IRIDEX CORP
Form SC 13G/A
February 12, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13G
(Rule 13d-102)

Information Statement Pursuant to Rules 13d-1 and 13d-2
Under the Securities Exchange Act of 1934
(Amendment No. 1)*

IRIDEX Corp.

(Name of Issuer)

Common Stock

(Title of Class of Securities)

462684101

(CUSIP Number)

December 31st, 2013

Date of Event Which Requires Filing of the Statement

Check the appropriate box to designate the rule pursuant to which this Schedule is filed:

x Rule 13d-1(b)

¨ Rule 13d-1(c)

¨ Rule 13d-1(d)

*The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

1 NAME OF REPORTING PERSON
S.S. OR I.R.S. IDENTIFICATION NO. OF ABOVE PERSON

CLAYTON PARTNERS, LLC

2 CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP

(a) o
(b) o

3 SEC USE ONLY

4 CITIZENSHIP OR PLACE OF ORGANIZATION

DELAWARE

NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH	5	SOLE VOTING POWER 322,012
	6	SHARED VOTING POWER -0-
	7	SOLE DISPOSITIVE POWER 322,012
	8	SHARED DISPOSITIVE POWER -0-

9 AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON

322,012

10 CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES

o

11 PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)

3.28%

12 TYPE OF REPORTING PERSON

IA

Item 1(a) Name of Issuer

IRIDEX Corporation

Item 1(b) Address of Issuer's Principal Executive Offices

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Item 2(a) Name of Person Filing

Clayton Partners, LLC

Item 2(b) Address of Principal Business Office

575 Market Street, Suite 1825
San Francisco, CA 94105

Item 2(c) Citizenship

Delaware

Item 2(d) Title of Class of Securities

Common Stock

Item 2(e) CUSIP Number

462684101

Item 3 If this statement is filed pursuant to Rules 13d-1(b), or 13d-2(b) or (c), check whether the person filing is a:

(a)	o	Broker or dealer registered under Section 15 of the Exchange Act;
(b)	o	Bank as defined in Section 3(a)(6) of the Exchange Act;
(c)	o	Insurance company as defined in Section 3(a)(19) of the Exchange Act;
(d)	o	Investment company registered under Section 8 of the Investment Company Act;
(e)	x	An investment adviser in accordance with Rule 13d-1(b)(1)(ii)(E);
(f)	o	An employee benefit plan or endowment fund in accordance with Rule 13d-1(b)(1)(ii)(F);
(g)	o	A parent holding company or control person in accordance with Rule 13d-1(b)(1)(ii)(G);
(h)	o	A savings association as defined in Section 3(b) of the Federal Deposit Insurance Act;
(i)	o	A church plan that is excluded from the definition of an investment company under Section 3(c)(14) of the Investment Company Act;
(j)	o	Group, in accordance with Rule 13d-1(b)(1)(ii)(J).

If filing as a non-U.S. institution in accordance with Rule 13d-1(b)(1)(ii)(J), please specify the type of institution: _____.

Item 4 Ownership

A. Clayton Partners, LLC

(a) 322,012 Shares

(b) 3.28%

(c) Number of shares as to which such person has:

(i) sole power to vote or to direct the vote: 322,012 Shares

(ii)	shared power to vote or to direct the vote: -0-
(iii)	sole power to dispose or to direct the disposition of: 322,012 Shares
(iv)	shared power to dispose or to direct the disposition of: -0-

Item 5 Ownership of Five Percent or Less of a Class

If this statement is being filed to report the fact that as of the date hereof the reporting person has ceased to be the beneficial owner of more than 5 percent of the class of securities, check the following x.

Item 6 Ownership of More than Five Percent on Behalf of Another Person

Item 7 Identification and Classification of the Subsidiary which Acquired the Security Being Reported on by the Parent Holding Company

Item 8 Identification and Classification of Members of the Group

Item 9 Notice of Dissolution of Group

Item 10 Certification

By signing below I certify that, to the best of my knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect.

After reasonable inquiry and to the best of its knowledge and belief, the undersigned certify that the information set forth in this statement is true, complete and correct.

Clayton Partners, LLC

Dated this 11th day of February, 2014. By: /s/ Jason Stankowski
Jason Stankowski
Partner

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3. 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.

The Company recognizes revenue related to product sales when delivery is confirmed by its external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. Shipments for all products are currently received directly by the Company’s customers.

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters. This agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. The first two payments have been received. The Company recognizes the fixed license revenue on a straight line basis over the forty-two month expected obligation period which ends on December 31, 2014. Any difference between payments received and recognized revenue is reported as deferred revenue.

Deferred revenue on the accompanying September 30, 2012 condensed consolidated balance sheet is approximately $1,585,000 and is related to the License Agreement with Bellco. The total fixed payments to be received as a result of this agreement approximate $2,465,000 and the Company has recognized approximately $874,000 of revenue related to this license agreement to date and approximately $509,000 for the nine months ended September 30, 2012, resulting in $1,585,000 being deferred over the remainder of the expected obligation period and approximately $6,000 was accounted for as foreign exchange gain. The total deferred revenue of $1,585,000 is shown as $704,000 in current liabilities and $881,000 in long-term liabilities on the accompanying September 30, 2012 condensed consolidated balance sheet.

The final guaranteed fixed payment of approximately $771,000 is due in January 2013 and is included in current trade receivables on the accompanying September 30, 2012 condensed consolidated balance sheet.

4. Stock-Based Compensation

The Company accounts for stock option grants to employees and non-employee directors under the provisions of ASC 718, Stock Compensation. ASC 718 requires the recognition of the fair value of stock-based compensation in the statement of operations. In addition, the Company accounts for stock option grants to consultants under the provisions of ASC 505-50, Equity-Based Payments to Non-Employees, and as such, these stock options are revalued at each reporting period through the vesting period.

The fair value of stock option awards is estimated using a Black-Scholes option pricing model. The fair value of stock-based awards is amortized over the vesting period of the award using the straight-line method.

The Company granted 1,547,550 stock options during the nine months ended September 30, 2012 to employees, non-employees, directors and consultants. These stock options vest over a three-year or four-year period and will be expensed over the applicable vesting period. The fair value of all stock-based awards granted during the nine months ended September 30, 2012 was approximately $1,590,986.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

4. Stock-Based Compensation (continued)

The following assumptions were used for options granted for the nine months ended September 30, 2012.

Assumptions for Option Grants	Nine Months Ended September 30, 2012
Risk-free interest rate	0.93 – 1.32%
Volatility	123.48 – 128.54%
Expected dividend yield	0
Expected term	5.75 – 6.25 yrs

The Company calculates expected volatility for a stock-based grant based on historic monthly stock price observations of common stock during the period immediately preceding the grant that is equal in length to the expected term of the grant. The Company also estimates future forfeitures at 5.8% as a part of the estimate of expense as of the grant date. The Company has used historical data to estimate expected employee behaviors related to forfeitures. With respect to grants of options, the risk free rate of interest is based on the U.S. Treasury rates appropriate for the expected term of the grant.

On April 23, 2012, the Company entered into a License and Supply Agreement (the “License and Supply Agreement”) with Medica S.p.A. (“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 the Company’s filtration products. In addition to cash payments as further described in Note 10 Commitments and Contingencies, the Company granted Medica options to purchase 300,000 shares of the Company’s common stock. The fair market value of these stock options was approximately $273,000 at the time of their issuance. The fair market value of the options has been capitalized as a long-term intangible asset along with the total installment payments. Other long-term assets on the accompanying September 30, 2012 condensed consolidated balance sheet is approximately $2,160,000, net of $90,000 accumulated amortization, and is related to the License and Supply Agreement. The asset is being amortized as an expense on a straight-line basis over the life of the agreement. Approximately $90,000 has been charged to amortization expense for the nine months ended September 30, 2012 on the condensed consolidated statement of operations and comprehensive loss. The term of the License and Supply Agreement commenced on April 23, 2012 and continues in effect through December 31, 2022, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

Stock-based compensation expense for the Company was approximately $335,000 and $197,000 for the nine months ended September 30, 2012 and 2011, respectively. This expense is presented in the operating results as approximately $21,000 and $42,000 in the Research and Development expenses and $314,000 and $155,000 in the Selling, General and Administrative expenses for the nine months ended September 30, 2012 and 2011, respectively on the accompanying condensed consolidated statement of operations.

There was no tax benefit related to expense recognized in the nine months ended September 30, 2012 and 2011, as the Company is in a net operating loss position. As of September 30, 2012, there was approximately $1,179,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans which will be amortized over the weighted average remaining requisite service period of 3.2 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the total $1,179,000, the Company expects to recognize approximately 9% in the remaining interim period of 2012, approximately 32% in 2013, approximately 27% in 2014, approximately 26% in 2015, and approximately 6% in 2016.

During the nine months ended September 30, 2012, 22,622,899 warrants were exercised, resulting in proceeds of approximately $451,000 and the issuance of 1,126,425 shares of the Company’s common stock. Additional warrants were exercised subsequent to the balance sheet that resulted in the issuance of 80,854 shares of the Company’s common stock.

5. Comprehensive Income (Loss)

Comprehensive income (loss), as defined in ASC 220, is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)) such as foreign currency translation adjustments. As of September 30, 2012 and December 31, 2011, accumulated other comprehensive income was approximately $56,000 and $49,000, respectively. Accumulated other comprehensive income was impacted by foreign exchange currency translation adjustments in the nine months ended September 30, 2012 and 2011.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

6. Loss per Common Share

In accordance with ASC 260-10, net loss per common share amounts ("basic EPS") are computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution ("diluted EPS") is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. However, because their effect is anti-dilutive, the Company has excluded stock options and warrants aggregating 17,620,657 and 17,546,200 shares, respectively, from the computation of diluted EPS for the nine-month periods ended September 30, 2012 and 2011, respectively.

7. Recently Adopted Accounting Pronouncements

In December 2011, the FASB issued an update on comprehensive income, which pertains to the deferral of the effective date for amendments to the presentation of reclassification of items out of accumulated other comprehensive income in a previous accounting standard update that pertained to the presentation of comprehensive income. The update defers the presentation on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods. All other requirements of the previous accounting standard on the presentation of comprehensive income, issued in June 2011, are not affected. The previous presentation related to the comprehensive income standard requires that entities report components of comprehensive income in either a continuous statement of comprehensive income or two separate but consecutive statements. Under the continuous statement approach, the statement would include the components and total of net income, the components and total of other comprehensive income and the total of comprehensive income. Under the two statement approach, the first statement would include the components and total of net income and the second statement would include the components and total of other comprehensive income and the total of comprehensive income. It does not change the items that must be reported in other comprehensive income and it is effective retrospectively for interim and annual periods beginning after December 15, 2011, with early adoption permitted. The Company adopted the update on January 1, 2012, resulting in no impact to the Company's condensed consolidated balance sheets, statements of operations and comprehensive loss and cash flows.

8. New Accounting Pronouncements

There were various updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

9. Inventory, net

Inventory is stated at the lower of cost or market using the first-in first-out method and consists entirely of finished goods. The Company's inventory as of September 30, 2012 and December 31, 2011 was approximately as follows:

	Unaudited September 30, 2012	Audited December 31, 2011
Total Gross Inventory, finished goods	$ 443,000	$ 465,000
Less: Inventory reserve	(150,000)	(218,000)
Total Inventory	$ 293,000	$ 247,000

10. Commitments and Contingencies

Manufacturing and Suppliers

The Company has not and does not intend in the near future, to manufacture any of its products and components. With regard to the OLpūr MD190 and MD220, on June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where the Company does not sell the Products as well as non-European countries, all such countries herein referred to as the Territory.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

10. Commitments and Contingencies (continued)

In exchange for the rights granted to it under the Bellco License Agreement through December 31, 2014, Bellco agreed to pay Nephros installment payments of €500,000, €750,000, €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. Such installment payments, herein referred to as the Installment Payments, are Bellco's sole financial obligations through December 31, 2014. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay Nephros a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 103,000 units sold, Bellco will pay €4.50 per unit; thereafter, Bellco will pay €4.00 per unit. Bellco must meet minimum sales targets of 15,000 units in each quarter of 2015 and 2016. If Bellco fails to meet a quarterly minimum, the license in Italy, France, Belgium, Spain and Canada will, at our discretion, convert to a non-exclusive one. All sums payable under the agreement will be paid in Euros, as adjusted to account for currency exchange fluctuations between the Euro and the U.S. dollar that occur between July 1, 2011, the effective date of the agreement, and the date of payment.

License and Supply Agreement

On April 23, 2012, the Company entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("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 the Company's 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 the Company 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, the Company granted to Medica an exclusive license under the Company's intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, the Company has agreed to make minimum annual aggregate purchases from Medica of €300,000, €500,000 and €750,000 for the years 2012, 2013 and 2014, respectively. For the nine months ended September 30, 2012, the Company's aggregate purchase commitments totaled approximately €438,000. For calendar years thereafter, annual minimum amounts will be mutually agreed upon between Medica and the Company.

As consideration for the license and other rights granted to the Company, the Company is required to pay Medica installment payments of €500,000 and €1,000,000 on April 23, 2012 and January 25, 2013, respectively. The April 23,

2012 payment was made. The January 25, 2013 payment is included on the accompanying September 30, 2012 consolidated condensed balance sheet as license and supply agreement fee payable of approximately $1,285,000. The total installment payments approximate $1,928,000. As further consideration for the license and other rights granted to the Company, the Company granted Medica options to purchase 300,000 shares of the Company's common stock. The fair market value of these stock options was approximately $273,000 at the time of their issuance, calculated as described in Footnote 4 Stock-based Compensation. The fair market value of the options has been capitalized as a long-term intangible asset along with the total installment payments described. Other long-term assets on the accompanying September 30, 2012 consolidated condensed balance sheet is approximately $2,160,000, net of $90,000 accumulated amortization, and is related to the License and Supply Agreement. The asset is being amortized as an expense over the life of the agreement. Approximately $90,000 has been charged to amortization expense for the nine months ended September 30, 2012 on the consolidated condensed statement of operations and comprehensive loss. In addition, for the period beginning April 23, 2014 through December 31, 2022, the Company will pay Medica a royalty rate of 3% of net sales of the Filtration Products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. The term of the License and Supply Agreement commenced on April 23, 2012 and continues in effect through December 31, 2022, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement. On April 23, 2012, the Company issued a press release announcing its entry into the License and Supply Agreement.

Contractual Obligations

At September 30, 2012, the Company had an operating lease that will expire on November 30, 2012 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately $7,813. On June 26, 2012, the Company signed a one year lease extension for the same office space which will expire on November 30, 2013 with a monthly cost of approximately $8,399 beginning December 1, 2012.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

10. Commitments and Contingencies (continued)

Employment Agreement

On April 20, 2012, the Company entered into an Employment Agreement (the "Employment Agreement"), effective as of April 20, 2012, with Mr. Houghton. The Employment Agreement has a term of four years, ending on April 20, 2016. The Employment Agreement provides that Mr. Houghton's annual base salary will be $350,000. Mr. Houghton will be eligible to receive a target discretionary bonus of 30% of annual base salary, as determined by the Company. The targets with respect to the bonus for the year ending December 31, 2012 were mutually agreed upon between Mr. Houghton and the Compensation Committee of the Board within 60 days following April 20, 2012 and such bonus will be appropriately prorated for such annual period. The targets for each subsequent annual period will be mutually agreed upon at the beginning of each calendar year between Mr. Houghton and the Compensation Committee.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This discussion should be read in conjunction with our consolidated financial statements included in this Quarterly Report on Form 10-Q and the notes thereto, as well as the other sections of this Quarterly Report on Form 10-Q, including the "Risk Factors" section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2011, including the "Risk Factors" and "Business" sections thereof. This discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2011. Our actual results may differ materially.

Business Overview

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers and healthcare facilities for the production of ultrapure water and bicarbonate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they eliminate a wide variety of bacteria, viruses, fungi, parasites, and endotoxins harmful to humans.

All of our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to be the only commercially available filters for healthcare applications that optimize the three elements critical to filter performance:

- Filtration – as low as 0.005 microns
- Flow rate – minimal disruption
- Filter life – up to 12 months

By comparison, competitive filters on the market today are typically effective only to the 0.2 micron level and are prone to clog more quickly, thus reducing their useful lives.

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). In 2009, we began to extend our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Presently, we offer seven types of ultrafilters for sale to customers in four markets:

- *Dialysis Centers – Water/Bicarbonate*: Treatment of both water and bicarbonate for the production of ultrapure dialysate
- *Hospitals and Other Healthcare Facilities*: Removal of infectious agents in drinking and bathing water, particularly in high risk patient areas
- *Military*: Highly compact, individual water purification devices used by soldiers to produce safe drinking water in the field
- *Dialysis Centers – Blood*: Clearance of toxins from blood using an alternative method to HD in patients with chronic renal failure

We have designed our ultrafilters as either in-line products, filters that are incorporated into the existing plumbing of healthcare facilities, or point-of-use products, filters that can be easily installed onto a faucet or as a replacement shower head or can be used stand-alone to purify small quantities of water immediately prior to use.

Dialysis Centers – Water/Bicarbonate. To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce pure water and bicarbonate. Water and bicarbonate are essential ingredients for making dialysate, the liquid that removes waste material from the blood. Within the U.S., there are approximately 5,700 clinics with 100,000 dialysis machines providing over 50 million dialysis treatments to 370,000 patients annually.

Medicare is the main payor for dialysis treatment in the U.S. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate 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 make patients healthier and reduce their dependence on erythropoietin (EPO), an expensive drug 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, cytokine levels within a patient stay low, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient's responsiveness to EPO is enhanced, consequently the overall need for the drug is reduced.

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

Hospitals and Other Healthcare Facilities. According to the United States Centers for Disease Control and Prevention (CDC), healthcare acquired infections (HAIs) annually account for 1.7 million infections, 99,000 deaths, and $4.5 - $6.5 billion in extra costs in U.S. hospitals. At the root of many HAIs are waterborne pathogens such as Legionella and Pseudomonas which can thrive in aging or complex plumbing systems often found in healthcare facilities. According to the CDC, 23% of Legionella infections originate in healthcare facilities and Pseudomonas infections account for 10% of all water-related HAIs. These pathogens are most harmful to patients in intensive care, neonatal, burn, cancer, and transplant units.

The Affordable Care Act (ACA) 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. The ACA encompasses HAIs and shifts the costs associated with their treatment back onto the healthcare provider. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce the potential for HAIs.

Our ultrafilters are designed to reduce the risk of HAIs in the hospital/healthcare setting by treating water just prior to use. Our products can be used for reactive infection control. For example, during acute disease outbreaks (such as Legionnaires' disease), our ultrafilters have been used at hospitals and other healthcare facilities to quickly and efficiently assist in the control of such outbreaks. Our ultrafilters are also being used as a preventative measure in healthcare facilities, particularly in areas where high risk patients are being treated. Our point-of-use filters can be easily installed onto the end of faucets or as replacement shower heads.

Military. 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, resource intensive, and prone to constant supply disruptions.

We offer our individual water purifier (IWP), which allows a soldier in the field to filter fresh water from any source. Our IWP is available in both in-line and point-of-use configurations. Our IWP is one of the few portable filters that has been validated by the military to meet the NSF Protocol P248 standard and could become more widely used by soldiers in the future. To date, we have received purchase orders for approximately 1,300 IWPs from individual units of the U.S. armed forces.

Dialysis Centers – Blood. The current standard of care in the U.S. for patients with chronic renal failure is HD, a process where 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 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 multiple 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 which is more patient-friendly, less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an on-line mid-dilution hemodiafiltration (mid-HDF) system and it consists of our OLpūr H2H Module and OLpūr MD 220 Hemodiafilter. On April 30, 2012, we announced that we received clearance from the U.S. Food and Drug Administration 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. Like HD, on-line mid-HDF treatment is given to patients at least 3 times weekly for 3-4 hours per treatment. Our mid-HDF system is the only HDF system of its kind to be cleared by the FDA to date.

We have not begun to market our mid-HDF system and plan to seek a commercialization partner in the U.S.

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*.

Financial Operations Overview

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

Cost of Goods Sold: Cost of goods sold represents the acquisition cost for the products we purchase from our third party manufacturers as well as damaged and obsolete inventory written off.

Research and Development: Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees of our scientific and engineering consultants and subcontractors and related costs, clinical studies, machine and product parts and software and product testing. We expense research and development costs as incurred.

Selling, General and Administrative: Selling, general and administrative expenses consist primarily of sales and marketing expenses as well as personnel and related costs for general corporate functions, including finance, accounting, legal, human resources, facilities and information systems expense.

Critical Accounting Policies

The discussion and analysis of our consolidated financial condition and results of operations are based upon our condensed consolidated financial statements. These condensed consolidated financial statements have been prepared following the requirements of accounting principles generally accepted in the United States (“GAAP”) and Rule 8-03 of Regulation S-X for interim periods and require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to potential impairment of investments and share-based

compensation expense. As these are condensed consolidated financial statements, you should also read expanded information about our critical accounting policies and estimates provided in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Form 10-K for the year ended December 31, 2011. There have been no material changes to our critical accounting policies and estimates from the information provided in our Form 10-K for the year ended December 31, 2011.

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 quarterly 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, as well as marketing expenses related to product launches. 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.

Three Months Ended September 30, 2012 Compared to the Three Months Ended September 30, 2011

Revenues

Total net revenues for the three months ended September 30, 2012 were approximately $604,000 compared to approximately $407,000 for the three months ended September 30, 2011. Total net revenues increased approximately $197,000. The increase of approximately 48% is due to increased sales of our ultrafilters to Dialysis Centers and Hospitals in the United States of approximately $200,000, initial sales of our water filter products to the U.S. military of approximately $114,000, increased licensing revenue of approximately $133,000 and initial sales of our ultrafilters in Europe of approximately $10,000 for the three months ended September 30, 2012 compared to the same period in 2011. These increases were partially offset by $154,000 less revenue related to the STERIS project and $106,000 less revenue for the ONR project for the three months ended September 30, 2012 compared to the same period in 2011.

Cost of Goods Sold

Cost of goods sold was approximately $191,000 for the three months ended September 30, 2012 compared to approximately $98,000 for the three months ended September 30, 2011. The increase of approximately $93,000, or 95%, in cost of goods sold is primarily related to a $77,000 increase in cost of DSU sales due to increased sales volume and an increase of $81,000 in the cost of sales of water filters to the U.S. military for the three months ended September 30, 2012 compared to the same period in 2011. These increases were partially offset by decreases of approximately $61,000 in costs related to the ONR project for the three months ended September 30, 2012 compared to the same period in 2011.

Research and Development

Research and development expenses were approximately $208,000 and $137,000 for the three months ended September 30, 2012 and September 30, 2011, respectively. This increase of approximately $71,000 or 52% is primarily due to an increase in research and development personnel related costs of approximately $46,000 and an increase in purchases of research and development materials of $25,000 during the three months ended September 30, 2012 compared to the same period in 2011.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately $52,000 for the three months ended September 30, 2012 compared to approximately $23,000 for the three months ended September 30, 2011, an increase of 126%. The increase of approximately $29,000 is due to an increase of $50,000 in amortization expense related to the Medica license and supply agreement. The increase is partially offset by approximately $21,000 less depreciation expense, primarily due to several assets having been fully depreciated as of year-end 2011 resulting in no depreciation expense for those assets during the three months ended September 30, 2012. There were no disposals of assets during the three months ended September 30, 2012.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $1,006,000 for the three months ended September 30, 2012 compared to approximately $574,000 for the three months ended September 30, 2011, an increase of $432,000 or 75%. The increase is due to a $216,000 increase in US personnel costs, an increase of $134,000 in stock compensation expense, an increase of $114,000 in legal fees, an increase of $43,000 in business travel costs, and an

increase of $39,000 in marketing and other US administrative costs. These increases were partially offset by a reduction of $78,000 in recruiting fees, a reduction of $12,000 in insurance expense, a reduction of $15,000 in professional services fees, and a reduction of $9,000 in marketing and administrative costs in Europe.

Interest Income

Interest income was approximately $2,000 for the three months ended September 30, 2011. There was no interest income for the three months ended September 30, 2012.

Interest Expense

We had no interest expense for the three months ended September 30, 2012 and September 30, 2011.

Amortization of Debt Issuance Costs

There was no amortization of debt issuance costs in the three months ended September 30, 2012 and September 30, 2011.

Other income

We had no other income for the three months ended September 30, 2012. Other income in the amount of approximately $10,000 for the three months ended September 30, 2011 related to a foreign currency gain on invoices paid to an international supplier.

Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011

Revenues

Total net revenues for the nine months ended September 30, 2012 were approximately $1,439,000 compared to approximately $1,725,000 for the nine months ended September 30, 2011. Total net revenues decreased approximately $286,000. The decrease of approximately 17% is due to decreased revenue of approximately $721,000 in sales of our MD filters in our Target European Market, due to the Licensing Agreement with Bellco which began July 1, 2011. This decrease was partially offset by increased Licensing revenue of approximately $476,000 for the nine months ended September 30, 2012 compared to the same period in 2011. Sales of our ultrafilters to Dialysis Centers and Hospitals in the United States increased by approximately $270,000 or 65% and initial sales of our water filter products to the U.S. military of approximately $114,000. These increases were offset by decreased revenue of approximately $238,000 less revenue related to the our contract with the office of U.S. Naval Research, and $187,000 less revenue related to the STERIS project for the nine months ended September 30, 2012 compared to the same period in 2011.

Cost of Goods Sold

Cost of goods sold was approximately $448,000 for the nine months ended September 30, 2012 compared to approximately $1,014,000 for the nine months ended September 30, 2011. The decrease of approximately $566,000, or 56%, in cost of goods sold is related to a $582,000 reduction in cost of sales of our MD filters in our Target European Market, due to the Licensing Agreement with Bellco which began July 1, 2011 and a $23,000 decrease in cost of goods sold related to license revenue from that same Agreement for the nine months ended September 30, 2012 compared to the same period in 2011. In addition, the costs related to the ONR project decreased by approximately $136,000 for the nine months ended September 30, 2012 compared to the same period in 2011 due to that project ending as of March 31, 2012. These decreases were partially offset by approximately $94,000 in increased cost of goods sold related to increased DSU sales to Dialysis Centers and Hospitals in the United states and approximately $81,000 increase in cost of goods sold related to the initial sales of water filter products to the U.S. military for the nine months ended September 30, 2012 compared to the same period in 2011.

Research and Development

Research and development expenses were approximately $552,000 and $377,000 for the nine months ended September 30, 2012 and September 30, 2011, respectively. This increase of approximately $175,000, or 46%, is primarily due to an increase in research and development personnel related costs of approximately $69,000 and an increase in purchases of research and development materials of $106,000 during the nine months ended September 30, 2012 compared to the same period in 2011.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately $96,000 for the nine months ended September 30, 2012 compared to approximately $71,000 for the nine months ended September 30, 2011, an increase of 35%. The decrease of approximately $25,000 is primarily due to an increase of $90,000 in amortization expense related to the Medica license and supply agreement. The increase is partially offset by approximately $65,000 less depreciation expense which relates to several assets having been fully depreciated as of year-end 2011 resulting in no depreciation expense for those assets during the nine months ended September 30, 2012. There were no disposals of assets during the nine months ended September 30, 2012.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $2,564,000 for the nine months ended September 30, 2012 compared to approximately $1,932,000 for the nine months ended September 30, 2011, an increase of $632,000 or 33%. The increase is primarily due to a $283,000 increase in US personnel costs, an increase of $173,000 in stock compensation expense, an increase of $245,000 in legal fees, an increase of $83,000 in business travel costs, a $2,000 increase in professional services fees, and an $18,000 increase in US marketing and other administrative costs. These increases were partially offset by a reduction of $34,000 in recruiting fees, a reduction of $33,000 in insurance expense, and a reduction of $105,000 in marketing and administrative costs in Europe during the nine months ended September 30, 2012 compared to the same period in 2011.

Interest Income

Interest income was approximately $2,000 for the nine months ended September 30, 2012 compared to approximately $3,000 for the nine months ended September 30, 2011.

Interest Expense

We had no interest expense for the nine months ended September 30, 2012. Interest expense was approximately $12,000 for the nine months ended September 30, 2011. This interest relates to interest accrued on the $500,000 senior secured note issued to Lambda Investors LLC, which was paid in March 2011.

Amortization of Debt Issuance Costs

There was no amortization of debt issuance costs in the nine months ended September 30, 2012 as there was no debt during that period. Amortization of debt issuance costs of $40,000 for the nine months ended September 30, 2011 is associated with the senior secured note issued to Lambda Investors LLC and paid in March 2011. These capitalized costs were fully amortized as of March 31, 2011.

Other income (expense)

Other income in the amount of approximately $55,000 for the nine months ended September 30, 2012 was comprised of approximately $18,000 of write-offs of old vendor invoices which are no longer due, and approximately $37,000 of net foreign currency gain on the adjustment of the license and supply fee payable to the September 30, 2012 exchange rate and net foreign currency loss on invoices paid to and due to an international supplier Other expense in the amount of approximately $4,000 for the nine months ended September 30, 2011 related to foreign currency loss on invoices paid to an international supplier.

Liquidity and Capital Resources

At September 30, 2012, we had an accumulated deficit of approximately $96,432,000 and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, licensing revenue and the March 2011 rights offering and concurrent private placement.

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

- receipt of scheduled payments per the Bellco S.r.l. license agreement;
- 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/or 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.

At September 30, 2012, we had cash and cash equivalents totaling approximately $366,000 and tangible assets of approximately $1,796,000. Tangible assets consist of total assets of approximately $3,956,000, reduced by other intangible assets (related to the Medica License and Supply Agreement) of approximately $2,160,000.

The Company entered into a License Agreement with Bellco, as licensee, which is discussed in the Business Overview. This Agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. The first two fixed payments have been received. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to Nephros a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. Anticipated payments from this License Agreement would be a positive source of cash flow to the Company.

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, we will be forced to curtail our planned activities and operations or cease operations entirely. There can be no assurance that we will be able to raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately $1,089,000 for the nine months ended September 30, 2012 compared to net cash used in operating activities of approximately $679,000 for the nine months ended September 30, 2011. The most significant items contributing to this increase of approximately $410,000 in cash used in operating activities during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 are highlighted below:

- our net loss increased by approximately $442,000 for the 2012 period compared to the 2011 period;
- during the 2012 period, we had no amortization of debt issuance costs, whereas amortization of debt issuance costs were $40,000 during the 2011 period;
- during the 2012 period, we had no noncash interest, whereas noncash interest was $12,000 during the 2011 period;
- our inventory increased by approximately $47,000 during the 2012 period compared to a decrease of approximately $350,000 during the 2011 period;
- during the 2012 period, we had approximately $3,000 of gain on translation adjustments; and
- during the 2012 period, we recorded deferred revenue of approximately $542,000, whereas deferred revenue in the 2011 period was approximately $37,000;

Offsetting the above changes are the following items:

- our noncash stock-based compensation expense increased by approximately $138,000 for the 2012 period compared to the 2011 period;
- our accounts receivable decreased by approximately $852,000 during the 2012 period compared to a decrease of approximately $137,000 during the 2011 period;
- depreciation and amortization expense increased by approximately $25,000 for the 2012 period compared to the 2011 period;
- our accounts payable and accrued expenses increased by approximately $286,000 in the aggregate in the 2012 period compared to a decrease of approximately $306,000 in the 2011 period; and
- our prepaid expenses and other current assets decreased by approximately $65,000 in the 2012 period compared to a decrease of approximately $58,000 in the 2011 period.

Net cash used in investing activities for the nine months ended September 30, 2012 was approximately $666,000 due to $7,000 used for the purchase of equipment and $659,000 for the purchase of intangible assets associated with the Medica License and Supply Agreement. We used no net cash in investing activities during the 2011 comparable period.

Net cash provided by financing activities for the nine months ended September 30, 2012 resulted from the exercise of warrants, providing approximately $451,000. Net cash provided by financing activities was approximately $2,550,000 for the nine months ended September 30, 2011, resulting from the issuance of stock and warrants, providing cash of $3,190,000, which was offset by the payment of debt of $500,000 and the payment of deferred financing costs of $140,000.

Safe Harbor for Forward-Looking Statements

This report contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended (the “PSLRA”). Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for the continued development of such products 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,” “potential” or similar words. For such statement claim the protection of the PSLRA. 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 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 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 encounter problems with our suppliers and manufacturers;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- 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 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 us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements contained in this Quarterly Report on Form 10-Q, is set forth in our filings 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. 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.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the nine month period ended September 30, 2012 and 2011.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Required.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which is designed to provide reasonable assurance that information required to be disclosed in our reports filed pursuant to the Exchange Act is accumulated and communicated to management in a timely manner. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud have been or will be detected. At the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures pursuant to Securities and Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, has concluded that there were no changes in our internal control over financial reporting, that occurred during the quarter ended September 30, 2012, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Through the evaluation of the Sarbanes-Oxley internal control assessment, a more structured approach, including checklists, reconciliations and analytical reviews, has been implemented to reduce risk in the financial reporting process.

PART II - OTHER INFORMATION

Item 1. 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 1A. Risk Factors

The following risk factors replace the risk factors contained in the Company's Form 10-K for the year ended December 31, 2011 in Item 1A in their entirety:

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, 2011, expressed substantial 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 financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011 expressing doubt as to our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. However, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

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

We have not been profitable since our inception in 1997. As of September 30, 2012, we had an accumulated deficit of approximately $96,458,000, primarily 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.

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

Our products are new to the market, and we do not yet have an established market or customer base for our products. Acceptance of our 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. If we fail to successfully commercialize our products, then we will not be profitable.

We expect to rely on a limited number of independent manufacturers to produce our 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 and, in either case, our sales and revenues will suffer.

Our strategy requires us to distribute our products and provide a significant amount of customer service and maintenance and other technical service. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure 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, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, "European Community"), for our OLpur MDHDF filter series product and our Dual Stage Ultrafilter ("DSU"). We have not yet obtained the CE mark for any of our other products. Recently, we received clearance from the FDA to market our OLpūr MD 220 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 yet begun to market these products 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.

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

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

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;
- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and
- if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to gain market acceptance of our medically approved 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 medically approved products.

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

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

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

- to obtain product liability insurance; or
- to indemnify manufacturers against liabilities resulting from the sale of our products.

For example, the agreement with our contract manufacturer, or CM, requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, provided they do not arise out of our CM's breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, then we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

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

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

- fines;
- injunctions;
- civil penalties;
- recalls or seizures of products;
- total or partial suspension of the production of our products;
- withdrawal of any existing approvals or pre-market clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations that we not be allowed to enter into government contracts; and
- criminal prosecution.

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

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

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

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

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 16 granted U.S. patents will expire at various times from 2018 to 2026, 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, or GMP. 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 MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. 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.

Risks Related to Owning Our Common Stock

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

Our Common Stock currently does not meet all of the requirements for initial listing on a registered stock exchange. Our Common Stock is quoted on the OTC Bulletin Board. Trading in our Common Stock on the OTC Bulletin Board 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.

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

In the 33 months ended September 30, 2012, our Common Stock has traded at prices ranging from a high of $2.25 to a low of $0.02 per share, after giving effect to the 1:20 reverse stock split effected on March 11, 2011. 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.

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

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

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

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

If management is unable to express a favorable opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

Our directors, executive officers and Lambda Investors LLC 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 September 30, 2012, our directors, executive officers and Lambda Investors LLC, our largest stockholder, beneficially owned approximately 33% of our outstanding Common Stock, representing approximately 56% on a fully-diluted basis.

As a result of this ownership, Lambda Investors has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda Investors, 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 Investors, 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 Investors 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 Investors 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.

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 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.

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 6. Exhibits

EXHIBIT INDEX

10.1	Non-Qualified Stock Option Agreement, made as of July 3, 2012, between Nephros, Inc. and John C. Houghton
31.1	Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications by the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NEPHROS, INC.

Date: November 9, 2012 By: /s/ John C. Houghton
Name: John C. Houghton
Title: President and Chief Executive Officer (Principal Executive Officer)

Date: November 9, 2012 By: /s/ Gerald J. Kochanski
Name: Gerald J. Kochanski
Chief Financial Officer (Principal Financial and

Accounting Officer)

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