

NEPHROS INC  
Form 10-Q  
May 11, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended: **March 31, 2016**

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.**

Edgar Filing: NEPHROS INC - Form 10-Q

(Exact name of Registrant as Specified in Its Charter)

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

**41 Grand Avenue**  
**07661**  
**River Edge, NJ**  
(Address of Principal Executive Offices) (Zip code)

**(201) 343-5202**  
Registrant's Telephone Number, Including Area Code

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

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

YES  NO

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

YES  NO

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

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

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

YES  NO

As of May 5, 2016, 48,825,461 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

**Table of Contents**

	<b>Page No.</b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets - March 31, 2016 (unaudited) and December 31, 2015 (audited)</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) - Three months ended March 31, 2016 and 2015 (unaudited)</u>	4
<u>Consolidated Statement of Changes in Stockholders' Equity - Three months ended March 31, 2016 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows - Three months ended March 31, 2016 and 2015 (unaudited)</u>	6
<u>Notes to Unaudited Condensed Consolidated Interim Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 4. <u>Controls and Procedures</u>	26
<b><u>PART II - OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	27
Item 6. <u>Exhibits</u>	27
<b><u>SIGNATURES</u></b>	28

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

	(Unaudited) March 31, 2016	(Audited) December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash	\$ 701	\$1,248
Accounts receivable, net	569	397
Investment in lease, net – current portion	22	-
Inventory, net	476	591
Prepaid expenses and other current assets	105	228
Total current assets	1,873	2,464
Property and equipment, net	41	12
Investment in lease, net – less current portion	71	-
Other assets, net	1,442	1,494
Total assets	\$ 3,427	\$3,970
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 744	\$652
Accrued expenses	290	237
Deferred revenue, current portion	70	70
Total current liabilities	1,104	959
Long-term portion of deferred revenue	330	347
Total liabilities	1,434	1,306

**Commitments and Contingencies****Stockholders' equity:**

Preferred stock, \$.001 par value; 5,000,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31,	-	-
---	---	---

Edgar Filing: NEPHROS INC - Form 10-Q

2015

Common stock, \$.001 par value; 90,000,000 shares authorized at March 31, 2016 and December 31, 2015; 48,825,461 and 48,580,355 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively.	49	49
Additional paid-in capital	119,961	119,797
Accumulated other comprehensive income	72	71
Accumulated deficit	(118,089 )	(117,253)
Total stockholders' equity	1,993	2,664
Total liabilities and stockholders' equity	\$ 3,427	\$3,970

*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 INCOME  
(LOSS)

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net revenues:		
Product revenues	\$545	\$527
License and royalty revenues	45	17
Total net revenues	590	544
Cost of goods sold	295	262
Gross margin	295	282
Operating expenses:		
Research and development	269	192
Depreciation and amortization	55	53
Selling, general and administrative	777	843
Total operating expenses	1,101	1,088
Loss from operations	(806)	(806)
Change in fair value of warrant liability	-	1,009
Interest expense	(14)	(11)
Interest income	1	-
Other income (expense)	(17)	51
Net income (loss)	(836)	243
Other comprehensive income, foreign currency translation adjustments	1	-
Total comprehensive income (loss)	\$(835)	\$243
Net income (loss) per common share, basic	\$(0.02)	\$0.01
Weighted average common shares outstanding, basic	48,173,521	30,259,823
Net loss per common share, diluted	\$(0.02)	\$(0.02)
Weighted average common shares outstanding, diluted	48,173,521	37,082,499

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

## NEPHROS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income		Accumulated Deficit	Total
	Shares	Amount					
Balance, December 31, 2015 (audited)	48,580,355	\$ 49	\$ 119,797	\$ 71		\$ (117,253 )	\$ 2,664
Net loss		-				(836 )	(836 )
Net unrealized gains on foreign currency translation, net of tax				1			1
Issuance of restricted stock	244,200		16				16
Exercise of warrants	906	-	1				1
Noncash stock-based compensation		-	147				147
Balance, March 31, 2016	48,825,461	\$ 49	\$ 119,961	\$ 72		\$ (118,089 )	\$ 1,993

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



## NEPHROS, INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31, 2016	2015
Operating activities:		
Net income (loss)	\$ (836 )	\$ 243
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation of property and equipment	3	1
Amortization of other assets	52	52
Non-cash stock-based compensation, including stock options and restricted stock	127	26
Non-employee stock-based compensation	20	-
Change in fair value of warrant liability	-	(1,009 )
Inventory reserve	27	-
Allowance for doubtful accounts reserve	9	-
(Gain)/loss on foreign currency transactions	14	(40 )
(Increase) decrease in operating assets:		
Accounts receivable	(181 )	(224 )
Inventory	106	(22 )
Prepaid expenses and other current assets	7	22
Increase (decrease) in operating liabilities:		
Accounts payable	78	(39 )
Accrued expenses	69	90

Edgar Filing: NEPHROS INC - Form 10-Q

Deferred revenue	(17	)	(17	)
Net cash used in operating activities	(522	)	(917	)
Investing activities:				
Purchase of property, plant and equipment	(26	)	-	
Net cash used in investing activities	(26	)	-	
Financing activities:				
Proceeds from exercise of warrants	1		1	
Net cash provided by financing activities	1		1	
Effect of exchange rates on cash	-		(1	)
Net decrease in cash	(547	)	(917	)
Cash, beginning of period	1,248		1,284	
Cash, end of period	\$ 701		\$ 367	
Supplemental disclosure of cash flow information				
Cash paid for interest	\$ 12		\$ 14	
Cash paid for income taxes	\$ 2		\$ -	
Supplemental disclosure of noncash investing and financing activities				
Investment in lease receivable, net	\$ 92		\$ -	
Cost of equipment in direct financing lease	\$ 92		-	
Restricted stock issued to settle liability	\$ 16		\$ -	
Reclassification of inventory from prepaid and other current assets	\$ 18		\$ -	
Reclassification of property, plant and equipment from prepaid and other current assets	\$ 98		\$ -	

*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. (collectively with subsidiary, “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 (“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 Nephros, Inc. In August 2003, the Company established a European Customer Service and financial operations center in Dublin, Ireland.

The U.S. facilities, located at 41 Grand Avenue, River Edge, New Jersey, 07661, are used to house the Company’s corporate headquarters and research facilities.

**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 should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 30, 2016. 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, 2015 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. All intercompany transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

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

### **Reclassifications**

Certain reclassifications were made to the prior year's amounts to conform to the 2016 presentation.

### **Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The Company's consolidated 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 and has not generated positive cash flow from operations since inception. To become profitable, the Company must increase revenue substantially and achieve and maintain income from operations. If the Company is not able to increase revenue and generate income from operations sufficiently to achieve profitability, its results from operations and its financial condition will be materially and adversely affected.



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

Based on current cash flow projections, the Company expects that the proceeds from the Lambda Class D warrant exercise and the additional warrant exercises that resulted from the tender offer and the projected increases in product sales will allow the Company to fund its operations at least into the third quarter of 2016, depending on the timing and market up-take of the Company's new products. This assumption excludes the impact of future cash receipts from recurring operations. 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 - Major Customers and Concentration of Credit Risk**

For the three months ended March 31, 2016 and 2015, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2016	2015
A	42 %	28 %
B	17 %	18 %
C	11 %	- %
D	2 %	30 %

As of March 31, 2016 and December 31, 2015, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2016	2015
A	51 %	37 %
B	12 %	3 %
C	11 %	11 %
D	2 %	23 %

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was approximately \$24,000 and \$15,000 as of March 31, 2016 and December 31, 2015, respectively.

#### **Note 4 - Revenue Recognition**

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

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

Deferred revenue on the accompanying March 31, 2016 condensed consolidated balance sheet is approximately \$400,000 and is related to the License Agreement with Bellco, which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,623,000 of license revenue related to the License Agreement to date and approximately \$17,000 for the three months ended March 31, 2016. The Company recognized approximately \$17,000 of license revenue related to this License Agreement for the three months ended March 31, 2015. Approximately \$52,000 of revenue will be recognized in the remaining nine months of fiscal year 2016 and approximately \$69,000 of revenue will be recognized in each of the years ended December 31, 2017 through 2021. Beginning on January 1, 2015, Bellco pays the Company a royalty based on the number of units of certain products sold per year due one fiscal quarter in arrears. For the three months ended March 31, 2016, the Company recognized royalty revenue of approximately \$28,000. See Note 11, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

**NEPHROS, INC.**

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

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

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

The 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).

Fair Value of Investment in Lease, net

The carrying value of the investment in lease, net, approximates fair value as of March 31, 2016.

Warrant Liability

The Company had outstanding warrants originally issued in 2007 (the "2007 Warrants") that were accounted for as a derivative liability until they were fully exercised on September 29, 2015. The 2007 Warrants were classified as a



liability because the transactions that would trigger the anti-dilution adjustment provision in the 2007 Warrants were not inputs to the fair value of the 2007 Warrants. The 2007 Warrants were 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 utilized a binomial options pricing model to value the 2007 Warrants at each reporting period.

The estimated fair value of the 2007 Warrants as of March 31, 2015 was 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 estimated the volatility of its common stock based on historical volatility that matched the expected remaining life of the 2007 Warrants. The risk-free interest rate was 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 2007 Warrants. The expected life of the 2007 Warrants was assumed to be equivalent to their remaining contractual term. The dividend rate was based on the historical rate, which the Company anticipated to remain at zero.

On the condensed consolidated statement of operations and comprehensive income (loss) for the three-month period ended March 31, 2015, the Company recorded income of \$1,009,000 as a result of the change in fair value of the warrant liability. A reconciliation of the warrant liability is as follows:

	2007 Warrants
Balance at December 31, 2014	\$7,386,000
Decrease in fair value of warrant liability	(1,009,000)
Balance at March 31, 2015	\$6,377,000

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

The following table summarizes the calculated aggregate fair value of the 2007 Warrants, along with the assumptions utilized in each calculation:

	March 31,	
	2015	
Calculated aggregate value	\$6,377,000	
Weighted average exercise price	\$0.30	
Closing price per share of common stock	\$0.60	
Volatility	138	%
Weighted average remaining expected life (years)	4.7	
Risk-free interest rate	1.4	%
Dividend yield	-	

On September 29, 2015, the Company entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda Investors, LLC ("Lambda"), the Company's largest stockholder who owns approximately 62% of the Company's outstanding common stock. Pursuant to the Amendment, the Company agreed to reduce the current exercise price of the 2007 Warrants by 50%, to \$0.15 per share, in exchange for Lambda's agreement to exercise the 2007 Warrants in their entirety immediately following the modification.

**Note 6 - Stock Plans and Share-Based Payments****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, and as such, these stock options are revalued at each reporting period through the vesting period.

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

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

Stock-based compensation expense was approximately \$102,000 and \$20,000 for the three months ended March 31, 2016 and 2015, respectively. For the three months ended March 31, 2016, approximately \$7,000 and approximately \$95,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive income (loss). For the three months ended March 31, 2015, approximately \$16,000 and approximately \$4,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive income (loss).

There was no tax benefit related to expense recognized in the three months ended March 31, 2016 and 2015, as the Company is in a net operating loss position. As of March 31, 2016, there was approximately \$1,096,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately \$158,000 of the \$1,096,000 total unrecognized compensation will be recognized at the time that certain performance conditions are met. The remaining approximately \$938,000 will be amortized over the weighted average remaining requisite service period of 2.9 years. Such amount does not include the effect of future grants of equity compensation, if any.

**NEPHROS, INC.**

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

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

**Restricted Stock**

On January 1, 2016, the Company issued 89,773 shares of restricted stock as compensation for services previously rendered by a non-employee director. The grant date fair value of the outstanding restricted stock awards was approximately \$16,000.

During the three months ended March 31, 2016, the Company issued 154,427 shares of restricted stock as payment for non-employee services to be rendered. The grant date fair value of the outstanding restricted stock awards was approximately \$46,000 and was based on the fair value of the common stock on the date of grant. Of the total grant date fair value of approximately \$46,000, approximately \$20,000 was recorded during the three months ended March 31, 2016.

Additionally, restricted stock expense of approximately \$25,000 was recorded during the three months ended March 31, 2016 related to shares of restricted stock issued to employees during the year ended December 31, 2015.

Total stock based compensation for the restricted stock grants was approximately \$45,000 and \$6,000 for the three months ended March 31, 2016 and 2015, respectively, and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive income (loss). As of March 31, 2016, there was approximately \$41,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next three or six months, dependent upon the respective restricted stock agreements.

**Note 7 - Warrants**

For the three months ended March 31, 2016, 19,621 warrants were exercised, resulting in proceeds of approximately \$1,000 and the issuance of 906 shares of the Company's common stock. For the three months ended March 31, 2015, 20,927 warrants were exercised, resulting in proceeds of approximately \$1,000 and the issuance of 967 shares of the Company's common stock.

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

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

	For the three months	
	March 31, 2016	March 31, 2015
Income (loss) per share - Basic:		
Numerator for basic income (loss) per share	\$(836,000 )	\$243,000
Denominator for basic income (loss) per share	48,173,521	30,259,823
Basic income (loss) per common share	\$(0.02 )	\$0.01
Income (loss) per share - Diluted:		
Numerator for diluted income (loss) per share	\$(836,000 )	\$243,000
Adjust: Change in fair value of dilutive warrants outstanding	-	(1,009,000 )
Numerator for diluted income (loss) per share	\$(836,000 )	\$(766,000 )
Denominator for basic income (loss) per share	48,173,521	30,259,823
Plus: Incremental shares underlying warrants outstanding	-	6,822,676
Denominator for diluted income (loss) per share	48,173,521	37,082,499
Diluted income (loss) per common share	\$(0.02 )	\$(0.02 )

**NEPHROS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 8 - Net Income (Loss) per Common Share (continued)**

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

	March 31,	
	2016	2015
Shares underlying warrants outstanding	917,149	5,009,848
Shares underlying options outstanding	4,192,640	2,094,562
Unvested restricted stock	356,231	132,077

**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 to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and was to be effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. Early adoption was not permitted. In August, 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date”. The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting periods within that fiscal year. Earlier application is permitted only as of fiscal years beginning after December 31, 2016, including interim reporting periods with that fiscal year. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” ASU 2014-15 provides guidance about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to

continue as a going concern and sets rules for how this information should be disclosed in the financial statements. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating any impact the adoption of ASU 2014-15 might have on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. The Company does not believe that the adoption of ASU 2015-11 will have a significant impact on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, "Balance Sheet Classification of Deferred Taxes," that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. The Company does not believe that the adoption of ASU 2015-17 will have a significant impact on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases", that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity that is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is evaluating the impact of adopting this guidance on our consolidated financial statements.

**NEPHROS, INC.**

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

**Note 9 - Recent Accounting Pronouncements (continued)**

In March 2016, the FASB issued ASU No. 2016-08, "Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," which clarifies the implementation guidance on principal versus agent considerations. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting," which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2017. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, "Identifying Performance Obligations and Licensing," which clarifies the implementation guidance performance obligations and licensing. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

**Note 10 - Inventory, net**

Inventory is stated at the lower of cost or market using the first-in first-out method and consists entirely of finished goods. The Company's inventory as of March 31, 2016 and December 31, 2015 was as follows:



	March 31, 2016 (Unaudited)	December 31, 2015 (Audited)
Total Gross Inventory, Finished Goods	\$ 536,000	\$ 634,000
Less: Inventory reserve	(60,000 )	(43,000 )
Total Inventory, net	\$ 476,000	\$ 591,000

## Note 11 - Commitments and Contingencies

### Manufacturing and Suppliers

The Company has not and does not intend in the foreseeable 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 (the "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 License Agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon our written approval, other European countries where the Company does not sell the Products as well as non-European countries (referred to as the "Territory").

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the "First Amendment"), by and between the Company and Bellco, which amends the License Agreement. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement from December 31, 2016 to December 31, 2021. The First Amendment also expands the Territory covered by the License Agreement to include, on an exclusive basis, Sweden, Denmark, Norway and Finland, and, on a non-exclusive basis, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. The Company has agreed to reduce the fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (approximately \$1.91) per unit; thereafter, €1.25 (approximately \$1.36) per unit. In addition, the Company received a total of €450,000 (approximately \$612,000) in upfront fees in connection with the First Amendment, half of which was received on February 19, 2014 and the remaining half was received on April 4, 2014. In addition, the First Amendment provides that, in the event that the Company pursues a transaction to sell, assign or transfer all right, title and interest to the licensed patents to a third party, the Company will provide Bellco with written notice thereof and a right of first offer with respect to the contemplated transaction for a period of thirty (30) days.

**NEPHROS, INC.**

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

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

License and Supply Agreement

On April 23, 2012, the Company entered into a License and Supply Agreement (the “License and Supply Agreement”) with Medica S.p.A. (“Medica”), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica’s proprietary Medisulfone ultrafiltration technology in conjunction with the Company’s filtration products (collectively, the “Filtration Products”), and to engage in an exclusive supply arrangement for the Filtration Products. Under the License and Supply Agreement, Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Filtration Products worldwide, excluding Italy for the first three years, during the term of the License and Supply Agreement. In addition, the Company granted to Medica an exclusive license under the Company’s intellectual property to make the Filtration Products during the term of the License and Supply Agreement. In exchange for the rights granted, the Company agreed to make minimum annual aggregate purchases from Medica of €300,000 (approximately \$400,000), €500,000 (approximately \$700,000) and €750,000 (approximately \$880,000) for the years 2012, 2013 and 2014, respectively. In the year ended December 31, 2015, the Company’s aggregate purchase commitments totaled approximately €999,000 (approximately \$1,119,000). For calendar years 2016 through 2022, annual minimum amounts will be mutually agreed upon between Medica and the Company. In December 2015, the Company and Medica formalized the agreed upon minimum purchase level for 2016 of €1,200,000 (approximately \$1,500,000). In exchange for the license, the Company paid Medica a total of €1,500,000 (approximately \$2,000,000) in three installments: €500,000 (approximately \$700,000) on April 23, 2012, €600,000 (approximately \$800,000) on February 4, 2013, and €400,000 (approximately \$500,000) on May 23, 2013.

As further consideration for the license and other rights granted to the Company, the Company granted Medica options to purchase 300,000 shares of the Company’s common stock. The fair market value of these stock options was approximately \$273,000 at the time of their issuance, calculated as described in Note 6 under Stock-Based Compensation. Together with the total installment payments described above, the fair market value of the options has been capitalized as a long-term intangible asset. The gross value of the intangible asset capitalized was approximately \$2,250,000. Included in other long-term assets on the consolidated balance sheet is approximately \$1,421,000 and \$1,473,000, as of March 31, 2016 and December 31, 2015, respectively, related to the License and Supply Agreement. Accumulated amortization is approximately \$829,000 and \$777,000 as of March 31, 2016 and December 31, 2015, respectively. The asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately \$52,000 has been charged to amortization expense for the three months ended March 31, 2016 and 2015 on the condensed consolidated statement of operations and comprehensive loss. Approximately \$158,000 of

amortization expense will be recognized in the remainder of 2016 and approximately \$210,000 will be recognized in each of the years ended December 31, 2017 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. Approximately \$15,000 and \$14,000 is included in accrued expenses as of March 31, 2016 and December 31, 2015, respectively. 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.

As of September 2013, 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 11 - Commitments and Contingencies (continued)**

Contractual Obligations

The Company has an operating lease that expires on November 30, 2018 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately \$9,000. Included in other assets, net, on the condensed consolidated balance sheet as of March 31, 2016 is approximately \$21,000 related to a security deposit for the U.S. office facility. Rent expense was approximately \$29,000 and \$38,000 for the three months ended March 31, 2016 and 2015, respectively.

Investment in Lease, net

On October 8, 2015, the Company entered into an equipment lease agreement with Biocon 1, LLC. The lease commenced on January 1, 2016 with a term of 60 months and monthly rental payments of approximately \$1,800 will be paid to the Company. At the completion of the lease term, Biocon 1, LLC will own the equipment provided under the agreement. An investment in lease was established for the direct financing lease receivable at the present value of the future minimum lease payments. Interest income will be recognized monthly over the lease term using the effective-interest method. Cash received will be applied against the direct financing lease receivable and will be presented within changes in operating assets and liabilities in the operating section of the Company's consolidated statement of cash flows. At lease inception, an investment in the lease of approximately \$92,000 was recorded, net of unearned interest of approximately \$14,000. During the three months ended March 31, 2016, approximately \$1,000 was recognized in interest income. As of March 31, 2016, investment in lease, current is approximately \$22,000, net of unearned interest of \$5,000. As of March 31, 2016, investment in lease, noncurrent, is approximately \$71,000, net of unearned interest of \$8,000.

As of March 31, 2016, scheduled maturities of minimum lease payments receivable were as follows:

2016	\$18,000
------	----------

Edgar Filing: NEPHROS INC - Form 10-Q

2017	17,000
2018	18,000
2019	19,000
2020	21,000
	93,000
Less: Current portion	(22,000)
Investment in sales-type lease, noncurrent	\$71,000

**Note 12 - Subsequent Events**

In April 2016, the Company filed for 510(k) clearance of an endotoxin cartridge filter. The endotoxin cartridge filter, EndoPur™, is designed to provide hemodialysis quality water through ultrafiltration of the water in a dialysis clinic's reverse osmosis loop. The EndoPur™ filter retains particles as small as 0.005 microns, is designed to handle higher flowrates and will be offered in 10", 20", 30" or 40" sizes. Because the EndoPur™ conforms to the design controls of the SSU-D, and has the same intended use, the Company believed that the cartridge qualified for the Special 510(k): Device Modification process, which has a 30 day FDA review timeline. On April 28, 2016, the Company received a response from FDA, in which FDA noted that it had determined that the Special 510(k) should be converted to a Traditional 510(k). FDA requested additional information on the 20", 30" and 40" filter sizes and on the reusable external filter housing. Following discussions with FDA, the Company converted the Special 510(k) submission to a Traditional 510(k) submission for the 20", 30" and 40" filter sizes. The Company filed a separate Special 510(k) for the EndoPur™ 10" filter size in May 2016.

Due to the longer FDA review process associated with a Traditional 510(k) submission, the Company aims to launch the 20", 30" and 40" filter sizes early in the fourth quarter of 2016, subject to completion of the FDA clearance process. As the 10" filter size still qualifies for the Special 510(k) process, the Company aims to launch the 10" filter size early in the third quarter of 2016, subject to completion of the FDA clearance process.

## **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, 2015, 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, 2015. 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.

### **Overview**

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration (“HDF”) systems. Our filters, which are generally classified

as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate, and used in hospitals for the prevention of infection from water borne pathogens, such as legionella and pseudomonas. 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 OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease (“ESRD”). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

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.

### **Going Concern**

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

We have incurred significant losses in operations in each quarter and have not generated positive cash flow from operations since inception. To become profitable, we must increase revenue substantially and achieve and maintain income from operations. If we are not able to increase revenue and generate income from operations sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

Based on our current cash flow projections, we expect that the proceeds from the Lambda Class D warrant exercise and the additional warrant exercises that resulted from the tender offer and the projected increase in product sales will allow us to fund our operations at least into the third quarter of 2016, depending on the timing and market up-take of our new products. There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our commitments, we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our 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 us to continue to satisfy our capital requirements.





## **Our Products**

Presently, we have two core product lines: HDF Systems and Ultrafiltration Products.

### ***HDF Systems***

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 Hemodiafiltration Module (“H2H Module”), our OLpūr MD 220 Hemodiafilter (“HDF Filter”) and our H2H Substitution Filter (“Dialysate Filter”).

The H2H Module utilizes a standard HD machine to perform on-line hemodiafiltration therapy. The HD machine controls and monitors the basic treatment functions, as it would normally when providing HD therapy. The H2H Module is a free-standing, movable device that is placed next to either side of an HD machine. The H2H Module is connected to the clinic’s water supply, drain, and electricity.

The H2H Module utilizes the HDF Filter and is very similar to a typical hollow fiber dialyzer assembled with a single hollow fiber bundle made with a high-flux (or high-permeability) membrane. The fiber bundle is separated into two discrete, but serially connected blood paths. Dialysate flows in one direction that is counter-current to blood flow in Stage 1 and co-current to blood flow in Stage 2.

In addition to the HDF Filter, the H2H Module also utilizes a Dialysate Filter during patient treatment. The Dialysate Filter is a hollow fiber, ultrafilter device that consists of two sequential (redundant) ultrafiltration stages in a single housing. During on-line HDF with the H2H Module, fresh dialysate is redirected by the H2H Module’s hydraulic (substitution) pump and passed through this dual-stage ultrafilter before being infused as substitution fluid into the extracorporeal circuit. Providing ultrapure dialysate is crucial for the success of on-line HDF treatment.

Our HDF System is cleared by the FDA to market for use with an 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.

In May 2014, DaVita Healthcare Partners initiated an evaluation of our HDF System to treat 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 do not believe that DaVita will restart the evaluation in the near term.

In March 2015, we announced that the Renal Research Institute (“RRI”), a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. As of February 2015, our HDF Systems had performed over 1,200 patient treatments. Over the last 18 months of commercial use, we have gathered direct feedback from users of our HDF System to help improve our system and our training methodology. In January 2016, we updated our training procedures and rolled out a software update, which was focused on improving the system’s alignment with nurse workflow.

We are in discussions to evaluate our HDF system at other clinics throughout the U.S. and hope to announce the deployment of our HDF System at a new site in the first half of 2016. Our goal over the next 12-18 months is to work with RRI and the potential new site to developing a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of a) improving the quality of life for the patient, b) reducing overall expenditure compared to other dialysis modalities, c) minimizing the impact on nurse work flow at the clinic, and d) demonstrating the phamacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. In addition, we are in the process of developing version 2.0 of our HDF System, which will enable us to manufacture at scale, as well as potentially reduce the per treatment cost of performing HDF.

### *Ultrafiltration Products*

Our ultrafiltration products target a number of 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.

*Military and Outdoor Recreation:* Individual water purification devices used by soldiers and backpackers to produce drinking water in the field, as well as filters customized to remote water processing systems.

*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 May 2015, we received a warning letter from the FDA resulting from an October 2014 inspection. In the letter, the FDA alleged deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter did not restrict our ability to manufacture, produce or ship any of our products, nor did it require the withdrawal of any product from the marketplace. In August 2015, we received a subsequent letter from the FDA noting that it had received our response correspondence detailing our completed corrective actions. The corrective actions included revisions to our standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection. In April 2016, we received a third letter from the FDA noting that the FDA had completed its evaluation of our corrective actions and that, based on its evaluation, it appeared that we had addressed the deficiencies specified in the May 2015 warning letter.

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 half 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, showerhead or ice machine. The new products are designed to be attached to the end of a faucet or shower line. On October 27, 2015 we announced that we had submitted the S100 Point of Use filter to the FDA for 510(k) clearance. In late December 2015, the FDA requested additional information. On April 14, 2016, we announced that we received 510(k) clearance from the FDA to market our S100 Point of Use filter. 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.

In September 2015, we launched a new marketing campaign focused on further expanding our products into dialysis clinics, the Nephros Challenge. The Nephros Challenge is a money-back guarantee if a dialysis clinic does not see any measurable self-defined benefit from using Nephros Ultrafilters at the HD station to provide ultrapure water and bicarbonate. We concluded the Nephros Challenge program to focus on the launch of EndoPur™ ultrafilters, our 10” cartridge platform.

In March 2016, we launched the SSUmini product, developed to provide a lower cost ultrafiltration solution for water and bicarbonate flowrates of 0.5 gallons per minutes (“GPM”) or less. The SSUmini can be used as a polish filter for small, portable reverse osmosis (“RO”) water systems or on bicarbonate concentrate lines in dialysis clinics with centralized bicarbonate concentrate systems.

In April 2016, we filed for 510(k) clearance of an endotoxin cartridge filter. The endotoxin cartridge filter, EndoPur™, is designed to provide hemodialysis quality water through ultrafiltration of the water in a dialysis clinic’s reverse osmosis loop. The EndoPur™ filter retains particles as small as 0.005 microns, is designed to handle higher flowrates and will be offered in 10”, 20”, 30” or 40” sizes. Because the EndoPur™ conforms to the design controls of the SSU-D, and has the same intended use, we believed that the cartridge qualified for the Special 510(k): Device Modification process, which has a 30 day FDA review timeline. On April 28, 2016, we received a response from FDA, in which FDA noted that it had determined that the Special 510(k) should be converted to a Traditional 510(k). FDA requested additional information on the 20”, 30” and 40” filter sizes and on the reusable external filter housing. Following discussions with FDA, we converted the Special 510(k) submission to a Traditional 510(k) submission for the 20”, 30” and 40” filter sizes. We filed a separate Special 510(k) for the EndoPur™ 10” filter size in May 2016.

Due to the longer FDA review process associated with a Traditional 510(k) submission, we aim to launch the 20”, 30” and 40” filter sizes early in the fourth quarter of 2016, subject to completion of the FDA clearance process. As the 10” filter size still qualifies for the Special 510(k) process, we aim to launch the 10” filter size early in the third quarter of 2016, subject to completion of the FDA clearance process.

*Military and Outdoor Recreation.* Water is a key requirement for the soldier to be fully mission-capable. The availability of 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, is resource intensive, and is 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.

In 2015, we began working with multiple companies developing portable water purification systems designed to provide potable water in remote locations. Specifically, we have provided flushable filter prototypes to these companies for validation as one potential component in systems that employ multiple technologies to purify water from streams, lakes and rivers.

*Commercial Facilities.* In 2014, we launched 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 0.005 microns in size and can be used as a component of a facility water treatment system, or to filter water used in ice machines and soda fountains.

In November 2015, we announced a strategic partnership with Biocon 1, LLC. Biocon 1’s AETHER® Water Systems technology, which includes patented water filtration media and water filtration products, provides solutions for

customers to address all contaminate issues and to provide clean-tasting, sediment-free, scale-free, and bacteria-free water for the food service industry. AETHER® Water Systems are used with ice machines, coffee stations, and soda fountains in hotels, casual dining restaurants, fast food restaurants and convenience stores. As part of the collaboration, we have access to Biocon 1's anti-scale and related water filtration technology to develop filter products for the medical industry. In March 2016, Nephros shipped the first lot of filter cartridges to Biocon 1 for inclusion with its AETHER® line of filtration products. Also in March 2016, Biocon 1 shipped the first anti-scale filter samples to Nephros for testing in the medical setting.

While our EndoPur™ ultrafilter cartridge platform is designed initially for use in the dialysis setting, we anticipate making the product available for commercial uses by the second half of 2016. 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.

Over the last few years, we have been developing a high-throughput, auto-flushing filter system capable of handling 25 GPM, or greater, through our proprietary 0.005 micron fiber membrane. The flushable filter system is designed to remove submicron particulates in closed loop water systems, including cooling systems for data centers and hot water return loops in commercial buildings. Initial data suggests the ability to remove both organic and inorganic particulates. We intend to provide limited release of a 25 GPM system to specific customers for additional testing and validation by the third quarter of 2016.

We intend to develop flushable filter cartridges capable to filtering 2.5, 5 and 10 GPM through our fiber membrane. These smaller flushable filter systems have potential utility as a point-of-entry water purification system in restaurants, convenience stores and households. We intend to provide limited release of these products initially through Biocon in the second half of 2016.

Going forward, as we grow our water filtration business, we will be exploring opportunities for new applications for our filter products and will be open to evaluating new potential partnerships to expand our water filtration foot print.



## **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 allowance for doubtful accounts, reserve for inventory obsolescence, impairment analysis of capitalized license fees, 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, 2015. 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, 2015.

## **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 to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption, and was to be effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption was not permitted. In August, 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date”. The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting periods within that fiscal year. Earlier application is permitted only as of fiscal years beginning after December 31, 2016, including interim reporting periods with that fiscal year. 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 July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory,” that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. We do not believe that the adoption of ASU 2015-11 will have a significant impact on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, “Balance Sheet Classification of Deferred Taxes,” that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We do not believe that the adoption of ASU 2015-17 will have a significant impact on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities,” that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases”, that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, “Principal versus Agent Considerations (Reporting Revenue Gross versus Net),” which clarifies the implementation guidance on principal versus agent considerations. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for us beginning in the first quarter of fiscal year 2017. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, “Identifying Performance Obligations and Licensing,” which clarifies the implementation guidance performance obligations and licensing. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements.

## **Results of Operations**

### *Fluctuations in Operating Results*

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

### *Three Months Ended March 31, 2016 Compared to the Three Months Ended March 31, 2015*

#### *Revenues*

Total net revenues for the three months ended March 31, 2016 were approximately \$590,000 compared to approximately \$544,000 for the three months ended March 31, 2015, an increase of approximately \$46,000 or 8%. This increase was primarily caused by growth in hospital and commercial filter sales. In addition, royalty revenue increased in the three months ended March 31, 2016 compared to the three months ended March 31, 2015 as royalty revenue from the Bellco License Agreement was not recorded until the three months ended June 30, 2015. These increases were partially offset by a decrease in dialysis filter sales.

#### *Cost of Goods Sold*

Cost of goods sold was approximately \$295,000 for the three months ended March 31, 2016 compared to approximately \$262,000 for the three months ended March 31, 2015. The increase of approximately \$33,000, or 13%, during the three months ended March 31, 2016 compared to the same period in 2015 is primarily due to increased unit sales.

#### *Research and Development*

Research and development expenses were approximately \$269,000 and \$192,000 for the three months ended March 31, 2016 and March 31, 2015, respectively. This increase of approximately \$77,000, or 40%, is primarily due to increased headcount.

#### *Depreciation and Amortization Expense*

Depreciation and amortization expense was approximately \$55,000 for the three months ended March 31, 2016 compared to approximately \$53,000 for the three months ended March 31, 2015. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$52,000 for each of the three months ended March 31, 2016 and 2015. The remaining \$3,000 and \$1,000 recognized in the three months ended March 31, 2016 and 2015, respectively, was depreciation on equipment and tools.

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

Selling, general and administrative expenses were approximately \$777,000 for the three months ended March 31, 2016 compared to approximately \$843,000 for the three months ended March 31, 2015, a decrease of approximately \$66,000, or 8%. The decrease is primarily due to a one time severance expense incurred in 2015 in connection with

the departure of our former CEO and reductions in professional service expenses, offset by increased stock compensation expense.

*Change in Fair Value of Warrant Liability*

During the three months ended March 31, 2015, certain liability classified warrants were recorded at their fair value with adjustments to their fair value recognized at each reporting period. The fair value of such warrants was estimated using a binomial options pricing model. For the three months ended March 31, 2015, the change in fair value of the warrant liability was a decrease of approximately \$1,009,000. These liability classified warrants were exercised in full on September 29, 2015.

*Interest Expense*

Interest expense of approximately \$13,000 and approximately \$11,000 for the three months ended March 31, 2016 and 2015, respectively, relates to interest due on outstanding payables to a vendor.

*Interest Income*

Interest income of approximately \$1,000 for the three months ended March 31, 2016 relates to interest income recognized on a lease receivable.

*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 \$17,000 was recognized for the three months ended March 31, 2016 compared to a foreign currency gain of approximately \$51,000 for the three months ended March 31, 2015.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of March 31, 2016 and 2015 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Edgar Filing: NEPHROS INC - Form 10-Q

	March 31,	
	2016	2015
Liquidity and capital resources		
Cash	\$701	\$367
Other current assets	1,172	624
Working capital surplus (deficit)	769	(265 )
Stockholders' equity (deficit)	1,993	(5,411)

At March 31, 2016, we had an accumulated deficit of approximately \$118,089,000 and we expect to incur additional operating losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or license revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, license revenue, and rights offerings.

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

the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;

the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;

the continued progress in, and the costs of, clinical studies and other research and development programs;

the costs involved in filing and enforcing patent claims and the status of competitive products; and

the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

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

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

for working capital purposes.

At March 31, 2016, we had cash totaling approximately \$701,000 and total assets of approximately \$2,006,000, excluding other intangible assets (related to the Medica License and Supply Agreement) of approximately \$1,421,000.

On December 23, 2015, we received proceeds of approximately \$688,000 in connection with our offer to holders of certain warrants of the opportunity to exercise their warrants at a temporarily reduced cash exercise price. Warrant holders elected to exercise warrants to purchase an aggregate of 3,442,521 shares of our common stock at the reduced cash exercise price of \$0.20 per share, providing a total of \$688,000 in gross proceeds to us. Of the 3,442,521 shares issued, 2,782,577 are held by Lambda. The warrants that were not exercised pursuant to the offer to exercise remained in effect through the original expiration date, with an exercise price of \$0.40 per share of common stock.

On September 29, 2015, we entered into a Warrant Amendment and Exercise Agreement (the "Amendment") with Lambda. Pursuant to the Amendment, we agreed to reduce the current exercise price of the Class D Warrant issued to Lambda on November 14, 2007 (together with all amendments thereto entered into prior to the Amendment, the "Warrant") representing the right to purchase 11,742,100 shares of our common stock by 50%, to \$0.15 per share, in exchange for Lambda's agreement to exercise such Warrant in its entirety. Upon exercise of the Warrant, we issued 11,742,100 shares of common stock to Lambda and received approximately \$1.76 million in cash proceeds from Lambda. Following such exercise, no Class D Warrants remain outstanding.

We expect that the proceeds from the Lambda Class D warrant exercise and the additional warrant exercises that resulted from the tender offer and the projected increase in product sales will allow us to fund our operations at least into the third quarter of 2016, and potentially longer depending on the timing and market up-take of our new products. This assumption excludes the impact of future cash receipts from recurring operations. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, in connection with offerings of our common stock or through other means, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in our Company. 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 \$523,000 for the three months ended March 31, 2016 compared to approximately \$917,000 for the three months ended March 31, 2015. Excluding the noncash impact of the change in fair value of the warrant liability during the three months ended March 31, 2015, our net loss was approximately \$836,000 for the three months ended March 31, 2016 compared to approximately \$766,000 for the three months ended March 31, 2015, an increase of approximately \$70,000.

Offsetting the increase in the net loss, the most significant items contributing to the net decrease of approximately \$394,000 in cash used in operating activities during the three months ended March 31, 2016 compared to the three months ended March 31, 2015 are highlighted below:



our stock-based compensation expense increased approximately \$121,000 during the 2016 period compared to the 2015 period primarily related to the forfeiture of the former CEO's unvested stock options during the 2015 period;

our inventory decreased by approximately \$106,000 during the 2016 period compared to an increase of approximately \$22,000 during the 2015 period as a result of increased sales volume;

our accounts payable increased by approximately \$78,000 during the 2016 period compared to a decrease of approximately \$39,000 during the 2015 period primarily as a result of timing of payments; and

we recognized a noncash loss on foreign currency transactions of approximately \$14,000 during the 2016 period compared to a gain of approximately \$40,000 during the 2015 period as a result of the change in foreign exchange rates.

Partially offsetting the above changes:

our accrued expenses increased approximately \$69,000 during the 2016 period compared to an increase of approximately \$90,000 during the 2015 period as a result of the timing of payments.

Net cash used in investing activities was approximately \$26,000 for the three months ended March 31, 2016 as a result of the purchase of property, plant and equipment.

Net cash provided by financing activities was approximately \$1,000 for the three months ended March 31, 2016 and March 31, 2015 as a result of proceeds received from the exercise of warrants.

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

We do not have any off-balance sheet arrangements as of March 31, 2016 or 2015.

## Forward-Looking Statements

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

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

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, 2015 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.

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 our disclosure controls and procedures as of the end of the period covered by this report were effective.

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

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.

## **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**

31.1 Certification by the Chief Executive Officer and Acting Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. \*

32.1 Certifications by the Chief Executive Officer and Acting Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*

101 Interactive Data File. \*

\* Filed herewith.

**SIGNATURES**

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

**NEPHROS, INC.**

Date: May 11, 2016 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)

