

NEPHROS INC  
Form 10-Q  
August 10, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended: **June 30, 2015**

OR

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

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

Commission File Number: 001-32288

**NEPHROS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**DELAWARE**

**13-3971809**

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

**41 Grand Avenue**

**07661**

**River Edge, NJ**

(Address of Principal Executive Offices)

(Zip code)

**(201) 343-5202**

Registrant's Telephone Number, Including Area Code

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

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

YES       NO

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

YES       NO

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

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

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

YES       NO

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As of August 6, 2015, 32,227,939 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

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December 31, 2014

Common stock, \$.001 par value; 90,000,000 shares authorized at June 30, 2015 and December 31, 2014; 32,227,939 and 30,391,513 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	32	30
Additional paid-in capital	109,705	108,382
Accumulated other comprehensive income	71	72
Accumulated deficit	(115,737 )	(114,165 )
Total stockholders' deficit	(5,929 )	(5,681 )
Total liabilities and stockholders' deficit	\$ 3,391	\$ 3,369

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

## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net revenues:				
Product revenues	\$521	\$248	\$1,049	\$467
License and royalty revenues	46	193	63	448
Total net revenues	567	441	1,112	915
Cost of goods sold	209	142	471	248
Gross margin	358	299	641	667
Operating expenses:				
Research and development	164	180	355	343
Depreciation and amortization	53	55	106	110
Selling, general and administrative	735	700	1,578	1,412
Total operating expenses	952	935	2,039	1,865
Loss from operations	(594)	(636)	(1,398)	(1,198)
Change in fair value of warrant liability	(1,196)	(4,685)	(188)	(7,436)
Interest expense	(9)	(17)	(21)	(212)
Other income (expense)	(16)	(1)	35	(4)
Net loss	(1,815)	(5,339)	(1,572)	(8,850)
Other comprehensive loss, foreign currency translation adjustments	(1)	(1)	(1)	(2)
Total comprehensive loss	(1,816)	(5,340)	(1,573)	(8,852)
Net loss per common share, basic and diluted	\$(0.06)	\$(0.21)	\$(0.05)	\$(0.40)
Weighted average common shares outstanding, basic and diluted	31,190,714	25,166,752	30,727,840	22,004,712

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount		Income	Deficit	
Balance, December 31, 2014 (audited)	30,391,513	\$ 30	\$ 108,382	\$ 72	\$ (114,165 )	\$(5,681)
Net loss					(1,572 )	(1,572)
Net unrealized losses on foreign currency translation, net of tax				(1 )		(1 )
Issuance of common stock, net of equity issuance costs of \$24	1,834,299	2	1,203			1,205
Exercise of warrants	2,127	-	1			1
Noncash stock-based compensation			119			119
Balance, June 30, 2015	32,227,939	\$ 32	\$ 109,705	\$ 71	\$ (115,737 )	\$(5,929)

*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, 2015	2014
Operating activities:		
Net loss	\$ (1,572 )	\$ (8,850 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	1	5
Amortization of other assets	105	105
Noncash stock-based compensation, including stock options and restricted stock	119	227
Change in fair value of warrant liability	188	7,436
Amortization of debt discount	-	142
Inventory reserve	-	31
Loss on foreign currency transactions	1	4
(Increase) decrease in operating assets:		
Accounts receivable	(185 )	9
Inventory	(233 )	(32 )
Prepaid expenses and other current assets	43	66
Increase (decrease) in operating liabilities:		

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Accounts payable	153		(46	)
Accrued expenses	(36	)	(134	)
Deferred revenue	(35	)	170	
Net cash used in operating activities	(1,451	)	(867	)
Financing activities:				
Proceeds from issuance of common stock	1,205		2,013	
Proceeds from exercise of warrants	1		2	
Payment of senior secured note	-		(1,500	)
Net cash provided by financing activities	1,206		515	
Effect of exchange rates on cash and cash equivalents	(2	)	(2	)
Net decrease in cash	(247	)	(354	)
Cash, beginning of period	1,284		579	
Cash, end of period	\$ 1,037		\$ 225	
Supplemental disclosure of cash flow information				
Cash paid for income taxes	\$ 2		\$ 4	
Cash paid for interest	\$ 25		\$ 54	

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

**NEPHROS, INC.**

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

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

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

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

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

**Interim Financial Information**

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

purchase warrants originally issued in November 2007 as components of equity instead of as derivative liabilities. Accordingly, certain amounts as of and for the three and six months ended June 30, 2014 presented herein reflect these previously restated amounts. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying condensed consolidated interim financial statements do not include all of the information and notes required by GAAP for a complete financial statement presentation. The condensed consolidated balance sheet as of December 31, 2014 was derived from the Company's audited consolidated financial statements but does not include all disclosures required by GAAP. In the opinion of management, the condensed consolidated interim financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. Certain reclassifications were made to the prior year's amounts to conform to the 2015 presentation. All intercompany transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

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

**NEPHROS, INC.**

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

**Note 2 - Basis of Presentation and Going Concern (continued)**

**Going Concern and Management's Response**

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

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

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

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

**Note 3 - Concentration of Credit Risk**

For the six months ended June 30, 2015 and 2014, the following customers accounted for the following percentages of the Company's revenues, respectively.

Customer	2015	2014
A	26 %	25 %
B	25 %	- %
C	16 %	5 %
D	3 %	49 %

As of June 30, 2015 and December 31, 2014, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2015	2014
A	52 %	22 %
B	10 %	25 %
C	3 %	35 %

**NEPHROS, INC.**

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

**Note 4 - Revenue Recognition**

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

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

Deferred revenue on the accompanying June 30, 2015 condensed consolidated balance sheet is approximately \$452,000 and is related to the Company's License Agreement with Bellco (see Note 11), which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,624,000 of revenue related to the Bellco License Agreement to date and approximately \$35,000 for the six months ended June 30, 2015. The Company recognized approximately \$448,000 of revenue related to this License Agreement for the six months ended June 30, 2014. Revenue recognized in the six months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the License Agreement were fully recognized as revenue as of December 31, 2014. Approximately \$35,000 of revenue will be recognized in the remaining six months of fiscal year 2015 and approximately \$70,000 of revenue will be recognized in each of the years ended December 31, 2016 through 2021. See Note 11, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

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

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

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

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

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

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

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

The estimated fair value of the 2007 Warrants is determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.



## NEPHROS, INC.

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

## Note 5 - Fair Value of Financial Instruments (continued)

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014 (in thousands):

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At June 30, 2015:				
Warrant liability	\$ -	\$ -	\$ 7,574	\$ 7,574

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

On the condensed consolidated statement of operations for the three month periods ended June 30, 2015 and 2014, the Company recorded expense of \$1,196,000 and \$4,685,000, respectively, as a result of the change in fair value of the warrant liability. On the condensed consolidated statement of operations for the six month periods ended June 30,

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2015 and 2014, the Company recorded expense of \$188,000 and \$7,436,000, respectively, as a result of the change in fair value of the warrant liability.

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

	June 30, 2015	December 31, 2014		
Calculated aggregate value	\$ 7,574	\$ 7,386		
Weighted average exercise price	\$ 0.30	\$ 0.30		
Closing price per share of common stock	\$ 0.71	\$ 0.79		
Volatility	135.0 %	136.9 %		
Weighted average remaining expected life (years)	4.5	5.0		
Risk-free interest rate	1.6 %	1.6 %		
Dividend yield	-	-		

**NEPHROS, INC.**

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

**Note 6 - Stock-Based Compensation**

**Stock Options**

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

The fair value of stock option awards is estimated using a Black-Scholes option pricing model. The fair value of stock-based awards that vest upon service conditions is amortized over the vesting period of the award using the straight-line method. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

The Company granted 2,242,693 stock options during the six months ended June 30, 2015 to employees. These stock options will be expensed over their respective applicable vesting periods, which are based on service and performance conditions. The fair value of all stock-based awards granted during the six months ended June 30, 2015 was approximately \$1,191,000.

The following assumptions were used for options granted for the six months ended June 30, 2015:

Assumptions for Option Grants	Six Months Ended June 30, 2015	
Stock Price Volatility	122.9	%
Risk-Free Interest Rates	1.53	%

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Expected Life (in years)	6.15	
Expected Dividend Yield	0	%

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 \$110,000 and \$224,000 for the six months ended June 30, 2015 and 2014, respectively. For the six months ended June 30, 2015, approximately \$100,000 and approximately \$10,000 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, 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 statements of operations.

There was no tax benefit related to expense recognized in the six months ended June 30, 2015 and 2014, as the Company is in a net operating loss position. As of June 30, 2015, there was approximately \$1,157,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Included in the \$1,157,000 of total unrecognized compensation, approximately \$167,000 will be recognized at the time that certain performance conditions are met. The remaining approximately \$990,000 will be amortized over the weighted average remaining requisite service period of 3.8 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$990,000 of unrecognized compensation cost, the Company expects to recognize approximately 17% in the remaining interim periods of 2015, approximately 30% in 2016, approximately 21% in 2017, approximately 21% in 2018, approximately 7% in 2019 and approximately 4% in 2020.

**NEPHROS, INC.**

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

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

**Restricted Stock**

Total stock-based compensation expense for the restricted stock grants was approximately \$9,000 and \$3,000, respectively, for the six months ended June 30, 2015 and 2014 and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations. All compensation expense related to the restricted stock awards has been recognized as of June 30, 2015.

**Note 7 - Warrants**

For the six months ended June 30, 2015, 2,127 shares of common stock were issued as a result of warrants exercised, resulting in proceeds of \$851.

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

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

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	For the three months		For the six months	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Loss per share - Basic:				
Numerator for basic loss per share	\$(1,815,000 )	\$(5,339,000 )	\$(1,572,000 )	\$(8,850,000 )
Denominator for basic loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Basic loss per common share	\$(0.06 )	\$(0.21 )	\$(0.05 )	\$(0.40 )
Loss per share - Diluted:				
Numerator for diluted loss per share	\$(1,815,000 )	\$(5,339,000 )	\$(1,572,000 )	\$(8,850,000 )
Adjust: Change in fair value of dilutive warrants outstanding	1,196,000	4,685,000	188,000	7,436,000
Numerator for diluted loss per share	\$(619,000 )	\$(654,000 )	\$(1,384,000 )	\$(1,414,000 )
Denominator for basic loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Plus: Incremental shares underlying warrants outstanding	-	-	-	-
Denominator for diluted loss per share	31,190,714	25,166,752	30,727,840	22,004,712
Diluted loss per common share	\$(0.06 )	\$(0.21 )	\$(0.05 )	\$(0.40 )

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

	June 30,	
	2015	2014
Shares underlying warrants outstanding	17,667,937	16,819,881
Shares underlying options outstanding	3,634,502	2,424,612

**NEPHROS, INC.**

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

**Note 9 - Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, "Revenue from Contracts with Customers," related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. Early adoption is permitted, but not before the original effective date for public companies (annual reporting periods beginning after December 15, 2016). In July 2015, the FASB approved a one-year deferral of the effective date of the new standard, making it effective for annual and interim reporting periods beginning January 1, 2018. The Company has not yet determined 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 has not yet determined the impact, if any, of the adoption of ASU 2014-15 might have on its consolidated financial statements.

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

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory (Subtopic 2015-11).” ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value, and methods for valuing inventory that consider market value will be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. The Company has not yet determined the impact, if any, the adoption of ASU 2015-11 might have on its consolidated financial statements.

**Note 10 - Inventory, net**

Inventory is stated at the lower of cost or market using the first-in first-out method and consists entirely of finished goods. The Company’s inventory as of June 30, 2015 and December 31, 2014 was as follows:

	June 30, 2015 (Unaudited)	December 31, 2014 (Audited)
Total Gross Inventory, Finished Goods	\$ 478,000	\$ 297,000
Less: Inventory reserve	(59,000 )	(111,000 )
Total Inventory	\$ 419,000	\$ 186,000

**Note 11 - Commitments and Contingencies**

Manufacturing and Suppliers

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



**NEPHROS, INC.**

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

**Note 11 - Commitments and Contingencies (continued)**

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the “First Amendment”), by and between the Company and Bellco, which amends the License Agreement. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. The Company has agreed to reduce the fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (estimated at approximately \$1.95 using current exchange rates) per unit; thereafter, €1.25 (estimated at approximately \$1.40 using current exchange rates) per unit. As of June 30, 2015, the Company recognized approximately \$28,000 related to the royalty payable by Bellco. 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.

License and Supply Agreement

On April 23, 2012, the Company entered into a License and Supply Agreement (the “License and Supply Agreement”) with Medica S.p.A. (“Medica”), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica’s proprietary Medisulfone ultrafiltration technology in conjunction with the Company’s filtration products (collectively, the “Filtration Products”), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, the Company granted to Medica an exclusive license under the Company’s intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, the Company agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000

(approximately \$700,000) and €750,000 (approximately \$880,000) for the years 2012, 2013 and 2014, respectively. In the six months ended June 30, 2015, the Company's aggregate purchase commitments totaled approximately €567,000 (approximately \$630,000). For calendar years 2015 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. The annual minimum amount for calendar 2015 is €1,000,000 (estimated at approximately \$1,110,000 using current exchange rates). In exchange for the license, the Company paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013.

As further consideration for the license and other rights granted to the Company, the Company granted Medica options to purchase 300,000 shares of the Company's common stock. The fair market value of these stock options was approximately \$273,000 at the time of their issuance, calculated as described in Note 6 under Stock-Based Compensation. The fair market value of the options has been capitalized as a long-term intangible asset along with the total installment payments described. Other long-term assets on the consolidated balance sheet is approximately \$1,579,000, net of \$672,000 accumulated amortization, and is related to the License and Supply Agreement. The asset is being amortized as an expense over the life of the agreement. Approximately \$105,000 has been charged to amortization expense in each of the six month periods ended June 30, 2015 and 2014 on the consolidated statements of operations and comprehensive loss. Approximately \$105,000 of amortization expense will be recognized in the remaining six months of fiscal year 2015 and approximately \$210,000 of amortization expense will be recognized in each of the years ended December 31, 2016 through 2022. In addition, for the period beginning April 23, 2014 through December 31, 2022, the Company will pay Medica a royalty rate of 3% of net sales of the Filtration Products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. The term of the License and Supply Agreement commenced on April 23, 2012 and continues in effect through December 31, 2022, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

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

**NEPHROS, INC.**

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

**Note 12 - Subsequent Events**

On July 24, 2015, the Company entered into a purchase agreement (the “Purchase Agreement”), together with a registration rights agreement (the “Registration Rights Agreement”), with Lincoln Park Capital Fund, LLC (“Lincoln Park”), an Illinois limited liability company.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to \$10.0 million in shares of the Company’s common stock, subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which the Company agreed to file with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 200,000 shares depending upon the closing sale price of the common stock (such purchases, “Regular Purchases”). However, in no event shall a Regular Purchase be more than \$500,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price as set forth in the Purchase Agreement. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the common stock is not below the threshold price as set forth in the Purchase Agreement. The Company’s sales of shares of common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then-outstanding shares of the common stock.

In connection with the Purchase Agreement, the Company issued to Lincoln Park 250,000 shares of common stock. Lincoln Park represented to the Company, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the “Securities Act”)), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities issued may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. There are no trading volume requirements or restrictions under the Purchase Agreement. Lincoln Park has no right to require any sales by the Company, but is obligated to make purchases from the Company as it directs in accordance with the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of Company shares.

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Purchase Agreement will be used for general corporate purposes and working capital requirements.

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*This discussion should be read in conjunction with our consolidated financial statements included in this Quarterly Report on Form 10-Q and the notes thereto, as well as the other sections of this Quarterly Report on Form 10-Q, including the “Forward-Looking Statements” section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2014, including the “Risk Factors” and “Business” sections thereof. This discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014. Our actual results may differ materially.*

### **Financial Operations Overview**

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

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

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

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

### **Business Overview**

## Edgar Filing: NEPHROS INC - Form 10-Q

Nephros is a commercial stage medical device company that develops and sells high performance liquid purification filters. Our filters, which we call ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water, bicarbonate concentrate and/or blood. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our ultrafilters use proprietary hollow fiber technology. We believe the hollow fiber design allows our ultrafilters to optimize the three elements critical to filter performance:

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

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

### Our Products

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

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

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

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

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



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

## Our Target Markets

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

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

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



In the first part of 2016, we plan to launch new products to expand on our hospital product line. The DSU-H and the SSU-H are both in-line filters designed to be installed between the wall water outlet and the point of delivery fixture, be it sink faucet, shower head or ice machine. The new products are designed to be attached to the end of a faucet or shower line. These products will compete directly with other end-of-faucet filters for short term use.

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

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

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

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

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

In the fall of 2015, we plan to launch a new marketing campaign focused on further expanding our products into dialysis clinics. We will be working with our distributors to leverage recent data generated by users of our dialysis products. We anticipate that one or more of those data sets will be presented at the America Society of Nephrology in November 2015.

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

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

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

Reduction in number of hospitalizations and overall length of stay

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

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

We completed preparation of our OLpūr H2H HDF Modules and have manufactured lots of our OLpūr MD220 Hemodiafilters, H2H Substitution filters and H2H water filters. We also finalized our service contract to support the commercialization of our system in the field. In May 2014, DaVita Healthcare Partners announced that it had commenced delivering and evaluating on-line mid-dilution hemodiafiltration treatments to select patients at DaVita's North Colorado Springs Clinic. In February 2015, we announced that, in the course of the evaluation, DaVita informed Nephros that they would require additional validation of the system. Nephros and DaVita agreed upon a protocol for the additional validation work which was completed in March 2015. We have submitted the data report to DaVita, and have been informed that it is still under review. Upon confirmatory review of the additional validation work, it is anticipated that DaVita will continue its evaluation. In March 2015, we announced that the Renal Research Institute, a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. We also anticipate evaluating our on-line mid-dilution HDF system at other clinics throughout the U.S. with the intent of developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of improving the quality of life for the patient, reducing overall expenditure compared to other dialysis modalities, minimizing the impact on nurse work flow at the clinic, and demonstrating the phamacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems.

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

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

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

*Commercial Facilities.* In October 2013, we announced the voluntary recalls of our point of use (POU) and DSU in-line ultrafilters used in hospital water treatment applications. As a result, we recalled all production lots of our POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, for the DSU in-line ultrafilter, we also requested that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect our dialysis products. We are also in the process of addressing certain issues raised by the FDA in a warning letter that we received in May 2015. In the letter, the FDA alleges deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter does not restrict our ability to manufacture, produce or ship any of our products, nor does it require the withdrawal of any product from the marketplace. We have responded in writing to the FDA’s concerns and we intend to work diligently to address each concern to the FDA’s satisfaction.

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

We have been working with customers to test prototype filters in commercial settings, such as data centers, and other high-flow-rate applications where particle reduction can provide an advantage. In the first part of 2016, we intend to launch new products into the commercial market. Specifically, we will launch a 10” and 20” filter cartridges that insert into standard filter housings, such as Pentek, Cuno, Shelco and Graver. We will be working with existing distributors and their existing customers, and seeking new distributors to address customers not currently targeted by our existing distributors.

### **Critical Accounting Policies**

The discussion and analysis of our consolidated financial condition and results of operations are based upon our condensed consolidated interim financial statements. These condensed consolidated financial statements have been prepared following the requirements of accounting principles generally accepted in the United States (“GAAP”) and Rule 8-03 of Regulation S-X for interim periods and require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to potential impairment of investments and share-based compensation expense. As these are condensed consolidated financial statements, you should also read expanded information about our critical accounting policies and estimates provided in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Form 10-K for the year ended December 31, 2014. There have been no material changes to our critical accounting policies and estimates from the information provided in our Form 10-K for the year ended December 31, 2014.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. Early adoption is permitted, but not before the original effective date for public companies (annual reporting periods beginning after December 15, 2016). In July 2015, the FASB approved a one-year deferral of the effective date of the new standard, making it effective for annual and interim reporting periods beginning January 1, 2018. We are currently reviewing the revised guidance and assessing the potential impact on our consolidated financial statements.

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

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

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory (Subtopic 2015-11).” ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. We are currently evaluating the impact the adoption of ASU 2015-11 might have on its 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, 2015 Compared to the Three Months Ended June 30, 2014*

#### *Revenues*

Total net revenues for the three months ended June 30, 2015 were approximately \$567,000 compared to approximately \$441,000 for the three months ended June 30, 2014. Total net revenues increased approximately \$126,000 or 29%, arising from a 110% increase, or approximately \$273,000, in water filter sales on dialysis and commercial water as well as royalty revenue of approximately \$28,000 recognized in connection to the Bellco license agreement. These increases were partially offset by a 91% decrease, or approximately \$175,000, in licensing revenue related to the Bellco license agreement. The increase in water filter sales was primarily driven by an increase in sales in the hospital market resulting from the DSU-H and SSU-H product launch following the FDA 510k clearance in October 2014. Revenue recognized related to the Bellco license agreement in the three months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the Bellco license agreement were fully recognized as revenue as of December 31, 2014, accounting for the decrease in the higher recognition of licensing revenue in the six month period ended June 30, 2014.

*Cost of Goods Sold*

Cost of goods sold was approximately \$209,000 for the three months ended June 30, 2015 compared to approximately \$142,000 for the three months ended June 30, 2014. The increase of approximately \$67,000, or 47%, during the three months ended June 30, 2015 compared to the same period in 2014 is primarily due to an increase in sales volume and any cost of sales gains arising from favorable exchange rate impacts, offset by product mix changes in the three months ended June 30, 2015 compared to the three months ended June 30, 2014.

*Gross Margin*

Gross margin and gross margin as a percentage of product revenues was approximately \$312,000, or 60%, for the three months ended June 30, 2015 compared to approximately \$106,000, or 43%, for the six months ended June 30, 2014. The increase of approximately 17% was primarily related to both an increase in direct sales, which has higher margin than indirect sales, and a modification in the distributor pricing structure to focus on annual sales volume....

*Research and Development*

Research and development expenses were approximately \$164,000 and \$180,000 respectively, for the three months ended June 30, 2015 and June 30, 2014. This decrease of approximately \$16,000, or 9%, is primarily due to a decrease in research and development costs and other project costs related to our OLPür H2H Module, which is currently being used commercially to treat patients. .

*Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$53,000 for the three months ended June 30, 2015 compared to approximately \$55,000 for the three months ended June 30, 2014. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$53,000 for both the three months ended June 30, 2015 and the three months ended June 30, 2014. The remaining \$2,000 recognized in the three months ended June 30, 2014 was depreciation on equipment and tools.

*Selling, General and Administrative Expenses*



Selling, general and administrative expenses were approximately \$735,000 for the three months ended June 30, 2015 compared to approximately \$700,000 for the three months ended June 30, 2014, an increase of approximately \$35,000 or 5%. The increase is primarily due to an increase in travel expenses of approximately \$32,000 as a result of an increased sales effort and an increase in professional service and legal expenses of approximately \$21,000 partially offset by a decrease in personnel costs of approximately \$18,000. The decrease in personnel costs of approximately \$18,000 was primarily related to a decrease of in salaries and stock based compensation expense as a result of the departure of the former CEO. This decrease was partially offset by an increase of approximately \$23,000 in sales commission due to the increased sales effort in addition to an increase in directors' compensation expense of approximately \$13,000 due to an increase in the number of Board members.

*Interest Expense*

The table below summarizes interest expense for the three months ended June 30, 2015 and 2014:

	2015	2014
Interest - outstanding payables due to a vendor	\$9,000	\$16,000
Other	-	1,000
Total interest expense	\$9,000	\$17,000

*Change in Fair Value of Warrant Liability*

Certain warrants are classified as liabilities at their fair value and adjusted to their fair value at each reporting period. The fair value of such warrants issued have been estimated using a binomial options pricing model. For the three months ended June 30, 2015 and 2014, the change in fair value of the warrant liability was an increase of approximately \$1,196,000 and an increase of approximately \$4,685,000, respectively.

*Other Income (Expense)*

Other income (expense) relates to foreign currency gains and losses on invoices paid to an international supplier. A foreign currency loss of approximately \$16,000 was recognized for the three months ended June 30, 2015 compared to a foreign currency loss of approximately \$1,000 for the three months ended June 30, 2014.

*Six Months Ended June 30, 2015 Compared to the Six Months Ended June 30, 2014*

*Revenues*

Total net revenues for the six months ended June 30, 2015 were approximately \$1,112,000 compared to approximately \$915,000 for the six months ended June 30, 2014. Total net revenues increased approximately \$197,000 or 22%, arising from a 197% increase, or approximately \$582,000, in water filter sales on dialysis and commercial water as well as royalty revenue of approximately \$28,000 recognized in connection to the Bellco license agreement. These increases were partially offset by a \$413,000 decrease, or approximately 92%, in licensing revenue related to the Bellco license agreement. The increase in water filter sales was primarily driven by an increase in sales in the hospital market resulting from the DSU-H and SSU-H product launch following the FDA 510k clearance in October 2014. Revenue recognized related to the Bellco license agreement in the six months ended June 30, 2015 relates only to the upfront payment received in February 2014. All previously received payments related to the Bellco license agreement were fully recognized as revenue as of December 31, 2014, accounting for the decrease in the higher recognition of licensing revenue in the six month period ended June 30, 2014.

*Cost of Goods Sold*

Cost of goods sold was approximately \$471,000 for the six months ended June 30, 2015 compared to approximately \$248,000 for the six months ended June 30, 2014. The increase of approximately \$223,000, or 90%, during the three months ended June 30, 2015 compared to the same period in 2014 is primarily due to increase in sales volume and any cost of sales gains arising from favorable exchange rate impacts, offset by product mix changes in the six months ended June 30, 2015 compared to the six months ended June 30, 2014.

*Gross Margin*

Gross margin and gross margin as a percentage of product revenues was approximately \$578,000, or 55%, for the six months ended June 30, 2015 compared to approximately \$219,000, or 47%, for the six months ended June 30, 2014. This increase of approximately 8% was primarily related both an increase in direct sales, which has higher margin than indirect sales, and a modification in the distributor pricing structure to focus on annual sales volume.

*Research and Development*

Research and development expenses were approximately \$355,000 and \$343,000 respectively, for the six months ended June 30, 2015 and June 30, 2014. This increase of approximately \$12,000, or 3%, is primarily due to a slight increase in research and development costs and other project costs primarily related to our OLPür H2H Module as a result of timing of incurred expenses.

#### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$106,000 for the six months ended June 30, 2015 compared to approximately \$110,000 for the six months ended June 30, 2014. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$105,000 for the six months ended June 30, 2015 compared to approximately \$106,000 for the six months ended June 30, 2014. The remaining \$1,000 and \$4,000, respectively, recognized in the six months ended June 30, 2015 and 2014 was depreciation on equipment and tools.

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

Selling, general and administrative expenses were approximately \$1,578,000 for the six months ended June 30, 2015 compared to approximately \$1,412,000 for the six months ended June 30, 2014, an increase of approximately \$166,000, or 12%. The increase is primarily due to an increase in personnel costs of approximately \$65,000, an increase in travel related expense of approximately \$34,000 as a result of an increased sales effort and an increase in professional services expenses of approximately \$90,000 primarily related to the additional expenses incurred. These costs were partially offset by a decrease in legal expenses of approximately \$28,000. Legal expenses were higher for the six months ended June 30, 2014 as a result of fees incurred in relation to the October 2013 product recall. The increase in personnel costs of approximately \$65,000 was primarily related to an increase in salaries and commissions of approximately \$148,000 related to the hiring of a new CEO and an increase in the sales effort in addition to an increase in directors' compensation expense of approximately \$29,000 due to an increase in the number of Board members. Partially offsetting the increase in personnel costs was a decrease of approximately \$112,000 primarily related to the forfeiture of the former CEO's unvested stock options.

*Interest Expense*

The table below summarizes interest expense for the six months ended June 30, 2015 and 2014:

	2015	2014
Interest related to November 2013 senior secured note	\$-	\$37,000
Amortization of debt discount - November 2013 senior secured note	-	142,000
Interest - outstanding payables due to a vendor	21,000	32,000
Other	-	1,000
Total interest expense	\$21,000	\$212,000

*Change in Fair Value of Warrant Liability*

Certain warrants are classified as liabilities at their fair value and adjusted to their fair value at each reporting period. The fair value of such warrants issued have been estimated using a binomial options pricing model. For the six months ended June 30, 2015 and 2014, the change in fair value of the warrant liability was an increase of approximately \$188,000 and \$7,436,000, respectively.

*Other Income (Expense)*

Other income (expense) relates to foreign currency gains and losses on invoices paid to an international supplier. A foreign currency gain was recognized for the six months ended June 30, 2015 of approximately \$35,000 compared to a foreign currency loss of approximately \$4,000 for the six months ended June 30, 2014.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of June 30, 2015 and 2014 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

June 30,

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Liquidity and capital resources	2015	2014
Cash	\$1,037	\$225
Other current assets	775	335
Working capital (deficit)	448	(1,124)
Stockholders' equity (deficit)	(5,929)	216

At June 30, 2015, we had an accumulated deficit of approximately \$115,737,000 and we expect to incur additional operating losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or license revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, license revenue, and rights offerings.

On July 24, 2015, we entered into a purchase agreement, together with a registration rights agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Under the terms and subject to the conditions of the purchase agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to \$10.0 million in shares of our common stock, subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which we agreed to file with the SEC pursuant to the registration rights agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 200,000 shares depending upon the closing sale price of the common stock. However, in no event shall these purchases be more than \$500,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price as set forth in the purchase agreement. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a purchase the closing sale price of the common stock is not below the threshold price as set forth in the purchase agreement. Our sales of shares of common stock to Lincoln Park under the purchase agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then-outstanding shares of the common stock.

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

On February 19, 2014, we entered into the First Amendment to License Agreement (the “First Amendment”), with Bellco, which amends the License Agreement entered into as of July 1, 2011. Pursuant to the First Amendment, both parties agreed to extend the term of the License Agreement through December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at our discretion, result in conversion of the license to non-exclusive status. We have agreed to reduce the fixed royalty payment payable to us for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay us a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (estimated at approximately \$1.95 using current exchange rates) per unit; thereafter, €1.25 (estimated at approximately \$1.40 using current exchange rates) per unit. As of June 30, 2015, the Company recorded a receivable of approximately \$28,000 related to the royalty payable by Bellco. In addition, we received a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that we pursue a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, we will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.

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

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

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

- for the marketing and sales of our water-filtration products;

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

for working capital purposes.

At June 30, 2015, we had cash totaling approximately \$1,037,000 and total assets of approximately \$1,812,000, excluding other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,579,000.

We expect that the approximately \$1.23 million of gross proceeds that we received upon the closing of the May 2015 private placement of 1,834,299 units of our securities, the \$10.0 million available to us pursuant to the purchase agreement with Lincoln Park, and the projected increase in product sales from the hospital market, will allow us to fund our operations through fiscal year 2016. If our sales are not sufficient to meet our cash needs, and our stock price goes below the floor set in the Lincoln Park purchase agreement of \$0.35, then we would not have access to the Lincoln Park funding mechanism and would need to raise additional financing using an alternative method. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must use additional financing available to us through the purchase agreement with Lincoln Park to fund our operations. We may need to raise additional financing in the future, and if we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we may be forced to curtail our planned activities and operations or cease operations entirely. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$1,450,000 for the six months ended June 30, 2015 compared to approximately \$867,000 for the six months ended June 30, 2014. Although our net loss decreased by approximately \$7,278,000 during the six months ended June 30, 2015 compared to the six months ended June 30, 2014, the primary reason for the decrease was due to the noncash impact of the change in fair value of the warrant liability. The warrant liability increased by approximately \$188,000 in the six months ended June 30, 2015 compared to an increase of approximately \$7,436,000 in the six months ended June 30, 2014.

The most significant items contributing to the net increase of approximately \$584,000 in cash used in operating activities during the six months ended June 30, 2015 compared to the six months ended June 30, 2014 are highlighted below:

our deferred revenue decreased by approximately \$35,000 in the 2015 period compared to an increase of approximately \$170,000 in the 2014 period as a result of the upfront payment received from Bellco in February 2014;

our stock based compensation was approximately \$119,000 during the 2015 period compared to approximately \$227,000 during the 2014 period. The decrease was due to the forfeiture of unvested options as a result of the departure of the former CEO;

during the 2014 period, our inventory reserve increased by approximately \$31,000. There was no additional inventory reserve need during the 2015 period as a result of increased sales volume.

during the 2015 period, our amortization of debt discount decreased by approximately \$142,000 compared to the 2014 period. There was no outstanding debt during the 2015 period.

our accounts receivable increased by approximately \$184,000 during the 2015 period compared to a decrease of approximately \$9,000 during the 2014 period as a result of increased revenue; and

our inventory increased by approximately \$233,000 during the 2015 period compared to an increase of approximately \$32,000 during the 2014 period as a result of increased sales volume; and

Offsetting the above changes are the following items:

our accounts payable increased by approximately \$152,000 in the 2015 period compared to a decrease of approximately \$46,000 in the 2014 period as a result of an increase in inventory; and

our accrued expenses decreased by approximately \$37,000 in the 2015 period compared to a decrease of approximately \$134,000 in the 2014 period.

Net cash provided by financing activities for the six months ended June 30, 2015 of \$1,206,000 resulted from net proceeds of approximately \$1,205,000 resulting from the issuance of common stock and approximately \$1,000 of proceeds resulting from the exercise of warrants.



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

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as of June 30, 2015 or 2014.

## Forward-Looking Statements

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

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

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

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

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

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

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

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

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

we may not be able to effectively market our products;

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

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

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

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

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

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

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

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

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

Not required for smaller reporting companies.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which is designed to provide reasonable assurance that information required to be disclosed in our reports filed pursuant to the Exchange Act is accumulated and communicated to management in a timely manner. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud have been or will be detected.

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

At the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Acting Chief Financial Officer concluded that, due to the material weakness in our internal control over financial reporting described below, our disclosure controls and procedures as of the end of the period covered by this report were not effective.

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

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

In connection with the preparation of our financial statements for the year ended December 31, 2014, our management discovered that we had improperly accounted for our warrants as components of equity instead of as derivative liabilities, and our management and auditors determined that this resulted from a material weakness in internal control over financial reporting. During the quarter ended June 30, 2015, we expanded and improved our review process for complex securities and related accounting standards to remediate this material weakness; however, as of June 30, 2015, this material weakness continues to exist. We plan to further improve our review process by enhancing access to accounting literature, identification of third party professionals with whom to consult regarding complex accounting applications and consideration of additional staff with the requisite experience and training to supplement existing accounting professionals.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 6. Exhibits

#### EXHIBIT INDEX

- 10.1 Employment Agreement dated April 15, 2015, between Daron Evans and Nephros, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 21, 2015).
- 10.2 Form of Common Stock Purchase Warrant to be issued to various investors (incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2015).
- 10.3 Form of Securities Purchase Agreement entered into among the Company and various accredited investors on May 12, 2015 (incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2015).
- 10.4 Second Amendment to License and Supply Agreement, between Nephros, Inc. and Medica S.p.A., dated May 4, 2015. \*
- 10.5 Sublicense Agreement, between Nephros, Inc. and CamelBak Products, LLC, dated May 6, 2015. \* +
- 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.

+ Confidential treatment has been requested for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

**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 10, 2015      By:      /s/ Daron Evans  
Name:      Daron Evans  
Title:      President, Chief Executive Officer and  
                 Acting Chief  
                 Financial Officer (Principal Executive  
                 Officer and  
                 Principal Financial and Accounting Officer)