

NEPHROS INC  
Form 10-Q  
November 13, 2014

**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: **September 30, 2014**

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)

**DELAWARE**

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





**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 - September 30, 2014 (unaudited) and December 31, 2013 (audited)</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss - Three and nine months ended September 30, 2014 and 2013 (unaudited)</u>	2
<u>Consolidated Statement of Changes in Stockholders' Deficit - Nine months ended September 30, 2014 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Cash Flows - Nine months ended September 30, 2014 and 2013 (unaudited)</u>	4
<u>Notes to Unaudited Condensed Consolidated Interim Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
Item 4. <u>Controls and Procedures</u>	21
<b><u>PART II - OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	22
Item 6. <u>Exhibits</u>	22
<u>SIGNATURES</u>	22

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

	(Unaudited) September 30, 2014	(Audited) December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,047	\$ 579
Accounts receivable	179	122
Inventory, less allowances of \$84 at September 30, 2014 and \$365 at December 31, 2013	108	162
Prepaid expenses and other current assets	33	125
Total current assets	1,367	988
Property and equipment, net	1	7
Other assets, net of accumulated amortization	1,737	1,894
Total assets	\$ 3,105	\$ 2,889
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Senior secured notes, net of debt discount of \$146 at September 30, 2014 and \$142 at December 31, 2013	\$ 1,604	\$ 1,358
Accounts payable	908	1,073
Accrued expenses	300	365
Deferred revenue	245	703
Total current liabilities	3,057	3,499
Long-term portion of deferred revenue	434	-
Total liabilities	3,491	3,499

## Commitments and Contingencies (Note 13)

## Stockholders' deficit:

Preferred stock, \$.001 par value; 5,000,000 shares authorized at September 30, 2014 and December 31, 2013; no shares issued and outstanding at	-	-
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September 30, 2014 and December 31, 2013

Common stock, \$.001 par value; 90,000,000 shares authorized at September 30, 2014 and December 31, 2013; 25,249,054 and 18,082,043 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	25		18	
Additional paid-in capital	102,864		100,526	
Accumulated other comprehensive income	73		74	
Accumulated deficit	(103,348	)	(101,228	)
Total stockholders' deficit	(386	)	(610	)
Total liabilities and stockholders' deficit	\$ 3,105		\$ 2,889	

*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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net revenues:				
Product revenues	\$298	\$242	\$765	\$979
License revenues	193	176	641	535
Total net revenues	491	418	1,406	1,514
Cost of goods sold	175	189	423	610
Gross margin	316	229	983	904
Operating expenses:				
Research and development	178	204	521	687
Depreciation and amortization	54	55	164	169
Selling, general and administrative	765	578	2,177	2,293
Total operating expenses	997	837	2,862	3,149
Loss from operations	(681 )	(608 )	(1,879 )	(2,245 )
Interest expense	(65 )	(5 )	(277 )	(256 )
Gain on sale of equipment	-	1	-	3
Other income (expense)	40	1	36	(25 )
Net loss	(706 )	(611 )	(2,120 )	(2,523 )
Other comprehensive income(loss), foreign currency translation adjustments	1	-	(1 )	(2 )
Total comprehensive loss	\$(705 )	\$(611 )	\$(2,121 )	\$(2,525 )
Net loss per common share, basic and diluted	\$(0.03 )	\$(0.03 )	\$(0.09 )	\$(0.17 )
Weighted average common shares outstanding, basic and diluted	25,238,412	17,787,356	23,094,457	14,805,395

*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	Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount	Capital	Income(Loss)	Deficit	
Balance, December 31, 2013	18,082,043	\$ 18	\$ 100,526	\$ 74	\$ (101,228 )	\$(610 )
Net loss					(2,120 )	(2,120)
Net unrealized losses on foreign currency translation				(1 )		(1 )
Shareholder rights offering (March 2014), net	7,140,823	7	2,006			2,013
Exercise of warrants	26,188		11			11
Noncash stock-based compensation			321			321
Balance, September 30, 2014	25,249,054	\$ 25	\$ 102,864	\$ 73	\$ (103,348 )	\$(386 )

*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)

	Nine Months Ended September	
	30,	2013
	2014	
Operating activities:		
Net loss	\$ (2,120	) \$ (2,523
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	6	7
Amortization of other assets	158	162
Noncash stock-based compensation	321	401
Noncash warrant inducement	-	14
Amortization of debt discount	173	204
Inventory reserve	31	5
(Gain)loss on foreign currency transactions	(40	) 17
Gain on sale of equipment	-	(3
(Increase) decrease in operating assets:		
Accounts receivable	(57	) 831
Inventory	24	16
Prepaid expenses and other current assets	92	71
Decrease in operating liabilities:		
Accounts payable and accrued expenses	(229	) (45
License and supply agreement fee payable	-	(1,318
Deferred revenue	(23	) (535
Net cash used in operating activities	(1,664	) (2,696
Investing activities:		
Proceeds from sale of equipment	-	3
Net cash provided by investing activities	-	3
Financing activities:		
Proceeds from issuance of common stock, net of equity issuance costs of \$128 and \$229, respectively	2,013	2,771
Proceeds from issuance of senior secured note	1,610	1,300
Proceeds from exercise of warrants	11	248
Payment of senior secured note	(1,500	) (1,300
Payment of financing costs	-	(204
Net cash provided by financing activities	2,134	2,815
Effect of exchange rates on cash and cash equivalents	(2	) (1

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Net increase in cash	468	121
Cash, beginning of period	579	47
Cash, end of period	\$ 1,047	\$ 168
Supplemental disclosure of cash flow information		
Cash paid for income taxes	\$ 6	\$ 2
Cash paid for interest	\$ 70	\$ -
Restricted stock issued to settle liability	\$ -	\$ 116

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

## **NEPHROS, INC. AND SUBSIDIARY**

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

#### **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.

#### **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 should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 28, 2014. 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 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, 2013 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 interim condensed consolidated 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 2014 presentation. All significant 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. The more significant estimates used by management relate to the valuation of inventory reserves and the measurement of deferred revenue. Actual results could differ materially from those estimates.

### **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 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. For the nine months ended September 30, 2014 and 2013, the Company has incurred net losses of \$2,120,000 and \$2,523,000, respectively. 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.

In October 2013, the Company announced the voluntary recalls of its point of use ("POU") and DSU in-line ultrafilters used in hospital water treatment applications. As a result, the Company recalled all production lots of its POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, the Company also requested, for the DSU in-line ultrafilter, that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect the Company's dialysis products. The Company is working towards a resolution of the issues raised by the Food and Drug Administration ("FDA") and is unable to predict at this time what additional effect this recall might have on its business, financial condition, future prospects or reputation or whether it may be subject to future actions from the FDA. On March 20, 2014, the Company requested termination of its product recall from the FDA. As of the date of this filing, there has been no additional communication from the FDA regarding the product recall. The voluntary recalls of POU and DSU ultrafilters used in hospital water treatment applications and the related circumstances could subject the Company to

claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact the Company's sales and revenues.

## NEPHROS, INC. AND SUBSIDIARY

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### 2. Basis of Presentation and Going Concern (continued)

On August 29, 2014, the Company issued a senior secured note to Lambda Investors LLC (“Lambda”) in the principal amount of \$1.75 million. The note bears interest at the rate of 12% per annum and is scheduled to mature on February 28, 2015, at which time all principal and accrued interest will be due. In addition, the Company is planning a \$3 million rights offering, which will enable the Company to pay the principal and interest prior to the maturity date. For a more detailed discussion of the terms of the senior secured note, see Note 11, Senior Secured Notes.

On March 21, 2014, the Company completed a rights offering which resulted in gross proceeds of \$2.1 million. See Note 12, Stockholders’ Equity, for a more detailed discussion of the rights offering. The Company repaid the November 12, 2013 senior secured note issued to Lambda in the principal amount of \$1.5 million with a portion of the proceeds from the rights offering. For a more detailed discussion of the terms of the senior secured note, see Note 11, Senior Secured Notes.

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the “First Amendment”), by and between the Company and Bellco S.r.l. (“Bellco”), which amends the License Agreement, entered into as of July 1, 2011 by and between the Company and Bellco. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement through December 31, 2021. 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 other half of which was received on April 4, 2014. See Note 13, Commitments and Contingencies, for further discussion of, and additional terms related to, the First Amendment.

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.

#### 3. Concentration of Credit Risk

For the nine months ended September 30, 2014 and 2013, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2014	2013
A	46 %	36 %
B	25 %	31 %
C	9 %	16 %

As of September 30, 2014 and December 31, 2013, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2014	2013
A	61 %	69 %
B	15 %	- %
C	13 %	- %
D	- %	28 %

#### **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

**NEPHROS, INC. AND SUBSIDIARY**

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

**4. Revenue Recognition (continued)**

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 September 30, 2014 condensed consolidated balance sheet is approximately \$679,000 and is related to the License Agreement with Bellco, which is being deferred through December 31, 2021, the remainder of the expected obligation period. The Company has recognized approximately \$2,396,000 of revenue related to the License Agreement to date and approximately \$641,000 for the nine months ended September 30, 2014. See Note 13, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

**5. 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 until the measurement date is reached.

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.



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The Company granted 302,519 stock options during the nine months ended September 30, 2014 to employees, non-employees, directors and consultants. These stock options vest over a two-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, 2014 was approximately \$127,000.

The following assumptions were used for options granted for the nine months ended September 30, 2014:

Assumptions for Option Grants	Nine Months	
	Ended	September 30, 2014
Risk-free interest rate	1.76 - 1.91	%
Volatility	129.2 - 133.4	%
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 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 \$318,000 and \$300,000 for the nine months ended September 30, 2014 and 2013, respectively. For the nine months ended September 30, 2014, approximately \$302,000 and approximately \$16,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. For the nine months ended September 30, 2013, approximately \$275,000 and approximately \$25,000 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 nine months ended September 30, 2014 and 2013, as the Company is in a net operating loss position. As of September 30, 2014, there was approximately \$580,000 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 1.9 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$580,000 of total unrecognized compensation cost, the Company expects to recognize approximately 16% in the remaining interim periods of 2014, approximately 64% in 2015, approximately 17% in 2016 and approximately 3% in 2017.

**NEPHROS, INC. AND SUBSIDIARY**

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

**5. Stock-Based Compensation (continued)**

**Restricted Stock**

Total stock-based compensation expense for the restricted stock grants was approximately \$3,000 for the nine months ended September 30, 2014 and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated interim statement of operations. As of September 30, 2014, all compensation expense related to the restricted stock awards has been recognized.

**6. Warrants**

For the nine months ended September 30, 2014, 566,631 warrants were exercised, resulting in proceeds of approximately \$11,000 and the issuance of 26,188 shares of the Company's common stock.

**7. Comprehensive Income (Loss)**

Comprehensive income (loss), as defined in ASC Topic 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.

**8. Loss per Common Share**

In accordance with ASC Topic 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, the exercise of stock options and warrants and any outstanding shares of unvested restricted stock.

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

	September 30,	
	2014	2013
Shares underlying warrants outstanding	16,763,301	13,888,262
Shares underlying options outstanding	2,424,612	2,380,644
Unvested restricted stock	-	150,423

As a result of the March 2014 rights offering, the full ratchet anti-dilution protection for Class D warrants held by Lambda was triggered. The respective warrants are now exercisable for 11,742,100 shares of common stock at an exercise price of \$0.30 per share compared to the 8,806,575 shares of common stock and \$0.40 exercise price prior to the March 2014 rights offering.

## 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.

**NEPHROS, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****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 September 30, 2014 and December 31, 2013 was as follows:

	Unaudited September 30, 2014	Audited December 31, 2013
Total Gross Inventory, Finished Goods	\$ 192,000	\$ 527,000
Less: Inventory reserve	(84,000 )	(365,000 )
Total Inventory	\$ 108,000	\$ 162,000

During the nine months ended September 30, 2014, approximately \$66,000 of DSU inventory near expiration or replaced by newer versions and approximately \$216,000 related to the POU product recall initiated in 2013 was written off.

**11. Senior Secured Notes**

On August 29, 2014, the Company issued a senior secured note to Lambda, in the principal amount of \$1.75 million. The note bears interest at the rate of 12% per annum and is scheduled to mature on February 28, 2015, at which time all principal and accrued interest will be due. In connection with the note, the Company incurred an 8%, or \$140,000, sourcing/transaction fee with Lambda. The Company will also pay Lambda's legal fees and other expenses incurred in connection with the note and the anticipated fourth quarter 2014 rights offering in the amount of \$75,000. The \$140,000 sourcing/transaction fee and \$37,500, 50% of the legal fees and other expenses, are reflected as a debt discount which is being amortized over the term of the August 2014 senior secured note. As of September 30, 2014, approximately \$31,000 was recognized as amortization of debt discount and is included in interest expense on the condensed consolidated interim statement of operations. As of September 30, 2014, approximately \$19,000 of interest expense has been accrued. In addition, under the terms of the note, the Company has undertaken to conduct a \$3 million rights offering of common stock at an anticipated offering price of \$0.60 per share. All of the Company's stockholders and warrant holders will be eligible to participate in the offering on a pro rata basis based upon their proportionate ownership of the Company's common stock on an as-converted basis. The note requires the Company to

repay the senior secured note with the proceeds from the anticipated fourth quarter 2014 rights offering or any other financing transaction.

On November 12, 2013, the Company issued a senior secured note to Lambda, in the principal amount of \$1.5 million. The note bore interest at the rate of 12% per annum and was scheduled to mature on May 12, 2014, at which time all principal and accrued interest was due. However, the Company paid amounts due under the note, including all accrued interest thereon of \$61,000, on March 18, 2014 with the cash proceeds from the rights offering that closed in March 2014. In connection with the note, the Company incurred an 8%, or \$120,000, sourcing/transaction fee with Lambda. In addition, the Company incurred additional legal fees and other expenses in connection with the note in the amount of \$75,000 with Lambda. Those payments totaling \$195,000 were made on November 12, 2013 and were reflected as a debt discount which was amortized over the term of the senior secured note and included in interest expense on the condensed consolidated interim statement of operations. Approximately \$53,000 was recognized in the fourth quarter of 2013 and approximately \$142,000 was recognized in the first quarter of 2014.

## **12. Stockholders' Deficit**

On January 7, 2014, the Company filed a Registration Statement on Form S-1 in connection with a \$2.8 million rights offering. On February 12, 2014, the Company's Registration Statement on Form S-1 related to the March 2014 rights offering was declared effective by the SEC. The March 2014 rights offering commenced on February 14, 2014 and expired on March 14, 2014. All of the Company's stockholders and warrant holders were eligible to participate in the March 2014 rights offering on a pro rata basis based upon their proportionate ownership of the Company's common stock on a fully-diluted basis. Pursuant to the March 2014 rights offering, the Company distributed to holders of its common stock and/or warrants one non-transferable subscription right for each share of common stock, and each share of common stock underlying a warrant, held as of January 30, 2014. Each right entitled the holder to purchase 0.28673 of a share of the Company's common stock at a subscription price of \$0.30 per share. The Company rounded up any fractional shares to the nearest whole share.

On March 21, 2014, the Company completed the March 2014 rights offering that resulted in gross proceeds of \$2.1 million. The aggregate net proceeds were approximately \$581,000, after deducting the repayment of the November 2013 \$1.5 million senior secured note and the \$61,000 of accrued interest thereon.

## NEPHROS, INC. AND SUBSIDIARY

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### 12. Stockholders' Deficit (continued)

The Company issued a total of 7,140,823 shares of common stock to the holders of subscription rights who validly exercised their subscription rights, which represents 77% of the total shares offered in the March 2014 rights offering. Fees of approximately \$128,000 were also incurred related to the March 2014 rights offering and were recorded as reduction to equity.

#### 13. Commitments and Contingencies

##### Manufacturing and Suppliers

The Company has not and does not intend to in the near future, 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, an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of the Company's 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, entered into as of July 1, 2011 by and between the Company and Bellco. 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 \$2.40) per unit; thereafter, €1.25 (approximately \$1.71) 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.

#### **14. Other Assets**

##### License and Supply Agreement

On April 23, 2012, the Company entered into a License and Supply Agreement (the “Medica 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. The term of the Medica 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 Medica License and Supply Agreement. Under the Medica 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 Medica 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 Medica 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 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$1,000,000) for the years 2012, 2013 and 2014, respectively. For the nine months ended September 30, 2014, the Company has committed to make aggregate purchases totalling approximately €310,000 (approximately \$425,000). 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 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

**NEPHROS, INC. AND SUBSIDIARY**

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

**14. Other Assets (continued)**

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 5, 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 condensed consolidated interim balance sheet as of September 30, 2014 is approximately \$1,737,000, net of \$514,000 accumulated amortization, and is related to the Medica License and Supply Agreement. The asset is being amortized as an expense over the life of the agreement. Approximately \$158,000 has been charged to amortization expense for the nine months ended September 30, 2014 on the condensed consolidated interim statement of operations and comprehensive loss. Approximately \$53,000 of amortization expense will be recognized in the remainder of the year ended December 31, 2014 and approximately \$210,000 will be recognized in each of the years ended 2015 and 2016, respectively. 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 Medica License and Supply Agreement. For the nine months ended September 30, 2014, the Company has recognized approximately \$8,000 as a result of royalty payments due to Medica for the period April 23, 2014 through September 30, 2014, based on net Filtration Product sales of approximately \$437,000. Approximately \$4,000 of royalty payments were made during the three months ended September 30, 2014 and approximately \$8,000 is accrued as of September 30, 2014.

**15. Subsequent Events**

On October 20, 2014, the Company filed a Registration Statement on Form S-1 with the SEC in connection with the \$3 million rights offering (described in Note 11), which was amended by Amendment No.1 to the Registration Statement on Form S-1, filed with the SEC on October 31, 2014 and declared effective by the SEC on November 4, 2014.

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



intended to provide water that can be used as a substitute for USP sterile water.

## **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 “Certain Risks and Uncertainties” section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2013, 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, 2013. 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 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:

•*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 (“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

•*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 surgeon’s hands

•*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

*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, 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 erythropoietin (“EPO”) is enhanced, consequently the overall need for ESA’s 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. On July 14, 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 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 online mid-dilution hemodiafiltration (mid-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 U.S. Food and Drug Administration (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. On May 13, 2014, DaVita announced that they had commenced delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select patients at DaVita's North Colorado Springs Clinic. We also anticipate evaluating our on-line mid-dilution HDF system at other clinics throughout the U.S. and although we have not begun to broadly market our on-line mid-dilution HDF system, we are actively seeking a commercialization partner in the U.S.

*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 ("CDC") 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 ("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. 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 just prior to it being used.

On June 30, 2014 we submitted to the U.S. Food and Drug Administration ("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 July 22, 2014, we were notified that our submission had been accepted for review. On October 28, 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters for use in the hospital setting. The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of a surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.

*Military and Outdoor Recreation.* Water is a key requirement for the warfighter 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 offer our individual water purification device (“IWPD”) in both in-line (HydraGuard in-line) and point-of-use (HydraGuard universal) configurations. Our IWPD allows a soldier in the field to derive drinking water from any fresh water source. This enables the warfighter to remain hydrated which will maintain mission effectiveness and unit readiness, and extend mission reach. Our IWPD 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 (“USAPHC”) and U.S. Army Test and Evaluation Command (“ATEC”) for deployment. To date, we have received purchase orders for approximately 2,000 IWPDs from individual units of the U.S. armed forces.

In February 2013, Nephros submitted its response to a U.S. Army request for proposal (RFP) relating to IWPDs (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. We also received a request for 180 of our IWPDs to be used for testing during the Limited User Evaluation (“LUE”) phase of the source selection. 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 IWPD 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 have informed us that they plan to re-visit the requirements for the IWPD and will re-solicit the requirements in a new RFP at a future date.

We continue to make our IWPD available to the U.S. military outside of the RFP. During 2013, we signed distributor agreements with W.S. Darley & Company, Source One Distribution Inc. and Atlantic Diving Supply, Inc. In July 2014, we were awarded a contract for both our HydraGuard in-line and HydraGuard universal IWPD’s in response to solicitation RFQ902286 from the U.S. Army. The HydraGuard inline and universal were recently listed on the Darley website and in their on-line catalogue. Also, in June 2014 and September 2014, we attended the Darley Defense Expo in Virginia Beach and Modern Day Marine, respectively.

*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, we also requested, for the DSU in-line ultrafilter, that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect our dialysis products. We are working towards a resolution of the issues raised by the FDA and we are unable to predict at this time what additional effect this recall might have on our business, financial condition, future prospects or reputation or whether we may be subject to future actions from the FDA. On March 20, 2014, we requested termination of our product recall from the FDA. As of the date of this filing, there has been no additional communication from the FDA.



According to the United States EPA, public drinking water systems consist of 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 e.g. municipalities, mobile home parks, 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.

We have launched our new NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water which is to be used for drinking and washing in non-transient non-community water systems i.e. 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.

### **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 assets 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, 2013. 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, 2013.

### **Recently Adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board 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.

## **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 while noting that our net loss for the nine months ended September 30, 2014 has decreased by \$403,000 to \$2,120,000 compared to \$2,523,000 for the nine months ended September 30, 2013.

*Three Months Ended September 30, 2014 Compared to the Three Months Ended September 30, 2013*

*Revenues*

Total net revenues for the three months ended September 30, 2014 were approximately \$491,000 compared to approximately \$418,000 for the three months ended September 30, 2013. Total net revenues increased approximately \$73,000, or 17%, arising from approximately \$56,000 of higher water filter sales as well as an increase of approximately \$17,000 in licensing revenue related to the Belco license agreement compared to the 2013 period. Water filter sales for current product sales increased approximately \$83,000 and were partially offset by a decrease in sales for recalled product of approximately \$27,000 when comparing the three months ended September 30, 2014 with the three months ended September 30, 2013.

*Cost of Goods Sold*

Cost of goods sold was approximately \$175,000 for the three months ended September 30, 2014 compared to approximately \$189,000 for the three months ended September 30, 2013 and remained relatively unchanged. Cost of goods sold as a percentage of sales was 59% and 78%, respectively for the three months ended September 30, 2014 and 2013. The increased percentage in the three months ended September 30, 2013 was a result of additional cost of goods sold recognized as a result of the recall product. Excluding the impact of the recall, cost of goods sold as a percentage of sales would have decreased approximately 3% as a result of product mix and an increase in average selling prices.

*Gross Margin*

Gross margin percentage for water filters was 41% and 22% for the three months ended September 30, 2014 and 2013. In the three month period ended September 30, 2013, the estimated impact of the product recall was recorded which resulted in a reduction of gross margin percentage of approximately 19%. Excluding this impact, gross margin percentage increased approximately 3% as a result of product mix and increase in average selling prices when comparing the three months ended September 30, 2014 and 2013. The gross margin percentage excludes license revenues for which there is no related cost of goods sold.

*Research and Development*

Research and development expenses were approximately \$178,000 and \$204,000 respectively, for the three months ended September 30, 2014 and September 30, 2013. This decrease of approximately \$26,000, or 13%, is due to a decrease in stock compensation expense, primarily related to restricted stock awards, for research and development personnel. Similar expenses were not incurred in the three month period ended September 30, 2014.

#### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$54,000 for the three months ended September 30, 2014 compared to approximately \$55,000 for the three months ended September 30, 2013. Depreciation and amortization expense was approximately \$53,000 for both three month periods ended September 30, 2014 and 2013 and is due to amortization related to the intangible asset recognized in conjunction with the Medica License and Supply Agreement with Medica S.p.A (“License and Supply Agreement”) which began on April 23, 2012. The remaining \$1,000 and \$2,000, respectively, is depreciation on equipment and tools for the three months ended September 30, 2014 and September 30, 2013.

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

Selling, general and administrative expenses were approximately \$765,000 for the three months ended September 30, 2014 compared to approximately \$578,000 for the three months ended September 30, 2013, an increase of approximately \$187,000 or 32%. The increase is primarily related to regulatory and quality system management resource costs of approximately \$92,000 as a result of the product recall as well as increases in professional and legal fees of approximately \$118,000 as a result of services provided in anticipation of a fourth quarter rights offering. The increase in regulatory, professional services and legal fees was partially offset by a decrease in personnel costs of approximately \$27,000 related to a decrease in stock compensation expense, primarily related to restricted stock awards, for selling, general and administrative personnel.

#### *Interest Expense*

Interest expense was approximately \$65,000 for the three months ended September 30, 2014. Interest expense includes interest of approximately \$15,000 related to outstanding payables due to a vendor, approximately \$19,000 of interest related to the August 2014 senior secured note and amortization of debt discount of approximately \$31,000 related to fees paid to Lambda Investors LLC in connection with the August 2014 senior secured note. The Company accounts for debt issuance costs in accordance with ASC 835, which requires that costs paid directly to the issuer of the notes be reported in the balance sheet as a debt discount and amortized over the term of the associated debt.

Interest expense was approximately \$5,000 for the three months ended September 30, 2013 and related to accrued interest recognized on outstanding payables due to a vendor.

*Other Income/Expense*

Other income, net, in the amounts of approximately \$40,000 for the three months ended September 30, 2014 primarily relates to foreign currency gains on invoices paid to an international supplier. Other income, net, in the amount of approximately \$1,000 for the three months ended September 30, 2013 was due to \$15,000 received as a result of the STERIS agreement termination which was partially offset by approximately \$14,000 of foreign currency losses on invoices paid to an international supplier.

***Nine Months Ended September 30, 2014 Compared to the Nine Months Ended September 30, 2013***

*Revenues*

Total net revenues for the nine months ended September 30, 2014 were approximately \$1,406,000 compared to approximately \$1,514,000 for the nine months ended September 30, 2013. Total net revenues decreased approximately \$108,000, or 7%, arising from approximately \$214,000 of lower water filter sales partially offset by an increase of approximately \$106,000 in licensing revenue related to the Bellco license agreement compared to the 2013 period. Water filter sales for current product sales decreased approximately \$87,000 and sales for recalled product decreased approximately \$127,000 when comparing the nine months ended September 30, 2014 with the nine months ended September 30, 2013.

*Cost of Goods Sold*

Cost of goods sold was approximately \$423,000 for the nine months ended September 30, 2014 compared to approximately \$610,000 for the nine months ended September 30, 2013. The decrease of approximately \$187,000, or 31%, during the nine months ended September 30, 2014 compared to the same period in 2013 is primarily due to the reduction in sales volume. Cost of goods sold as a percentage of sales was 55% and 62%, respectively for the nine months ended September 30, 2014 and 2013. The increased percentage in the three months ended September 30, 2013 was a result of additional cost of goods sold recognized as a result of the recall product. Excluding the impact of the recall, cost of goods sold as a percentage of sales would have decreased approximately 4% as a result of product mix and an increase of average selling prices.

### *Gross Margin*

Gross margin percentage for water filters was 45% and 38% for the nine months ended September 30, 2014 and 2013, respectively. The estimated impact of the product recall was recorded in the nine month period ended September 30, 2013 and resulted in a decreased gross margin percentage. Excluding the impact of the product recall, increases in average selling prices and product mix contributed to an increase in the gross margin percentage of approximately 4%. This percentage excludes license revenues for which there is no related cost of goods sold.

### *Research and Development*

Research and development expenses were approximately \$521,000 and \$687,000 respectively, for the nine months ended September 30, 2014 and September 30, 2013, respectively. This decrease of approximately \$166,000, or 24%, is primarily due to a decrease in research and development costs primarily related to our OLpūr H2H Module incurred in the nine month period ended September 30, 2013 as well as a decrease in stock compensation expense, primarily related to restricted stock awards, for research and development personnel. Similar expenses were not incurred in the nine month period ended September 30, 2014.

### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$164,000 for the nine months ended September 30, 2014 compared to approximately \$169,000 for the nine months ended September 30, 2013. Approximately \$159,000 and \$162,000, respectively, of the depreciation and amortization expense for the nine months ended September 30, 2014 and 2013 is due to amortization related to the intangible asset recognized in conjunction with the Medica License and Supply Agreement which began on April 23, 2012. The remaining approximately \$5,000 and \$7,000, respectively, is depreciation on equipment and tools, for the nine months ended September 30, 2014 and September 30, 2013.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$2,177,000 for the nine months ended September 30, 2014 compared to approximately \$2,293,000 for the nine months ended September 30, 2013, a decrease of approximately \$116,000 or 5%. Despite an increase in selling, general and administrative expenses of approximately \$92,000 as a result of increased regulatory and quality system management resource costs due to the product recall, selling general and administrative expenses decreased. The overall decrease is due to a decrease in personnel costs of approximately \$207,000 primarily related to the absence of a chief financial officer in the nine months ended September 30, 2014 compared to the 2013 period and decreases in legal, professional services and other expense as a

result of lower spending.

17

*Interest Expense*

Interest expense was approximately \$277,000 for the nine months ended September 30, 2014. Interest includes amortization of debt discount of approximately \$173,000, interest of approximately \$37,000 on the November 2013 senior secured note issued to Lambda Investors LLC, interest of approximately \$19,000 related to the August 2014 senior secured note issued to Lambda Investors LLC and interest of approximately \$48,000 related to outstanding payables due to a vendor. Amortization of debt discount includes approximately \$142,000 related to fees paid to Lambda Investors LLC in connection with the November 2013 senior secured note and approximately \$31,000 related to fees paid to Lambda Investors LLC in connection with the August 2014 senior secured note. The Company accounts for debt issuance costs in accordance with ASC Topic 835, which requires that costs paid directly to the issuer of the notes be reported in the balance sheet as a debt discount and amortized over the term of the associated debt.

Interest expense was approximately \$256,000 for the nine months ended September 30, 2013. During such period, interest expense includes amortization of debt discount of approximately \$204,000 related to fees paid to Lambda Investors LLC in connection with the February 2013 senior secured note, approximately \$47,000 related to interest recognized as a result of the Senior Secured Note and approximately \$5,000 related to accrued interest recognized on outstanding payable due to a vendor.

*Gain on Sale of Equipment*

There was no disposal of equipment in the nine months ended September 30, 2014. A gain of approximately \$3,000 was recognized for the nine months ended September 30, 2013 related to the sale of fully depreciated equipment.

*Other Income/Expense*

Other income, net, in the amount of approximately \$36,000 for the nine months ended September 30, 2014 relates to foreign currency gains on invoices paid to an international supplier. Other expense in the amount of approximately \$25,000 for the nine months ended September 30, 2013 was due to approximately \$14,000 related to warrant inducement expense and approximately \$27,000 of foreign currency losses on invoices paid to an international supplier. These expenses were partially offset by approximately \$15,000 received as a result of the STERIS agreement termination and approximately \$1,000 of other income.

**Liquidity and Capital Resources**



At September 30, 2014, we had an accumulated deficit of approximately \$103,348,000 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 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 sales of equity securities or otherwise, on commercially reasonable terms or at all;
- the costs involved in connection with the voluntary recalls of our point of use and DSU in-line ultrafilters used in hospital water treatment applications announced on October 30, 2013 and the related circumstances;
- 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 filtration products;
- to pursue business development opportunities with respect to our chronic renal treatment system; and

· for working capital purposes.

At September 30, 2014, we had cash totaling approximately \$1,047,000 and tangible assets of approximately \$1,368,000. Tangible assets consist of total assets of approximately \$3,105,000, reduced by other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,737,000.

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, entered into as of July 1, 2011 by and between the Company and Bellco. Pursuant to the First Amendment, the Company and Bellco 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 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, 2016, 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, €1.75 (approximately \$2.40) per unit; thereafter, €1.25 (approximately \$1.71) per unit. In addition, the Company will receive a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was paid on February 19, 2014, and the other half of which was paid 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. Anticipated payments from this License Agreement will be a positive source of cash flow to us.

As of the date of this Quarterly Report, we expect that the proceeds from the August 29, 2014 senior secured note and the anticipated fourth quarter rights offering will allow us to fund our operations into the third quarter of fiscal year 2015. This assumption excludes the impact of future cash receipts from operations. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, 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 \$1,664,000 for the nine months ended September 30, 2014 (“2014 period”) compared to net cash used in operating activities of approximately \$2,696,000 for the nine months ended September 30, 2013 (“2013 period”). The most significant items contributing to this decrease of approximately \$1,069,000 of cash used in operating activities during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 are highlighted below:

- during the 2014 period, our net loss decreased by approximately \$403,000;

during the 2013 period, our license and supply fee payable decreased by approximately \$1,318,000 for which there was no comparable activity during the 2014 period;

our deferred revenue decreased by approximately \$23,000 in the 2014 period compared to a decrease of approximately \$535,000 in the 2013 period; and

our inventory reserve increased by approximately \$31,000 in the 2014 period compared to an increase of approximately \$5,000 in the 2013 period.

Offsetting the above changes are the following items:

our accounts receivable increased by approximately \$57,000 during the 2014 period compared to a decrease of approximately \$831,000 during the 2013 period;

our accounts payable and accrued expenses decreased by approximately \$229,000 in the aggregate in the 2014 period compared to a decrease of approximately \$45,000 in the aggregate in the 2013 period;

our stock based compensation expense was approximately \$321,000 during the 2014 period compared to approximately \$401,000 during the 2013 period;

our gain on foreign currency transactions was approximately \$40,000 during the 2014 period compared to a loss on foreign currency transactions of approximately \$17,000 in the 2013 period and

during the 2014 period, our amortization of debt discount decreased by approximately \$31,000 compared to the 2013 period.

Net cash provided by financing activities for the nine months ended September 30, 2014 of approximately \$2,134,000 resulted from net proceeds of approximately \$2,013,000 resulting from the issuance of common stock in the March 2014 rights offering, proceeds from the issuance of the August 2014 senior secured note of \$1.6 million, net of financing costs, and approximately \$11,000 of proceeds resulting from the exercise of warrants. These proceeds were partially offset by the payment of the November 2013 senior secured note of \$1,500,000 and payment of financing costs of approximately \$140,000.

Net cash provided by financing activities for the nine months ended September 30, 2013 of \$2,815,000 resulted from net proceeds of \$2,771,000 related to the issuance of common stock related to the March 2014 rights offering, proceeds from the issuance of the Senior Secured Note of \$1.3 million and approximately \$248,000 of proceeds resulting from the exercise of warrants. Net cash provided by financing activities was partially offset by the repayment of the \$1.3 million Senior Secured Note and by the payment of approximately \$204,000 in financing costs related to the February 2013 senior secured note.

### **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 find a strategic partner to successfully market our HDF system;
- our HDF system may not be accepted by patients or health care providers in the U.S. marketplace;
- we may not be able to continue as a going concern;
- a default under the terms of the secured note with Lambda Investors LLC would result in the lender foreclosing upon substantially all of our assets and could result in our inability to continue business operations;
- we may not be able to complete the contemplated rights offering which could result in our inability to continue business operations;
-

even if we are able to complete the rights offering, we may not have sufficient capital to successfully implement our business plan;

restrictions in the secured note and related security agreement, which require the prior consent of the lender, may restrict our ability to operate our business, sell the company or sell our assets;

the voluntary recalls of 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 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;

there are product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur 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/or 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 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 contained 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, 2013 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.

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

We did not engage in any off-balance sheet arrangements during the nine month periods ended September 30, 2014 and 2013.

### **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 Acting 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 Acting 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 Acting 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, 2014, 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 6. Exhibits**

#### **EXHIBIT INDEX**

- Senior Secured Note, dated August 29, 2014, issued to Lambda Investors LLC, incorporated by reference to
- 10.1 Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 3, 2014.
- Registration Rights Agreement, dated as of August 29, 2014, by and between Nephros, Inc. and Lambda
- 10.2 Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 3, 2014.
- Security Agreement, dated as of August 29, 2014, by and between Nephros, Inc. and Lambda Investors LLC,
- 10.3 incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 3, 2014.
- Intellectual Property Security Agreement, dated as of August 29, 2014, made by Nephros, Inc. and Lambda
- 10.4 Investors LLC, incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 3, 2014.
- 10.5 First Amendment to Registration Rights Agreement, dated as of September 23, 2014, by and between Nephros, Inc. and Lambda Investors LLC. \*
- 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: November  
13, 2014

By: /s/ John C. Houghton

Name: John C. Houghton

Title: President, Chief Executive Officer and Acting Chief Financial Officer, and Director  
(Principal Executive Officer and Principal Financial and Accounting Officer)