

NEPHROS INC  
Form 10-Q  
May 15, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended: **March 31, 2015**

OR

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32288

**NEPHROS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**DELAWARE**

**13-3971809**

(State or Other Jurisdiction of Incorporation or Organization)(I.R.S. Employer Identification No.)

**41 Grand Avenue**

**07661**

**River Edge, NJ**

(Address of Principal Executive Offices)

(Zip code)

**(201) 343-5202**

Registrant's Telephone Number, Including Area Code

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days

YES     NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

YES     NO

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

Large accelerated filer

Accelerated filer

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES     NO

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As of May 8, 2015, 30,393,640 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

**Table of Contents**

	<b>Page No.</b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets - March 31, 2015 (unaudited) and December 31, 2014 (audited)</u>	2
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss - Three months ended March 31, 2015 and 2014 (unaudited)</u>	3
<u>Consolidated Statement of Changes in Stockholders' Deficit – Three months ended March 31, 2015 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows - Three months ended March 31, 2015 and 2014 (unaudited)</u>	5
<u>Notes to Unaudited Condensed Consolidated Interim Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	23
<b><u>PART II - OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	24
Item 6. <u>Exhibits</u>	24
<u>SIGNATURES</u>	25

**PART I - FINANCIAL INFORMATION****Item 1. Financial Statements.****NEPHROS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share amounts)**

	(Unaudited) March 31, 2015	(Audited) December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash	\$ 367	\$1,284
Accounts receivable, net	334	110
Inventory, net	208	186
Prepaid expenses and other current assets	82	104
Total current assets	991	1,684
Property and equipment, net	-	1
Other assets, net of accumulated amortization	1,631	1,684
Total assets	\$ 2,622	\$3,369
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 754	\$835
Accrued expenses	432	342
Deferred revenue, current portion	70	70
Total current liabilities	1,256	1,247
Warrant liability	6,377	7,386
Long-term portion of deferred revenue	400	417
Total liabilities	8,033	9,050

**Commitments and Contingencies**

## Stockholders' deficit:

Preferred stock, \$.001 par value; 5,000,000 shares authorized at March 31, 2015 and December 31, 2014; no shares issued and outstanding at March 31, 2015 and December 31, 2014

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Common stock, \$.001 par value; 90,000,000 shares authorized at March 31, 2015 and December 31, 2014; 30,392,480 and 30,391,513 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively.	30	30
Additional paid-in capital	108,409	108,382
Accumulated other comprehensive income	72	72
Accumulated deficit	(113,922 )	(114,165 )
Total stockholders' deficit	(5,411 )	(5,681 )
Total liabilities and stockholders' deficit	\$ 2,622	\$3,369

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*

## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Net revenues:		
Product revenues	\$ 527	\$ 219
License revenues	17	254
Total net revenues	544	473
Cost of goods sold	262	106
Gross margin	282	367
Operating expenses:		
Research and development	192	163
Depreciation and amortization	53	55
Selling, general and administrative	843	711
Total operating expenses	1,088	929
Loss from operations	(806	) (562
Change in fair value of warrant liability	1,009	(2,751
Interest expense	(11	) (195
Other income (expense)	51	(3
Net income (loss)	243	(3,511
Other comprehensive loss, foreign currency translation adjustments	-	(1
Total comprehensive income (loss)	\$ 243	\$ (3,512
Net income (loss) per common share, basic	\$ 0.01	\$ (0.19
Weighted average common shares outstanding, basic	30,259,823	18,816,746
Net loss per common share, diluted	\$ (0.02	) \$ (0.19
Weighted average common shares outstanding, diluted	37,082,499	18,816,746

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2014 (audited)	30,391,513	\$ 30	\$ 108,382	\$ 72	\$ (114,165 )	\$ (5,681)
Net income					243	243
Exercise of warrants	967		1			1
Noncash stock-based compensation			26			26
Balance, March 31, 2015	30,392,480	\$ 30	\$ 108,409	\$ 72	\$ (113,922 )	\$ (5,411)

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*



## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Operating activities:		
Net income (loss)	\$243	\$(3,511)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation of property and equipment	1	2
Amortization of other assets	52	53
Noncash stock-based compensation, including stock options and restricted stock	26	120
Change in fair value of warrant liability	(1,009)	2,751
Amortization of debt discount	-	142
Inventory reserve	(2 )	17
(Gain)/loss on foreign currency transactions	(40 )	1
(Increase) decrease in operating assets:		
Accounts receivable	(224 )	(355 )
Inventory	(20 )	(46 )
Prepaid expenses and other current assets	22	53
Increase (decrease) in operating liabilities:		
Accounts payable	(39 )	(40 )
Accrued expenses	90	(172 )
Deferred revenue	(17 )	363
Net cash used in operating activities	(917 )	(622 )
Financing activities:		
Proceeds from issuance of common stock, net of equity issuance costs of \$125	-	2,016
Proceeds from exercise of warrants	1	1
Payment of senior secured note	-	(1,500)
Net cash provided by financing activities	1	517
Effect of exchange rates on cash	(1 )	(1 )
Net decrease in cash	(917 )	(106 )
Cash, beginning of period	1,284	579
Cash, end of period	\$367	\$473
Supplemental disclosure of cash flow information		
Cash paid for interest	\$14	\$77

*The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.*



**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 1 – Organization and Nature of Operations**

Nephros, Inc. (“Nephros” or the “Company”) was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease (“ESRD”) therapy technology and products. The Company has two products in the hemodiafiltration, or HDF, modality to deliver therapy for ESRD patients. These are the OLpūr mid-dilution HDF filter or “dialyzer,” designed expressly for HDF therapy, and the OLpūr H2H HDF module, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy. In 2009, the Company introduced its Dual Stage Ultrafilter (“DSU”) water filter, which represented a new and complementary product line to the Company’s ESRD therapy business. The DSU incorporates the Company’s unique and proprietary dual stage filter architecture.

On June 4, 2003, Nephros International Limited was incorporated under the laws of Ireland as a wholly-owned subsidiary of the Company. In August 2003, the Company established a European Customer Service and financial operations center in Dublin, Ireland.

**Note 2 – Basis of Presentation and Going Concern**

**Interim Financial Information**

The accompanying unaudited condensed consolidated interim financial statements of Nephros, Inc. and its wholly owned subsidiary, Nephros International Limited (collectively, the “Company” or “Nephros”) should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2014 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on April 15, 2015. In the Company’s Annual Report on Form 10-K for the year ended December 31, 2014, the Company restated (i) its audited consolidated financial statements as of and for the years ended December 31, 2013, 2012, 2011, 2010 and 2009, including the cumulative effect as of January 1, 2009, and (ii) its unaudited condensed consolidated interim financial statements as of, and for each of the quarterly periods ended, March 31, June 30, and September 30, in the years 2014 and 2013. The restatement results from the Company’s prior accounting for certain outstanding common stock purchase warrants originally issued in November 2007 as components of equity instead of as derivative liabilities.

Accordingly, certain amounts as of and for the quarter ended March 31, 2014 presented herein reflect these previously restated amounts. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying condensed consolidated interim financial statements do not include all of the information and notes required by GAAP for a complete financial statement presentation. The condensed consolidated balance sheet as of December 31, 2014 was derived from the Company’s audited consolidated financial statements but does not include all disclosures required by GAAP. In the opinion of management, the condensed consolidated interim financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. Certain reclassifications were made to the prior year’s amounts to conform to the 2015 presentation. All intercompany transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. Included in these estimates are assumptions about the valuation of the warrant liability, the collection of accounts receivable, value of inventories, useful life of fixed assets and intangible assets, and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate.

### **Going Concern and Management’s Response**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company’s recurring operating losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The Company’s condensed consolidated interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has incurred significant losses in operations in each quarter since inception. To become profitable, the Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

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

**Note 3 – Concentration of Credit Risk**

For the three months ended March 31, 2015 and 2014, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2015	2014
A	30 %	9 %
B	28 %	25 %
C	18 %	- %
D	3 %	54 %

As of March 31, 2015 and December 31, 2014, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2015	2014
A	35 %	22 %
B	17 %	- %
C	16 %	- %
D	12 %	25 %
E	- %	35 %

**Note 4 – 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 the Company. Shipments for all products are currently received directly by the Company's customers.

Deferred revenue on the accompanying March 31, 2015 condensed consolidated balance sheet is approximately \$470,000 and is related to the License Agreement with Bellico, which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,606,000 of revenue related to the License Agreement to date and approximately \$17,000 for the three months ended March 31, 2015. The Company recognized approximately \$254,000 of revenue related to this License Agreement for the three months ended March 31, 2014. Revenue recognized in the three months ended March 31, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the License Agreement were fully recognized as revenue as of December 31, 2014. Approximately \$52,000 of revenue will be recognized in the remaining nine months of fiscal year 2015 and approximately \$69,000 of revenue will be recognized in each of the years ended December 31, 2016 through 2021. See Note 11, Commitments and Contingencies, for further discussion of the Bellico License Agreement.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 5 – Fair Value of Financial Instruments**

The carrying amounts of cash, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments.

The Company's outstanding warrants that were originally issued in 2007 (the "2007 Warrants") are accounted for as a derivative liability because the transactions that would trigger the anti-dilution adjustment provision in the 2007 Warrants are not inputs to the fair value of the warrants. The 2007 Warrants are recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in changes in fair value of warrant liability in the Company's consolidated statement of operations and comprehensive income (loss) in each subsequent period. The Company utilizes a binomial options pricing model to value the 2007 Warrants at each reporting period.

The fair value guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The estimated fair value of the 2007 Warrants is determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield

curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 (in thousands):

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At March 31, 2015:				
Warrant liability	\$-	\$ -	\$ 6,377	\$6,377

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2014:				
Warrant liability	\$-	\$ -	\$ 7,386	\$7,386



**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 5 – Fair Value of Financial Instruments (continued)**

On the condensed consolidated statement of operations for the three month periods ended March 31, 2015 and 2014, the Company recorded income of \$1,009,000 and expense of \$2,751,000, respectively, as a result of the change in fair value of the warrant liability.

The following table summarizes the calculated aggregate fair values of the warrants, along with the assumptions utilized in each calculation:

	March 31, 2015	December 31, 2014		
Calculated aggregate value	\$6,377	\$ 7,386		
Weighted average exercise price	\$0.30	\$ 0.30		
Closing price per share of common stock	\$0.60	\$ 0.79		
Volatility	138 %	165.6 %		
Weighted average remaining expected life (years)	4.7	5.0		
Risk-free interest rate	1.4 %	1.8 %		
Dividend yield	-	-		

**Note 6 – Stock-Based Compensation****Stock Options**

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 calculates expected volatility for a stock-based grant based on historic monthly common stock price observations 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, using historical employee behaviors related to forfeitures, as a part of the estimate of expense as of the grant date. 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.

Stock-based compensation expense was approximately \$20,000 and \$118,000 for the three months ended March 31, 2015 and 2014, respectively. For the three months ended March 31, 2015, approximately \$16,000 and approximately \$4,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. For the three months ended March 31, 2014, approximately \$110,000 and approximately \$8,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations.

There was no tax benefit related to expense recognized in the three months ended March 31, 2015 and 2014, as the Company is in a net operating loss position. As of March 31, 2015, there was approximately \$111,000 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 3.1 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$111,000 of total unrecognized compensation cost, the Company expects to recognize approximately 65% in the remaining interim periods of 2015, approximately 27% in 2016 and approximately 8% in 2017.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 6 – Stock-Based Compensation (continued)**

**Restricted Stock**

Total stock-based compensation expense for the restricted stock grants was approximately \$6,000 for the three months ended March 31, 2015 and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statement of operations. As of March 31, 2015, there was approximately \$2,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next three months.

**Note 7 – Warrants**

For the three months ended March 31, 2015, 20,927 warrants were exercised, resulting in proceeds of approximately \$1,000 and the issuance of 967 shares of the Company's common stock.

**Note 8 – Net Income (Loss) per Common Share**

Basic income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted earnings (loss) per common share is calculated by dividing net income (loss) available to common shareholders, adjusted for the change in the fair value of the warrant liability by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants, as applicable. The Company calculates dilutive potential common shares using the treasury stock method, which assumes the Company will use the proceeds from the exercise of stock options and warrants to repurchase shares of common stock to hold in its treasury stock reserves.

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For the three months  
 March 31,      March 31,  
 2015              2014

Loss per share – Basic:

Numerator for basic income (loss) per share	\$243,000	\$(3,511,000 )
Denominator for basic income (loss) per share	30,259,823	18,816,746
Basic income (loss) per common share	\$0.01	\$(0.19 )

Loss per share – Diluted:

Numerator for diluted income (loss) per share	\$243,000	\$(3,511,000 )
Adjust: Change in fair value of dilutive warrants outstanding	(1,009,000 )	2,751,000
Numerator for diluted income (loss) per share	\$(766,000 )	\$(760,000 )

Denominator for basic income (loss) per share	30,259,823	18,816,746
Plus: Incremental shares underlying warrants outstanding	6,822,676	-
Denominator for diluted income (loss) per share	37,082,499	18,816,746
Diluted income (loss) per common share	\$(0.02 )	\$(0.19 )

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive:

	March 31,	
	2015	2014
Shares underlying warrants outstanding	5,009,848	16,820,281
Shares underlying options outstanding	2,094,562	2,375,748
Unvested restricted stock	132,077	59,199

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 9 – Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, "Revenue from Contracts with Customers," related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and it is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated financial statements.

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

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

**Note 10 – 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 March 31, 2015 and December 31, 2014 was as follows:

	March 31, 2015 (Unaudited)	December 31, 2014 (Audited)
Total Gross Inventory, Finished Goods	\$ 308,000	\$297,000
Less: Inventory reserve	(100,000 )	(111,000)
Total Inventory	\$ 208,000	\$186,000

## Note 11 – 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 OLpur 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 (referred to as the "Territory").

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the "First Amendment"), by and between the Company and Bellco, which amends the License Agreement. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. The Company has agreed to reduce the fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (approximately \$1.90) per unit; thereafter, €1.25 (approximately \$1.36) per unit. In addition, the Company received a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that the Company pursues a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, the Company will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.



**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 11 – Commitments and Contingencies (continued)**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 agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$880,000) for the years 2012, 2013 and 2014, respectively. In the three months ended March 31, 2015, the Company’s aggregate purchase commitments totaled approximately €243,000 (approximately \$265,000). For calendar years 2015 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. The annual minimum amount for calendar 2015 is €1,000,000 (approximately \$1,085,000). In exchange for the license, the Company paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013.

As 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 Note 6 under 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 consolidated balance sheet is approximately \$1,631,000, net of \$619,000 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 \$52,000 has been charged to amortization expense in each of the three month periods ended March 31, 2015 and 2014 on the consolidated statement of operations and comprehensive loss. Approximately \$158,000 of amortization expense will be recognized in the remaining nine months of fiscal year 2015 and approximately \$210,000 of amortization expense will be recognized in each of the years ended December 31, 2016 through 2022. 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.

The Company has an understanding with Medica whereby the Company has agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

**NEPHROS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**Note 12 – Subsequent Events**

The Board appointed Daron Evans as the Company's President and Chief Executive Officer, as well as its Acting Chief Financial Officer, effective April 15, 2015. Upon his appointment as President and Chief Executive Officer, Mr. Evans resigned as Chairman of the Board. Lawrence J. Centella, a member of the Board since 2001, was appointed Chairman of the Board. Mr. Evans succeeds Paul A. Mieyal, who had been serving as the Company's Acting President, Chief Executive Officer and Chief Financial Officer since January 2015. Dr. Mieyal resigned from such offices as of the Effective Date, but continues to serve as a member of the Board.

The terms of Mr. Evans' employment with the Company are set forth in an Employment Agreement dated as of April 15, 2015 (the "Employment Agreement"). The Employment Agreement provides for a four-year term expiring on April 14, 2019 (the "Term"), unless sooner terminated by either party. Pursuant to the Employment Agreement, Mr. Evans will receive an initial annualized base salary of \$240,000 and will be eligible to receive an annual performance bonus of up to 30% of his annualized base salary. At such time that the Company begins trading its shares on a national securities exchange, the Board may review and adjust Mr. Evans' base salary to a market competitive level. In addition, Mr. Evans was granted a 10-year stock option to purchase an aggregate of 2,184,193 shares of the Company's common stock pursuant to the Company's 2015 Equity Incentive Plan. 50% of the options will vest upon the achievement of annual revenue targets of \$3,000,000, \$6,000,000 and \$10,000,000; 15% of the options will vest upon the Company listing on a national securities exchange; and 35% of the options will vest over four years in 16 equal, quarterly installments. The option is exercisable at a price of \$0.60 per share, which represents the closing sale price of the Company's common stock on April 15, 2015.

On May 4, 2015, the Company entered into a Second Amendment to License and Supply Agreement (the "Second Amendment") with Medica S.p.A. ("Medica"). Pursuant to the Second Amendment, the Company and Medica agreed that the total minimum amount of purchases by the Company from Medica for calendar year 2015 will be €1,000,000 (approximately \$1,085,000). Additionally, the Company and Medica agreed that Italy will continue to be excluded from the worldwide license, and that, until December 31, 2022, the Company will pay Medica a royalty of 3% of net sales, in addition to any other payments required, except that if the Company sublicenses to a third party the right to market and sell its HydraGuard products, the Company will pay Medica a fee of €2.00 (approximately \$2.17) per HydraGuard unit in lieu of the 3% royalty.

On May 6, 2015, the Company entered into a Sublicense Agreement with CamelBak Products, LLC (“CamelBak”). Under this Sublicense Agreement, the Company granted to CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the Company’s HydraGuard individual water treatment devices. The sublicensed intellectual property is licensed to the Company by Medica pursuant to the License and Supply Agreement, as amended, between the Company and Medica, which granted the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell certain filtration products based upon Medica’s proprietary Medisulfone ultrafiltration technology in combination with the Company’s filtration products, which includes the HydraGuard individual water treatment devices.

In exchange for the rights granted to CamelBak, CamelBak agreed to pay the Company a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay the Company a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to the Company, and if such fees are not met or exceeded, the Company may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. Additionally, the Company has the right to terminate the sublicense with respect to a specific geographic area if CamelBak enters into an agreement or otherwise obtains or develops the rights to market or sell a product that competes with the HydraGuard individual water treatment devices in such geographic area. If the Company does not terminate the sublicense in such situation, and the sales of the competing product in such geographic area exceed the sales of the HydraGuard individual water treatment devices in the same area during any full calendar year, the Company may convert the exclusive sublicense to a non-exclusive sublicense solely with respect to such geographic area. The Sublicense Agreement will expire on December 31, 2022, unless earlier terminated in accordance with the terms of the Sublicense Agreement.

On May 7, 2015, the Board appointed Malcolm Persen as a director of the Company. Mr. Persen was also appointed to serve as the Chair of the Audit Committee of the Board. The Company will provide Mr. Persen with the standard compensation and indemnification approved for non-employee directors.

On May 12, 2015, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain purchasers identified therein. Pursuant to the Purchase Agreement, the Company agreed to issue and sell, and the purchasers agreed to purchase, an aggregate of approximately 1.8 million shares at a price of \$0.67 per share for total gross proceeds of approximately \$1.2 million. In addition, the Company will issue to the purchasers warrants to purchase approximately 0.9 million shares of common stock. The warrants will have an exercise price of \$0.85 per share and will be exercisable for 5 years from the closing date. The purchase and sale of the shares and warrants is expected to close on or about May 15, 2015, subject to satisfying customary closing conditions.

## **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 “Forward-Looking Statements” section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2014, 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, 2014. Our actual results may differ materially.*

### **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 and sell 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.

### **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 for the removal of biological

contaminants from water, bicarbonate concentrate and/or blood. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to 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

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

## Our Products

Presently, we offer ultrafilters for sale to customers in five markets:

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

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

*Dialysis Centers - Blood:* Treatment of patients with chronic renal failure using the OLpür H2H Hemodiafiltration, or HDF, Module in conjunction with a UF controlled hemodialysis machine and its accessories, the H2H Module accessories, appropriately prepared water and ultrapure dialysate for hemodialysis and the OLpür MD 220 Hemodiafilter.

*Military and Outdoor Recreation:* Highly compact, individual water purification devices used by soldiers and backpackers to produce drinking water in the field.

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



## Our Target Markets

*Hospitals and Other Healthcare Facilities.* According to the American Hospital Association there are approximately 5,700 hospitals and 920,000 beds in the U.S. and the United States Centers for Disease Control and Prevention estimates that healthcare associated infections (“HAI”) annually account for 1.7 million infections and 99,000 deaths. HAIs affect patients in a hospital or other healthcare facility, and are not present or incubating at the time of admission. They also include infections acquired by patients in the hospital or facility but appearing after discharge, and occupational infections among staff. Many HAIs are waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities. The Affordable Care Act, which was passed in March 2010, puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce the potential for HAIs. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the point of delivery, for example, from sinks and showers.

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

We anticipate that the impact of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (“ASHRAE”) proposed Standard 188, “Prevention of Legionellosis Associated with Building Water Systems”, when adopted, will be positive for the point of delivery filtration market. We will be enhancing our efforts to support our distributors by developing and delivering focused sales training to their sales forces on the use of our filters to support an overall program of infection risk prevention, as well as by offering the services of our sales representatives to jointly call on potential hospital customers to serve as a product expert when needed.

*Dialysis Centers - Water/Bicarbonate.* To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate. Water and bicarbonate concentrate are essential ingredients for making dialysate, the liquid that removes waste material from the blood. Within the U.S., there are approximately 6,000 clinics with 100,000 dialysis machines providing over 50 million dialysis treatments to 400,000 patients annually.

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

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

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

During March 2014 we signed a non-exclusive distributor agreement with Mar Cor Purification, a wholly-owned subsidiary of Cantel Medical Corp., to distribute our dialysis ultrafilters to U.S. and Canadian dialysis clinics. In July 2014, we received notification from Health Canada Therapeutic Products Directorate Medical Devices Bureau that we were successfully issued a license for our Single Stage Ultrafilter (“SSU”).

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



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

- Enhanced clearance of middle and large molecular weight toxins
- Improved survival - up to a 35% reduction in mortality risk
- Reduction in the occurrence of dialysis-related amyloidosis
- Reduction in inflammation
- Reduction in medication such as EPO and phosphate binders
- Improved patient quality of life
- Reduction in number of hospitalizations and overall length of stay

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

We have developed a modified approach to HDF that we believe is more patient-friendly, less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration (mid-dilution HDF) system and it consists of our OLpūr H2H Module and OLpūr MD 220 Hemodiafilter. The OLpūr H2H HDF Module and OLpūr MD 220 Hemodiafilter are cleared by the FDA to market for use with a ultrafiltration controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States. Our on-line mid-dilution HDF system is the only on-line mid-dilution HDF system of its kind to be cleared by the FDA to date.

We completed preparation of our OLpūr H2H HDF Modules and have manufactured lots of our OLpūr MD220 Hemodiafilters, H2H Substitution filters and H2H water filters. We also finalized our service contract to support the commercialization of our system in the field. In May 2014, DaVita Healthcare Partners announced that it had commenced delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select patients at DaVita’s North Colorado Springs Clinic. In February 2015, we announced that, in the course of the evaluation, DaVita

informed Nephros that they would require additional validation of the system. Nephros and DaVita agreed upon a protocol for the additional validation work which was completed in March. We have submitted the data report to DaVita, and have been informed that it is still under review. Upon confirmatory review of the additional validation work, it is anticipated that DaVita will continue its evaluation. In March 2015, we announced that the Renal Research Institute, a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. We also anticipate evaluating our on-line mid-dilution HDF system at other clinics throughout the U.S. with the intent of developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of improving the quality of life for the patient, reducing overall expenditure compared to other dialysis modalities, minimizing the impact on nurse work flow at the clinic, and demonstrating the phamacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems.

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

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

In February 2013, Nephros submitted its response to a U.S. Army request for proposal (RFP) relating to IWTDs (W911QY-13-R-0011). In March 2013, we received notification from the U.S. Army that the Government had completed the initial evaluation of our proposal and found Nephros to be within the competitive range to commence negotiations. On July 10, 2014, we received notification from the U.S. Army Contracting Command that discussions with offerors, who remain within the competitive range, had concluded. On August 29, 2014 we received Amendment 0005 to the IWTD solicitation, which notified offerors that the Government had cancelled the solicitation, as of the date of the amendment. Per subsequent discussions with the U.S. Army, they informed us that they planned to re-visit the requirements for the IWTD and re-solicit the requirements in a new RFP at a future date.

In October 2014, the U.S. Army re-solicited for proposal via RFI (Request for Information) with updated requirements for the IWTD. In the RFI pricing was also a request for a purchase of 50 devices for testing and evaluation for the selected devices. We believe that the Nephros HydraGuard Purifiers meet the requirements provided in the RFI and thus submitted a response to the RFI in November 2014. In January 2015, we received a Purchase Order from the U.S. Army and provided 50 devices for testing and evaluation.

On May 6, 2015, we entered into a Sublicense Agreement with CamelBak Products, LLC (“CamelBak”). Under this Sublicense Agreement, we granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the HydraGuard individual water treatment devices. In exchange for the rights granted to CamelBak, CamelBak agreed to pay us a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay us a fixed per-unit fee for any other sales made. CamelBak is also required to meet or exceed certain minimum annual fees payable to us, and if such fees are not met or exceeded, we may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. Additionally, we have the right to terminate the sublicense with respect to a specific geographic area if CamelBak enters into an agreement or otherwise obtains or develops the rights to market or sell a product that competes with the HydraGuard individual water treatment devices in such geographic area. If we do not terminate the sublicense in such situation, and the sales of the competing product in such geographic area exceed the sales of the HydraGuard individual water treatment devices in the same area during any full calendar year, we may convert the exclusive sublicense to a non-exclusive sublicense solely with respect to such geographic area.

*Commercial Facilities.* In October 2013, we announced the voluntary recalls of our point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. As a result, we recalled all production lots of our POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, for the DSU in-line ultrafilter, we also requested that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect our dialysis products. On March 20, 2014, we requested termination of our product recall from the FDA. As of the date of this report, there has been no additional communication from the FDA.

We have launched our new NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is to be used for non-medical drinking and washing in non-transient non-community water systems, or commercial facilities. The NanoGuard-D and NanoGuard-S trap particulates greater than 5nm in size and the water permeability (the ease at which water can pass through a membrane at a given pressure) of the membrane is higher than membranes with a similar pore size. This provides improved flow performance relative to the physical size of the filter. We anticipate that the filters will be used as a component of a facility water treatment system and also for filtering water to be used in ice machines and soda fountains.

With respect to public drinking water systems, EPA regulations make a distinction between community and non-community systems. A community water system supplies water to the same population year-round. It serves at least 25 people at their primary residences or at least 15 residences that are primary residences. Community water

systems include those that supply municipalities, mobile home parks, and residential sub-divisions.

Non-community water systems are composed of transient and non-transient water systems:

Transient non-community water systems provide water to 25 or more people for at least 60 days/year; however, not to the same people and not on a regular basis, e.g. gas stations, campgrounds.

Non-transient non-community water systems regularly supply water to at least 25 of the same people at least six months per year, but not year-round, e.g. office buildings, schools, hotels and factories which have their own water systems.

### **Critical Accounting Policies**

The discussion and analysis of our consolidated financial condition and results of operations are based upon our condensed consolidated interim 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, 2014. 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, 2014.

## **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, "Revenue from Contracts with Customers," related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and it is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. We are currently reviewing the revised guidance and assessing the potential impact on our consolidated financial statements.

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

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

## **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 March 31, 2015 Compared to the Three Months Ended March 31, 2014***

*Revenues*

Total net revenues for the three months ended March 31, 2015 were approximately \$544,000 compared to approximately \$473,000 for the three months ended March 31, 2014. Total net revenues increased approximately \$71,000 or 15%, arising from a 140% increase, or approximately \$308,000, in higher water filter sales on dialysis and commercial water partially offset by a 93% decrease, or approximately \$237,000, in licensing revenue related to the Bellco license agreement. The increase in water filter sales was primarily driven by an increase in sales in the hospital market resulting from the DSU-H and SSU-H product launch following the FDA 510k clearance in October 2014. Revenue recognized related to the Bellco license agreement in the three months ended March 31, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the Bellco license agreement were fully recognized as revenue as of December 31, 2014.

*Cost of Goods Sold*

Cost of goods sold was approximately \$262,000 for the three months ended March 31, 2015 compared to approximately \$106,000 for the three months ended March 31, 2014. The increase of approximately \$156,000, or 147%, during the three months ended March 31, 2015 compared to the same period in 2014 is primarily due to increase in sales volume and any cost of sales gains arising from favorable exchange rate impacts, offset by product mix changes in the three months ended March 31, 2015 compared to the three months ended March 31, 2014.

*Research and Development*

Research and development expenses were approximately \$192,000 and \$163,000 respectively, for the three months ended March 31, 2015 and March 31, 2014. This increase of approximately \$29,000, or 18%, is primarily due to an increase in research and development costs and other project costs primarily related to our OLPür H2H Module.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$53,000 for the three months ended March 31, 2015 compared to approximately \$55,000 for the three months ended March 31, 2014. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A (“License and Supply Agreement”) was \$52,000 for the three months ended March 31, 2015 and 2014. The remaining \$1,000 and \$3,000, respectively, recognized in the three months ended March 31, 2015 and 2014 was depreciation on equipment and tools.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$843,000 for the three months ended March 31, 2015 compared to approximately \$711,000 for the three months ended March 31, 2014, an increase of approximately \$132,000 or 19%. The increase is primarily due to an increase in personnel costs of approximately \$89,000 as a result of the former CEO severance, an increase in sales commission expense of approximately \$49,000 as a result of increased sales and an increase in professional services costs of approximately \$102,000 primarily related to timing of when services were rendered. In addition, other increases in selling, general and administrative expenses were related to an increase in directors’ compensation expense of approximately \$19,000 due to an increase in the number of Board members and an increase in investor relations of approximately \$33,000. These expenses were partially offset by a decrease in stock based compensation expense of approximately \$94,000 primarily related to the forfeiture of the former CEO’s unvested stock options and a decrease in legal expenses of approximately \$44,000. Legal expenses were higher for the three months ended March 31, 2014 as a result of fees incurred in relation to the October 2013 product recall.

*Interest Expense*

The table below summarizes interest expense for the three months ended March 31, 2015 and 2014:

	2015	2014
Interest related to November 2013 senior secured note	\$-	\$37,000
Amortization of debt discount – November 2013 senior secured note	-	142,000
Interest – outstanding payables due to a vendor	11,000	15,000
Other	-	1,000
Total interest expense	\$11,000	\$195,000

*Change in Fair Value of Warrant Liability*

Certain warrants are classified as liabilities at their fair value and adjusted to their fair value at each reporting period. The fair value of such warrants issued have been estimated using a binomial options pricing model. For the three months ended March 31, 2015 and 2014, the change in fair value of the warrant liability was a decrease of approximately \$1,009,000 and an increase of approximately \$2,751,000, respectively.

*Other Income (Expense)*

Other income (expense) relates to foreign currency gains and losses on invoices paid to an international supplier. A foreign currency gain was recognized for the three months ended March 31, 2015 of approximately \$51,000 compared to a foreign currency loss of approximately \$3,000 for the three months ended March 31, 2014.

**Liquidity and Capital Resources**

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

	March 31,	
	2015	2014
Liquidity and capital resources		
Cash	\$367	\$473
Other current assets	624	739
Working capital deficit	(265 )	(1,081)
Stockholders' deficit	(5,411)	(5,093)

At March 31, 2015, we had an accumulated deficit of approximately \$113,922,000 and we expect to incur additional operating losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or license revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, license revenue, and rights offerings.



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

- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;
- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the continued progress in, and the costs of, clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

- for the marketing and sales of our water-filtration products;
- to pursue business development opportunities with respect to our chronic renal treatment system; and
- for working capital purposes.

At March 31, 2015, we had cash totaling approximately \$367,000 and total assets of approximately \$991,000, excluding other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,631,000.

On May 12, 2015, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain purchasers identified therein. Pursuant to the Purchase Agreement, the Company agreed to issue and sell, and the purchasers agreed to purchase, an aggregate of approximately 1.8 million shares at a price of \$0.67 per share for total gross proceeds of approximately \$1.2 million. In addition, the Company will issue to the purchasers warrants to purchase approximately 0.9 million shares of common stock. The warrants will have an exercise price of \$0.85 per share and will be exercisable for 5 years from the closing date. The purchase and sale of the shares and warrants is expected to close on or about May 15, 2015, subject to satisfying customary closing conditions.

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

We expect that the approximately \$1.2 million of gross proceeds that we will receive upon the closing of the transactions contemplated by the May 2015 Purchase Agreement, and the projected increase in product sales from the hospital market, will allow us to fund our operations into the fourth quarter of fiscal year 2015. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$917,000 for the three months ended March 31, 2015 compared to approximately \$622,000 for the three months ended March 31, 2014. Although our net income increased by approximately \$3,754,000 during the three months ended March 31, 2015 compared to the three months ended March 31, 2014, the primary reason for the increase was due to the noncash impact of the change in fair value of the warrant liability. The warrant liability decreased by approximately \$1,009,000 in the three months ended March 31, 2015 compared to an increase of approximately \$2,751,000 in the three months ended March 31, 2014.

The most significant items contributing to the net increase of approximately \$295,000 in cash used in operating activities during the three months ended March 31, 2015 compared to the three months ended March 31, 2014 are highlighted below:

our deferred revenue decreased by approximately \$17,000 in the 2015 period compared to an increase of approximately \$363,000 in the 2014 period.

during the 2015 period, there was no amortization of debt discount compared to approximately \$142,000 in the 2014 period

Offsetting the above changes are the following items:

our stock based compensation was approximately \$26,000 during the 2015 period compared to approximately \$120,000 during the 2014 period;

our accounts receivable decreased by approximately \$224,000 during the 2015 period compared to approximately \$355,000 during the 2014 period; and

our accrued expenses increased by approximately \$90,000 in the 2015 period compared to a decrease of approximately \$172,000 in the 2014 period.

Net cash provided by financing activities for the three months ended March 31, 2015 of \$1,000 resulted from proceeds from the exercise of warrants.

Net cash provided by financing activities for the three months ended March 31, 2014 of \$517,000 resulted from proceeds of approximately \$2,016,000 resulting from the issuance of common stock in the 2014 rights offering and approximately \$1,000 of proceeds resulting from the exercise of warrants. These proceeds were offset by the payment of the November 2013 senior secured note of \$1,500,000.

### **Off-Balance Sheet Arrangements**

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

## Forward-Looking Statements

Certain statements in this Quarterly Report on Form 10-Q constitute “forward-looking statements.” 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 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. 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;

the voluntary recalls of point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances could subject us to claims or proceedings by consumers, the U.S. Food and Drug Administration, or FDA, or other regulatory authorities which may adversely impact our sales and revenues;

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

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

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

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

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

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

we may not be able to effectively market our products;

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

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

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

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

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

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

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

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this Quarterly Report on Form 10-Q, is set forth in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov). We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Not required for smaller reporting companies.

### **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.

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, the Acting Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2014, as a result of a material weakness in controls related to the accounting for warrants as described in Note 2 of the Annual Report on Form 10-K for the year ended December 31, 2014, including an insufficient number of resources in the accounting and finance department. In light of this material weakness, we performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with U.S. generally accepted accounting principles.

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 Acting Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Acting Chief Financial Officer concluded that, due to the material weakness in our internal control over financial reporting described below, our disclosure controls and procedures as of the end of the period covered by this report were not effective.

#### **Changes in Internal Control Over Financial Reporting**

Other than as described herein, there were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In connection with the preparation of our financial statements for the year ended December 31, 2014, our management discovered that we had improperly accounted for our warrants as components of equity instead of as derivative liabilities, and our management and auditors determined that this resulted from a material weakness in internal control over financial reporting. During the quarter ended March 31, 2015, we expanded and improved our review process for complex securities and related accounting standards to remediate this material weakness; however, as of March 31, 2015, this material weakness continues to exist. We plan to further improve our review process by enhancing access to accounting literature, identification of third party professionals with whom to consult regarding complex accounting applications and consideration of additional staff with the requisite experience and training to supplement existing accounting professionals.

## **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 6. Exhibits**

#### **EXHIBIT INDEX**

- 10.1 Separation Agreement and General Release between the Company and John C. Houghton, dated January 4, 2015. \*
- 10.2 Nephros, Inc. 2015 Equity Incentive Plan.\*
- 10.3 Form of Incentive Stock Option Agreement under the 2015 Equity Incentive Plan.\*
- 10.4 Form of Non-Qualified Stock Option Agreement under the 2015 Equity Incentive Plan.\*
- 10.5 Form of Restricted Stock Agreement under the 2015 Equity Incentive Plan.\*
- 10.6 Form of Restricted Stock Unit Agreement under the 2015 Equity Incentive Plan.\*
  
- 31.1 Certification by the Chief Executive Officer and Acting Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. \*
  
- 32.1 Certifications by the Chief Executive Officer and Acting 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. \*

\* Filed herewith.



**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: May 15, 2015 By: /s/ Daron Evans  
Name: Daron Evans  
Title: President, Chief Executive Officer and Acting Chief  
Financial Officer (Principal Executive Officer and  
Principal Financial and Accounting Officer)