow account. We will then issue and deliver the securities. We expect the closing to occur on or about , 2010, subject to customary closing conditions.

Our shares of common stock are quoted on the Over-the Counter Bulletin Board under the symbol NEPH.OB. On June 15, 2010, the last reported sale price of our common stock on the Over-the Counter Bulletin Board was \$0.53 per share.

Investing in the offered securities involves substantial risks. **In reviewing this prospectus, you should carefully consider the matters described under the heading Risk Factors beginning on page 5.**

	Per Unit	Total
Price to Public	\$	\$
Placement agent's fees	\$	\$
Proceeds, before expenses, to Nephros, Inc. <sup>(1)</sup>	\$	\$

(1) We estimate total expenses of this offering, excluding the placement agent's fees, will be approximately \$110,000.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved 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.

## **DAWSON JAMES SECURITIES, INC.**

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**NEPHROS, INC.**  
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OLpur™ and H<sub>2</sub>H™ are among our trademarks for which U.S. registrations are pending. H<sub>2</sub>H 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.

## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, which we refer to as the SEC or the Commission, utilizing a registration process. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus before making a decision whether to invest in the common stock. You should also read and consider the information contained in the exhibits filed with our registration statement, of which this prospectus is a part, as described in "Where You Can Find More Information" in this prospectus.

You should rely only on the information contained in this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with different information. We are not offering to sell or soliciting offers to buy, and will not sell, any securities in any jurisdiction where it is unlawful. You should assume that the information

contained in this prospectus or any prospectus supplement, as well as information contained in a document that we have previously filed or in the future will file with the SEC and incorporate by reference into this prospectus or any prospectus supplement, is accurate only as of the date of this prospectus, the applicable prospectus supplement or the document containing that information, as the case may be.

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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 in this prospectus, including the section entitled Risk Factors beginning on page 5 and our financial statements for the years ended December 31, 2008 and 2009, and the quarter ended March 31, 2010, and related notes, appearing elsewhere in this prospectus. 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 H<sub>2</sub>H, 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 H<sub>2</sub>H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved in 2010, our OLpur H<sub>2</sub>H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

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 H<sub>2</sub>H 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.

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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 H<sub>2</sub>H 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 March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H<sub>2</sub>H hemodiafiltration module and OLpur MD220 hemodiafilter. We obtained approval from the IRBs and completed the clinical trial near the end of the second quarter in 2008. The clinical data was compiled, analyzed, summarized and submitted with our FDA 510(k) in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, on March 10, 2010, were informed that our application is still under their review process.

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 worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former 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 our 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 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. Approximately \$878,000 of revenue has been recognized on this new project since September 2009 of which approximately \$455,000 was recognized on this new project during the three months ended March 31, 2010.

## 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](http://www.nephros.com).

Information contained in, or accessible through, our website does not constitute part of this prospectus.

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## **Where You Can Find More Information**

We make available on our website, *www.nephros.com*, our annual reports, quarterly reports, proxy statements and other filings made with the SEC. The registration statement on Form S-1, of which this prospectus is a part, and its exhibits, as well as our other reports filed with the SEC, can be inspected and copied at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information about the operation of the public reference room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a web site at *www.sec.gov* which contains our registration statement on Form S-1 and other reports, proxy and information statements and information regarding us that we file electronically with the SEC.

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## The Offering

Issuer

Nephros, Inc., a Delaware corporation

Securities offered

Up to 500,000 units, each unit consisting of 25 shares of our common, par value \$0.001 per share, and warrants to purchase up to 25 shares of common stock; and up to 25 shares of common stock issuable upon the exercise of the warrants.

Offering price

\$ per unit.

Description of Warrants

The warrants will be exercisable on or after the applicable closing date of this offering through and including close of business on , 20 at an exercise price of \$ per share.

Shares Outstanding

41,604,798 shares of common stock<sup>(1)</sup>

Number of shares of common stock to be outstanding after this offering

Up to 54,104,798 shares, which does not include 12,500,000 shares of common stock issuable upon exercise of the warrants offered hereby.

Manner of Offering

This is a reasonable best efforts offering through our placement agent, Dawson James Securities, Inc. See Plan of Distribution beginning on page 24.

No Minimum

There is no minimum for this offering. In connection with this offering, we will establish a non-interest-bearing escrow account with Signature Bank, which we refer to as the escrow account. On the closing of this offering, each purchaser will deliver funds equal to the purchase price directly to the escrow account. We will then issue and deliver the securities.

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. See Use of Proceeds on page 22.

Over-the-Counter Bulletin Board Symbol for Common Stock

NEPH.OB

Risk Factors

You should carefully consider the matters discussed under the heading Risk Factors for a discussion of factors you should carefully consider before deciding to invest in our common stock.

As of June 15, 2010. This amount does not include 1,555,782 shares of common stock issuable upon exercise of options or 8,191,827 shares of common stock issuable upon exercise of warrants outstanding on March 31, 2010 (1)(the number of shares of common stock issuable upon exercise of options was 1,349,532 on June 15, 2010). The number of shares issuable upon exercise of warrants will increase pursuant to anti-dilution provisions applicable to certain warrants in the event that the offering price per unit is less than \$0.90. See Dilution.

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## **RISK FACTORS**

*An investment in our securities 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 securities. 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, 2009, 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 this prospectus which expressed doubt as to our ability to continue as a going concern.

The accompanying financial statements 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, raise 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 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 March 31, 2010, we had an accumulated deficit of \$90,504,000 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.

**We require additional financing in the near future to fund our operations.**

At March 31, 2010, we had cash and cash equivalents totaling approximately \$564,000 and tangible assets of approximately \$2,289,000. We estimate that these funds will allow us to keep operating into the third quarter of 2010. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, our ability to operate will be significantly limited and we might need to cease operations.



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**If we do not receive FDA approval for our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter our operations will be significantly and adversely harmed.**

We have not received approval from the FDA for our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H 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 responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products 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. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, on March 10, 2010, were informed that our application is still under their review process. We can give no assurance when or if our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter will be approved by the FDA. If we fail to receive FDA approval or if the approval is delayed into the third quarter of 2010, our operations would be significantly and adversely harmed.

**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. We have limited experience at sales and marketing. 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, 2009, two customers accounted for 87% of our product sales. In addition, those customers represented 78% of our accounts receivable as of December 31, 2009. We believe that the loss of these customers would have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customers and/or self-distribute in the territories currently served by such customers.

**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 ( 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.

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

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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 waiting the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

If we are successful in our initial marketing efforts in some or all of our Target European Market and the United States, then we plan to market our 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.

**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 H 2 H 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 responded to these questions. We obtained approval from Western IRB, Inc., which enabled us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, on March 10, 2010, were informed that our application is still under their review process.

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

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

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;

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

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.

**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.**

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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.

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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 products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and 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, the agreement with our contract manufacturer, or CM, requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, provided they do not arise out of our CM'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.

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

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our 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 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.



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**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. Beginning in January 2008, we contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters under a first contract in an amount not to exceed \$866,000. In August 2009, we entered into a second contract with a value not to exceed \$2 million. These contracts would utilize the Federal appropriations from the U.S. Department of Defense not to exceed \$3 million that 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. Further, if we do not successfully complete the contract work or renew the contract work in the event that the research and development needs additional work to reach completion, our operations and potential revenues may be adversely affected.

**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 16 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

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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 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.

If we are not able to secure and enforce protection of our trade secrets through enforcement of our confidentiality a

We expect to rely on a limited number of independent manufacturers to produce our OLpur 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, if any, 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.

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**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 with our CM to assemble and produce our OLpur MD190, MD220 and possibly other filters, including our DSU, and have an agreement with FS, a manufacturer of medical and technical membranes for applications like dialysis, to produce the fiber for the OLpur 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.

**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 OLpur 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 OLpur H 2 H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A notified body is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

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To market our ESRD therapy products in the European Community, the United States and other countries, where approved, 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 elsewhere, or be the first to introduce hemodiafiltration therapy in the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace include whether:

such products will be safe for use;

such products will be effective;

such products will be cost-effective;

we will be able to demonstrate product safety, efficacy and cost-effectiveness;

there are unexpected side effects, complications or other safety issues associated with such products; and government or third party reimbursement for the cost of such products is available at reasonable rates, if at all.

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance and endurance standards. Our water filtration products and technology may not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial, military, industrial or retail applications.

Many of the same factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace will also apply to our water filtration products, except for those related to side effects, clinical trials and third party reimbursement.

**If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to**

**market and distribute our products effectively and/or customers may decide not to order our products, and, in either case, our sales and revenues will suffer.**

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



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difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products and our sales and revenues will suffer.

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

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

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;
  - we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;
  - local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;
  - political instability could disrupt our operations;
  - some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and
  - some countries could impose additional taxes or restrict the import of our products.
- Any one or more of these factors could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition and results of operations.

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

Our success depends upon the skills, experience and efforts of our management and other key personnel, including our chief executive officer, certain members of our scientific and engineering staff and our marketing executives. As a relatively new company, much of our corporate, scientific and technical knowledge is concentrated in the hands of these few individuals. We do not maintain key-man life insurance on any of our management or other key personnel.

The recent resignation of our Chief Executive Officer or the loss of the services of one or more of our present management or other key personnel could significantly delay the development and/or launch of our products as there could be a learning curve of several months or more for any replacement personnel. Furthermore, competition for the type of highly skilled individuals we require is intense and we may not be able to attract and retain new employees of the caliber needed to achieve our objectives. Failure to replace key personnel could have a material adverse effect on our business, financial condition and operations.

**Risks Related to the ESRD Therapy Industry**

**We expect to face significant competition from existing suppliers of renal replacement therapy devices, supplies and services. If we are not able to compete with them effectively, then we may not be profitable.**

We expect to compete in the ESRD therapy market with existing suppliers of hemodialysis and peritoneal dialysis devices, supplies and services. Our competitors include Fresenius Medical Care AG and Gambro AB, currently two of the primary machine manufacturers in hemodialysis, as well as B. Braun Biotech International GmbH, and Nikkiso Corporation and other smaller machine manufacturers in hemodialysis. B. Braun Biotech International GmbH, Fresenius Medical Care AG, Gambro AB and Nikkiso Corporation also manufacture HDF machines. These companies and most of our other competitors have longer operating histories and substantially greater financial, marketing, technical, manufacturing and research and development resources and experience than we have. Our competitors could use these resources and experiences to develop

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products that are more effective or less costly than any or all of our products or that could render any or all of our products obsolete. Our competitors could also use their economic strength to influence the market to continue to buy their existing products.

We do not have a significant established customer base and may encounter a high degree of competition in further developing one. Our potential customers are a limited number of nephrologists, national, regional and local dialysis clinics and other healthcare providers. The number of our potential customers may be further limited to the extent any exclusive relationships exist or are entered into between our potential customers and our competitors. We cannot assure you that we will be successful in marketing our products to these potential customers. If we are not able to develop competitive products and take and hold sufficient market share from our competitors, we will not be profitable.

**Some of our competitors own or could acquire dialysis clinics throughout the United States, our Target European Market and other regions of the world. We may not be able to successfully market our products to the dialysis clinics under their ownership. If our potential market is materially reduced in this manner, then our potential sales and revenues could be materially reduced.**

Some of our competitors, including Fresenius Medical Care AG and Gambro AB, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. In 2005, Gambro AB divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, Inc., whereby DaVita, Inc. will purchase a significant amount of renal products and supplies from Gambro AB Renal Products. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius Medical Care AG Form 20-F Annual Report for the year ended December 31, 2009, Fresenius Medical Care AG provides treatment in its own dialysis clinics to approximately 195,651 patients in its facilities around the world including facilities located in the North America. According to DaVita, Inc.'s Annual Report for the year ended December 31, 2009, DaVita, Inc. provides treatment in 1,530 outpatient dialysis centers serving approximately 118,000 patients in the United States.

We believe that there is currently a trend among ESRD therapy providers towards greater consolidation. If such consolidation takes the form of our competitors acquiring independent dialysis clinics, rather than such dialysis clinics banding together in independent chains, then more of our potential customers would also be our competitors. If our competitors continue to grow their networks of dialysis clinics, whether organically or through consolidation, and if we cannot successfully market our products to dialysis clinics owned by these competitors or any other competitors and do not acquire clinics ourselves, then our revenues could be adversely affected.

**If the size of the potential market for our products is significantly reduced due to pharmacological or technological advances in preventative and alternative treatments for ESRD,**

Some of our competitors own or could acquire dialysis clinics throughout the United States, our Target European M

**then our potential sales and revenues will suffer.**

Pharmacological or technological advances in preventative or alternative treatments for ESRD could significantly reduce the number of ESRD patients needing our products. These pharmacological or technological advances may include:

the development of new medications, or improvements to existing medications, which help to delay the onset or prevent the progression of ESRD in high-risk patients (such as those with diabetes and hypertension);

the development of new medications, or improvements in existing medications, which reduce the incidence of kidney transplant rejection; and

developments in the use of kidneys harvested from genetically-engineered animals as a source of transplants.

If these or any other pharmacological or technological advances reduce the number of patients needing treatment for ESRD, then the size of the market for our products may be reduced and our potential sales and revenues will suffer.

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**If government and other third party reimbursement programs discontinue their coverage of ESRD treatment or reduce reimbursement rates for ESRD products, then we may not be able to sell as many units of our ESRD therapy products as otherwise expected, or we may need to reduce the anticipated prices of such products and, in either case, our potential revenues may be reduced.**

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

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

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our ESRD therapy products or sell fewer units, and, in either case, our potential revenues would suffer.

**If HDF does not become a preferred therapy for ESRD, then the market for our ESRD therapy products may be limited and we may not be profitable.**

A significant portion of our success is dependent on the acceptance and implementation of HDF as a preferred therapy for ESRD. There are several treatment options currently available and others may be developed. HDF may not increase in acceptance as a preferred therapy for ESRD. If it does not, then the market for our ESRD therapy products

If government and other third party reimbursement programs discontinue their coverage of ESRD treatment or reduce

may be limited and we may not be able to sell a sufficient quantity of our products to be profitable.

**If the per-treatment costs for dialysis clinics using our ESRD therapy products are higher than the costs of clinics providing hemodialysis treatment, then we may not achieve market acceptance of our ESRD therapy products in the United States and our potential sales and revenues will suffer.**

If the cost of our ESRD therapy products results in an increased cost to the dialysis clinic over hemodialysis therapies and such cost is not separately reimbursable by governmental programs or private medical care plans and insurers outside of the per-treatment fee, then we may not gain market acceptance for such products in the United States unless HDF therapy becomes the standard treatment method for ESRD. If we do not gain market acceptance for our ESRD therapy products in the United States, then the size of our market and our anticipated sales and revenues will be reduced.

**Proposals to modify the health care system in the United States or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, then our margins and our profitability will be adversely affected.**

A substantial portion of the cost of treatment for ESRD in the United States is currently reimbursed by the Medicare program at prescribed rates. Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the U.S. Congress passed landmark healthcare legislation. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We anticipate that the U.S. Congress and state legislatures will continue to review and

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assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in the Medicare program could affect the pricing of our ESRD therapy products. As we are not yet established in our business and it will take some time for us to begin to recoup our research and development costs, our profit margins are likely initially to be lower than those of our competitors and we may be more vulnerable to small decreases in price than many of our competitors.

Health administration authorities in countries other than the United States may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the United States, these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates for dialysis products.

Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our ESRD therapy products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

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

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

## **Risks Related to Our Common Stock**

### **You will experience immediate and substantial dilution if you invest in this offering.**

As a purchaser in this offering, you will suffer immediate dilution of \$0.38 per share in net tangible book value, based on the assumed sale of 500,000 units, assumed offering expenses of \$110,000, and an assumed per share price of \$0.52 for each share included in a unit, which price was the closing price of our common stock on June 16, 2010. See Dilution.

The exercise of outstanding options and warrants, 1,555,782 and 8,191,827 of which were outstanding and exercisable, respectively, as of March 31, 2010 may result in further dilution. Certain of the warrants contain anti-dilution provisions that will be triggered in the event the per unit offering price is less than \$0.90 in the case of warrants for an aggregate of 7,389,565 shares, and less than \$0.706 in the case of warrants for an aggregate of 129,681 shares. These warrants contain full ratchet protection in which, if the per share price of the common stock contained in

each unit is less than the warrant's current exercise price (i) the exercise price of the warrant will be reduced to the per share price of the shares in each unit and (ii) the number of shares covered by the warrant will be increased to an amount derived by multiplying the number of shares covered by the warrant by (x) the per share exercise price in effect before the completion of the offering divided by (y) the new exercise price (which will be the per share price of each share contained in a unit).

The number of shares of common stock issuable upon exercise of options was 1,349,532 on June 15, 2010.

## **There currently is a limited market for our common stock.**

Our common stock is quoted on the Over-the-Counter, or OTC, Bulletin Board. Prior to January 22, 2009, our common stock was listed on the AMEX. Trading in our common stock on both AMEX and the OTC Bulletin Board has been very limited, which could affect the price of our stock. We have no plans,



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proposals, arrangements or understandings with any person with regard to the development of an active trading market for our common stock, and no assurance can be given that an active trading market will develop.

**The prices at which shares of our common stock trade have been and will likely continue to be volatile.**

Since January 1, 2008, our common stock has traded at prices ranging from a high of \$2.63 to a low of \$0.01 per share. Due to the lack of an active market for our common stock, you should expect the prices at which our common stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;  
delays or failures in initiating, completing or analyzing clinical trials or the unsatisfactory design or results of these trials;

achievement or rejection of regulatory approvals by our competitors or us;  
announcements of technological innovations or new commercial products by our competitors or us;  
developments concerning proprietary rights, including patents;  
regulatory developments in the United States and foreign countries;  
economic or other crises and other external factors;  
period-to-period fluctuations in our results of operations;  
changes in financial estimates by securities analysts; and  
sales of our common stock.

We are not able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations in recent years that might have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance.

**There is no public market for the warrants to purchase common stock in this offering.**

There is no established public trading market for the warrants included in the units being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144.

**We have never paid dividends and do not intend to pay cash dividends.**

We have never paid dividends on our common stock and currently do not anticipate paying cash dividends on our common stock for the foreseeable future. Consequently, any returns on an investment in our common stock in the foreseeable future will have to come from an increase in the value of the stock itself. As noted above, the lack of an active trading market for our common stock will make it difficult to value and sell our common stock. While our dividend policy will be based on the operating results and capital needs of our business, it is anticipated that all earnings, if any, will be retained to finance our future operations.

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**Because we are subject to the penny stock rules, you may have difficulty in selling our common stock.**

Our common stock is subject to regulations of the SEC relating to the market for penny stocks. Penny stock, as defined by the Penny Stock Reform Act, is any equity security not traded on a national securities exchange or quoted on any market of the NASDAQ Stock Market that has a market price of less than \$5.00 per share. The penny stock regulations generally require that a disclosure schedule explaining the penny stock market and the risks associated therewith be delivered to purchasers of penny stocks and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. The broker-dealer must make a suitability determination for each purchaser and receive the purchaser's written agreement prior to the sale. In addition, the broker-dealer must make certain mandated disclosures, including the actual sale or purchase price and actual bid offer quotations, as well as the compensation to be received by the broker-dealer and certain associated persons. The regulations applicable to penny stocks may severely affect the market liquidity for your common stock and could limit your ability to sell your securities in the secondary market.

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

Our fourth amended and restated certificate of incorporation, as amended, provides, with specific exceptions required by Delaware law, that our directors are not personally liable to us or our stockholders for monetary damages for any action or failure to take any action. In addition, we have agreed to, and our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws provide for, mandatory indemnification of directors and officers to the fullest extent permitted by Delaware law. These provisions may discourage stockholders from bringing suit against a director or officer for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against any of our directors or officers.

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

In April 2002, we entered into a letter agreement with Hermitage Capital Corporation ( Hermitage ), as placement agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, we entered into a settlement agreement with Hermitage pursuant to which, among other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement; and we agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between us and Lancer Offshore, Inc., warrants exercisable until February 2006 to purchase an aggregate of 60,000 shares of common

stock for \$2.50 per share (or 17,046 shares of our common stock for \$8.80 per share, if adjusted for the reverse stock split pursuant to the antidilution provisions of such warrant, as amended). Because Lancer Offshore, Inc. never satisfied the closing conditions and, consequently, a closing has not been held, we have not issued any warrants to Hermitage in connection with our settlement with them. In June 2004, Hermitage threatened to sue us for warrants it claims are due to it under its settlement agreement with us as well as a placement fee and additional warrants it claims are, or will be, owed in connection with our initial public offering completed on September 24, 2004, as compensation for allegedly introducing us to one of the underwriters. We had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. We have not heard from Hermitage since then.

If and to the extent we are found to have significant liability to Hermitage in any lawsuit Hermitage may bring against us, then our liquidity could be materially adversely affected and/or our stockholders could experience dilution in their investment in us and the value of our stockholders' interests in us could be impaired.

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

Our management has broad discretion over the use of our financial resources, including the net proceeds from all of our equity financings. Stockholders may not deem such uses desirable. Our use of our financial

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resources may vary substantially from our currently planned uses. We cannot assure you that we will apply such proceeds effectively or that we will invest such proceeds in a manner that will yield a favorable return or any return at all.

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

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

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

**As a relatively new company with little or no name recognition and with several risks and uncertainties that could impair our business operations, we are not likely to generate widespread interest in our common stock. Without widespread interest in our common stock, our common stock price may be highly volatile and an investment in our common stock could decline in value.**

Unlike many companies with publicly traded securities, we have little or no name recognition in the investment community. We are a relatively new company and very few investors are familiar with either our company or our products. We do not have an active trading market in our common stock, and one might never develop, or if it does develop, might not continue.

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

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

and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company's securities. As a result, we may become subject to this type of litigation in the future. Litigation of this type could be extremely expensive and divert management's attention and resources from running our company.

**If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results, which could have a material adverse effect on our business, financial condition and the market value of our securities.**

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our reputation and operating results may be harmed.

As of December 31, 2007, management reported a material weakness in our internal control over financial reporting due to an insufficient number of resources in the accounting and finance department that does not allow for a thorough review process. Throughout fiscal year 2008, we implemented the following measures which resulted in the remediation of this material weakness as of December 31, 2008:

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Developed procedures to implement a formal quarterly closing calendar and process and held quarterly meetings to address the quarterly closing process;

Established a detailed timeline for review and completion of financial reports to be included in our Forms 10-Q and 10-K;

Enhanced the level of service provided by outside accounting service providers to further support and provide additional resources for internal preparation and review of financial reports and supplemented our internal staff in accounting and related areas; and

Employed the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-Q and 10-K.

In addition, beginning with our financial statements for the year ending December 31, 2010, we will be subject to the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 that require a report by our independent registered public accounting firm addressing the effectiveness of our internal control over financial reporting. If the auditors were unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

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

As of June 15, 2010, our directors, executive officers and principal stockholders beneficially owned approximately 52.65% of our outstanding common stock. As of June 15, 2010, Lambda Investors LLC beneficially owned 44.21% of our outstanding common stock. As of June 15, 2010, we believe that Stagg Capital Group LLC beneficially owned 8.85% of our outstanding common stock.

Our principal stockholders may have significant influence over our policies and affairs, including the election of directors. Should they act as a group, they will have the power to elect all of our directors and to control the vote on substantially all other corporate matters without the approval of other stockholders. Furthermore, such concentration of voting power could enable those stockholders to delay or prevent another party from taking control of our company even where such change of control transaction might be desirable to other stockholders.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*Certain statements in this prospectus constitute forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. The words or phrases can be, may, could, would, expects, seeks, estimates, projects and similar words and phrases are intended to identify such forward-looking statements.*

*These forward-looking statements may include, among other things, statements concerning the expectations of Nephros regarding its business, growth prospects, revenue trends, operating costs, working capital requirements, competition, results of operations, and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends, and similar expressions concerning matters that are not historical facts. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the preceding pages, and we caution you that any forward-looking information provided by or on behalf*

*of us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.*



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## **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.

## **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share and the pro forma net tangible book value per share. Our historical net tangible book value as of March 31, 2010 was approximately \$1,412,000, or approximately \$0.03 per share. Historical net tangible book value per share is determined by dividing our net tangible book value by the actual number of outstanding shares of common stock. Dilution in historical net tangible book value per share represents the difference between the amount per share paid by the purchaser of shares of common stock in this offering and the pro forma net tangible book value per share of common stock immediately after the closing of this offering.

After giving effect to the assumed sale of 500,000 units, with an assumed price of \$0.52 per share included in a unit, which was the closing price of our common stock on June 16, 2010, and after deducting estimated offering expenses payable by us of \$110,000, our pro forma net tangible book value as of March 31, 2010 would have been approximately \$7,802,000, or \$0.14 per share of common stock. This would represent an immediate increase in pro forma net tangible book value of \$0.11 per share to existing stockholders and an immediate dilution of \$0.38 per share to the investor purchasing units in this offering.

The shares outstanding as of March 31, 2010 used to calculate the information in this section exclude the following items:

1,555,782 shares issuable upon the exercise of stock options outstanding on March 31, 2010 (the number of shares of common stock issuable upon exercise of options was 1,349,532 on June 15, 2010); or 8,191,827 shares issuable upon the exercise of warrants outstanding on March 31, 2010, which number will increase pursuant to anti-dilution provisions applicable to certain warrants in the event that the offering price per unit is less than \$0.90 in the case of warrants for an aggregate of 7,389,565 shares, and less than \$0.706 in the case of warrants for an aggregate of 129,681 shares. These warrants contain full ratchet protection in which, if the per share price of the common stock contained in each unit is less than the warrant's current exercise price (i) the exercise price of the warrant will be reduced to the per share price of the shares in each unit and (ii) the number of shares covered by the warrant will be increased to an amount derived by multiplying the number of shares covered by the warrant by (x) the per share exercise price in effect before the completion of the offering divided by (y) the new exercise price (which will be the per share price of each share contained in a unit).

## **DIVIDEND POLICY**

We do not anticipate paying any dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our board of directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our board of directors may deem relevant. Additionally, our ability to pay future dividends may be restricted by the terms of any debt



TABLE OF CONTENTS**MARKET FOR OUR COMMON STOCK**

On January 22, 2009 the AMEX removed our common stock from trading on the AMEX. Until such date, our common stock had been trading on the AMEX under the symbol NEP. Effective February 4, 2009, our common stock is now quoted on the OTC Bulletin Board under the symbol NEPH.OB . The following table sets forth the high and low sales prices for our common stock as reported on the AMEX and the high and low bid and ask prices for our common stock as reported on AMEX or the Over the Counter Bulletin Board for each quarter listed.

Quarter Ended	High	Low
March 31, 2008	\$ 1.60	\$ .33
June 30, 2008	\$ .97	\$ .50
September 30, 2008	\$ .65	\$ .24
December 31, 2008	\$ .48	\$ .05
March 31, 2009	\$ .15	\$ .04
June 30, 2009	\$ 1.77	\$ .01
September 30, 2009	\$ 2.63	\$ .99
December 31, 2009	\$ 1.75	\$ .70
March 31, 2010	\$ 1.30	\$ .65

As of June 15, 2010, there were 35 holders of record and approximately 900 beneficial holders of our common stock.

On June 15, 2010, the last reported sale price of our common stock on the Over-the Counter Bulletin Board was \$0.53 per share.

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## PLAN OF DISTRIBUTION

We are offering up to 500,000 units, with each unit consisting of 25 shares of common stock and a warrant to purchase 25 shares of common stock. The price per unit is \$\_\_\_\_. Units will not be issued or certificated. The units will separate immediately and the common stock and warrants will be issued separately and the common stock and warrants will trade separately. The terms of the warrants are described below under the caption Description of Warrants. Pursuant to a Placement Agency Agreement, we have engaged Dawson James Securities, Inc. to act as our exclusive placement agent on a reasonable best efforts basis. The placement agent is not purchasing or selling any securities pursuant to this prospectus, nor is it required to sell any specific number or dollar amount of the securities offered hereby. Therefore, we may not sell the entire amount of units offered pursuant to this prospectus.

Confirmations and definitive prospectuses will be delivered, or otherwise made available, to all purchasers who agree to purchase units, informing purchasers of the closing date as to such units. In connection with this offering, we will establish a non-interest-bearing escrow account with Signature Bank, which we refer to as the escrow account. On the closing of this offering, each purchaser will deliver funds equal to the purchase price directly to the escrow account. We currently anticipate the closing of the sale of the common stock and warrants to occur on or about \_\_\_\_\_, 2010, subject to customary closing conditions. Purchasers will also be informed of the date and manner in which they must transmit the purchase price for their units.

On such closing date, the following will occur:

we will receive from escrow funds in the amount of the aggregate purchase price of the securities being sold by us on such closing date;  
we will deliver the shares of common stock being sold on such closing date in book-entry form and the warrants being sold on such closing date in certificate form; and  
we will pay to the placement agent the placement agent fee in accordance with the terms of our Placement Agency Agreement.

We have agreed to pay the placement agent a cash fee equal to 7% of the gross proceeds of the offering and to issue warrants to the placement agent to purchase a number of shares of common stock equal to 5% of the aggregate shares of common stock sold in this offering, excluding the shares that may be issued upon exercise of the warrants. Pursuant to FINRA Rule 5110(f)(2)(D), we have also agreed to reimburse certain expenses of the placement agent incurred in connection with the offering up to an aggregate of \$40,000. In addition, we have agreed to pay the placement agent a tail fee on sales of our securities in the 12 months after the close of this offering to investors introduced to us by the placement agent. The warrants issued to the placement agent will be substantially identical to the warrants offered by this prospectus except that the warrants issued to the placement agent will have an exercise price per share of \$\_\_\_\_\_, which is 125% of the public offering price, and the expiration date of such warrants shall be \_\_\_\_\_, or the five year anniversary of the effective date of this offering. Pursuant to FINRA Rule 5110(g), for a period of six months after the issuance date of the placement agent warrants, neither the placement agent warrants nor any warrant shares issued upon exercise of the placement agent warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security:

- (i) by operation of law or by reason of reorganization of the Company;
- (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period;
- (iii)

if the aggregate amount of securities of the Company held by the holder of the placement agent warrants or related person do not exceed 1% of the securities being offered;

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that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no (iv) participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

The estimated offering expenses payable by us, in addition to the placement agent's fee, are approximately \$110,000, which include legal, accounting and printing costs and various other fees associated with registering the units and listing the common stock. We have made a payment of \$20,000 to the placement agent as an advance against reimbursable expenses of up to an aggregate of \$40,000. In case of termination of the placement agent's engagement, we must pay the placement agent all fees earned and reimburse the placement agent for all expenses incurred.

The following table sets forth the cash fee to be paid to the placement agent for this offering on a per unit basis and assuming all of the units offered pursuant to this prospectus are sold at closing and that the maximum fee is paid for the sale of each unit.

	Per Unit	Maximum Total
Placement Agent's Fee	\$	\$

We are offering pursuant to this prospectus up to 500,000 of our units, but there can be no assurance that the offering will be fully subscribed. Accordingly, we may sell substantially less than 500,000 of our units, in which case our net proceeds would be substantially reduced and the total placement agent fees may be substantially less than the maximum total set forth above.

We have agreed to indemnify the placement agent against certain liabilities arising out of the offering. We may also be required to contribute to payments the placement agent may be required to make in respect of such liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and any commission received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be an underwriting discount or commission under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants to purchase shares of common stock by the placement agent. Under these rules and regulations, the placement agent may not engage in any stabilization activity in connection with our securities; and may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

The placement agent may, from time to time in the future, engage in transactions with and perform services for us in the ordinary course of its business, but we have no present arrangements or understandings to do so.

The transfer agent for our common stock is Continental Stock Transfer & Trust Company. We will act as transfer agent for the warrants being offered hereby.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol NEPH.OB. The warrants being offered hereby are not expected to be eligible for trading on any market.



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# MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

## Immediate Need for Capital

We have incurred significant losses in our operations in each quarter since inception. In addition, we have not generated positive cash flow from operations for the year ended December 31, 2008 or 2009 or for the three months ended March 31, 2010. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. We need to raise operating funds through either the licensing or sale of our technologies or public or private offerings of our securities. While we are investigating strategic funding opportunities, we might not be able to raise funds on a timely basis or on acceptable terms or at all. If we fail to raise capital, our funds will be depleted in the third quarter of 2010, and we might not be able to continue our operations.

## Business Overview

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190 and MD220, which are dialyzers (our OLpur MDHDF Filter Series ), OLpur H 2 H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines. We began selling our OLpur MD190 dialyzer in some parts 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) in March 2004, and have developed units suitable for clinical evaluation for our OLpur H 2 H product. We are developing our OLpur NS2000 product by modifying an existing HDF platform and incorporating our proprietary H 2 H technology.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval for our ESRD products, establishing manufacturing and marketing relationships and establishing our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European n Market and the United States upon their approval by appropriate regulatory authorities. We submitted to the FDA our 510(k) application in November 2008 for approval of our OLpur H2H module and OLpur MD 220 filter. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, on March 10, 2010, were informed that our application is still under their review process.

We have also applied our filtration technologies to water filtration and in 2006 we introduced our new Dual Stage Ultrafilter (the 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. 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.

In the fourth quarter of 2008, we also filed a 510(k) with the FDA for approval to use our DSU product with reverse osmosis (RO) water systems found within dialysis centers and hospitals. Due the nature of this application our DSU



will be categorized as a medical device and therefore requires a 510(k). While waiting for FDA action on both of our ESRD and DSU 510(k) applications we redirected much of our resources to our sales and marketing efforts of our DSU product here in the US in its non-medical device applications. Our goal is to expand distribution to the hospital market and identify other short term applications. Following its review of our DSU 510(k) application, the FDA requested additional information from us. On February 24, 2009, we provided a formal response to the FDA. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

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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 worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former 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 our 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 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. Approximately \$878,000 of revenue has been recognized on this second project since September 2009, of which approximately \$455,000 was recognized in the three months ended March 31, 2010.

Since our inception, we have incurred annual net losses. As of March 31, 2010, we had an accumulated deficit of \$90,504,000, and we expect to incur additional losses in the foreseeable future. We recognized net losses of \$2,026,000 and \$6,337,000 for the years ended December 31, 2009 and 2008, respectively, and a net loss of \$528,000 for the three months ended March 31, 2010.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through March 31, 2010, we received net offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately \$53.3 million in the aggregate. An additional source of finances was our license agreement with Asahi, pursuant to which we received an up front license fee of \$1.75 million in March 2005.

The following trends, events and uncertainties may have a material impact on our potential sales, revenue and income from operations:

- 1) receiving regulatory approval for each of our ESRD therapy products and our DSU product in our target territories;
- 2) the completion and success of additional clinical trials;
- 3) the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
  - 4) our ability to effectively and efficiently manufacture, market and distribute our products;
  - 5) our ability to sell our products at competitive prices which exceed our per unit costs;
  - 6) the consolidation of dialysis clinics into larger clinical groups; and
- 7) the current U.S. healthcare plan is to bundle reimbursement for dialysis treatment which may force dialysis clinics to change therapies due to financial reasons.

To the extent we are unable to succeed in accomplishing (1) through (7), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (6), the impact could either be positive, in the case where dialysis clinics consolidate into independent chains, or negative, in the case where competitors acquire these dialysis clinics and use their own products, as competitors have historically tended to use their own products in clinics they have acquired.



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## Recently Issued and Adopted Accounting Standards

We follow accounting standards set by the Financial Accounting Standards Board ( FASB ). The FASB sets generally accepted accounting principles ( GAAP ) that we follow to ensure we consistently report our financial condition, results of operations, and cash flows. References to GAAP issued by the FASB in these footnotes are to the *FASB Accounting Standards Codification*,<sup>TM</sup> sometimes referred to as the Codification or ASC. In June 2009, the FASB issued ASC

Topic 105, Generally Accepted Accounting Principals, which became the single source of authoritative nongovernmental U.S. GAAP, superseding existing FASB, American Institute of Certified Public Accountants ( AICPA ), Emerging Issues Task Force ( EITF ), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant SEC guidance organized using the same topical structure in separate sections and has been adopted by us for the year ended December 31, 2009. This has an impact on our financial disclosures since all future references to authoritative accounting literature will be referenced in accordance with ASC Topic 105.

**Fair Value Measurements** In September 2006, the FASB issued guidance regarding fair value measurements. This guidance defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, FASB issued a pronouncement, which delayed the effective date of its prior guidance regarding fair value measurements, specifically for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We adopted the guidance for financial assets and liabilities on January 1, 2008. It did not have any impact on our results of operations or financial position and did not result in any additional disclosures and we adopted the guidance for non-financial assets and non-financial liabilities on January 1, 2009, resulting in no impact to our consolidated financial position, results of operations or cash flows.

In April 2009, the FASB issued new accounting guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and identifying transactions that are not orderly. The guidance affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. It provides guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. It applies to all fair value measurements when appropriate. The adoption of this guidance did not have a significant impact on our consolidated financial position, results of operations or cash flows, or related footnotes.

In April 2009, the FASB issued new accounting guidance on interim disclosures about fair value of financial instruments, which is effective for our quarterly period beginning April 1, 2009. The guidance requires an entity to provide the annual disclosures required by a prior pronouncement regarding disclosures about fair value of financial instruments, in its interim financial statements. The application of the guidance did not have a significant impact on our consolidated financial position, results of operations or cash flows, or related footnotes.

In August 2009, the FASB issued an update to provide further guidance on how to measure the fair value of a liability, an area where practitioners have been seeking further guidance. It primarily does three things: 1) sets forth the types of valuation techniques to be used to value a liability when a quoted price in an active market for the identical liability is not available, 2) clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability and 3) clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the

quoted price of the asset are required are Level 1 fair value measurements. This standard is effective beginning the fourth quarter of 2009. The adoption of this standard update is not expected to impact our consolidated financial position, results of operations or cash flows.

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**Business Combinations** In December 2007, the FASB issued new accounting guidance on business combinations. The pronouncement establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. The pronouncement determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning after December 15, 2008. We adopted the pronouncement on January 1, 2009 resulting in no impact to our consolidated financial position, results of operations or cash flows.

**Subsequent Events** On May 28, 2009, the FASB issued guidance regarding subsequent events, which we adopted on a prospective basis beginning April 1, 2009. The guidance is intended to establish general standards of accounting and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date. The application of the pronouncement did not have an impact on our consolidated financial position, results of operations or cash flows.

**Recognition and Presentation of Other-Than-Temporary Impairments** In April 2009, the FASB issued an accounting pronouncement, which is effective for our interim and annual reporting periods ending after June 15, 2009, that amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity's management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. We have no debt securities as of December 31, 2009 therefore there is no impact on our December 31, 2009 consolidated financial position, results of operations or cash flows.

## **New Accounting Pronouncements**

In December 2009, the FASB issued ASU No. 2009-17, Consolidations (Topic 810) Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities (ASU No. 2009-17). ASU No. 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We are assessing what impact, if any, adoption of this standard will have on our consolidated financial statements.

## **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management's subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this prospectus, we

believe that the following accounting policies require the application of significant judgments and estimates.

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### **Revenue Recognition**

Revenue is recognized in accordance with ASC Topic 605. Four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed and determinable; and (iv) collectability is reasonably assured.

We recognize revenue related to product sales when delivery is confirmed by its external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by our customers.

### **Stock-Based Compensation**

We account for stock-based compensation in accordance with ASC 718 by recognizing the fair value of stock-based compensation in net income. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

### **Accounts Receivable**

We provide credit terms to our customers in connection with purchases of our products. We periodically review customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect our best estimate of potential losses.

### **Inventory Reserves**

Our inventory reserve requirements are based on factors including the products' expiration date and estimates for the future sales of the product. If estimated sales levels do not materialize, we will make adjustments to its assumptions for inventory reserve requirements.

### **Accrued Expenses**

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



We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

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## **Results of Operations**

### **Fluctuations in Operating Results**

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our annual results of operations will be impacted for the foreseeable future by several factors including the progress and timing of expenditures related to our research and development efforts, marketing expenses related to product launches, timing of regulatory approval of our various products and market acceptance of our products. Due to these fluctuations, we believe that the period to period comparisons of our operating results are not a good indication of our future performance.

## **The Fiscal Year Ended December 31, 2009 Compared to the Fiscal Year Ended December 31, 2008**

### **Product Revenues**

Total product revenues for the year ended December 31, 2009 were \$2,661,000 compared to \$1,473,000 for the year ended December 31, 2008. The \$1,188,000, or 81%, increase is primarily due to \$1,093,000 related to revenue generated from the Office of Naval Research project in the United States. The revenue derived from this project was \$1,093,000 for the twelve months ended December 31, 2009 compared to \$196,000 for the same period in 2008, which was the project's initial period beginning in January 2008. Sales of the OLpur MD190 and MD220 Dialyzers in Europe were \$1,265,000 for the twelve months ended December 31, 2009 compared to \$1,228,000 for the same period in 2008. This \$37,000 or 3% increase in revenue was impacted by the adverse currency translation of the Euro to the U.S. dollar. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Although the sales price of these units, which is in Euro, remained constant approximately \$53,000 was lost due to currency translation. In addition, revenues in the United States from sales of the Dual Stage Ultrafilter (the DSU) water filter were \$303,000 for the twelve months ended December 31, 2009 compared to \$49,000 for the same period in 2008. The DSU represents a new and complementary product line introduced in 2008.

### **Cost of Goods Sold**

Cost of goods sold was \$1,744,000 for the year ended December 31, 2009 compared to \$1,064,000 for the year ended December 31, 2008. The \$680,000, or 64%, increase is primarily due to costs related to the Office of Naval Research project in the United States. The cost of goods sold related to the Office of Naval Research project was \$692,000 for the twelve months ended December 31, 2009 compared to \$141,000 for the same period in 2008, an increase of \$551,000. The increased cost is correlated to the higher revenue recognized from this project for the year ended December 31, 2009 compared to the same period in 2008. Cost of goods sold related to the OLpur MD190 and MD220 Dialyzers sold in Europe for the year ended December 31, 2009 was \$969,000 an increase of \$46,000, or 5%, over the comparable period in 2008. This increase was due primarily to higher sales volume. Units sold were 47,532 for the twelve months ended December 31, 2009 compared to 44,623 units for the same period in 2008, a 6.5% increase. Cost of goods sold related to the DSU water filters sold in the United States were \$83,000 for the year ended December 31, 2009. The DSU represents a new and complementary product line introduced in 2008 and there were no cost of goods sold incurred for the year ended December 31, 2008.

### **Research and Development**

Research and development expenses were \$280,000 for the year ended December 31, 2009 compared to \$1,977,000 for the year ended December 31, 2008, a decrease of \$1,697,000 or 86%. This decrease is related to the fact that a clinical trial was conducted in 2008 and there was no clinical trial conducted during 2009. Clinical trial expenses decreased by approximately \$964,000 during the twelve months ended December 31, 2009 compared to the same period in 2008. Related reductions in personnel and lab testing resulted in reduced expenses of \$491,000 and \$226,000 respectively during the twelve months ended December 31, 2009 compared to the same period in 2008. A reduction in travel expenses in the amount of \$23,000 was offset by an increase of \$13,000 in development expenses related to the DSU water filter during the twelve months ended December 31, 2009 compared to the same period in 2008.

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**Depreciation and Amortization Expense**

Depreciation expense was \$231,000, for the year ended December 31, 2009 compared to \$447,000 for the year ended December 31, 2008, a decrease of \$216,000, or 48.3%. An additional \$59,000 of depreciation was recorded in 2008 related to furniture and fixtures and tooling to reflect the assessed utility of these assets as of December 31, 2008.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses were \$2,812,000 for the year ended December 31, 2009 compared to \$4,702,000 for the year ended December 31, 2008, a decrease of \$1,890,000 or 40%. A reduction in personnel and related expenses resulted in a decrease of \$1,072,000 for the twelve months ended December 31, 2009 compared to the same period in 2008. Reductions of \$246,000 in legal expenses, \$232,000 in marketing expenses, \$186,000 in recruiting expenses, \$70,000 in insurance expenses and \$85,000 in facility expenses for the twelve months ended December 31, 2009 compared to the same period in 2008 were also achieved. The legal expense reduction was due to less activity and transition to a new law firm in 2009. Marketing activities related to trade shows were curtailed in 2009. Recruiting fees were incurred for four hires in 2008 and none in 2009. The reduction in facility expenses resulted from both the Ireland and U.S. offices moving to less expensive locations for 2009.

**Interest Income**

Interest income was \$9,000 for the year ended December 31, 2009 compared to \$199,000 for the year ended December 31, 2008. The decrease of \$190,000, or 95.5%, reflects the impact of having less cash on hand in 2009 compared to 2008 and therefore, fewer investments to generate interest income.

**Interest Expense**

We incurred approximately \$2,000 of interest expense for the year ended December 31, 2009. This interest relates primarily to financing of premiums for product liability insurance. No interest expense was incurred during 2008. We had no outstanding debt during 2009 or 2008.

**Impairment of Auction Rate Securities and Gain on sale of investments**

During the fiscal year 2008, we had investments in auction rate securities ( ARS ) which 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. With the liquidity issues experienced in global credit and capital markets, the ARS held by us had experienced multiple failed auctions since February 2008, and as a result, we did not consider these affected ARS liquid in the first quarter of 2008. Accordingly, while we had classified its ARS as current assets as of January 1, 2008, we reclassified them as noncurrent assets at March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, we wrote down ARS with an original par value of \$4,400,000 to an estimated fair value of \$4,286,000 as of March 31, 2008. We reviewed impairments associated with the above in accordance with ASC Topic 320 to determine the classification of the impairment as temporary or other-than-temporary. We determined the ARS classification to be other-than-temporary, and charged an impairment loss of \$114,000 on the ARS to its results of operations for the three months ended March 31, 2008 and twelve months ended December 31, 2008.

During the three months ended June 30, 2008, \$300,000 of principal on our ARS had been paid back by the debtor, resulting in our investment in ARS having decreased from \$4,400,000 to \$4,100,000 (par value) at June 30, 2008. The net book value of our ARS at June 30, 2008 was \$3,986,000 million, due to the approximate \$114,000 impairment recorded at March 31, 2008. On July 22, 2008 we sold our ARS to a third party at 100% of par value, for proceeds of \$4,100,000. We reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with ASC Topic 320, the ARS, classified as Trading Securities, were valued at their fair value of \$4,100,000 at June 30, 2008. The adjustment of the investment's carrying value from \$3,986,000 net book value to \$4,100,000 fair value resulted in an Unrealized Holding Gain of \$114,000 which is included in our Statement of Operations for the three and six months ended June 30, 2008.

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We subsequently reversed the Unrealized Holding Gain and recorded in the results of operations for the twelve months ended December 31, 2008, a Realized Gain on Sale of Investments of \$114,000 in July 2008 due to the sale transaction being executed.

We had no investments in Auction Rate Securities during the year ended December 31, 2009.

### **Other Income**

Other income in the amount of approximately \$373,000 and \$181,000 for the years ended December 31, 2009 and December 31, 2008, respectively, resulted primarily from receipt of New York State Qualified Emerging Technology Company ( QETC ) tax refunds in each of these periods. Tax credits for the years 2006 and 2007 were received and recognized during the year ended December 31, 2009. The tax credit for the year 2005 was received and recognized during the year ended December 31, 2008.

## **Three Months Ended March 31, 2010 Compared to the Three Months Ended March 31, 2009**

### **Revenues**

Total revenues for the three months ended March 31, 2010 were approximately \$989,000 compared to approximately \$631,000 for the three months ended March 31, 2009. Total revenues increased approximately \$358,000. The increase of approximately 57% is due to increased revenue of approximately \$120,000 during the three months ended March 31, 2010 over the same period in 2009, related to our contract with the Office of U.S. Naval Research and an increase of approximately \$98,000 in sales of our DSU in the United States for the three months ended March 31, 2010 over the same period in 2009. Sales of our MD filters in our Target European Market were approximately \$140,000 higher in the three months ended March 31, 2010 compared to the same period in 2009. Approximately \$124,000 of the European revenue increase was due to more units sold and the remaining \$16,000 was due to foreign currency exchange rate fluctuation. Unit sales in Europe increased approximately 42% for the three months ended March 31, 2010 compared to the same period in 2009.

### **Cost of Goods Sold**

Cost of goods sold was approximately \$600,000 for the three months ended March 31, 2010 compared to approximately \$452,000 for the three months ended March 31, 2009. The increase of approximately \$148,000, or 33%, in cost of goods sold is primarily due to increased costs related to higher sales of our MD filters in our Target European Market of approximately \$102,000 and an increase of approximately \$51,000 in costs related to higher sales of our DSU in the United States for the three months ended March 31, 2010 over the same period in 2009. Approximately \$83,000 of the European cost of goods sold increase was due to more units sold and the remaining \$19,000 was due to foreign currency exchange rate fluctuation. Costs related to the contract with the Office of U.S. Naval Research were approximately \$5,000 lower for the three months ended March 31, 2010 compared to the same period in 2009.

### **Research and Development**

Research and development expenses were approximately \$73,000 and \$58,000 respectively, for the three months ended March 31, 2010 and March 31, 2009. This increase of approximately \$15,000 or 26% is primarily due to an increase in research and development personnel related costs of approximately \$18,000; increased development costs

of approximately \$3,000; increased lab supplies of approximately \$3,000 offset by reduced water development expenses of approximately \$18,000 during the three months ended March 31, 2010 compared to the same period in 2009. There were approximately \$7,000 of clinical trial related expenses and approximately \$16,000 in credits to research and development expenses related to the contract with the Office of U.S. Naval Research that were incurred during the three months ended March 31, 2009 that did not occur during the same period in 2010.

### **Depreciation Expense**

Depreciation expense was approximately \$36,000 for the three months ended March 31, 2010 compared to approximately \$72,000 for the three months ended March 31, 2009, a decrease of 50%. The decrease of approximately \$36,000 is primarily due to several assets having been fully depreciated as of year end 2009

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resulting in no depreciation expense for those assets during the three months ended March 31, 2010. There were no disposals of assets during the three months ended March 31, 2010.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses were approximately \$807,000 for the three months ended March 31, 2010 compared to approximately \$789,000 for the three months ended March 31, 2009, an increase of \$18,000 or 2%. The increase is due to an increase in severance expense of approximately \$55,000 as well as an increase in legal and accounting fees of approximately \$92,000. These increases were offset by a decrease in marketing expenses of approximately \$81,000 and personnel related expenses of \$37,000 during the three months ended March 31, 2010 compared to the same period in 2009. Approximately \$11,000 in moving expenses were incurred in the three months ended March 31, 2009 as the move to the Company's new headquarters was completed. There were no moving expenses incurred in the three months ended March 31, 2010.

### **Interest Income**

Interest income was approximately \$1,000 for the three months ended March 31, 2010 compared to approximately \$5,000 for the three months ended March 31, 2009. The decrease of approximately \$4,000 is due to the decreased investments held during the three months ended March 31, 2010 compared to the three months ended March 31, 2009.

### **Other expense**

Other expense in the amount of approximately \$2,000 for the three months ended March 31, 2010 was a currency loss related to an international funds transfer. There was no other expense incurred for the three months ended March 31, 2009.

## **Off-Balance Sheet Arrangements**

We did not engage in any off-balance sheet arrangements during the years ended December 31, 2009 and December 31, 2008 or the three months ended March 31, 2010.

## **Liquidity and Capital Resources**

Our future liquidity sources and requirements will depend on many factors, including:

the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;

the market acceptance of our products, and our ability to effectively and efficiently produce and market our products; the timing and costs associated with obtaining United States regulatory approval or the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory pre requisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MDHDF filter series, for which the CE mark was obtained in July 2003);

the continued progress in and the costs of clinical studies and other research and development programs;

the costs involved in filing and enforcing patent claims and the status of competitive products; and

the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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



for the marketing and sales of our products;  
to obtain appropriate regulatory approvals and expand our research and development with respect to our ESRD  
therapy products;

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to continue our ESRD therapy product engineering;  
to pursue business opportunities with respect to our DSU water-filtration product; and  
for working capital purposes.

In response to liquidity issues experienced with our auction rate securities, and in order to facilitate greater liquidity in our short-term investments, on March 27, 2008, our board of directors adopted an Investment, Risk Management and Accounting Policy. Such policy limits the types of instruments or securities in which we may invest our excess funds in the future to: U.S. Treasury Securities; Certificates of Deposit issued by money center banks; Money Funds by money center banks; Repurchase Agreements; and Eurodollar Certificates of Deposit issued by money center banks. This policy provides that our primary objectives for investments shall be the preservation of principal and achieving sufficient liquidity to meet our forecasted cash requirements. In addition, provided that such primary objectives are met, we may seek to achieve the maximum yield available under such constraints.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In the event that our plans change, our assumptions change or prove inaccurate, or if our existing cash resources, together with other funding resources including increased sales of our products, otherwise prove to be insufficient to fund our operations and we are unable to obtain additional financing, we will be required to adopt alternatives, such as curtailing our planned activities or ceasing our operations.

At March 31, 2010, we had an accumulated deficit of \$90,504,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering in September 2004, from licensing revenue received from Asahi Kasei Medical Co., Ltd. ( Asahi ) in March 2005, a private placement of convertible debenture in June 2006 and a private investment in public equity in September 2007 and a private placement in July 2009.

Net cash used in operating activities was \$2,612,000 for the year ended December 31, 2009 compared to \$5,725,000 for the year ended December 31, 2008.

During 2009, the net cash used in operating activities was \$3,113,000 less than the net cash used in operating activities during 2008. The most significant items contributing to the reduction in cash used in operating cash are highlighted below:

Our net loss in 2009 was \$2,026,000 compared to \$6,337,000 in 2008. This represents an improvement of \$4,311,000 in operating cash in 2009. Noncash adjustments to reconcile net loss to net cash used in operating activities were: stock-based compensation was \$108,000 and \$155,000 in 2009 and 2008 respectively, a reduction of \$47,000, depreciation expense was \$231,000 and \$447,000 in 2009 and 2008 respectively, a reduction of \$216,000 and an increase to the inventory reserve of \$18,000 in 2009.

During 2009, our accounts receivable, other current assets and other assets increased by \$193,000. This compares to a decrease of \$236,000 in 2008. This represents a \$429,000 use of operating cash in 2009.

During 2009, our inventory decreased by \$75,000. This compares to an increase in inventory of \$409,000 in 2008. This represents a \$484,000 source of operating cash in 2009.

During 2009, accounts payable and accrued expenses decreased by \$807,000. This compares to an increase in accounts payable and accrued expenses of \$183,000 during 2008. This represents a \$990,000 use of operating cash in 2009.

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Net cash used by investing activities was \$21,000 for the year ended December 31, 2009 compared to \$4,599,000 of net cash provided by investing activities for the year ended December 31, 2008. In 2009, \$28,000 was used to purchase equipment and \$7,000 was provided by the maturity of a short-term investment. In 2008, \$4,693,000 was provided due to the maturity of short-term investments. Approximately \$97,000 of funds was used to purchase property, plant and equipment and \$3,000 was provided by the sale of equipment.

Net cash provided by financing activities was \$1,336,000 for the year ended December 31, 2009 resulting from the sale of common stock of \$1,251,000 and proceeds from the exercise of stock options of \$85,000. There were no financing activities in 2008.

Net cash used in operating activities was approximately \$434,000 for the three months ended March 31, 2010 compared to approximately \$660,000 for the three months ended March 31, 2009. The most significant items contributing to this decrease of approximately \$226,000 cash used in operating activities during the three months ended March 31, 2010 compared to the three months ended March 31, 2009 are highlighted below:

During the 2010 period, our net loss decreased by approximately \$207,000;

During the 2010 period, our stock-based compensation expense increased by approximately \$16,000;

Our accounts receivable increased by approximately \$9,000 during the 2009 period compared to an increase of approximately \$51,000 during the 2009 period;

Our accounts payable and accrued expenses increased by approximately \$135,000 in the aggregate in the 2010 period compared to an increase of approximately \$13,000 in the 2009 period; and

Our accrued severance expenses were approximately \$55,000 in the aggregate in the 2010 period compared to a reversal of expense of approximately \$90,000 in the 2009 period.

Offsetting the above changes are the following items:

During the 2010 period, depreciation expense decreased by approximately \$36,000;

Our inventory increased by approximately \$156,000 during the 2010 period compared to a decrease of approximately \$105,000 during the 2009 period; and

Our prepaid expenses and other assets decreased by approximately \$7,000 in the 2010 period compared to a decrease of approximately \$15,000 in the 2009 period.

There was no net cash provided by investing activities for the three months ended March 31, 2010. Net cash provided by investing activities was approximately \$7,000 for the three months ended March 31, 2009 and resulted from the maturities of short-term investments. There was no cash provided or used in financing activities for the three months ended March 31, 2010 or during the 2009 comparable period.

## Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2009:

	Payments Due in Period				
	Total	Within 1 Year	Years 1 3	Years 3 5	More than 5 Years
Leases	\$ 186,000	\$ 101,000	\$ 85,000	\$	\$
Employment Contracts	244,000	195,000	49,000		
Total	\$ 430,000	\$ 296,000	\$ 134,000	\$	\$

## Certain Risks and Uncertainties

Certain statements in this prospectus, including certain statements contained in Description of Business and Management's Discussion and Analysis, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases can be, may, could, would, expects, believes,

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seeks, estimates, projects and similar words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

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## **BUSINESS**

### **Overview**

Founded in 1997, we are a Delaware corporation that has been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. In January 2006, we introduced our new Dual Stage Ultrafilter (the DSU ) water filtration system, which represents a new and complementary product line to our existing ESRD therapy business.

We currently have three products in various stages of development in the HDF modality 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); to our knowledge, the only filter designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;

OLpur H 2 H, 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 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, in June 2005.

OLpur and H 2 H are among our trademarks for which U.S. registrations are pending. H 2 H 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.

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 H 2 H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy, and that, if approved in 2010, our OLpur H 2 H and MDHDF filters will be the first, and only, HDF therapy available in the United States at that time.

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 H 2 H 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 the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption ( IDE ) application for the clinical evaluation of our OLpur H2H module and OLpur MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products 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. The FDA has not provided us with any additional requests for information or rendered a decision on our application. We have made additional inquiries to the FDA about the status of our application and, on March 10, 2010, were informed that our application is still under their review process.

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In January 2006, we introduced our new Dual Stage Ultrafilter (the 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 H 2 H and MD 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 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 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of November 11, 2009), 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, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

During the twelve months ended December 31, 2009, we were granted four new patents. In the U.S., we were issued patent #7,534,349 for a Dual Stage Ultrafilter with pump mechanism and/or shower feature. In Canada, we were issued patent #2,430,575 for a valve mechanism used in Infusion Fluid systems which is a feature used on our H 2 H module and patent #2,396,852 for an Ionic Enhanced Dialysis/Diafiltration system which is related to mid-dilution HDF. In China, we were issued patent #200510092067.3 for a Dual Stage Hemodiafiltration cartridge used in its OLpur MD HDF Filter.

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 worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we have billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former 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 our 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 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. Approximately \$878,000 of revenue has been recognized on this second project since September 2009, of which approximately \$455,000 was recognized during the three months ended March 31, 2010.

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.



## Going Concern

The financial statements included in this prospectus 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 raise

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substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred losses in our operations in each quarter since inception. For the years ended December 31, 2009 and 2008, we have incurred net losses of \$2,026,000 and \$6,337,000, respectively. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2009 and 2008. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

At December 31, 2009, we had \$1,004,000 in cash and cash equivalents. There can be no assurance that our cash and cash equivalents will provide the liquidity we need to continue our operations. (See Certain Risks and Uncertainties ). These operating plans primarily include the continued development and support of our business in the European and Canadian markets, organizational changes necessary to enhance the commercialization of our water filtration business and the completion of current year milestones which are included in the Office of Naval Research appropriation.

There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our commitments we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

We continue to investigate additional funding opportunities by talking to various potential investors who could provide financing. However, there can be no assurance that we will be able to obtain further financing, do so on reasonable terms or do so on terms that would not substantially dilute your equity interests in us. If we are unable to raise additional funds on a timely basis, or at all, we will not be able to continue our operations.

In addition, on September 12, 2008, we received a letter from the NYSE Alternext US LLC (formerly, the American Stock Exchange or AMEX ) notifying us of our noncompliance with certain continued listing standards.

In response to that letter, we submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions we have taken, or will take, that would bring us into compliance with the continued listing standards by April 30, 2009.

On January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan of compliance regarding the following listing standards to which we were in noncompliance of:

Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;

Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and

Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

The AMEX further stated that the AMEX intended to strike our common stock from the AMEX by filing a delisting application with the SEC pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we decided not to seek an appeal of the AMEX's intention to delist our common stock.



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On January 22, 2009, we were informed by the AMEX that they had suspended trading in our common stock effective immediately. Immediately following the notification, our common stock was no longer traded on the AMEX.

Effective February 4, 2009, our common stock was quoted on the Over the Counter Bulletin Board under the symbol NEPH.OB .

In a letter dated April 13, 2009, we received a copy of the AMEX's application to strike our common stock from the AMEX.

## **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:

### *Dialysis*

*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.

*Hemofiltration* is a cleansing process without dialysate solution where blood is passed through a semi-permeable membrane, which filters out solute particles.

*Hemodiafiltration*, or HDF, in its basic form combines the principles of hemodialysis with hemofiltration. 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 over other dialysis therapies because of better ESRD patient tolerance, superior blood purification of both small and middle molecules, and a substantially improved mortality risk profile.



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## **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.