

NEPHROS INC  
Form 10-K  
March 30, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-K**

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

For the fiscal year ended December 31, 2015

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

**For the Transition Period from** \_\_\_\_\_ **to**

**Commission File Number 001-32288**

**NEPHROS, INC.**

(Exact name of registrant specified in its charter)

**Delaware** **13-3971809**  
(State or Other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) Identification No.)

**41 Grand Avenue**

**River Edge, NJ 07661**

(Address of Principal Executive Offices)

**(201) 343-5202**

(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: None

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

Common Stock, \$.001 par value per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes [X] No [ ]

Edgar Filing: NEPHROS INC - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2015, was approximately \$11,179,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, on June 30, 2015. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2015.

As of March 18, 2016 there were 48,581,261 shares of the registrant's common stock, \$0.001 par value, outstanding.

**NEPHROS, INC. AND SUBSIDIARY**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>Item 1. Business</u>	4
<u>Item 1A. Risk Factors</u>	14
<u>Item 1B. Unresolved Staff Comments</u>	22
<u>Item 2. Properties</u>	22
<u>Item 3. Legal Proceedings</u>	22
<u>Item 4. Mine Safety Disclosures</u>	22
<b><u>PART II</u></b>	
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	23
<u>Item 6. Selected Financial Data</u>	23
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	24
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	31
<u>Item 8. Financial Statements and Supplementary Data</u>	32
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	56
<u>Item 9A. Controls and Procedures</u>	56
<u>Item 9B. Other Information</u>	56
<b><u>PART III</u></b>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	57
<u>Item 11. Executive Compensation</u>	61
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	66
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	68
<u>Item 14. Principal Accounting Fees and Services</u>	69
<u>Item 15. Exhibits, Financial Statement Schedules</u>	71
<u>Signatures</u>	76

## FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K constitute “forward-looking statements”. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the timeline for regulatory review and approval of our products, the availability of funding sources for continued development of such products, and our ability to continue as a going concern and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “p” words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

we may not be able to continue as a going concern;

we face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues;

product-related deaths or serious injuries or product malfunctions could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products;

we face potential liability associated with the production, marketing and sale of our products and the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our reputation;

to the extent our products or marketing materials are found to violate any provisions of the U.S. Food, Drug and Cosmetic Act, or FDC Act or any other statutes or regulations then we could be subject to enforcement actions by the FDA or other governmental agencies;

we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;

we may not have sufficient capital to successfully implement our business plan;

we may not be able to effectively market our products;

we may not be able to sell our water filtration products or chronic renal failure therapy products at competitive prices or profitably;

we may encounter problems with our suppliers, manufacturers and distributors;

we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;

we may not obtain appropriate or necessary regulatory approvals to achieve our business plan;

products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;

we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and

we may not be able to achieve sales growth in key geographic markets.

More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this Annual Report on Form 10-K, is set forth in our filings with the SEC, including our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov). We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

## **PART I**

### **Item 1. Business**

#### **Overview**

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration (“HDF”) systems. Our filters, which are generally classified as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate, and used in hospitals for the prevention of infection from water borne pathogens, such as legionella and pseudomonas. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites and endotoxins.

Our OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease (“ESRD”). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis (“HD”). We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

#### **Our Products**

Presently, we have two core product lines: HDF Systems and Ultrafiltration Products.

#### ***HDF Systems***

The current standard of care in the U.S. for patients with chronic renal failure is HD, a process in which toxins are cleared via diffusion. Patients typically receive HD treatment at least 3 times weekly for 3-4 hours per treatment. HD is most effective in removing smaller, easily diffusible toxins. For patients with acute renal failure, the current standard of care in the U.S. is hemofiltration (“HF”), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD. However, HF treatment is performed on a daily basis, and typically takes 12-24 hours.

Hemodiafiltration (“HDF”) is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the U.S., HDF is much more prevalent in Europe and is performed in approximately 16% of patients. Clinical experience and literature show the following clinical and patient benefits of HDF:

Enhanced clearance of middle and large molecular weight toxins

Improved survival - up to a 35% reduction in mortality risk

Reduction in the occurrence of dialysis-related amyloidosis

Reduction in inflammation

Reduction in medication such as EPO and phosphate binders

Improved patient quality of life

Reduction in number of hospitalizations and overall length of stay

However, like HF, HDF can be resource intensive and can require a significant amount of time to deliver one course of treatment.

We have developed a modified approach to HDF that we believe is more patient-friendly, less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration (“mid-dilution HDF”) system and it consists of our OLpür H2H Hemodiafiltration Module (“H2H Module”), our OLpür MD 220 Hemodiafilter (“HDF Filter”) and our H2H Substitution Filter (“Dialysate Filter”).

The H2H Module utilizes a standard HD machine to perform on-line hemodiafiltration therapy. The HD machine controls and monitors the basic treatment functions, as it would normally when providing HD therapy. The H2H Module is a free-standing, movable device that is placed next to either side of an HD machine. The H2H Module is connected to the clinic’s water supply, drain, and electricity.



The H2H Module utilizes the HDF Filter and is very similar to a typical hollow fiber dialyzer assembled with a single hollow fiber bundle made with a high-flux (or high-permeability) membrane. The fiber bundle is separated into two discrete, but serially connected blood paths. Dialysate flows in one direction that is counter-current to blood flow in Stage 1 and co-current to blood flow in Stage 2.

In addition to the HDF Filter, the H2H Module also utilizes a Dialysate Filter during patient treatment. The Dialysate Filter is a hollow fiber, ultrafilter device that consists of two sequential (redundant) ultrafiltration stages in a single housing. During on-line HDF with the H2H Module, fresh dialysate is redirected by the H2H Module's hydraulic (substitution) pump and passed through this dual-stage ultrafilter before being infused as substitution fluid into the extracorporeal circuit. Providing ultrapure dialysate is crucial for the success of on-line HDF treatment.

Our HDF System is cleared by the FDA to market for use with an ultrafiltration controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States. Our on-line mid-dilution HDF system is the only on-line mid-dilution HDF system of its kind to be cleared by the FDA to date.

In May 2014, DaVita Healthcare Partners initiated an evaluation of our HDF System to treat patients at DaVita's North Colorado Springs Clinic. In February 2015, we announced that, in the course of the evaluation, DaVita informed Nephros that they would require additional validation of the system. Nephros and DaVita agreed upon a protocol for the additional validation work which was completed in March 2015. We do not believe that DaVita will restart the evaluation in the near term.

In March 2015, we announced that the Renal Research Institute ("RRI"), a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. As of February 2015, our HDF Systems had performed over 1,200 patient treatments. Over the last 18 months of commercial use, we have gathered direct feedback from users of our HDF System to help improve our system and our training methodology. In January 2016, we updated our training procedures and rolled out a software update, which was focused on improving the system's alignment with nurse work flow.

We are in discussions to evaluate our HDF system at other clinics throughout the U.S. and hope to announce the deployment of our HDF System at a new site in the first half of 2016. Our goal over the next 12-18 months is to work with RRI and the potential new site to developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of a) improving the quality of life for the patient, b) reducing overall expenditure compared to other dialysis modalities, c) minimizing the impact on nurse work flow at the clinic, and d) demonstrating the pharmaco-economic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. In addition, we are in the process of developing version 2.0 of our HDF System, which will enable us to manufacture at scale, as well as potentially reduce

the per treatment cost of performing HDF.

### *Ultrafiltration Products*

Our ultrafiltration products target a number of markets.

*Hospitals and Other Healthcare Facilities:* Filtration of water to be used for patient washing and drinking as an aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeons' hands.

*Dialysis Centers - Water/Bicarbonate:* Filtration of water or bicarbonate concentrate used in hemodialysis devices.

*Military and Outdoor Recreation:* Individual water purification devices used by soldiers and backpackers to produce drinking water in the field, as well as filters customized to remote water processing systems.

*Commercial Facilities:* Filtration of water for washing and drinking including use in ice machines and soda fountains.

### Our Target Markets

*Hospitals and Other Healthcare Facilities.* According to the American Hospital Association approximately 5,700 hospitals, with approximately 915,000 beds, treated over 35 million patients in the U.S. in 2013. The United States Centers for Disease Control and Prevention estimates that healthcare associated infections, or HAIs, occurred in approximately 1 out of every 25 hospital patients. HAIs affect patients in a hospital or other healthcare facility, and are not present or incubating at the time of admission. They also include infections acquired by patients in the hospital or facility but appearing after discharge, and occupational infections among staff. Many HAIs are waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities. The Affordable Care Act, which was passed in March 2010, puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce the potential for HAIs. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the point of delivery, for example, from sinks and showers.

On June 30, 2014 we submitted to the FDA, for 510(k) clearance, the DSU-H and SSU-H Ultrafilters to filter EPA quality drinking water to remove microbiological contaminants and waterborne pathogens. On October 28, 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters as medical devices for use in the hospital setting. The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of a surgeon's hands. The filters are not intended to provide water that can be used as a substitute for United States Pharmacopeia ("USP") sterile water.

In May 2015, we received a warning letter from the FDA resulting from an October 2014 inspection. In the letter, the FDA alleged deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter did not restrict our ability to manufacture, produce or ship any of our products, nor did it require the withdrawal of any product from the marketplace. In August 2015, we received a subsequent letter from the FDA noting that it had received our response correspondence detailing our completed corrective actions. The corrective actions included revisions to our standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring.

In June 2015, the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. ("ASHRAE") approved Standard 188-2015, "Legionellosis: Risk Management for Building Water Systems". We believe the approval of ASHRAE 188-2015 ("S188") as a national standard will have a positive impact on point of delivery filtration market. The S188 applies to any human occupied building that is not a single family residence; requires the building to have a plan to control for waterborne infection; requires heat, chemical or both cleaning in the event of a suspected or confirmed presence of legionella; and recommends point-of-use filters in areas of high risk. We are enhancing our efforts to support our distributors by developing and delivering focused sales training to their sales forces on the use of our filters to support an overall program of infection risk prevention; and by, whenever possible, doing joint sales calls with our distributors on potential hospital customers to both serve as a product expert and to field train their sales representatives.

In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection.

In the first half of 2016, we plan to launch new products to expand on our hospital product line. The DSU-H and the SSU-H are both in-line filters designed to be installed between the wall water outlet and the point of delivery fixture, be it sink faucet, shower head or ice machine. The new products are designed to be attached to the end of a faucet or shower line. On October 27<sup>th</sup>, 2015 we announced that we had submitted the S100 Point of Use filter to the FDA for 510(k) clearance. In late December 2015, the FDA requested additional information. We subsequently performed additional testing and filed the needed supplemental information with the FDA in March 2016. These products will compete directly with other end-of-faucet filters for short term use.

*Dialysis Centers - Water/Bicarbonate.* To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate. Water and bicarbonate concentrate are essential ingredients for making dialysate, the liquid that removes waste material from the blood. According to the American Journal of Kidney Diseases, there are approximately 6,300 dialysis clinics in the United States servicing approximately 430,000 patients annually. We estimate that there are over 100,000 hemodialysis machines in operation in the United States.

Medicare is the main payer for dialysis treatment in the U.S. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate concentrate quality set by the Association for the Advancement of Medical Instrumentation (“AAMI”), the American National Standards Institute (“ANSI”) and the International Standards Organization (“ISO”). We anticipate that the stricter standards approved by these organizations in 2009 will be adopted by Medicare in the near future.

Published studies have shown that the use of ultrapure dialysate can reduce the overall need for erythropoietin stimulating agents (“ESA”), expensive drugs used in conjunction with HD. By reducing the level of dialysate contaminants, specifically cytokine-inducing substances that can pass into a patient’s blood stream, the stimulation of inflammation-inducing cytokines is reduced, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient’s responsiveness to erythropoietin (“EPO”) is enhanced, consequently the overall need for ESAs is reduced.

We believe that our ultrafilters are attractive to dialysis centers because they exceed currently approved and newly proposed standards for water and bicarbonate concentrate purity, assist in achieving those standards and may help dialysis centers reduce costs associated with the amount of ESA required to treat a patient. Our in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine.

In September 2015, we launched a new marketing campaign focused on further expanding our products into dialysis clinics, the Nephros Challenge. The Nephros Challenge is a money-back guarantee if a dialysis clinic does not see any measurable self-defined benefit from using Nephros Ultrafilters at the HD station to provide ultrapure water and bicarbonate. We will be concluding this program on March 31, 2016 as we shift marketing focus to the launch of our 10" cartridge platform.

In March 2016, we launched the SSUmini product, developed to provide a lower cost ultrafiltration solution for water and bicarbonate flowrates of 0.5 gallons per minutes ("GPM") or less. The SSUmini can be used as a polish filter for small, portable reverse osmosis ("RO") water systems or on bicarbonate concentrate lines in dialysis clinics with centralized bicarbonate concentrate systems.

In the second quarter of 2016, we intend to file for 510(k) clearance of an endotoxin cartridge filter. The endotoxin cartridge filter is designed to provide hemodialysis quality water through ultrafiltration of the water in a dialysis clinic's RO loop. The 10" filter retains particles as small as 0.005 microns, is designed to handle higher flowrates and can be stacked to provide a 20", 30" or 40" form factor. Because the cartridge conforms to the design controls of the DSU-D, and has the same intended use, the cartridge qualifies for the Special 510(k): Device Modification process, which has a 30 day FDA review timeline. Pending FDA clearance, we aim to launch the filter by the end of second quarter of 2016.

*Military and Outdoor Recreation.* Water is a key requirement for the soldier to be fully mission-capable. The availability of water supplies and immediate on-site water purification is critical to enhance the ability to operate in any environment. Currently, the military is heavily reliant on the use of bottled water to support its soldiers in the field. Bottled water is not always available, is very costly to move, is resource intensive, and is prone to constant supply disruptions. Soldiers conducting operations in isolated and rugged terrain must be able to use available local water sources when unable to resupply from bulk drinking water sources or bottled water. Therefore, the soldier needs the capability to purify water from indigenous water sources in the absence of available potable water. Soldiers must have the ability to remove microbiological contaminants in the water to Environmental Protection Agency ("EPA") specified levels.

We developed our individual water treatment device ("IWTD") in both in-line (HydraGuard in-line) and point-of-use (HydraGuard Universal) configurations. Our IWTD allows a soldier in the field to derive drinking water from any fresh water source. This enables the soldier to remain hydrated which will maintain mission effectiveness and unit readiness, and extend mission reach. Our IWTD is one of the few portable filters that has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by U.S. Army Public Health Command and U.S. Army Test and Evaluation Command for deployment.

On May 6, 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC (“CamelBak”). Under this Sublicense Agreement, we granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the HydraGuard individual water treatment devices. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay us a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay us a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to us, and if such fees are not met or exceeded, we may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales.

In 2015, we began working with multiple companies developing portable water purification systems designed to provide potable water in remote locations. Specifically, we have provided flushable filter prototypes to these companies for validation as one potential component in systems that employ multiple technologies to purify water from streams, lakes and rivers.

#### *Commercial Facilities.*

In 2014, we launched NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is to be used for non-medical drinking and washing in non-transient non-community water systems, or commercial facilities. The NanoGuard-D and NanoGuard-S trap particulates greater than 0.005 microns in size and can be used as a component of a facility water treatment system, or to filter water used in ice machines and soda fountains.

In November 2015, we announced a strategic partnership with Biocon 1, LLC. Biocon’s AETHER® Water Systems technology, which includes patented water filtration media and water filtration products, provides solutions for customers to address all contaminate issues and to provide clean-tasting, sediment-free, scale-free, and bacteria-free water for the food service industry. AETHER® Water Systems are used with ice machines, coffee stations, and soda fountains in hotels, casual dining restaurants, fast food restaurants and convenience stores. As part of the collaboration, we have access to Biocon’s anti-scale and related water filtration technology to develop filter products for the medical industry. In March 2016, Nephros shipped the first lot of filter cartridges to Biocon for inclusion with its AETHER® line of filtration products. Also in March 2016, Biocon shipped the first anti-scale filter samples to Nephros for testing in the medical setting.

Our 10” filter cartridge platform, initially intended for use in the dialysis setting, should be available for commercial uses by the second half of 2016. We will be working with existing distributors and their existing customers, and seeking new distributors to address customers not currently targeted by our existing distributors.

Over the last few years, we have been developing a high-throughput, auto-flushing filter system capable of handling 25 GPM, or greater, through our proprietary 0.005 micron fiber membrane. The flushable filter system is designed to remove submicron particulates in closed loop water systems, including cooling systems for data centers and hot water return loops in commercial buildings. Initial data suggests the ability to remove both organic and inorganic particulates. We intend to provide limited release of a 25 GPM system to specific customers for additional testing and validation by the third quarter of 2016.

We intend to develop flushable filter cartridges capable to filtering 2.5, 5 and 10 GPM through our fiber membrane. These smaller flushable filter systems have potential utility as a point-of-entry water purification system in restaurants, convenience stores and households. We intend to provide limited release of these products initially through Biocon in the second half of 2016.

Going forward, as we grow our water filtration business, we will be exploring opportunities for new applications for our filter products and will be open to evaluating new potential partnerships to expand our water filtration foot print.

## **Corporate Information**

We were incorporated under the laws of the State of Delaware in April 1997. Our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey, 07661, and our telephone number is (201) 343-5202. We also have an office in Dublin, Ireland. For more information about Nephros, please visit our website at [www.nephros.com](http://www.nephros.com).

## **Going Concern**

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. 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. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred significant losses in operations in each quarter since inception. In addition, we have not generated positive cash flow from operations for the years ended December 31, 2015 and 2014. 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.

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.

## Recent Developments

On December 23, 2015, we received proceeds of approximately \$688,000 in connection with our offer to holders of certain warrants of the opportunity to exercise their warrants at a temporarily reduced cash exercise price. Warrant holders elected to exercise warrants to purchase an aggregate of 3,442,521 shares of our common stock at the reduced cash exercise price of \$0.20 per share, providing a total of \$688,000 in gross proceeds to us. Of the 3,442,521 shares issued, 2,782,577 are held by Lambda Investors LLC (“Lambda”), our largest stockholder who owns approximately 62% of our outstanding common stock. The warrants that were not exercised pursuant to the offer to exercise remained in effect, with an exercise price of \$0.40 per share of common stock.

On September 29, 2015, we entered into a Warrant Amendment and Exercise Agreement (the “Amendment”) with Lambda. Pursuant to the Amendment, the Company agreed to reduce the current exercise price of the Class D Warrant issued to Lambda on November 14, 2007 (together with all amendments thereto entered into prior to the Amendment, the “Warrant”) representing the right to purchase 11,742,100 shares of the Company’s common stock by 50%, to \$0.15 per share, in exchange for Lambda’s agreement to exercise such Warrant in its entirety. Upon exercise of the Warrant, the Company issued 11,742,100 shares of common stock to Lambda and received approximately \$1.76 million in cash proceeds from Lambda. Following such exercise, no Class D Warrants remain outstanding.



## **Manufacturing and Suppliers**

We do not, and do not intend to in the near future, manufacture any of our products and components. With regard to the OLpūr MD190 and MD220, on June 27, 2011, we entered into a license agreement, effective July 1, 2011, as amended by the first amendment dated February 19, 2014, with Bellco S.r.l. (“Bellco”), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD190, MD220). Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. In addition, under the agreement, as amended by the first amendment, we granted Bellco a license to manufacture, market and sell these products under its own name, label and CE mark in Italy, France, Belgium, Spain, Canada, Denmark, Finland, Norway and Sweden on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom, Greece, Brazil, China, Korea, Mexico and the Netherlands and, upon our written approval, other European countries where we do not sell these products as well as non-European countries.

In April 2012, we entered into a license and supply agreement with Medica S.p.A., an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica’s proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products, and to engage in an exclusive supply arrangement for the filtration products. Under the license and supply Agreement, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, excluding Italy, during the term of the agreement.

## **Sales and Marketing**

Under the Bellco license agreement, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label and CE mark in the Territory. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated Territory.

Our New Jersey office oversees global sales and marketing activity of our ultrafilter products. We work with multiple distributors for our ultrafilter products in the dialysis water market and the hospital water market. In the food service market, Biocon has the exclusive right to distribute our custom filter cartridge developed for the AETHER® Water System. For each prospective market for our ultrafilter products, we are pursuing alliance opportunities for joint product development and/or distribution. Our ultrafilter manufacturer in Europe shares certain intellectual property rights with us for one of our Dual Stage Ultrafilter (DSU) designs.

## **Research and Development**

Our research and development efforts continue on several fronts directly related to our current product lines. On the water filter business, we are continually working with existing and potential distributors of ultrafilter products to develop solutions to meet customer needs. On the HDF System business, we are working with our current customers to develop version 2.0 of the HDF System. For the years ended December 31, 2015 and 2014, we spent approximately \$826,000 and \$781,000, respectively, on research and development activities.

## **Major Customers**

For the year ended December 31, 2015, four customers accounted for 64% of our revenues. For the year ended December 31, 2014, three customers accounted for 78% of our revenues.

As of December 31, 2015 three customers accounted for 71% of our accounts receivable. As of December 31, 2014, three customers accounted for 83% of our accounts receivable.

## **Competition**

With respect to the water filtration market, we expect to compete with companies that are well entrenched in the water filtration domain. These companies include Pall Corporation, which manufactures end-point water filtration systems, as well as 3M, Siemens and Everpure. Our methods of competition in the water filtration domain include:

developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;

offering unique attributes that illustrate our product reliability, “user-friendliness,” and performance capabilities;

selling products to specific customer groups where our unique product attributes are mission-critical; and

pursuing alliance opportunities for joint product development and distribution.

The dialyzer and renal replacement therapy market is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical goals of nephrologists, improve patient outcomes and remain cost-effective for payers.

We compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG and Baxter International Inc., currently two of the primary machine manufacturers in hemodialysis. At present, Fresenius Medical Care AG and Baxter International Inc. also manufacture HDF machines that are not currently approved in the U.S.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis products include Baxter International Inc., Fresenius Medical Care AG, Asahi Kasei Medical Co. Ltd., B. Braun Melsungen AG, Nipro Medical Corporation Ltd., Nikkiso Co., Ltd., Terumo Medical Corporation and Toray Medical Co., Ltd.

Other competitive considerations include pharmacological and technological advances in preventing the progression of ESRD in high-risk patients such as those with diabetes and hypertension, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants.

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of competing in the ESRD marketplace to include:

continuing our efforts to develop, have manufactured and sell products which, when compared to existing products, perform more efficiently and are available at prices that are acceptable to the market;

displaying our products and providing associated literature at major industry trade shows in the United States;

initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;

pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities; and

entering into license agreements similar to the Bellco S.r.l. agreement to expand market share.

## Intellectual Property

### *Patents*

We protect our technology and products through patents and patent applications. In addition to the United States, we also applied for patents in other jurisdictions, such as the European Patent Office, Canada and Japan, to the extent we deem appropriate. We have built a portfolio of patents and applications covering our products, including their hardware design and methods of hemodiafiltration.

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge," have claims that cover the OLpur MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have issued patents on our water filtration products and applications in process to cover various applications in residential, commercial, and remote environments.

As of December 31, 2015, we have twenty two issued U.S. patents, one issued Eurasian patent, seven Mexican patents, four South Korean patents, three Russian patents, six Chinese patents, nine French patents, nine German patents, five Israeli patents, seven Italian patents, three Spanish patents, nine United Kingdom patents, fourteen Japanese patents, three Hong Kong patents, ten Canadian patents, one Australian patent, two patents in Brazil, one patent in Sweden and one patent in the Netherlands. Our issued U.S. patents expire between 2018 and 2033. In addition, we have one pending U.S. patent application, two pending patent applications in Canada, two pending patent applications in the European Patent Office, and one pending patent application in Brazil. Our pending patent applications relate to a range of filter technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance and ensure performance.

### *Trademarks*

As of December 31, 2015, we secured registrations of the trademarks H2H and OLpūr in the European Union and OLpūr in the United States.

### **Governmental Regulation**

The research and development, manufacturing, promotion, marketing and distribution of our ESRD therapy products in the United States, Europe and other regions of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and analogous agencies.

#### **United States**

The FDA regulates the manufacture and distribution of medical devices in the United States pursuant to the FDC Act. All of our ESRD therapy products are regulated in the United States as medical devices by the FDA under the FDC Act. Under the FDC Act, medical devices are classified in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

Class I devices are medical devices for which general controls are deemed sufficient to ensure their safety and effectiveness. General controls include provisions related to (1) labeling, (2) producer registration, (3) defect notification, (4) records and reports and (5) quality service requirements, or QSR.

Class II devices are medical devices for which the general controls for the Class I devices are deemed not sufficient to ensure their safety and effectiveness and require special controls in addition to the general controls. Special controls include provisions related to (1) performance and design standards, (2) post-market surveillance, (3) patient registries and (4) the use of FDA guidelines.

Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before a new medical device can be introduced to the market, FDA clearance of a pre-market notification under Section 510(k) of the FDC Act or FDA clearance of a pre-market approval, or PMA, application under Section 515 of the FDC Act must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is “substantially equivalent” to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process.

For any devices cleared through the Section 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require a new Section 510(k) pre-market notification submission. Accordingly, if we do obtain Section 510(k) pre-market clearance for any of our ESRD therapy and DSU products, we will need to submit another Section 510(k) pre-market notification if we significantly affect that product’s safety or effectiveness through subsequent modifications or enhancements.

On July 1, 2009, we received FDA clearance of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

On August 11, 2011, we filed a 510(k) application with the FDA for clearance of our hemodiafiltration (HDF) system for end-stage renal disease. On April 30, 2012, we announced that 510(k) clearance was received from the FDA to market the OLpūr H2H Module and OLpūr MD 220 Hemodiafilter for use with a UF controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States.

On October 28, 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters as medical devices for use in the hospital setting. The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of a surgeon’s hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.

The FDC Act requires that medical devices be manufactured in accordance with the FDA's current QSR regulations which require, among other things, that:

the design and manufacturing processes be regulated and controlled by the use of written procedures;

the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;

any deficiencies in the manufacturing process or in the products produced be investigated;

detailed records be kept and a corrective and preventative action plan be in place; and

manufacturing facilities be subject to FDA inspection on a periodic basis to monitor compliance with QSR regulations.

If violations of the applicable QSR regulations are noted during FDA inspections of our manufacturing facilities or the manufacturing facilities of our contract manufacturers, there may be a material adverse effect on our ability to produce and sell our products.

In addition to the requirements described above, the FDC Act requires that:

all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;

information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur; and

certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

### ***European Union***

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive 93/42/EEC. The European Union directive applies to both the manufacturer's quality assurance system and the product's technical design and discusses the various ways to obtain approval of a device (dependent on device classification), how to properly CE Mark a device and how

to place a device on the market.

The regulatory approach necessary to demonstrate to the European Union that the organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices requires the certification of a full quality management system by a notified body. Initially, we engaged TÜV Rheinland of North America, Inc. (“TÜV Rheinland”) as the notified body to assist us in obtaining certification to the International Organization for Standardization, or ISO, 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

European Union requirements for products are set forth in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. A company demonstrates conformity to these requirements, with respect to a product, by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

Once a manufacturer’s full quality management system is determined to be in compliance with ISO 13485/2003 and other statutory requirements, and the manufacturer’s products conform to harmonized European standards, the notified body will recommend and document such conformity. The manufacturer will receive a CE marking and ISO certifications, and then may place a CE mark on the relevant products. The CE mark, which stands for Conformité Européenne, demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported to, or sold or distributed within, the European Union.



In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms to the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. In April 2010, we changed our notified body from TÜV Rheinland to BSI America, Inc. and expanded our scope to include design and development and production of water filters.

Under the Bellco license agreement, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label and CE mark in the stated territory. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated territory.

### ***Regulatory Authorities in Regions Outside of the United States and the European Union***

We also plan to sell our ESRD therapy products in foreign markets outside the United States that are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. In November 2007 and May 2011, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpūr MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the Canadian approval of our OLpūr MD220 Hemodiafilter and DSU products, we have not obtained any regulatory approvals to sell any of our products outside of the United States and the European Union and there is no assurance that any such clearance or certification will be issued.

### **Reimbursement**

In both domestic markets and markets outside of the United States, sales of our ESRD therapy products will depend in part, on the availability of reimbursement from third-party payers. In the United States, ESRD providers are reimbursed through Medicare, Medicaid and private insurers. In countries other than the United States, ESRD providers are also reimbursed through governmental and private insurers. In countries other than the United States, the pricing and profitability of our products generally will be subject to government controls. Despite the continually expanding influence of the European Union, national healthcare systems in its member nations, including reimbursement decision-making, are neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government.

## **Product Liability and Insurance**

The production, marketing and sale of our products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our products in the amount of \$2 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.

Some of our existing and potential agreements with manufacturers of our products and components of our products do or may require us (1) to obtain product liability insurance or (2) to indemnify manufacturers against liabilities resulting from the sale of our products. If we are not able to maintain adequate product liability insurance, we will be in breach of these agreements, which could materially adversely affect our ability to produce our products. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

## **Employees**

As of December 31, 2015, we employed a total of 11 employees, 10 of whom are full time and 1 who is employed on a part-time basis. We also have engaged 2 consultants on an ongoing basis. Of the 13 total employees and consultants, 2 are employed in a sales/marketing/customer support capacity, 5 in general and administrative and 6 in research and development.

## Item 1A. Risk Factors

### Risks Related to Our Company

*Our independent registered public accounting firm, in its audit report related to our financial statements for the fiscal year ended December 31, 2015, expressed doubt about our ability to continue as a going concern.*

Our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements included in this Annual Report on Form 10-K expressing doubt as to our ability to continue as a going concern. The accompanying consolidated 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 expect that the proceeds from the Lambda Class D warrant exercise and the additional warrant exercises that resulted from the tender offer and the projected increase in product sales will allow us to fund our operations at least into the third quarter of 2016, and potentially longer depending on the timing and market up-take of our new products. As a result, 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 may be required to cease operations.

*We have a history of operating losses and a significant accumulated deficit, and we may not achieve or maintain profitability in the future.*

As of December 31, 2015, we had an accumulated deficit of approximately \$117,253,000, as a result of historical operating losses. 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 market acceptance 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

our ability to continue to develop products and maintain a competitive advantage in our industry.

***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 medically approved products.

On May 28, 2015, we received a warning letter from the FDA resulting from an October 2014 inspection of our facility in River Edge, New Jersey. The warning letter alleges deficiencies relating to our compliance with the Quality System regulation and the Medical Device Reporting regulation. We take the matters identified in the warning letter seriously and are in the process of evaluating the corrective actions required to address the matters raised in the warning letter. We responded to the warning letter within 15 business days as requested by the FDA, and intend to work diligently and expeditiously to resolve the issues raised by the FDA. The warning letter does not restrict the manufacture, production or shipment of any of our products, nor require the withdrawal of any product from the marketplace. On August 12, 2015, we received an additional letter from the FDA acknowledging our responses and noting that it will verify our implementation of corrective measures at its next inspection of our facility. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection.

If we violate the FDC Act or other regulatory requirements (either with respect to our POU or DSU ultrafilters or otherwise) 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:

finest;

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 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.

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

We cannot assure you that our products will prove to be safe or that there will not be product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm.

Under the FDC Act, we are required to submit medical device reports (“MDRs”) to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

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

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

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

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our 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 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. Voluntary recalls could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance 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 (“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.



*We face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues.*

We do not yet have an established market or customer base for our products. Acceptance of our products in the marketplace by both potential users, including chronic renal failure 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 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 chronic renal failure 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 chronic renal failure 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 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. The extent to which we fail to successfully commercialize our products will limit our ability to be profitable.

We expect to rely on a limited number of independent manufacturers to produce our products. 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.

***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. 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 that 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 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 have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.***

Our business strategy depends in part on our ability to sell our products to hospitals and other healthcare facilities that include dialysis clinics. We have limited experience with respect to sales and marketing. If we are unsuccessful at manufacturing, marketing and selling our products, our operations and potential revenues will be materially adversely affected.

***We cannot sell our products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. 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 have obtained a Conformité Européene (“CE”) mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpūr mid dilution hemodiafilter series product and our Dual Stage Ultrafilter (“DSU”). We have not yet obtained the CE mark for any of our other products. On April 30, 2012, we announced that we received clearance from the FDA to market our OLpūr MD220 Hemodiafilter and OLpūr H2H Module for use with a hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of chronic renal failure patients. We have not begun to broadly market these products and are actively seeking a commercialization partner in the U.S.

There is no assurance that any existing products that have not yet been approved, or any new products developed by us in the future, will be approved for marketing. The clearance and/or approval processes 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 regulatory approval for any of our existing or new 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 would prevent us from selling our affected products in the applicable regions. If we cannot sell some of our products in such regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

We intend to market our products globally. Requirements pertaining to the sale of our products vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our products in many countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our products in a particular region, then the size of our potential market could be reduced, which would

limit our potential sales and revenues.

*Clinical studies that may be required for our products are costly and time-consuming, and their outcome is uncertain.*

Before obtaining regulatory approvals for the commercial sale of any of our products, other than those for which we have already received marketing approval in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective.

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

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

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

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

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

longer treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product;

adverse medical events or side effects in treated subjects; and

lack of effectiveness of the 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 regulatory policy for device approval during the period of product development and regulatory review of each submitted new device application. 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 products, which may result in significant expense and delay. Regulatory agencies 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 certain regulatory standards, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our products. It is possible that regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

***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.

***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 18 granted U.S. patents will expire at various times from 2018 to 2027, assuming they are properly maintained.

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

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

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

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

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

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

Approval or clearance of our products could be withdrawn, delayed or denied 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 products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MD HDF 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. 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.

To market our 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 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 products manufactured in such facilities and our revenues may be materially adversely affected.

***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 globally. 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 maintain effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and the market price of our securities may be negatively affected.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to maintain internal control over financial reporting and to report any material weaknesses in such internal control. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We also are required to furnish a report by management on the effectiveness of our internal control over financial reporting. We perform system and process evaluation and testing of our internal controls over financial reporting to allow management to prepare and furnish such a report.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2014, we discovered that we had improperly accounted for our warrants as components of equity instead of as derivative liabilities, and our management and auditors determined that this resulted from a material weakness in internal control over financial reporting. This material weakness led to the need for the restatement of (i) our audited consolidated financial statements as of and for the years ended December 31, 2013, 2012, 2011, 2010 and 2009, including the cumulative effect as of January 1, 2009, and (ii) our unaudited condensed consolidated interim financial statements as of, and for each of the quarterly periods ended, March 31, June 30, and September 30, in the years 2014 and 2013.

While the above material weakness has been remediated, if we are unable to maintain proper and effective internal control over financial reporting in the future, we may not be able to produce timely and accurate financial statements. If that were to happen, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

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

*There currently is a limited trading market for our Common Stock.*

We do not currently meet all of the requirements for initial listing of our Common Stock on a registered stock exchange. Our Common Stock is quoted on the OTCQB. Trading in our Common Stock on the OTCQB has been very limited. As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our Common Stock, and our Common Stock may be less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes. There is no guarantee

that we will ever become listed on the Nasdaq Capital Market, or any other exchange, or that a liquid trading market for our Common Stock will develop.

***Our Common Stock could be further diluted as a result of the issuance of additional shares of Common Stock, warrants or options.***

In the past we have issued Common Stock and warrants in order to raise money. We have also issued stock options and restricted stock as compensation for services and incentive compensation for our employees, directors and consultants. We have shares of Common Stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional Common Stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our Common Stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our Common Stock), or could obligate us to issue additional shares of Common Stock.

Market sales of large amounts of our Common Stock, or the potential for those sales even if they do not actually occur, may have the effect of depressing the market price of our Common Stock, the supply of Common Stock available for resale could be increased which could stimulate trading activity and cause the market price of our Common Stock to drop, even if our business is doing well. Furthermore, the issuance of any additional shares of our Common Stock or securities convertible into our Common Stock could be substantially dilutive to holders of our Common Stock if they do not invest in future offerings.

***The prices at which shares of the Common Stock trade have been and will likely continue to be volatile.***

During the two years ended December 31, 2015, our Common Stock has traded at prices ranging from a high of \$1.29 to a low of \$0.20 per share. Due to the lack of an active trading 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:

achievement or rejection of regulatory approvals by our competitors or us;

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;



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;

threatened or actual litigation;

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 medical technology 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. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

***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.

***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 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.

***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 smaller reporting 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 “Risk Factors” 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 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. 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.

***Our directors, executive officers and Lambda 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 December 31, 2015, Lambda, our largest stockholder, beneficially owned approximately 62% of our outstanding Common Stock. As a result of this ownership, Lambda has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda, whether acting alone or acting with other stockholders, could 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 Lambda, whether acting alone or acting with other 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. The interests of Lambda in any matter put before the stockholders may differ from those of any other stockholder.

***Future sales of our Common Stock could cause the market price of our Common Stock to decline.***

The market price of our Common Stock could decline due to sales of a large number of shares in the market, including sales of shares by Lambda or any other large stockholder, or the perception that such sales could occur. These sales could also make it more difficult or impossible for us to sell equity securities in the future at a time and price that we deem appropriate to raise funds through future offerings of Common Stock. Future sales of our Common Stock by stockholders could depress the market price of our Common Stock.

*Shares eligible for future sale may adversely affect the market.*

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of Common Stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after holding their shares for six months and affiliates may sell freely after holding their shares for one year, in each case, subject to current public information, notice and other requirements. Any substantial sales of our Common Stock pursuant to Rule 144 may have a material adverse effect on the market price of our Common Stock.

#### **Item 1B. Unresolved Staff Comments**

Not required.

#### **Item 2. Properties**

Our U.S. facilities are located at 41 Grand Avenue, River Edge, New Jersey, 07661 and consist of approximately 4,688 square feet of space. The current rental agreement expires in November 2018 with a monthly cost of approximately \$9,000. We use these facilities to house our corporate headquarters and research facilities.

Our facilities in Europe are currently located at A5 Clonlara Avenue, Baldonnell Business Park, Dublin, Ireland, and consist of approximately 500 square feet of space. The lease agreement was entered into on July 1, 2010. The lease term is renewable for 6 month terms with a 2 month notice to discontinue, on a rolling basis. Our monthly cost is 500 Euro (approximately \$545).

We use these facilities to house our accounting, operations and customer service departments.

We believe our current facilities will be adequate to meet our needs. We do not own any real property for use in our operations or otherwise.

### **Item 3. Legal Proceedings**

There are no currently pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject.

### **Item 4. Mine Safety Disclosures**

Not applicable.



**PART II****Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock is quoted on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, under the symbol “NEPH.” The following table sets forth the high and low bid and ask prices for our common stock as reported on the OTCQB for each quarter listed. Such over the counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
March 31, 2014	\$0.75	\$0.30
June 30, 2014	\$1.29	\$0.35
September 30, 2014	\$1.19	\$0.76
December 31, 2014	\$1.00	\$0.61
March 31, 2015	\$0.96	\$0.50
June 30, 2015	\$0.80	\$0.49
September 30, 2015	\$0.77	\$0.37
December 31, 2015	\$0.43	\$0.20

As of March 18 , 2016, there were approximately 64 holders of record and approximately 2,650 beneficial holders of our common stock.

We have neither paid nor declared dividends on our common stock since our inception. 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 financing, tax considerations and applicable law.

*Recent Sales of Unregistered Securities*

Except as previously reported in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, we have not sold any other equity security during the year ended December 31, 2015 which was not registered under the

Securities Act of 1933, as amended.

*Issuer Repurchases of Equity Securities*

There were no repurchases of our Common Stock during the fourth quarter of 2015.

**Item 6. Selected Financial Data**

Not required for smaller reporting companies.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion includes forward-looking statements about our business, financial condition and results of operations, including discussions about management's expectations for our business. These statements represent projections, beliefs and expectations based on current circumstances and conditions and in light of recent events and trends, and you should not construe these statements either as assurances of performances or as promises of a given course of action. Instead, various known and unknown factors are likely to cause our actual performance and management's actions to vary, and the results of these variances may be both material and adverse. A list of the known material factors that may cause our results to vary, or may cause management to deviate from its current plans and expectations, is included in Item 1A "Risk Factors." The following discussion should also be read in conjunction with the consolidated financial statements and notes included herein.*

### Business Overview

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration ("HDF") systems. Our filters, which are generally classified as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate, and used in hospitals for the prevention of infection from water borne pathogens, such as legionella and pseudomonas. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites and endotoxins.

Our ultrafilters OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patient with end stage renal disease ("ESRD"). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis ("HD"). We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

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

the market acceptance of our products 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;

the consolidation of dialysis clinics into larger clinical groups; and

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 the foregoing, our sales could be lower than expected and dramatically impair our ability to generate income from operations.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and was effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption was not permitted. In August, 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date”. The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in ASU 2014-09 to fiscal years beginning December 15, 2017, including interim reporting periods within that fiscal year. Earlier application is permitted only as of fiscal years beginning after December 31, 2016, including interim reporting periods with that fiscal year. We are currently reviewing the revised guidance and assessing the potential impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and sets rules for how this information should be disclosed in the financial statements. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. We are currently evaluating any impact the adoption of ASU 2014-15 might have on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 2015-03): Simplifying the Presentation of Debt Issuance Costs" related to the presentation requirements for debt issuance costs and debt discount and premium. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 is effective for annual and interim periods beginning after December 15, 2015. Early adoption of the amendments in ASU 2015-03 is permitted for financial statements that have not been previously issued. We do not believe that the adoption of ASU 2015-03 will have a significant impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. We do not believe that the adoption of ASU 2015-11 will have a significant impact on our consolidated financial statements.

In August 2015, the FASB issued ASU No. 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements" which clarifies the presentation requirements for debt issuance costs discussed in ASU 2015-03 as they relate to line-of-credit arrangements. The SEC will not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. We do not believe that the adoption of ASU 2015-15 will have a significant impact on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, "Balance Sheet Classification of Deferred Taxes," that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We do not believe that the adoption of ASU 2015-17 will have a significant impact on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities,” that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases”, that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

### **Going Concern**

Our independent registered public accounting firm has included an explanatory paragraph in their report on our consolidated financial statements included in this Form 10-K which expressed doubt as to our ability to continue as a going concern. The accompanying consolidated 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 operating 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.

## **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management's subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2015, we believe that the following accounting policies require the application of significant judgments and estimates.

### **Revenue Recognition**

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

We recognize revenue related to product sales when delivery is confirmed by our 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 us. Shipments for all products are currently received directly by our customers.

We are recognizing the remaining deferred revenue under the Bellco license agreement on a straight line basis over the remaining eighty-four month expected obligation period which ends on December 31, 2021. Any difference between payments received and recognized revenue is reported as deferred revenue.

Deferred revenue on the accompanying December 31, 2015 consolidated balance sheet is approximately \$417,000 and is related to the Bellco license agreement. We have recognized approximately \$2,659,000 of revenue related to this license agreement to date and approximately \$70,000 for the year ended December 31, 2015, resulting in \$417,000 being deferred over the remainder of the expected obligation period. We amortize the deferred revenue monthly over the expected obligation period which ends on December 31, 2021. As a result, expected revenue to be recognized will be approximately \$70,000 in each of the next six years.

## **Stock-Based Compensation**

The fair value of stock options is recognized as stock-based compensation expense in net income. We calculate employee stock-based compensation expense in accordance with ASC 718. We account for stock option grants to consultants under the provisions of ASC 505-50, and as such, these stock options are revalued at each reporting period through the vesting period. 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.

## **Warrants**

We account for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for modification of the warrant exercise price under certain conditions are accounted for as derivative liabilities. We classify derivative warrant liabilities on the balance sheet as a liability, which is revalued using a binomial options pricing model at each balance sheet date subsequent to the initial issuance. A binomial options pricing model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. The changes in fair value of the derivative warrant liabilities resulting from their remeasurement at each balance sheet date are recorded in current period earnings.

## **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 our 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 consolidated 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.

## **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, 2015 Compared to the Fiscal Year Ended December 31, 2014**

#### Revenues

Total revenues for the year ended December 31, 2015 were approximately \$1,944,000 compared to approximately \$1,748,000 for the year ended December 31, 2014. Total revenues increased approximately \$196,000, or 11.2%.

Increases of approximately \$856,000, or 96%, in ultrafilter sales and approximately \$84,000 in Bellco royalties were partially offset by a decrease of approximately \$764,000 in revenue recognized under the Bellco license agreement.

#### Cost of Goods Sold

Cost of goods sold was approximately \$884,000 for the year ended December 31, 2015 compared to approximately \$549,000 for the year ended December 31, 2014. The increase of approximately \$335,000, or 61%, in cost of goods sold was primarily related to an increase in ultrafilter sales.

#### Research and Development

Research and development expenses were approximately \$826,000 and \$781,000, respectively, for the years ended December 31, 2015 and December 31, 2014. This increase of approximately \$45,000, or 5.8%, is primarily due to increases in product development expenses relating to new ultrafilter products and the addition of personnel.

#### Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$212,000 for the year ended December 31, 2015 compared to approximately \$217,000 for the year ended December 31, 2014, representing a decrease of 2.3%.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$3,443,000 for the year ended December 31, 2015 compared to approximately \$2,870,000 for the year ended December 31, 2014, representing an increase of \$573,000 or 20%. The increase is due to a severance expense of approximately \$175,000, to an increase in auditor expenses of \$120,000, to an increase in marketing expenses of approximately \$110,000, and to an increase in travel expenses of approximately \$84,000. The increases were partially offset by a decrease in stock option expenses of approximately \$97,000.

## Interest Expense

The table below summarizes interest expense for the years ended December 31, 2015 and 2014:

	2015	2014
Interest related to August 2014 senior secured note	\$-	\$63,000
Interest related to November 2013 senior secured note	-	37,000
Amortization of debt discount - August 2014 senior secured note	-	178,000
Amortization of debt discount - November 2013 senior secured note	-	142,000
Interest - outstanding payables due to a vendor	41,000	61,000
Other	1,000	2,000
Total interest expense	\$42,000	\$483,000

## Change in Fair Value of Warrant Liability

We classified certain warrants as liabilities at their fair value and adjusted the warrant liability to fair value at each reporting period. This liability was subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our consolidated statement of operations and comprehensive income (loss). The fair value of such warrants issued has been estimated using a binomial options pricing model. The change in fair value of the warrant liability resulted in income of approximately \$2,099,000 for the year ended December 31, 2015 and expense of approximately \$4,277,000 for the year ended December 31, 2014. These liability classified warrants were exercised in full on September 29, 2015.

## Other Income/Expense

Other income of approximately \$37,000 and \$58,000, respectively, for the years ended December 31, 2015 and 2014 is due to foreign currency gains.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as of December 31, 2015 or 2014.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of December 31, 2015 and 2014 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	December 31,	
	2015	2014
Cash	\$1,248	\$1,284
Other current assets	1,216	400
Working capital	1,505	437
Stockholders' equity (deficit)	2,664	(5,681)

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 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 water-filtration products;

to pursue business development opportunities with respect to our chronic renal treatment system; and

for working capital purposes.

We operate under an Investment, Risk Management and Accounting Policy adopted by our board of directors. Such policy limits the types of instruments or securities in which we may invest our excess funds: 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.

At December 31, 2015, we had an accumulated deficit of approximately \$117,253,000, and we expect to incur additional operating losses from operations in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue.

On December 23, 2015, we received proceeds of approximately \$688,000 in connection with our offer to holders of certain warrants of the opportunity to exercise their warrants at a temporarily reduced cash exercise price. Warrant holders elected to exercise warrants to purchase an aggregate of 3,442,521 shares of our common stock at the reduced cash exercise price of \$0.20 per share, providing a total of \$688,000 in gross proceeds to us. Of the 3,442,521 shares issued, 2,782,577 are held by Lambda. The warrants that were not exercised pursuant to the offer to exercise remained in effect, with an exercise price of \$0.40 per share of common stock.

On September 29, 2015, we entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda. Pursuant to the Amendment, the Company agreed to reduce the current exercise price of the Class D Warrant issued to Lambda on November 14, 2007 (together with all amendments thereto entered into prior to the Amendment, the "Warrant") representing the right to purchase 11,742,100 shares of the Company's common stock by 50%, to \$0.15 per share, in exchange for Lambda's agreement to exercise such Warrant in its entirety. Upon exercise of the Warrant, the Company issued 11,742,100 shares of common stock to Lambda and received approximately \$1.76 million in cash proceeds from Lambda. Following such exercise, no Class D Warrants remain outstanding.

On July 24, 2015, we entered into a purchase agreement, together with a registration rights agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Under the terms and subject to the

conditions of the purchase agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to \$10.0 million in shares of our common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 200,000 shares depending upon the closing sale price of the common stock. However, in no event shall these purchases be more than \$500,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price as set forth in the purchase agreement. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a purchase the closing sale price of the common stock is not below the threshold price as set forth in the purchase agreement. Our sales of shares of common stock to Lincoln Park under the purchase agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then-outstanding shares of the common stock. In connection with the Purchase Agreement, we issued to Lincoln Park 250,000 shares of common stock for no proceeds. The fair value of the 250,000 shares of common stock issued was approximately \$163,000 and was recorded as a commitment fee. Pursuant to the Purchase Agreement, in year ended December 31, 2015, we issued and sold an additional 300,000 shares of common stock to Lincoln Park at a per share price of \$0.45, resulting in gross proceeds of \$135,000.

On May 18, 2015, we raised gross proceeds of \$1.23 million through the private placement of 1,834,299 units of our securities. Each unit consisted of one share of our common stock and a five-year warrant to purchase one-half of one share of our common stock. The purchase price for each unit was \$0.67. The 917,149 warrants issued are exercisable at a price of \$0.85 per share.

On February 19, 2014, we entered into the First Amendment to License Agreement (the "First Amendment"), with Bellco, which amends the License Agreement, entered into as of July 1, 2011. Pursuant to the First Amendment, both parties agreed to extend the term of the License Agreement through December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at our discretion, result in conversion of the license to non-exclusive status. We have agreed to reduce the fixed royalty payment payable to us for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay us a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (approximately \$1.90) per unit; thereafter, €1.25 (approximately \$1.36) per unit. In addition, we received a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that we pursue a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, we will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.

On April 23, 2012, we entered into a License and Supply Agreement (the “License and Supply Agreement”) with Medica, an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica’s proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products (collectively, the “Filtration Products”), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, we agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$1,000,000) for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2015, our aggregate purchase commitments totaled approximately €999,000 (approximately \$1,119,000). For calendar years 2016 through 2022, annual minimum amounts will be mutually agreed upon between Medica and us. In December 2015, we formalized the agreed upon minimum purchase level for 2016 of €1,200,000 with Medica. In exchange for the license, we paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013. As part of the agreement, we have granted to Medica 300,000 options to purchase our common stock which will vest over the first three years of the agreement. As of September 2013, we have an understanding with Medica whereby we have agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

As of the date of this Form 10-K, we expect that the proceeds from the Lambda Class D warrant exercise and the additional warrant exercises that resulted from the tender offer and the projected increase in product sales will allow us to fund our operations at least into the third quarter of 2016, and potentially longer depending on the timing and market up-take of our new products. This assumption excludes the impact of future cash receipts from recurring operations. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in our Company. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$3,815,000 for the year ended December 31, 2015 compared to approximately \$2,495,000 for the year ended December 31, 2014. Excluding the noncash impacts of the change in fair value of the warrant liability and the warrant modification, our net loss was approximately \$3,426,000 for the year ended December 31, 2015 compared to approximately \$3,094,000 for the year ended December 31, 2014, an increase of approximately \$332,000.

In addition to the increase in the net loss, the most significant items contributing to the net increase of approximately \$1,320,000 in cash used in operating activities during the year ended December 31, 2015 compared to the year ended December 31, 2014 are highlighted below: