Form 10-Q August 08, 2017
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549
FORM 10-Q
(Mark One)
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended: June 30, 2017
OR
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from: to

NEPHROS, INC.

Commission File Number: 001-32288

NEPHROS INC

Exact name of registrant as specif	ied in	1ts	charter)
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<b>DELAWARE</b> (State or other jurisdiction of	<b>13-3971809</b> (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	a aman anda	
Registrant's telephone number, including	g area code	
N/A		
(Former name, former address and former	er fiscal year, if changed since las	st report)
the Securities Exchange Act of 1934 dur	ing the preceding 12 months (or	quired to be filed by Section 13 or 15(d) of for such shorter period that the registrant was rements for the past 90 days. [X] YES [ ]
any, every Interactive Data File required	to be submitted and posted pursuceding 12 months (or for such sh	y and posted on its corporate Web site, if the sant to Rule 405 of Regulation S-T corter period that the registrant was required
smaller reporting company, or an emergi	ng growth company. See the def	an accelerated filer, a non-accelerated filer, a initions of "large accelerated filer", "accelerated Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer [ ] Non-accelerated filer [ ] (Do not check i Emerging growth company [ ]	f a smaller reporting company)	Accelerated filer [ ] Smaller reporting company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

As of August 5, 2017, 54,160,547 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

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# **PART I - FINANCIAL INFORMATION**

# **Item 1. Financial Statements.**

# NEPHROS, INC. AND SUBSIDIARY

# CONDENSED CONSOLIDATED BALANCE SHEETS

# (In thousands, except share amounts)

	(Unaudited)	(Audited)
	June 30,	December
	2017	31, 2016
ASSETS		
Current assets:		
Cash	\$ 301	\$275
Accounts receivable, net	584	388
Investment in lease, net-current portion	15	27
Inventory, net	603	479
Prepaid expenses and other current assets	50	95
Total current assets	1,553	1,264
Property and equipment, net	56	70
Investment in lease, net-less current portion	54	61
License and supply agreement, net	1,157	1,262
Other asset	21	21
Total assets	\$ 2,841	\$2,678
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$513	\$585
Accrued expenses	340	240
Deferred revenue, current portion	70	70
Total current liabilities	923	895
Unsecured long-term note payable, net of debt issuance costs and debt discount of \$295 and \$349, respectively	892	838
Long-term portion of deferred revenue	243	278
Total liabilities	2,058	2,011
Town Industry	-,000	-,011

Commitments and Contingencies (Note 13)

# Stockholders' equity:

Preferred stock, \$.001 par value; 5,000,000 shares authorized at June 30, 2017 and		
December 31, 2016; no shares issued and outstanding at June 30, 2017 and December 31,	-	-
2016		
Common stock, \$.001 par value; 90,000,000 shares authorized at June 30, 2017 and		
December 31, 2016; 54,160,547 and 49,782,797 shares issued and outstanding at June 30,	54	50
2017 and December 31, 2016, respectively.		
Additional paid-in capital	122,417	120,835
Accumulated other comprehensive income	75	67
Accumulated deficit	(121,763)	(120,285)
Total stockholders' equity	783	667
Total liabilities and stockholders' equity	\$ 2,841	\$2,678

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

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Endouble June 30,		s Er	nded		
	2017		2016		2017		2016	
Net revenues:								
Product revenues	\$785		\$452		\$1,475		\$997	
License, royalty and other revenues	74		57		118		102	
Total net revenues	859		509		1,593		1,099	
Cost of goods sold	342		212		621		507	
Gross margin	517		297		972		592	
Operating expenses:								
Research and development	277		254		507		523	
Depreciation and amortization	60		56		119		111	
Selling, general and administrative	880		804		1,651		1,582	
Total operating expenses	1,217		1,114		2,277		2,216	
Loss from operations	(700	)	(817	)	(1,305	)	(1,624	)
Interest expense	(64	)	(30	)	(130	)	(44	)
Interest income	1		1		2		3	
Other income (expense)	(23	)	11		(33	)	(6	)
Net loss	(786	)	(835	)	(1,466	)	(1,671	)
Other comprehensive income (loss), foreign currency translation adjustments	7		(1	)	8		-	
Total comprehensive loss	\$(779	)	\$(836	)	\$(1,458	)	\$(1,671	)
Net loss per common share, basic and diluted	\$(0.01	)	\$(0.02	)	\$(0.03	)	\$(0.03	)
Weighted average common shares outstanding, basic and diluted	53,626,7	707	48,545,7	20	51,625,0		48,359,6	520

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

# CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Sto	ock	Additional Paid-in	O	ccumulate ther omprehens	Accumulat	ed	Total Stockhold	lers'
	Shares	Amour	ıt Capital	In	come	Deficit	E	Equity	
Balance, December 31, 2016 (audited)	49,782,797	\$ 50	\$120,835	\$	67	\$ (120,285	) \$	6 667	
Net loss						(1,466	)	(1,466	)
Cumulative effect of change in accounting principle			12			(12	)	-	
Net unrealized gains on foreign currency translation, net of tax					8			8	
Issuance of common stock, net of equity issuance costs of \$152	4,059,994	4	1,062					1,066	
Issuance of common stock	300,000		113					113	
Issuance of restricted stock	17,756							-	
Noncash stock-based compensation			395					395	
Balance, June 30, 2017	54,160,547	\$ 54	\$122,417	\$	75	\$ (121,763	) \$	783	

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

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Mont Ended Ju 2017	
Operating activities: Net loss	\$(1.466)	\$(1,671)
Adjustments to reconcile net loss to net cash used in operating activities:	ψ(1,400)	Ψ(1,0/1)
Depreciation of property and equipment	14	6
Amortization of other assets	105	105
Non-cash stock-based compensation, including stock options and restricted stock	395	233
Non-employee stock-based compensation	-	41
Non-cash interest expense	54	6
Inventory reserve	_	27
Allowance for doubtful accounts reserve	2	15
Loss on foreign currency transactions	13	3
(Increase) decrease in operating assets:		
Accounts receivable	(176)	36
Inventory	(124)	169
Prepaid expenses and other current assets	45	17
Increase (decrease) in operating liabilities:		
Accounts payable	(85)	178
Accrued expenses	100	75
Deferred revenue	(35)	(34)
Net cash used in operating activities	(1,158)	(794)
Investing activities:		
Purchase of property, plant and equipment	-	(40)
Net cash used in investing activities	-	(40)
Financing activities:		
Proceeds from issuance of common stock, net of equity issuance costs	1,179	-
Proceeds from issuance of unsecured note	-	1,187
Proceeds from exercise of warrants	-	1
Net cash provided by financing activities	1,179	1,188
Effect of exchange rates on cash	5	-
Net increase (decrease) in cash	26	354
Cash, beginning of period	275	1,248
Cash, end of period	\$301	\$1,602
Supplemental disclosure of cash flow information		
Cash paid for interest	\$77	\$26
Cash paid for income taxes	\$4	\$2

Supplemental disclosure of noncash investing and financing activities		
Fair value of warrants issued with unsecured note payable	\$-	\$393
Investment in lease receivable, net	\$-	\$92
Cost of equipment in sales-type lease	\$-	92
Restricted stock issued to settle liability	\$-	\$16
Deposit on inventory reclassified from prepaid expenses and other current assets to inventory	\$-	\$18
Deposit on property and equipment reclassified from prepaid expenses and other current assets to	<b>\$</b>	\$124
property and equipment	φ-	φ12 <del>4</del>
Purchase of property and equipment in accounts payable	\$-	\$5

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

# NEPHROS, INC. AND SUBSIDIARY

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

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

Nephros, Inc. ("Nephros" or the "Company") was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease ("ESRD") therapy technology and products. The Company has two products in the hemodiafiltration ("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 expanded into ultrapure water filtration products as a complement to the ESRD therapy business, introducing its proprietary dual stage ultrafilter architecture. The company has since introduced a variety of ultrafiltration and microfiltration products that address water quality and infection control in both medical and commercial applications.

The Company is currently headquartered at 41 Grand Avenue, River Edge, New Jersey 07661, which houses the Company's executive offices and research facilities, and has a subsidiary, Nephros International Limited, in Dublin, Ireland.

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

#### **Interim Financial Information**

The accompanying unaudited consolidated condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for annual financial statements. Results for the period ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

The consolidated condensed financial statements and notes thereto should be read in conjunction with the consolidated financial statements and notes for the year ended December 31, 2016 included in our Annual Report on Form 10-K.

#### **Use of Estimates**

The preparation of consolidated 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 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.

#### **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 inability to generate 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.

In order to support the Company's cash needs, management is pursuing a short-term asset-based credit facility with a commercial lender. In addition, the Company has received approval to sell a portion of its New Jersey net operating loss and research and development tax credits through a program administered by the New Jersey Economic Development Authority ("NJEDA"), which the Company anticipates will result in cash proceeds of approximately \$1.5 million. Based on the Company's existing cash balances, its current cash flow projections, including projected increases in product sales from the launch of new products, and the anticipated proceeds from the planned short-term asset-based credit facility and NJEDA tax credit program, the Company believes it will have sufficient cash resources to fund its operations at least into 2018, if not longer. However, these transactions have not been closed as of the filing date of this Form 10-O. These estimates are subject to a number of uncertainties, including the timing and market acceptance of the Company's new products and the Company's ability to obtain the planned short-term credit facility and proceeds from the NJEDA tax credit program. There can be no assurance that any of such events will occur, or 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 meet its operating requirements and other commitments, obtain the planned short-term credit facility or obtain the anticipated proceeds from the NJEDA tax credit program, 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.

# NEPHROS, INC. AND SUBSIDIARY

# NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

# Note 3 - Major Customers and Concentration of Credit Risk

For the three months ended June 30, 2017 and 2016, the following customers accounted for the following percentages of the Company's revenues, respectively:

Customer	2017	7	2016		
A	16	%	10	%	
В	14	%	2	%	
C	12	%	5	%	
D	12	%	19	%	

For the six months ended June 30, 2017 and 2016, the following customers accounted for the following percentages of the Company's revenues, respectively:

Customer	2017	7	2016			
A	21	%	14	%		
В	13	%	23	%		
C	11	%	10	%		
D	11	%	8	%		

As of June 30, 2017 and December 31, 2016, the following customers accounted for the following percentages of the Company's accounts receivable, respectively:

Customer	istomer 2017		2016	
A	22	%	36	%
В	13	%	12	%
C	13	%	6	%

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 \$27,000 and \$50,000 as of June 30, 2017 and December 31, 2016, 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 product is shipped via external logistics provider and the other criteria of ASC Topic 605 are met. Product revenue is recorded net of returns and allowances. Shipments for all products are currently received directly by the Company's customers.

#### License Agreement Revenue

Deferred revenue was approximately \$313,000 and \$348,000 on the accompanying consolidated balance sheets as of June 30, 2017 and December 31, 2016, respectively, and is related to the Company's License Agreement with Bellco (see Note 13, below), which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,763,000 of revenue related to the Bellco License Agreement to date and approximately \$18,000 and \$35,000, respectively, for the three and six months ended June 30, 2017. The Company recognized approximately \$17,000 and \$34,000, respectively, of revenue related to this License Agreement for the three and six months ended June 30, 2016. Approximately \$34,000 of revenue will be recognized in the remaining six months of fiscal year 2017 and approximately \$69,000 of revenue will be recognized in each of the years ended December 31, 2018 through 2021.

### NEPHROS, INC. AND SUBSIDIARY

# NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the three months ended June 30, 2017 and 2016, the Company recognized royalty revenue from Bellco of approximately \$31,000 and \$29,000, respectively. For the six months ended June 30, 2017 and 2016, the Company recognized royalty revenue of approximately \$58,000 and \$57,000, respectively.

See Note 13, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

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

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

The carrying value of the investment in lease, net, approximates fair value as of June 30, 2017.

### 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.

During the three and six months ended June 30, 2017, the Company granted stock options to purchase 418,709 shares and 998,280 shares, respectively of common stock to an employee. These stock options will be expensed over their respective applicable vesting periods, which are based on service and performance conditions. The fair value of all stock-based awards granted during the three months ended June 30, 2017 was approximately \$98,000. The fair value of all stock-based awards granted during the six months ended June 30, 2017 was approximately \$321,000.

The fair value of stock-based awards is amortized over the vesting period of the award. For stock-based awards that vest based on performance conditions (e.g., achievement of certain milestones), expense is recognized when it is probable that the condition will be met. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The below weighted average assumptions for the risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility were used for the awards granted during the six months ended June 30, 2017.

Assumptions for Option Grants	Six Months Ended June 30 2017	,
Stock Price Volatility	108.0	%
Risk-Free Interest Rates	2.04	%
Expected Life (in years)	6.01	
Expected Dividend Yield	-	%

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. 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. As a result of adopting ASU 2016-09, the Company has elected to recognize forfeitures as they occur.

### Stock-Based Compensation for the Three Months Ended June 30, 2017

Stock-based compensation expense was approximately \$111,000 and \$92,000 for the three months ended June 30, 2017 and 2016, respectively. For the three months ended June 30, 2017, approximately \$103,000 and approximately \$8,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. For the three months ended June 30, 2016, approximately \$84,000 and approximately \$8,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statements of operations and comprehensive loss.

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

#### Stock-Based Compensation for the Six Months Ended June 30, 2017

Stock-based compensation expense was approximately \$213,000 and \$194,000 for the six months ended June 30, 2017 and 2016, respectively. For the six months ended June 30, 2017, approximately \$194,000 and approximately \$19,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. For the six months ended June 30, 2016, approximately \$179,000 and approximately \$15,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statements of operations and comprehensive loss.

There was no tax benefit related to expense recognized in the six months ended June 30, 2017 and 2016, as the Company is in a net operating loss position. As of June 30, 2017, there was approximately \$1,087,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately \$230,000 of the \$1,087,000 total unrecognized compensation will be recognized at the time that certain performance conditions are met. The remaining unrecognized compensation expense of approximately \$857,000 will be amortized over the weighted average remaining requisite service period of 1.9 years. Such amount does not include the effect of future grants of equity compensation, if any.

#### **Restricted Stock**

During the six months ended June 30, 2017, the Company issued 17,756 shares of restricted stock as compensation for services to its chief executive officer in consideration of deferred cash salary of \$7,000. The grant date fair value of the outstanding restricted stock awards was approximately \$7,000.

Total stock-based compensation expense for the restricted stock grants was approximately \$85,000 and \$35,000 for the three months ended June 30, 2017 and 2016, respectively, and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations and comprehensive loss.

Total stock-based compensation expense for the restricted stock grants was approximately \$182,000 and \$79,000 for the six months ended June 30, 2017 and 2016, respectively, and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations and comprehensive loss.

As of June 30, 2017, there was approximately \$3,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next three months, dependent upon the respective restricted stock grant dates.

#### Note 7 - Warrants

There were no warrants exercised during the six months ended June 30, 2017. For the six months ended June 30, 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.

### 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.

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

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

	June 30,		
	2017	2016	
Shares underlying warrants outstanding	7,432,342	3,291,149	
Shares underlying options outstanding	5,459,015	4,222,640	
Unvested restricted stock	17,756	128,234	

#### **Note 9 - Recent Accounting Pronouncements**

#### **Recently Adopted Accounting Pronouncements**

In July 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 adopted ASU 2015-11 during the three months ended March 31, 2017 and the adoption of this guidance did not have a significant impact on the Company's 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 adopted ASU 2015-17 during the three months ended March 31, 2017 and the adoption of this guidance did not have a significant impact on the Company's consolidated 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 adopted ASU 2016-09 during the three months ended March 31, 2017 and elected to recognize forfeitures as they occur. Prior to the adoption of ASU 2016-09, the Company recognized stock based compensation based on the estimated fair value of the award, net of expected forfeitures. As of January 1, 2017, a cumulative effect adjustment of approximately \$12,000 was recognized to reflect the forfeiture rate that had been applied to unvested option awards prior to fiscal year 2017.

#### **Recent Accounting Pronouncements, Not Yet Effective**

In May 2014, the FASB issued 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 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.

#### NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM 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 consolidated 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 the Company 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. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU 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 assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, "Identifying Performance Obligations and Licensing," which clarifies the implementation guidance for 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 consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, "Narrow Scope Improvements and Practical Expedients," which clarifies the accounting for certain aspects of guidance issued in ASU 2014-09, including assessing collectability and noncash consideration. The clarifications 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 consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments," which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Classification of Certain Cash Receipts and Cash Payments," which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-17, "Restricted Cash," which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, "Clarifying the Definition of a Business," which clarifies the definition of a business in a business combination. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, "Simplifying the Test for Goodwill Impairment," which simplifies the test for goodwill impairment. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual goodwill impairments tests after January 1, 2017. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, "Scope of Modification Accounting," which clarifies the application of stock based accounting guidance when a change is made to the terms or conditions of a share-based payment award. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

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

#### Note 10 - Inventory, net

Inventory is stated at the lower of cost or net realizable value using the standard cost method and consists entirely of finished goods. The Company's inventory as of June 30, 2017 and December 31, 2016 was as follows:

	June 30,	December
	2017	31, 2016
	(Unaudited)	(Audited)
Total gross inventory, finished goods	\$ 646,000	\$528,000
Less: inventory reserve	(43,000)	(49,000)
Total inventory, net	\$ 603,000	\$479,000

#### **Note 11 - Unsecured Promissory Notes and Warrants**

On June 7, 2016, the Company entered into a Note and Warrant Purchase Agreement (the "2016 Purchase Agreement") with certain accredited investors identified therein under which the Company issued and sold unsecured promissory notes ("Notes") and common stock warrants ("Warrants") resulting in total gross proceeds to the Company of approximately \$1,187,000 over multiple closings under the Purchase Agreement during June 2016. The outstanding principal under the Notes accrues interest at a rate of 11% per annum. The Company is required to make interest only payments on a semi-annual basis, and all outstanding principal under the Notes is repayable in cash in June 2019, the third anniversary of the date of issuance. In connection with the transactions contemplated by the 2016 Purchase Agreement, the Company incurred approximately \$13,000 in legal fees.

In addition to the Notes, the Company issued Warrants to purchase approximately 2.4 million shares of the Company's common stock to the Note investors. The Warrants are exercisable at \$0.30 per share for a period of 5 years from the issuance date. The Warrants issued under the 2016 Purchase Agreement are indexed to the Company's common stock, therefore, the Company is accounting for the Warrants as a component of equity.

The approximately \$1,187,000 in gross proceeds from the 2016 Purchase Agreement, along with the legal fees of approximately \$13,000, were allocated between the Notes and Warrants based on their relative fair values. The portion of the gross proceeds allocated to the Warrants of approximately \$393,000 was accounted for as additional paid-in capital. Approximately \$4,000 of the legal fees were allocated to the Warrants and recorded as a reduction to additional paid-in capital. The remainder of the gross proceeds of approximately \$794,000, net of the remainder of the fees of approximately \$9,000, was allocated to the Notes with the fair value of the Warrants resulting in a debt discount. The debt discount is being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the 2016 Purchase Agreement.

For the three and six months ended June 30, 2017, approximately \$27,000 and \$54,000, respectively, was recognized as amortization of debt discount and is included in interest expense on the condensed consolidated interim statement of operations and comprehensive loss. For the three and six months ended June 30, 2016, approximately \$6,000 was recognized as amortization of debt discount and is included in interest expense on the condensed consolidated interim statement of operations and comprehensive loss.

For the three and six months ended June 30, 2017, approximately \$33,000 and \$66,000, respectively, of interest expense has been incurred. As of June 30, 2017, approximately \$12,000 is included in accrued expenses on the condensed consolidated interim balance sheet. As of June 30, 2017 and December 31, 2016, the portion of the outstanding unsecured promissory notes due to entities controlled by a member of management and to the majority shareholder amounted to \$30,000 and \$300,000, respectively.

Note 12 – Stockholders' Equity

#### **March 2017 Private Placement**

On March 22, 2017, the Company entered into a Securities Purchase Agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 4,059,994 units of its securities resulting in gross proceeds to the Company of approximately \$1,218,000. Each unit consisted of one share of the Company's common stock and a five-year warrant to purchase one additional share of common stock. The purchase price for each unit was \$0.30. The warrants are exercisable at a price of \$0.30 per share and are indexed to the Company's common stock; therefore, the Company is accounting for the warrants as a component of equity. The portion of the gross proceeds received from certain members of management and existing shareholders amounted to \$315,000. Proceeds, net of equity issuance costs of \$152,000, recorded as a result of the private placement were approximately \$1,066,000. In addition to the equity issuance costs incurred as a result of the private placement, the Company also issued a warrant to purchase 81,199 shares of its common stock to the placement agent engaged in connection with the private placement. The form and terms of the placement agent warrant is substantially the same as the form of warrants issued to the investors under the Securities Purchase Agreement, except that the exercise price is \$0.33 per share.

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

#### July 2015 Purchase Agreement and Registration Rights Agreement

On July 24, 2015, the Company entered into both a securities purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Under the terms and subject to the conditions of the securities purchase agreement, the Company has the right to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$10.0 million in shares of the Company's common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. Pursuant to the securities purchase agreement, in January 2017, the Company issued and sold 300,000 shares of common stock to Lincoln Park resulting in gross proceeds of \$113,000.

#### **Note 13 - 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 \$1.87 using current exchange rates) per unit; thereafter, €1.25 (approximately \$1.34 using current exchange rates) 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.

### 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. Our aggregate purchase commitments totaled approximately €1,200,000 (approximately \$1,300,000) and €999,000 (approximately \$1,119,000) for the years ended December 31, 2016 and 2015, respectively. 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.

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

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 license and supply agreement, net. The gross value of the intangible asset capitalized was approximately \$2,250,000. License and supply agreement, net, on the consolidated balance sheet is approximately \$1,157,000 and \$1,262,000, as of June 30, 2017 and December 31, 2016, respectively. Accumulated amortization is approximately \$1,093,000 and \$988,000 as of June 30, 2017 and December 31, 2016, respectively. The asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately \$53,000 has been charged to amortization expense for the three months ended June 30, 2017 and 2016 on the condensed consolidated statement of operations and comprehensive loss. Approximately \$105,000 has been charged to amortization expense for the six months ended June 30, 2017 and 2016 on the condensed consolidated statement of operations and comprehensive loss. Approximately \$105,000 of amortization expense will be recognized in the remainder of 2017 and approximately \$210,000 will be recognized in each of the years ended December 31, 2018 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 \$22,000 and \$18,000 is included in accrued expenses as of June 30, 2017 and December 31, 2016, 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. For the three and six months ended June 30, 2017, approximately \$2,000 and \$10,000 of interest, respectively, was recognized as interest expense. For the three and six months ended June 30, 2016, approximately \$14,000 and \$26,000 of interest, respectively, was recognized as interest expense.

On May 5, 2017, the Company entered into a Third Amendment to License and Supply Agreement (the "Third Amendment") with Medica, which amended the original License and Supply Agreement, dated April 23, 2012 (as amended, the "License and Supply Agreement"). Pursuant to the Third Amendment, Medica expanded the products covered by the original License and Supply Agreement to include both certain filtration products based on Medica's proprietary Versatile microfiber technology and certain filtration products based on Medica's proprietary Medisulfone ultrafiltration technology (collectively, the "Filtration Products"). The Third Amendment also limits the territory in which Medica granted the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale, and sell the Filtration Products to North America, Central America, Columbia, Venezuela, Chile, Ecuador, Peru, Ireland, the United Kingdom, Australia and New Zealand. The Company's multinational distributors

retain the right to market certain of the products worldwide, other than in Italy, on a non-exclusive basis.

In exchange for the rights granted, the Company has agreed to make minimum annual aggregate purchases from Medica of €1,600,000 (approximately \$1,700,000 using current exchange rates), €2,500,000 (approximately \$2,700,000 using current exchange rates), €3,000,000 (approximately \$3,300,000 using current exchange rates), €3,150,000 (approximately \$3,400,000 using current exchange rates), €3,300,000 (approximately \$3,600,000 using current exchange rates), and €3,475,000 (approximately \$3,800,000 using current exchange rates) in each of calendar years 2017, 2018, 2019, 2020, 2021 and 2022, respectively.

#### **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 on the condensed consolidated balance sheet as of June 30, 2017 and December 31, 2016 is approximately \$21,000 related to a security deposit for the U.S. office facility. Rent expense was approximately \$28,000 and \$38,000 for the three months ended June 30, 2017 and 2016, respectively. Rent expense was approximately \$59,000 and \$67,000 for the six months ended June 30, 2017 and 2016, respectively.

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

#### 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 and six months ended June 30, 2017, approximately \$1,000 and \$2,000, respectively, was recognized in interest income. During the three and six months ended June 30, 2016, approximately \$1,000 and \$3,000, respectively, was recognized in interest income. As of June 30, 2017, investment in lease, current is approximately \$15,000, net of unearned interest of \$4,000. As of June 30, 2017, investment in lease, noncurrent, is approximately \$54,000, net of unearned interest of \$4,000.

As of June 30, 2017, scheduled maturities of minimum lease payments receivable were as follows:

2017	11,000
2018	18,000
2019	19,000
2020	21,000
	69,000
Less: Current portion	(15,000)
Investment in sales-type lease, noncurrent	\$54,000

Included in the above scheduled maturities of minimum lease payments receivable, approximately \$2,000 was due as of June 30, 2017.

Management's Discussion and Analysis of Financial Condition and Results of Operations

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, 2016, 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, 2016. Our actual results may differ materially.

#### **Business 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 are 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.

To support our cash needs, we are pursuing a short-term asset-based credit facility with a commercial lender. In addition, we have also received approval to sell a portion of our New Jersey net operating loss and research and development tax credits through a program administered by the New Jersey Economic Development Authority ("NJEDA"), which we anticipate will result in cash proceeds of approximately \$1.5 million. Based on our existing cash balances, our current cash flow projections, including projected increases in product sales from the launch of new products, and the anticipated proceeds from the planned short-term asset-based credit facility and NJEDA tax credit program, we believe we will have sufficient cash resources to fund our operations at least into 2018. These estimates are subject to a number of uncertainties, including the timing and market acceptance of the Company's new products and the Company's ability to obtain the planned short-term credit facility and proceeds from the NJEDA tax credit program. There can be no assurance, however, that our future cash flow will be sufficient to meet our obligations and commitments. See " – Liquidity and Capital Resources," below.

#### **Our Products**

Presently, we produce two core product lines: HDF systems and water ultrafiltration products. The ultrafiltration technology was originally developed as a component of the HDF system, and emerged as a separate business unit in 2009. HDF is a long-term investment that we expect to grow as we develop a second generation system and as the US dialysis market reimbursement migrates to full capitation. Water ultrafiltration is a near-term market opportunity that we expect to continue to grow rapidly as we launch new products and further penetrate the market.

Since 2014, we have focused on expanding our product portfolio to include standardized form factors to better "plug and play" into existing filtration infrastructure, and on developing relationships with value-added resellers ("VAR") to rapidly expand access to our target customers. While currently we primarily focus on customers in medical markets, our VARs who support our medical market customers, also support a wide range of commercial and industrial customers. We believe that our existing VAR relationships will facilitate growth in filter sales outside of the medical industry.

### **HDF Systems**

The current standard of care in the United States for patients with chronic renal failure is hemodialysis (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 United States 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 more challenging for patients, as it is performed on a daily basis, and typically takes 12-24 hours per treatment.

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

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 United States, HDF is much more prevalent in Europe and is performed in a growing number 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. Our solution consists of our OLpūr H2H Hemodiafiltration Module ("H2H Module"), our OLpūr MD 220 Hemodiafilter ("HDF Filter") and our H2H Substitution Filter ("Dialysate Filter").

Our H2H Module attaches to 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 conforms with current ANSI/AAMI/ISO standards, and is cleared by the FDA for the treatment of patients with chronic renal failure in the United States. Our solution is the only on-line mid-dilution HDF system cleared by the FDA to date.

Both DaVita Healthcare Partners and the Renal Research Institute (a research division of Fresenius Medical Care) have conducted evaluations of our hemodiafiltration system in their clinics. We gathered direct feedback from these evaluations, and, in January 2016, updated our training procedures and rolled out a software update focused on improving the system's alignment with nurse work flow.

Vanderbilt University began treating patients with our HDF Systems early in 2017. Our goal over the next 12-18 months is to develop 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 pharmacoeconomic 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. We filed a provisional patent on our new system design in June 2017 and intend to invest in the development of this new system upon achieving positive cash flow.

# NEPHROS, INC. AND SUBSIDIARY

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

#### **Ultrafiltration Products**

Nephros ultrafilters are used in both medical and non-medical applications. Like competing filters, they purify by passing liquids through the pores of polysulfone hollow fiber. Nephros filter pores are significantly smaller than competing products, resulting in highly effective elimination of water borne pathogens, including legionella bacteria (the cause of legionnaires disease). Additionally, the fiber structure and pore density in the Nephros hollow fiber enables significantly higher flow rates than other polysulfone hollow fiber.

During 2016 and 2017, Nephros developed several ultrafilter cartridge products that are designed to fit directly into existing water filtration systems, eliminating the need for plumbing modifications during installation and replacement. These "plug and play" systems are an important part of the Nephros strategy to penetrate the water filtration market.

#### Target Markets

Nephros ultrafiltration products currently target the following markets:

Hospitals and Other Healthcare Facilities: Filtration of water for washing and drinking as an aid in infection control. The filters 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 HD devices.

*Commercial Facilities*: Filtration of water for washing and drinking including use in ice machines and soft drink dispensers.

*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.

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 United States in 2013. The U.S. Centers for Disease Control and Prevention estimates that healthcare associated infections ("HAI") occurred in approximately 1 out of every 25 hospital patients, or about 1.4 million patients in 2013. 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 caused by waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities.

The Affordable Care Act, 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.

In June 2017, the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services ("CMS") announced the addition of requirements for facilities to develop policies and procedures that inhibit the growth and spread of Legionella and other opportunistic pathogens in building water systems. Going forward CMS Surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities are compliant with their requirements. We believe that these CMS regulations may have a positive impact on the sale of Nephros's HAI-inhibiting ultrafilters.

We currently have 510(k) clearance on the following portfolio of medical device products for use in the hospital setting to aid in infection control:

The DSU-H is an in-line, 0.005 micron ultrafilter that provides dual-stage protection from water borne pathogens. The DSU-H is primarily used to filter potable water feeding ice machines, sinks and medical equipment, such as endoscope washers and surgical room humidifiers. The DSU-H has an up to 6 month product life when used in the hospital setting.

# NEPHROS, INC. AND SUBSIDIARY

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

The SSU-H is an in-line, 0.005 micron ultrafilter that provides single-stage protection from water borne pathogens. The SSU-H is primarily used to filter potable water feeding sinks, showers and medical equipment. The SSU-H has an up to 3 month product life when used in the hospital setting.

The S100 is a Point of Use, 0.01 micron microfilter that provides protection from water borne pathogens. The S100 is primarily used to filter potable water at sinks and showers. The S100 has an up to 3 month product life when used in the hospital setting.

The HydraGuard is a 0.005 micron cartridge ultrafilter that provides single-stage protection from water borne pathogens. The HydraGuard is primarily used to filter potable water feeding ice machines and medical equipment, such as endoscope washers and surgical room humidifiers. The HydraGuard has an up to 6 month product life when used in the hospital setting.

The S100 and HydraGuard were both designed to work with existing plumbing infrastructure. We received 510(k) clearance from the FDA to market the HydraGuard in December 2016, and began shipping in July 2017. We expect to ramp to full production during the third quarter of 2017. We expect to launch a flushable version of the HydraGuard with an up to 12 month product life during the third quarter of 2017.

The complete hospital infection control product line, including in-line, point of use and cartridge filters, can be viewed on our website at <a href="http://www.nephros.com/infection-control/">http://www.nephros.com/infection-control/</a>. We are not including the information on our website as a part of, or incorporating it by reference into, this report.

<u>Dialysis Centers - Water/Bicarbonate.</u> To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate, two 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.

We currently have 510(k) clearance on the following portfolio of medical device products for use in the dialysis setting to aid in bacteria, virus and endotoxin retention:

The DSU-D, SSU-D and SSUmini are in-line, 0.005 micron ultrafilters that provide protection from bacteria, viruses, and endotoxins. All of these products have an up to 12 month product life in the dialysis setting, and are used to filter water following treatment with a reverse osmosis ("RO") system and to filter bicarbonate concentrate. These ultrafilters are primarily used in the water lines and bicarbonate concentrate lines leading into dialysis machines, and as a polish filter for portable RO machines.

EndoPur is a 0.005 micron cartridge ultrafilter that provides single-stage protection from bacteria, viruses and endotoxins. The EndoPur has an up to 12 month product life in the dialysis setting, and is used to filter water following treatment with an RO system. Specifically, the EndoPur is primarily used to filter water in large RO systems designed to provide ultrapure water to an entire dialysis clinic.

The EndoPur is a cartridge-based, "plug and play" market entry that requires no plumbing at installation or replacement. In March 2017, we received 510(k) clearance from the FDA to market the EndoPur 10" filter. We expect to begin shipping the EndoPur 10" filter in August of 2017, and expect to ship 20" and 30" versions of the filter in late August 2017.

<u>Commercial and Industrial Facilities.</u> We currently market the following portfolio of proprietary products for use in the commercial, industrial and food service settings:

The NanoGuard-D is an in-line, 0.005 micron ultrafilter that provides dual-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard-D is primarily used to filter potable water feeding ice machines, sinks and equipment that requires or benefits from ultrafiltered water, and filters up to 10,000 gallons of potable water, depending upon the particle load.

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#### Management's Discussion and Analysis of Financial Condition and Results of Operations

The NanoGuard-S is an in-line, 0.005 micron ultrafilter that provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard-S is primarily used to filter potable water feeding ice machines, sinks, showers and equipment that requires or benefits from ultrafiltered water, and filters up to 3,000 gallons of potable water, depending upon the particle load.

The NanoGuard-E is a 0.005 micron ultrafilter cartridge that plugs into an Everpure® filter manifold and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard-E is primarily used to filter potable water feeding ice machines, beverage dispensers, and other equipment that requires or benefits from ultrafiltered water, and filters up to 10,000 gallons of potable water, depending upon the particle load.

The NanoGuard-C is a 0.005 micron cartridge ultrafilter that fits with most 10", 20", 30" and 40" cartridge housings and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard-C is primarily used to filter potable water feeding ice machines and equipment that requires or benefits from ultrafiltered water, and filters up to 10,000 gallons of potable water per 10" of length, depending upon the particle load.

The NanoGuard-F is a 0.005 micron flushable cartridge ultrafilter, available in 10" or 20" sizes and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons. The NanoGuard-F is primarily used to filter potable water feeding ice machines, sinks and equipment that requires or benefits from ultrafiltered water. The NanoGuard-F has an up to 12 month product life and can filter up to 2.5 gallons per minute per 10" length, depending upon the particle load.

In April 2017, we announced a partnership with WorldWater & Solar Technology to provide ultrafiltration capabilities to their drinking water systems. This partnership centers on our NanoGuard-F product line.

In the third quarter of 2017, we expect to launch a lead filtration system that will address both soluble and particulate lead in potable water, with the ability to treat up to 10,000 gallons of water between filter change-outs.

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

In May 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 IWTD. 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. During the fiscal year ended December 31, 2016, we recognized royalty revenue of \$10,000 related to the Sublicense Agreement with CamelBak.

In 2015, we began working with multiple companies developing portable water purification systems designed to provide potable water in remote locations based on our filter's ability to meet the NSF Protocol P248 standard. 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.

## **Critical Accounting Policies**

For the six-month period ended June 30, 2017, there were no significant changes to the Company's critical accounting policies as identified in our Annual Report on Form 10-K for the year ended December 31, 2016.

#### **Recent Accounting Pronouncements**

The Company is subject to recently issued accounting standards, accounting guidance and disclosure requirements. For a description of these new accounting standards, see Note 9 (entitled "Recent Accounting Pronouncements") of the Notes to our Unaudited Condensed Consolidated Interim Financial Statements contained in Item 1 of Part I of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

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Management's Discussion and Analysis of Financial Condition and Results of Operations
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, period-to-period comparisons of our operating results may not be a reliable indication of future performance.
Three Months Ended June 30, 2017 Compared to the Three Months Ended June 30, 2016
Revenues
Total net revenues for the three months ended June 30, 2017 were approximately \$859,000 compared to approximately \$509,000 for the three months ended June 30, 2016, an increase of approximately \$350,000 or 69%. This increase was primarily driven by an increase in the number of filters sold in 2017 versus in 2016, which we believe indicates early success of our strategy to provide dialysis-quality water filtration into the water-borne infection control market within the hospital sector.
Cost of Goods Sold

Cost of goods sold was approximately \$342,000 for the three months ended June 30, 2017 compared to approximately \$212,000 for the three months ended June 30, 2016, an increase of approximately \$130,000, or 61%. The increase was

related to an increase in number of filters sold.

Research an	d Devel	lopment
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Research and development expenses were approximately \$277,000 and \$254,000 for the three months ended June 30, 2017 and June 30, 2016, respectively. This increase of approximately \$23,000, or 9%, is primarily due to increased expenses related to new product launches during the three months ended June 30, 2017 compared to the three months ended June 30, 2016.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$60,000 for the three months ended June 30, 2017 compared to approximately \$56,000 for the three months ended June 30, 2016. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$53,000 for each of the three months ended June 30, 2017 and 2016. The remaining \$7,000 and \$3,000 recognized in the three months ended June 30, 2017 and 2016, respectively, was depreciation on equipment and tools.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$880,000 for the three months ended June 30, 2017 compared to approximately \$804,000 for the three months ended June 30, 2016, an increase of approximately \$76,000, or 9%. The increase is primarily due to increased salary, commission and benefit expenses for increased selling, general and administrative personnel.

Interest Expense

Interest expense of approximately \$64,000 for the three months ended June 30, 2017 consisted of approximately \$33,000 of interest accruing under the promissory notes that we issued pursuant to the June 2016 Note and Warrant Agreement, approximately \$28,000 related the amortization of debt discount and approximately \$3,000 of interest due on outstanding payables to a vendor. Interest expense of approximately \$30,000 for the three months ended June 30, 2016 consisted of approximately \$10,000 of interest related to the promissory notes issued pursuant to our June 2016 Note and Warrant Purchase Agreement, approximately \$6,000 related the amortization of debt discount and approximately \$14,000 of interest due on outstanding payables to a vendor.

Interest Income

Interest income of approximately \$1,000 for each of the three months ended June 30, 2017 and 2016 relates to interest income recognized on a lease receivable.

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Research and Development

Management's Discussion and Analysis of Financial Condition and Results of Operations
Other Income (Expense)
Foreign currency losses of approximately \$23,000 were recognized for the three months ended June 30, 2017 related to foreign currency losses. Other income for the three months ended June 30, 2016 of approximately \$11,000 related to foreign currency gains of approximately \$9,000 on invoices paid to an international supplier and miscellaneous other income of approximately \$2,000.
Six Months Ended June 30, 2017 Compared to the Six Months Ended June 30, 2016
Revenues
Total net revenues for the six months ended June 30, 2017 were approximately \$1,593,000 compared to approximately \$1,099,000 for the six months ended June 30, 2016, an increase of approximately \$494,000 or 45%. This increase was primarily driven by an increase in the number of filters sold in 2017 versus in 2016, which we believe indicates early success of our strategy to provide dialysis-quality water filtration into the water-borne infection control market within the hospital sector.
Cost of Goods Sold
Cost of goods sold was approximately \$621,000 for the six months ended June 30, 2017 compared to approximately \$507,000 for the six months ended June 30, 2016, an increase of approximately \$114,000, or 22%. The increase was related to the increase in filters sold.

Research and development expenses were approximately \$507,000 and \$523,000 for the six months ended June 30, 2017 and June 30, 2016, respectively. This decrease of approximately \$16,000, or 3%, is primarily due to increased expenses related to new product launches in the three months ended June 30, 2017, offset partially by lower expenses in the three months ended March 31, 2017.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$119,000 for the six months ended June 30, 2017 compared to approximately \$111,000 for the six months ended June 30, 2016. Amortization expense related to the asset recognized in conjunction with the License and Supply Agreement with Medica S.p.A was \$105,000 for each of the six months ended June 30, 2017 and 2016. The remaining \$14,000 and \$6,000 recognized in the six months ended June 30, 2017 and 2016, respectively, was depreciation on equipment and tools.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$1,651,000 for the six months ended June 30, 2017 compared to approximately \$1,582,000 for the six months ended June 30, 2016, an increase of approximately \$69,000, or 4%. The increase is primarily due to salary, commission, and benefit expenses for increased selling, general and administrative personnel.

Interest Expense

Interest expense of approximately \$130,000 for the six months ended June 30, 2017 consisted of approximately \$66,000 of interest related to the June 2016 Note and Warrant Agreement, approximately \$54,000 related the amortization of debt discount and approximately \$10,000 of interest due on outstanding payables to a vendor. Interest expense of approximately \$44,000 for the six months ended June 30, 2016 consisted of approximately \$10,000 of interest related to the June 2016 Note and Warrant Agreement, approximately \$6,000 related the amortization of debt discount and approximately \$28,000 of interest due on outstanding payables to a vendor.

Interest Income

Interest income of approximately \$2,000 and \$3,000, respectively, for each of the six months ended June 30, 2017 and 2016 relates to interest income recognized on a lease receivable.

# NEPHROS, INC. AND SUBSIDIARY

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Other Income (Expense)

Foreign currency losses of approximately \$33,000 were recognized for the six months ended June 30, 2017 related to foreign currency losses. Other expense for the six months ended June 30, 2016 of approximately \$6,000 related to foreign currency losses of approximately \$8,000 on invoices paid to an international supplier offset partially by miscellaneous other income of approximately \$2,000.

#### **Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of June 30, 2017 and December 31, 2016 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	June 30, 2017	December 31, 2016
Cash	\$301	