

NEPHROS INC  
Form 10-Q  
August 14, 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: **June 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**

(State or Other Jurisdiction of Incorporation or Organization)

**13-3971809**

(I.R.S. Employer Identification No.)

**41 Grand Avenue**

**07661**

**River Edge, NJ**

(Address of Principal Executive Offices)

(Zip code)

**(201) 343-5202**

Registrant's Telephone Number, Including Area Code

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

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

YES     NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).     YES     NO

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

Large accelerated filer   

Accelerated filer   

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

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

As of August 12, 2014, 25,247,120 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.



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

	(Unaudited) June 30, 2014	(Audited) December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash	\$ 225	\$ 579
Accounts receivable	113	122
Inventory, less allowances of \$92 at June 30, 2014 and \$365 at December 31, 2013	163	162
Prepaid expenses and other current assets	59	125
Total current assets	560	988
Property and equipment, net	3	7
Other assets, net of accumulated amortization	1,789	1,894
Total assets	\$ 2,352	\$ 2,889
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Senior secured note, net of debt discount of \$142 at December 31, 2013	\$ -	\$ 1,358
Accounts payable	1,030	1,073
Accrued expenses	233	365
Deferred revenue	421	703
Total current liabilities	1,684	3,499
Lon-term portion of deferred revenue	452	-
Total liabilities	2,136	3,499

## Commitments and Contingencies (Note 13)

## Stockholders' equity (deficit):

Preferred stock, \$.001 par value; 5,000,000 shares authorized at June 30, 2014 and December 31, 2013; no shares issued and outstanding at June 30, 2014 and December 31, 2013	-	-
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Common stock, \$.001 par value; 90,000,000 shares authorized at June 30, 2014 and December 31, 2013; 25,226,104 and 18,082,043 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	25	18	
Additional paid-in capital	102,761	100,526	
Accumulated other comprehensive income	72	74	
Accumulated deficit	(102,642 )	(101,228 )	)
Total stockholders' equity (deficit)	216	(610 )	)
Total liabilities and stockholders' equity (deficit)	\$ 2,352	\$ 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net revenues:				
Product revenues	\$248	\$391	\$467	\$737
License revenues	193	184	448	359
Total net revenues	441	575	915	1,096
Cost of goods sold	142	226	248	421
Gross margin	299	349	667	675
Operating expenses:				
Research and development	180	259	343	483
Depreciation and amortization	55	58	110	114
Selling, general and administrative	700	660	1,412	1,714
Total operating expenses	935	977	1,865	2,311
Loss from operations	(636 )	(628 )	(1,198 )	(1,636 )
Interest expense	(17 )	(24 )	(70 )	(47 )
Gain on sale of equipment	-	-	-	2
Amortization of debt discount	-	-	(142 )	(204 )
Other income (expense)	(1 )	(19 )	(4 )	(27 )
Net loss	(654 )	(671 )	(1,414 )	(1,912 )
Other comprehensive loss, foreign currency translation adjustments	(1 )	(2 )	(2 )	(2 )
Total comprehensive loss	(655 )	(673 )	(1,416 )	(1,914 )
Net loss per common share, basic and diluted	\$(0.03 )	\$(0.05 )	\$(0.06 )	\$(0.14 )
Weighted average common shares outstanding, basic and diluted	25,166,752	14,556,050	22,004,712	13,289,703

*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' EQUITY (DEFICIT)

(In Thousands, Except Share Amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive	Accumulated Deficit	Total
	Shares	Amount		Income		
Balance, December 31, 2013	18,082,043	\$ 18	\$ 100,526	\$ 74	\$(101,228 )	\$(610 )
Net loss					(1,414 )	(1,414)
Net unrealized losses on foreign currency translation				(2 )		(2 )
Shareholder rights offering, net	7,140,823	7	2,006			2,013
Exercise of warrants	3,238		2			2
Noncash stock-based compensation			227			227
Balance, June 30, 2014	25,226,104	\$ 25	\$ 102,761	\$ 72	\$(102,642 )	\$216

*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)

	Six Months Ended June 30,	
	2014	2013
Operating activities:		
Net loss	\$(1,414)	\$(1,912)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	5	5
Amortization of other assets	105	109
Noncash stock-based compensation	227	248
Amortization of debt discount	142	204
Inventory reserve	31	-
Loss on foreign currency transactions	4	3
Gain on sale of equipment	-	(2 )
(Increase) decrease in operating assets:		
Accounts receivable	9	577
Inventory	(32 )	166
Prepaid expenses and other current assets	66	37
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(180 )	(316 )
License and supply agreement fee payable	-	(1,318)
Deferred revenue	170	(359 )
Net cash used in operating activities	(867 )	(2,558)
Investing activities:		
Proceeds from sale of equipment	-	2
Net cash provided by investing activities	-	2
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	-	1,300
Proceeds from exercise of warrants	2	239
Payment of senior secured note	(1,500)	(1,300)
Payment of financing costs	-	(204 )
Net cash provided by financing activities	515	2,806
Effect of exchange rates on cash and cash equivalents	(2 )	1
Net increase (decrease) in cash	(354 )	251
Cash, beginning of period	579	47

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Cash, end of period	\$225	\$298
Supplemental disclosure of cash flow information		
Cash paid for income taxes	\$4	\$2
Cash paid for interest	\$54	\$24
Restricted stock issued to settle liability	\$-	\$77

*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 six months ended June 30, 2014 and 2013, the Company has incurred net losses of \$1,414,000 and \$1,912,000, 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.

The voluntary recalls of point of use ("POU") and DSU used in hospital water treatment applications announced on October 30, 2013 and the related circumstances could subject the Company to claims or proceedings by consumers, the Food and Drug Administration ("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 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 Investors LLC 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 six months ended June 30, 2014 and 2013, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2014	2013
A	59 %	33 %
B	20 %	29 %
C	4 %	24 %

As of June 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	56 %	69 %
B	35 %	- %
C	- %	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 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 June 30, 2014 condensed consolidated balance sheet is approximately \$873,000 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 \$2,203,000 of revenue related to the License Agreement to date and approximately \$448,000 for the six months ended June 30, 2014. See Note 13, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

**NEPHROS, INC. AND SUBSIDIARY**

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

**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 through the vesting period.

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

The Company granted 302,519 stock options during the six months ended June 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 six months ended June 30, 2014 was approximately \$127,000.

The following assumptions were used for options granted for the six months ended June 30, 2014:

Assumptions for Option Grants	Six Months Ended June 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 \$224,000 and \$206,000 for the six months ended June 30, 2014 and 2013, respectively. For the six months ended June 30, 2014, approximately \$212,000 and approximately \$12,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. For the six months ended June 30, 2013, approximately \$190,000 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.

There was no tax benefit related to expense recognized in the six months ended June 30, 2014 and 2013, as the Company is in a net operating loss position. As of June 30, 2014, there was approximately \$674,000 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 2.1 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$674,000 of total unrecognized compensation cost, the Company expects to recognize approximately 28% in the remaining interim periods of 2014, approximately 55% in 2015, approximately 15% in 2016 and approximately 2% in 2017.

## **Restricted Stock**

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

## **6. Warrants**

For the six months ended June 30, 2014, 70,147 warrants were exercised, resulting in proceeds of approximately \$2,000 and the issuance of 3,238 shares of the Company's common stock.



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

	Six Months Ended June 30,	
	2014	2013
Shares underlying warrants outstanding	16,819,881	13,910,395
Shares underlying options outstanding	2,424,612	2,380,644
Unvested restricted stock	-	264,770

As a result of the 2014 rights offering, the full ratchet anti-dilution protection for Class D warrants held by Lambda Investors LLC 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 2014 rights offering.

**9. Recent 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. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated 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 June 30, 2014 and December 31, 2013 was as follows:

	Unaudited June 30, 2014	Audited December 31, 2013
Total Gross Inventory, Finished Goods	\$ 255,000	\$ 527,000
Less: Inventory reserve	(92,000 )	(365,000 )
Total Inventory	\$ 163,000	\$ 162,000

During the six months ended June 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.

## NEPHROS, INC. AND SUBSIDIARY

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### 11. Senior Secured Notes

On November 12, 2013, the Company issued a senior secured note to Lambda Investors LLC, a major shareholder, 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 paid Lambda Investors an 8%, or \$120,000, sourcing/transaction fee. In addition, the Company paid Lambda Investors' legal fees and other expenses incurred in connection with the note in the amount of \$75,000. 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, of which 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' Equity

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 2014 rights offering was declared effective by the SEC. The 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 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 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 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, plus \$61,000 of accrued interest thereon, issued to Lambda Investors LLC, the payment of an 8% sourcing transaction fee of \$120,000, with respect to the November 2013 senior secured note and an aggregate of \$75,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the November 2013 senior

secured note and the 2014 rights offering. 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 rights offering. Fees of approximately \$128,000 were also incurred related to the 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.

## NEPHROS, INC. AND SUBSIDIARY

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### 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 six months ended June 30, 2014, the Company’s aggregate purchase commitments totaled approximately €252,000 (approximately \$350,000). 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 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 June 30, 2014 is approximately \$1,789,000, net of \$462,000 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 \$105,000 has been charged to amortization expense for the six months ended June 30, 2014 on the condensed consolidated interim statement of operations and comprehensive loss. Approximately \$105,000 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 six months ended June 30, 2014, the Company has accrued approximately \$4,000 as a result of royalty payments due to Medica for the period April 23, 2014 through June 30, 2014, based on net Filtration Product sales of approximately \$148,000.



## **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 four markets:

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

·*Dialysis Centers - Blood:* Clearance of toxins from blood using an alternative method to HD in patients with chronic renal failure

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

·*Commercial Facilities including Hospitals:* Filtration of water for drinking and washing

## 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<sup>th</sup>, 2014, DaVita announced it is now delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select patients in Colorado Springs. The evaluation will be performed at DaVita's North Colorado Springs Clinic over a period of six months. During this period, DaVita clinical experts will determine whether there are improved outcomes of dialysis treatment and patient quality of life compared to those associated with hemodialysis. We 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.

*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. In March 2013, we received notification from the U.S. Army that the Government has 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 as test assets during the Limited User Evaluation (“LUE”) phase of the source selection. On July 10, 2014, we received notification from U.S. Army Contracting Command that discussions with offerors, who remain within the competitive range, has now concluded. A request for final proposal revisions, if needed was also made. The U.S. Army may award several, one or no contracts as a result of this solicitation. The maximum quantity of all contracts combined is not to exceed 450,000 units or \$45,000,000 over a 3 year period.

In addition to the RFP, we continue to make our IWPD available to the U.S. military. During 2013, we signed distributor agreements with W.S. Darley & Company, Source One Distribution Inc. and Atlantic Diving Supply, Inc. The HydraGuard in-line and universal were recently listed on the Darley website and in their on-line catalogue. Also,

in June 2014, we attended the Darley Defense Expo in Virginia Beach.

In September 2013, we were awarded the contract for 30 HydraGuard in-line units in response to RFI Solicitation Number: M67854-13-I-7310 from the U.S. Marine Corp Warfighting Laboratory. We are currently waiting for final feedback from this testing.

*Commercial Facilities including Hospitals.* 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.

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, hospitals, 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 properties. 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.

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 has been accepted for review.

### **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.

## Results of Operations

### *Fluctuations in Operating Results*

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

### *Three Months Ended June 30, 2014 Compared to the Three Months Ended June 30, 2013*

#### *Revenues*

Total net revenues for the three months ended June 30, 2014 were approximately \$441,000 compared to approximately \$575,000 for the three months ended June 30, 2013. Total net revenues decreased approximately \$134,000, or 23%, arising from approximately \$143,000 of lower water filter sales partially offset by an increase of approximately \$9,000 in licensing revenue related to the Bellico license agreement compared to the 2013 period.

#### *Cost of Goods Sold*

Cost of goods sold was approximately \$142,000 for the three months ended June 30, 2014 compared to approximately \$226,000 for the three months ended June 30, 2013. The decrease of approximately \$84,000, or 37%, during the three months ended June 30, 2014 compared to the same period in 2013 is primarily due to the reduction in product sales volume.

#### *Gross Margin*

Gross margin percentage for water filters of 43% and 42% for the three months ended June 30, 2014 and 2013, respectively, was primarily unchanged. This percentage excludes license revenues for which there is no related cost of goods sold.





*Research and Development*

Research and development expenses were approximately \$180,000 and \$259,000 respectively, for the three months ended June 30, 2014 and June 30, 2013. This decrease of approximately \$79,000, or 31%, is primarily due to a decrease in research and development costs primarily related to our OLpūr H2H Module. The expenses related to our OLpūr H2H Module were incurred in the three month period ended June 30, 2013. Similar expenses were not incurred in the three month period ended June 30, 2014.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$55,000 for the three months ended June 30, 2014 compared to approximately \$58,000 for the three months ended June 30, 2013. Approximately \$53,000 and \$56,000, respectively, of the depreciation and amortization expense for the three months ended June 30, 2014 and 2013 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 \$2,000 is depreciation on equipment and tools, which is unchanged for the three months ended June 30, 2014 compared to the same period in 2013.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$701,000 for the three months ended June 30, 2014 compared to approximately \$660,000 for the three months ended June 30, 2013, an increase of approximately \$41,000 or 6%. The increase is primarily due to increases in professional services and legal fees of approximately \$105,000 as a result of the timing of professional services and legal fees for the three months ended June 30, 2014 compared to the 2013 period. The increase in professional services and legal fees was partially offset by a decrease in personnel costs of approximately \$62,000 primarily related to the absence of a chief financial officer during the three months ended June 30, 2014 compared to the same period in 2013.

*Interest Expense*

Interest expense was approximately \$17,000 for the three months ended June 30, 2014 and primarily relates to interest of approximately \$16,000 related to outstanding payables due to a vendor. Interest expense was approximately \$24,000 for the three months ended June 30, 2013 as a result of the February 2013 senior secured note outstanding as

of June 30, 2013.

*Other Expense*

Other expense in the amounts of approximately \$1,000 and \$19,000 for the three months ended June 30, 2014 and June 30, 2013, respectively, relate to foreign currency losses on invoices paid to an international supplier.

***Six Months Ended June 30, 2014 Compared to the Six Months Ended June 30, 2013***

*Revenues*

Total net revenues for the six months ended June 30, 2014 were approximately \$915,000 compared to approximately \$1,096,000 for the six months ended June 30, 2013. Total net revenues decreased approximately \$181,000, or 17%, arising from approximately \$270,000 of lower water filter sales partially offset by an increase of approximately \$89,000 in licensing revenue related to the Bellco license agreement compared to the 2013 period.

*Cost of Goods Sold*

Cost of goods sold was approximately \$248,000 for the six months ended June 30, 2014 compared to approximately \$421,000 for the six months ended June 30, 2013. The decrease of approximately \$173,000, or 41%, during the six months ended June 30, 2014 compared to the same period in 2013 is primarily due to the reduction in sales volume.

*Gross Margin*

Gross margin percentage for water filters of 47% and 43% for the six months ended June 30, 2014 and 2013, respectively, increased slightly due to a decrease in expense recognized for product samples and testing for the six months ended June 30, 2014 compared to the 2013 period. This percentage excludes license revenues for which there is no related cost of goods sold.

*Research and Development*

Research and development expenses were approximately \$343,000 and \$483,000 respectively, for the six months ended June 30, 2014 and June 30, 2013, respectively. This decrease of approximately \$140,000, or 29%, is primarily due to a decrease in research and development costs primarily related to our OLPūr H2H Module. The expenses related to our OLPūr H2H Module were incurred in the six month period ended June 30, 2013. Similar expenses were not incurred in the six month period ended June 30, 2014.

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$110,000 for the six months ended June 30, 2014 compared to approximately \$114,000 for the six months ended June 30, 2013. Approximately \$106,000 and \$109,000, respectively, of the depreciation and amortization expense for the six months ended June 30, 2014 and 2013 is due to amortization related to the asset recognized in conjunction with the Medica License and Supply Agreement which began on April 23, 2012. The remaining \$4,000 is depreciation on equipment and tools, which is unchanged for the six months ended June 30, 2014 compared to the same period in 2013.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$1,412,000 for the six months ended June 30, 2014 compared to approximately \$1,714,000 for the six months ended June 30, 2013, a decrease of approximately \$302,000 or 18%. The decrease is primarily due to decreases in personnel costs of approximately \$158,000 primarily related to the absence of a chief financial officer in the six months ended June 30, 2014 compared to the 2013 period, decreases in legal fees of approximately \$65,000, decreases in professional services costs of approximately \$10,000 and decreases in other expenses of approximately \$69,000 during the six months ended June 30, 2014 compared to the same period in 2013.

*Interest Expense*

Interest expense was approximately \$70,000 for the six months ended June 30, 2014 and relates primarily to interest on the November 2013 senior secured note issued to Lambda Investors LLC of approximately \$37,000 and interest of

approximately \$32,000 related to outstanding payables due to a vendor. Interest expense was approximately \$47,000 for the six months ended June 30, 2013 as a result of the February 2013 senior secured note outstanding as of June 30, 2013.

#### *Gain on Sale of Equipment*

There was no disposal of equipment in the six months ended June 30, 2014 and a gain of approximately \$2,000 was recognized for the six months ended June 30, 2013 related to the sale of fully depreciated equipment.

#### *Amortization of Debt Discount*

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. Amortization of debt discount of approximately \$142,000 for the six months ended June 30, 2014, was due to fees paid to Lambda Investors LLC in connection with the November 2013 senior secured note. Amortization of debt discount of approximately \$204,000 for the six months ended June 30, 2013 was due to fees paid to Lambda Investors LLC in connection with the February 2013 senior secured note.

#### *Other Expense*

Other expense in the amounts of approximately \$4,000 for the six months ended June 30, 2014 relate to foreign currency losses on invoices paid to an international supplier. Other expense in the amount of approximately \$27,000 for the six months ended June 30, 2013 was due to approximately \$14,000 related to warrant inducement expense and approximately \$13,000 of foreign currency losses on invoices paid to an international supplier.

## Liquidity and Capital Resources

At June 30, 2014, we had an accumulated deficit of approximately \$102,642,000 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 June 30, 2014, we had cash and cash equivalents totaling approximately \$225,000 and tangible assets of approximately \$563,000. Tangible assets consist of total assets of approximately \$2,352,000, reduced by other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,789,000.

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 March 2014 rights offering and the First Amendment with Bellco will allow us to fund our operations into the third quarter of fiscal year 2014. 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 \$867,000 for the six months ended June 30, 2014 (“2014 period”) compared to net cash used in operating activities of approximately \$2,558,000 for the six months ended June 30, 2013 (“2013 period”). The most significant items contributing to this decrease of approximately \$1,691,000 of cash used in operating activities during the six months ended June 30, 2014 compared to the six months ended June 30, 2013 are highlighted below:

- during the 2014 period, our net loss decreased by approximately \$498,000;
- 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 \$170,000 in the 2014 period compared to a decrease of approximately \$359,000 in the 2013 period.
- our inventory reserve increased by approximately \$31,000 in the 2014 period for which there was no comparable activity during the 2013 period; and
- our accounts payable and accrued expenses decreased by approximately \$180,000 in the aggregate in the 2014 period compared to a decrease of approximately \$316,000 in the aggregate in the 2013 period.

Offsetting the above changes are the following items:

- our accounts receivable decreased by approximately \$9,000 during the 2014 period compared to a decrease of approximately \$577,000 during the 2013 period;
- our inventory increased by approximately \$32,000 during the 2014 period compared to a decrease of approximately \$166,000 during the 2013 period; and
- during the 2014 period, our amortization of debt discount decreased by approximately \$62,000 compared to the 2013 period.

There was no cash provided by investing activities for the six months ended June 30, 2014. Cash provided by investing activities of approximately \$2,000 for the six months ended June 30, 2013 resulted from proceeds from the sale of fully depreciated equipment.



Net cash provided by financing activities for the six months ended June 30, 2014 of \$515,000 resulted from net proceeds of approximately \$2,013,000 resulting from the issuance of common stock in the 2014 rights offering and approximately \$1,000 of proceeds resulting from the exercise of warrants. These proceeds were offset by the payment of the November 2013 senior secured note of \$1,500,000.

Net cash provided by financing activities for the six months ended June 30, 2013 of \$2,806,000, net of equity issuance costs of approximately \$229,000, resulted primarily from gross proceeds of \$3.0 million related to the issuance of common stock related to the Rights Offering, proceeds from the issuance of the Senior Secured Note of \$1.3 million and approximately \$239,000 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 “could.” 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;

- 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 six month periods ended June 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 June 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**

10.1 First Amendment to Registration Rights Agreement, dated as of April 14, 2014, by and between Nephros, Inc. and Lambda Investors LLC., incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed with the Securities and Exchange Commission on May 14, 2014.

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: August 14,  
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)