

NEPHROS INC
Form 10-Q
May 09, 2018

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, 2018**

OR

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

For the transition period from: _____ to _____

Commission File Number: 001-32288

NEPHROS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

13-3971809

(I.R.S. Employer

Identification No.)

380 Lackawanna Place

07079

South Orange, NJ

(Address of principal executive offices) (Zip Code)

(201) 343-5202

Registrant's telephone number, including area code

N/A

(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. [X] 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). [X] YES [] NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth 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 [X]

Emerging growth company []

Edgar Filing: NEPHROS INC - Form 10-Q

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 May 9, 2018, 63,710,322 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

NEPHROS, INC. AND SUBSIDIARY

TABLE OF CONTENTS

<u>PART I - FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements.</u>	3
<u>CONDENSED CONSOLIDATED BALANCE SHEETS – March 31, 2018 (unaudited) and December 31, 2017 (audited)</u>	3
<u>CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS – Three months ended March 31, 2018 and 2017 (unaudited)</u>	4
<u>CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS’ EQUITY – Three months ended March 31, 2018 (unaudited)</u>	5
<u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS – Three months ended March 31, 2018 and 2017 (unaudited)</u>	6
<u>NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk.</u>	24
<u>Item 4. Controls and Procedures.</u>	25
<u>PART II - OTHER INFORMATION</u>	26
<u>Item 6. Exhibits</u>	26
<u>SIGNATURES</u>	27

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	(Unaudited) March 31, 2018	(Audited) December 31, 2017
ASSETS		
Current assets:		
Cash	\$ 1,819	\$2,194
Accounts receivable, net	678	836
Investment in lease, net-current portion	26	20
Inventory, net	928	674
Prepaid expenses and other current assets	63	85
Total current assets	3,514	3,809
Property and equipment, net	35	52
Investment in lease, net-less current portion	34	39
License and supply agreement, net	1,038	1,072
Other asset	11	11
Total assets	\$4,632	\$4,983
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Secured revolving credit facility	\$ 150	\$711
Current portion of secured note payable	184	-
Accounts payable	1,069	872
Accrued expenses	328	218
Deferred revenue, current portion	-	70
Total current liabilities	1,731	1,871
Secured note payable, net of current portion	1,003	-
Unsecured long-term note payable, net of debt issuance costs and debt discount of \$0 and \$233, respectively	-	954
Long-term portion of deferred revenue	-	208
Total liabilities	2,734	3,033

Commitments and Contingencies (Note 15)

Edgar Filing: NEPHROS INC - Form 10-Q

Stockholders' equity:

Preferred stock, \$.001 par value; 5,000,000 shares authorized at March 31, 2018 and December 31, 2017; no shares issued and outstanding at March 31, 2018 and December 31, 2017	-	-
Common stock, \$.001 par value; 90,000,000 shares authorized at March 31, 2018 and December 31, 2017; 57,169,653 and 55,293,267 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	57	55
Additional paid-in capital	124,018	122,924
Accumulated other comprehensive income	80	77
Accumulated deficit	(122,257)	(121,106)
Total stockholders' equity	1,898	1,950
Total liabilities and stockholders' equity	\$ 4,632	\$4,983

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

NEPHROS, INC. AND SUBSIDIARY**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(In thousands, except share and per share amounts)****(Unaudited)**

	Three Months Ended March 31,	
	2018	2017
Net revenues:		
Product revenues	\$958	\$690
License and royalty revenues	27	44
Total net revenues	985	734
Cost of goods sold	518	279
Gross margin	467	455
Operating expenses:		
Research and development	289	231
Depreciation and amortization	41	59
Selling, general and administrative	1,260	770
Total operating expenses	1,590	1,060
Loss from operations	(1,123)	(605)
Loss on extinguishment of debt	(199)	-
Interest expense	(86)	(66)
Interest income	1	1
Other expense	(22)	(10)
Net loss	(1,429)	(680)
Other comprehensive income, foreign currency translation adjustments, net of tax	3	1
Total comprehensive loss	\$(1,426)	\$(679)
Net loss per common share, basic and diluted	\$(0.03)	\$(0.01)
Weighted average common shares outstanding, basic and diluted	55,568,575	49,601,521

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

NEPHROS, INC. AND SUBSIDIARY**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY****(In Thousands, Except Share Amounts)****(Unaudited)**

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Capital			
Balance, December 31, 2017 (audited)	55,293,267	\$ 55	\$ 122,924	\$ 77	\$ (121,106)	\$ 1,950
Net loss					(1,429)	(1,429)
Cumulative effect of adoption of ASC 606					278	278
Net unrealized gains on foreign currency translation, net of tax				3		3
Issuance of common stock	1,900,000	2	852			854
Cashless exercise of stock options	22,245	-				-
Cancelled restricted stock shares	(45,859)	-				-
Noncash stock-based compensation			242			242
Balance, March 31, 2018	57,169,653	\$ 57	\$ 124,018	\$ 80	\$ (122,257)	\$ 1,898

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,	
	2018	2017
Operating activities:		
Net loss	\$(1,429)	\$(680)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	7	7
Amortization of license and supply agreement	34	52
Non-cash stock-based compensation, including stock options and restricted stock	242	199
Loss on extinguishment of debt	199	-
Amortization of debt discount	34	26
Inventory reserve	50	-
Allowance for doubtful accounts reserve	-	2
Writeoff of equipment	10	-
Loss on foreign currency transactions	7	2
(Increase) decrease in operating assets:		
Accounts receivable	158	(185)
Inventory	(304)	78
Prepaid expenses and other current assets	22	(26)
Other assets	-	-
Increase (decrease) in operating liabilities:		
Accounts payable	190	(226)
Accrued expenses	111	109
Deferred revenue	-	(17)
Net cash used in operating activities	(669)	(659)
Financing activities:		
Proceeds from issuance of common stock, net of equity issuance costs of \$0 and \$144, respectively	854	1,187
Net payments on secured revolving credit facility	(561)	-
Proceeds from issuance of secured note	1,187	-
Repayment of secured long term note payable	(1,187)	-
Net cash provided by financing activities	293	1,187
Effect of exchange rates on cash	1	-
Net decrease in cash	(375)	528
Cash, beginning of period	2,194	275
Cash, end of period	\$1,819	\$803
Supplemental disclosure of cash flow information		
Cash paid for interest	\$64	\$5
Cash paid for income taxes	\$3	\$2

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. The Company was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced end stage renal disease (“ESRD”) therapy technology and products. Today, the Company has two FDA-cleared products in the hemodiafiltration (“HDF”) market that deliver therapy to 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.

Beginning in 2009, Nephros introduced an additional, complementary business developing and marketing high performance liquid purification filters to meet the demand for water purification in certain medical markets. The Company’s filters, generally classified as ultrafilters, are primarily used in hospitals for the prevention of infection from water-borne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. The Company is also exploring water purification applications in several commercial markets, including food and beverage, data center cooling, and military field applications.

The U.S. facilities, located at 380 Lackawanna Place, South Orange, New Jersey, 07079, are used to house the Company’s corporate headquarters and research facilities.

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

Note 2 - Basis of Presentation and Liquidity

Interim Financial Information

The accompanying unaudited condensed consolidated 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 March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

The condensed consolidated interim financial statements and notes thereto should be read in conjunction with the consolidated financial statements and notes for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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, and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate.

Liquidity

The Company has sustained operating losses and expects such losses to continue over the next several quarters. Net losses from operations since inception have generated an accumulated deficit of approximately \$122,257,000 as of March 31, 2018. On April 10, 2018, the Company completed a private placement transaction whereby the Company sold 6,540,669 shares of its common stock for aggregate net proceeds of approximately \$2.9 million. The Company believes that its cash and cash equivalents, together with the proceeds from the private placement, will be sufficient to fund the Company's current operating plan through at least the next twelve months.

Note 3 - Major Customers and Concentration of Credit Risk

For the three months ended March 31, 2018, three customers accounted for 37% of the Company's revenues. For the three months ended March 31, 2017, three customers accounted for 48% of the Company's revenues. As of March 31, 2018, three customers accounted for 36% of the Company's accounts receivable. As of December 31, 2017, three customers accounted for 34% of the Company's accounts receivable.

For the three months ended March 31, 2018 and 2017, the following customers accounted for the following percentages of the Company's revenues, respectively:

Customer	2018	2017
A	16 %	25 %
B	13 %	13 %
C	8 %	10 %

As of March 31, 2018 and December 31, 2017, the following customers accounted for the following percentages of the Company's accounts receivable, respectively:

Customer	March 31, 2018	December 31, 2017
D	14 %	5 %
B	14 %	18 %
E	8 %	11 %

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. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. 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 \$1,000 as of March 31, 2018 and December 31, 2017. There was no allowance for sales returns at March 31, 2018 or December 31, 2017.

Note 4 - Revenue Recognition

Edgar Filing: NEPHROS INC - Form 10-Q

The Company adopted Accounting Standards Codification (“ASC”) 606, Revenue from Contracts with Customers, as of January 1, 2018 using the modified retrospective method. ASC 606 prescribes a five step model for recognizing revenue which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price and (v) recognizing revenue.

The Company recognizes revenue related to product sales when product is shipped via external logistics provider and the other criteria of ASC 606 are met. Product revenue is recorded net of returns and allowances.

In addition to product revenue, the Company recognizes revenue related to license, royalty and other agreements in accordance with the five step model in ASC 606. During the three months ended March 31, 2018 and 2017, the Company recognized a total of approximately \$27,000 and \$44,000, respectively, related to the license agreement with Bellco. In accordance with the adoption of ASC 606, the remaining deferred revenue of approximately \$278,000 related to license revenue as of December 31, 2017 was recognized as a cumulative effect adjustment to accumulated deficit as of January 1, 2018. During the three months ended March 31, 2017, approximately \$17,000 was recognized as license revenue. The Company recognized royalty income from Bellco pursuant to the license agreement of approximately \$27,000 for each of the three months ended March 31, 2018 and 2017.

The following table presents the Company’s revenue for the three months ended March 31, 2018 under the ASC 606 model as compared to revenue under the previous guidance:

	Revenue as reported	Revenue under previous guidance	Difference
Product revenue	\$958,000	\$958,000	\$ -
Royalty revenue under the License Agreement with Bellco	27,000	27,000	-
License revenue under the License Agreement with Bellco ⁽¹⁾	-	17,000	(17,000)
Total net revenues	\$985,000	\$1,002,000	\$(17,000)

⁽¹⁾ Under ASC 606, amounts received related to the license under the Bellco license agreement would have been recognized as revenue at the time that the license was transferred, which was at the time the payments were received by the Company. Under previous guidance, amounts received under the Bellco license agreement were deferred and recognized as revenue over the term of the Bellco license agreement.

Note 5 - Fair Value of Financial Instruments

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

The carrying amounts of the investment in lease, net, the secured long-term note payable and the unsecured long-term note payable approximate fair value as of March 31, 2018 and December 31, 2017 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

Note 6 - Stock Plans and Share-Based Payments

Stock Options

The fair value of stock options is recognized as stock-based compensation expense in the Company's condensed consolidated statement of operations and comprehensive loss. The Company calculates employee stock-based compensation expense in accordance with ASC 718. 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 the Company's stock option awards is estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. The fair value of stock-based awards is amortized over the vesting period of the award.

Stock-Based Compensation

Stock-based compensation expense related to stock option grants was approximately \$130,000 and \$102,000 for the three months ended March 31, 2018 and 2017, respectively. For the three months ended March 31, 2018, approximately \$120,000 and approximately \$10,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying condensed consolidated statement of operations and comprehensive loss. During the three months ended March 31, 2018, previously issued stock options were modified for an employee who is no longer employed with the Company. As a result of this modification, approximately \$12,000 was recognized as stock option modification expense and included in research and development expenses on the accompanying condensed consolidated statement of operations and comprehensive loss. The remaining income recorded as stock-based compensation included in research and development expenses of approximately \$2,000 is primarily due to the reversal of expense due to the forfeiture of unvested stock options. For

the three months ended March 31, 2017, approximately \$94,000 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.

There was no tax benefit related to expense recognized in the three months ended March 31, 2018 and 2017, as the Company is in a net operating loss position. As of March 31, 2018, there was approximately \$1,179,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately \$230,000 of the \$1,179,000 total unrecognized compensation will be recognized at the time that certain performance conditions are met. The remaining unrecognized compensation expense of approximately \$949,000 will be amortized over the weighted average remaining requisite service period of 2.2 years. Such amount does not include the effect of future grants of equity compensation, if any.

Restricted Stock

Total stock-based compensation expense for restricted stock grants was approximately \$112,000 and \$97,000 for the three months ended March 31, 2018 and 2017, respectively. Approximately \$100,000 and \$97,000 is included in selling, general and administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2018 and 2017, respectively. Approximately \$12,000 is included in research and development expenses on the accompanying condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2018.

As of March 31, 2018, there was approximately \$103,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next three months.

Note 7 - Warrants

There were no warrants exercised during the three months ended March 31, 2018 or 2017.

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 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.

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,	
	2018	2017
Shares underlying warrants outstanding	7,099,010	7,432,342
Shares underlying options outstanding	6,474,527	5,040,306
Unvested restricted stock	753,528	584,467

Note 9 – Recent Accounting Pronouncements**Recently Adopted 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. In March, April and May 2016, the FASB issued ASU No. 2016-08, ASU No. 2016-10 and ASU No. 2016-12, respectively, which clarify implementation guidance, including the guidance on principal versus agent considerations, performance obligations and licensing and assessments of collectability and noncash considerations. 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. The Company adopted the new revenue recognition standard as of January 1, 2018 using the modified retrospective method, which requires the cumulative effect of adoption, if any, to be recognized as an adjustment to opening accumulated deficit in the period of adoption. The majority of the Company's revenue relates to the sale of finished products to various customers, and the adoption did not have any impact on revenue recognized from these transactions. The Company completed its analysis of the impact on certain less significant transactions involving third-party arrangements, and as a result of the analysis, the Company accelerated the remaining approximately \$278,000 of deferred revenue to be recognized under the Bellco license agreement as of December 31, 2017 and recorded a cumulative effect adjustment to opening accumulated deficit as of January 1, 2018.

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 was permitted. The Company adopted this guidance as of January 1, 2018 and the guidance did not have an impact 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 was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have a significant impact on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, “Restricted Cash,” which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact 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 was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation” which requires modification accounting to be used on shared-based payment awards if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

Recent Accounting Pronouncements, Not Yet Effective

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 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 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.

Note 10 – Inventory, net

Inventory is stated at the lower of cost or net realizable value using the first-in, first-out method and consists of raw materials and finished goods. The Company’s inventory as of March 31, 2018 and December 31, 2017 was as follows:

	March 31, 2018 (Unaudited)	December 31, 2017 (Audited)
Finished goods	\$ 936,000	\$ 654,000
Raw materials	73,000	51,000
Less: inventory reserve	(81,000)	(31,000)
Total inventory, net	\$ 928,000	\$ 674,000

Note 11 – Secured Note Payable

On March 27, 2018, the Company entered into a Secured Promissory Note (the “Secured Note”) with Tech Capital, LLC (“Tech Capital”) for a principal amount of \$1,187,000. As of March 31, 2018, the principal balance of the Secured Note was approximately \$1,187,000. The Company used these proceeds to repay the Company’s 11% unsecured promissory notes issued pursuant to the Note and Warrant Agreement dated June 3, 2016 (see Note 13 below).

The Secured Note has a maturity date of April 1, 2023. The unpaid principal balance accrues interest at a rate of 8% per annum. Principal and interest payments are due on the first day of each month commencing on May 1, 2018. The Secured Note is subject to the terms and conditions of and is secured by security interests granted by the Company in favor of Tech Capital under the Loan and Security Agreement between the Company and Tech Capital, dated August 16, 2017 and all of the riders and amendments thereto (the “Loan Agreement”) (see Note 12 below). An event of default under such Loan Agreement shall be an event of default under the Secured Note, and vice versa. In the event the principal balance under the Loan Agreement is due, all amounts due under the Secured Note shall also be due.

Debt issuance costs of approximately \$6,000 were recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2018.

Note 12 – Secured Revolving Credit Facility

On August 17, 2017, the Company entered into the Loan Agreement with Tech Capital. The Loan Agreement provides for a secured asset-based revolving credit facility of up to \$1,000,000, which the Company may draw upon and repay from time to time during the term of the Loan Agreement. The outstanding principal balance of the Loan Agreement was approximately \$150,000 and approximately \$711,000 as of March 31, 2018 and December 31, 2017, respectively. The Company is using these proceeds for working capital and general corporate purposes.

The Loan Agreement has a term of 12 months, which will automatically renew for successive 12-month periods unless cancelled. Availability under the Loan Agreement will be based upon periodic borrowing base certifications valuing certain of the Company's accounts receivable and inventory. Outstanding borrowings under the Loan Agreement accrue interest, which shall be payable monthly based on the average daily outstanding balance, at a rate equal to 3.5% plus the prime rate per annum, provided that such prime rate shall not be less than 4.25% per annum. As of March 31, 2018, the current interest rate was 8.25% per annum.

The Company also granted to Tech Capital a first priority security interest in its assets, including its accounts receivable and inventory, to secure all of its obligations under the Loan Agreement. In addition, Nephros International Limited, the Company's wholly-owned subsidiary, unconditionally guaranteed the Company's obligations under the Loan Agreement.

For the three months ended March 31, 2018, approximately \$6,000 was recognized as interest expense on the condensed consolidated statement of operations and comprehensive loss. As of March 31, 2018, approximately \$2,000 of the \$6,000 of interest expense incurred is included in accrued expenses on the condensed consolidated balance sheet.

Note 13 – Unsecured Promissory Notes and Warrants

On June 7, 2016, the Company entered into a Note and Warrant Agreement (the "Note and Warrant Agreement") with new creditors as well as existing stockholders under which the Company issued unsecured promissory notes and warrants resulting in total gross proceeds to the Company during June 2016 of approximately \$1,187,000. As of December 31, 2017, the portion of the outstanding unsecured promissory notes held by related parties comprised of

persons controlled by a member of management and by Lambda Investors LLC (“Lambda”), the majority shareholder, amounted to \$30,000 and \$300,000, respectively. The outstanding principal under the notes accrues interest at a rate of 11% per annum. The notes required the Company to make interest only payments on a semi-annual basis, with all outstanding principal under the notes being repayable in cash on June 7, 2019, the third anniversary of the date of issuance. In addition to the notes, the Company issued warrants to purchase approximately 2.4 million shares of the Company’s common stock. The portion of the gross proceeds allocated to the warrants of approximately \$393,000 was accounted for as additional paid-in capital resulting in a debt discount. The debt discount, which includes approximately \$9,000 of debt issuance costs in addition to the fair value of the warrants, is being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the Note and Warrant Agreement.

Approximately \$34,000 and \$26,000 was recognized as amortization of debt discount during the three months ended March 31, 2018 and 2017, respectively, and is included in interest expense on the condensed consolidated statement of operations and comprehensive loss. Approximately \$30,000 and \$33,000 was recognized as interest expense for the three months ended March 31, 2018 and 2017, respectively, for interest payable to noteholders.

For each of the three month periods ended March 31, 2018 and 2017, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda was approximately \$1,000 and \$8,000, respectively.

On March 30, 2018, using proceeds from the Secured Note, the principal balance of the notes was repaid in full. In addition, the remaining accrued interest of approximately \$43,000 was paid. While the notes were outstanding, approximately \$195,000 of interest was paid to noteholders. The remaining debt discount of approximately \$199,000 was written off and recorded as loss on extinguishment of debt in the Company’s condensed consolidated statements of operations and comprehensive loss.

Note 14 – Stockholders’ Equity

March 2017 Private Placement

On March 17, 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.

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, during the three months ended March 31, 2018 and 2017, the Company issued and sold 1,900,000 and 300,000 shares of common stock, respectively, to Lincoln Park. The issuance of the common shares to Lincoln Park resulted in gross proceeds of \$854,000 and \$113,000 for the three months ended March 31, 2018 and 2017, respectively.

Note 15 – Commitments and Contingencies

Manufacturing and Suppliers

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

On February 19, 2014, the Company entered into the first amendment to the license agreement with Bellco, pursuant to which 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 \$2.10) per unit; thereafter, €1.25 (approximately \$1.50) per unit. 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 30 days.

In accordance with the adoption of ASC 606, the remaining deferred revenue of approximately \$278,000 related to license revenue as of December 31, 2017 was recognized as a cumulative effect adjustment to accumulated deficit as of January 1, 2018. During the three months ended March 31, 2017, approximately \$17,000 was recognized as license revenue.

The Company recognized royalty income from Bellco pursuant to the license agreement of approximately \$27,000 for each of the three months ended March 31, 2018 and 2017.

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, and for 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.

On May 5, 2017, the Company and Medica entered into a Third Amendment to the License and Supply Agreement (the “Third Amendment”) which 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. 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.

On September 26, 2017, the Company and Medica entered into a Fourth Amendment to the License and Supply Agreement (the “Fourth Amendment”) which extended the term of the License and Supply Agreement from December 31, 2022 to December 31, 2025, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

In exchange for the rights granted, the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2018, the Company has agreed to make minimum annual aggregate purchases from Medica of €2,500,000 (approximately \$3,000,000). As of March 31, 2018, the Company’s aggregate purchase commitments totaled approximately €471,000 (approximately \$565,000).

In exchange for the license, the gross value of the intangible asset capitalized was approximately \$2,250,000. License and supply agreement, net, on the condensed consolidated balance sheet is approximately \$1,038,000 and \$1,072,000 as of March 31, 2018 and December 31, 2017, respectively. Accumulated amortization is approximately \$1,211,000 and \$1,178,000 as of March 31, 2018 and December 31, 2017, respectively. The asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately \$34,000 and \$52,000 has been charged to amortization expense for the three months ended March 31, 2018 and 2017, respectively, on the condensed consolidated statement of operations and comprehensive loss.

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 months ended March 31, 2018 and 2017, approximately \$10,000 and \$7,000 of interest, respectively, was recognized as interest expense.

In addition, for the period beginning April 23, 2014 through December 31, 2025, 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 \$29,000 and \$19,000 for the three months ended March 31, 2018 and 2017, respectively, was recognized as royalty expense and is included in cost of goods sold on the condensed consolidated statement of operations and comprehensive loss. Approximately \$29,000 in royalties are included in accrued expenses as of March 31, 2018. Approximately \$34,000 in royalties are included in accounts payable as of December 31, 2017.

Contractual Obligations

The Company entered into an operating lease that began in December 2017 for 380 Lackawanna Place, South Orange, New Jersey 07079, which consists of approximately 7,700 square feet of space. The rental agreement expires in November 2022 with a monthly cost of approximately \$11,000. Approximately \$11,000 related to a security deposit for this U.S. office facility is classified as other assets on the condensed consolidated balance sheet as of March 31, 2018 and December 31, 2017. We use these facilities to house our corporate headquarters and research facilities.

The lease agreement for the office space in Ireland was entered into on August 1, 2017 and includes a twelve month term.

Rent expense for the three months ended March 31, 2018 and 2017 totaled \$51,000 and \$31,000, respectively.

As of March 31, 2018, minimum lease payments are as follows:

2018	\$99,000
2019	136,000
2020	140,000
2021	145,000
2022	136,000

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 condensed consolidated statement of cash flows. At lease inception, an investment in lease of approximately \$92,000 was recorded, net of unearned interest of approximately \$14,000. Approximately \$1,000 was recognized in interest income during each of the three months ended March 31, 2018 and 2017. As of March 31, 2018, investment in lease, current is approximately \$26,000, net of unearned interest of \$3,000. As of March 31, 2018, investment in lease, noncurrent is approximately \$34,000, net of unearned interest of \$2,000.

As of March 31, 2018, scheduled maturities of minimum lease payments receivable were as follows:

2018	19,000
2019	19,000
2020	22,000
	60,000
Less: Current portion	(26,000)
Investment in lease, net – less current portion	\$34,000

Included in the above scheduled maturities of minimum lease payments receivable, approximately \$7,000 was due as of March 31, 2018.

Note 16 – Subsequent Event

On April 11, 2018, the Company completed a private placement in which it sold approximately 6,500,000 shares of common stock at a purchase price of \$0.45 per share, resulting in total gross proceeds to the Company of approximately \$2.9 million.

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, 2017, 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, 2017. Our actual results may differ materially.

Business Overview

We are 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 hospitals for the prevention of infection from water-borne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize patient exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our OLP_{ur} 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 a hemodialysis 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. We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Our Products

Presently, we produce two core product lines: water ultrafiltration products and HDF systems. Water ultrafiltration is our primary near-term market opportunity, which we expect to continue to grow rapidly as we launch new products and further penetrate the market. HDF is a long-term investment that we expect to grow as we develop a second-generation system and as the U.S. dialysis market reimbursement environment migrates to full capitation.

Ultrafiltration Products

Our 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. Our filters' pores are significantly smaller than those of 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 our hollow fiber enables significantly higher flow rates than in other polysulfone hollow fiber.

During 2016 and 2017, we 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 our strategy to penetrate the water filtration market.

Our sales strategy is a combination of direct selling to end customers and indirect selling through value-added resellers ("VARs"). Leveraging VARs has enabled us to expand rapidly our access to target customers in the medical market without significant sales staff expansion. In addition, while we are currently focused in medical markets, the VARs that support these customers also support a wide variety of commercial and industrial customers. We believe that our VAR relationships will facilitate growth in filter sales outside of the medical industry.

Target Markets

Our 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, including use in sinks, showers, and ice machines. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures, and washing of surgeons' hands.

Dialysis Centers: Filtration of water or bicarbonate concentrate used in hemodialysis.

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 hospitals or other healthcare facilities, 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 HAI potential. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the points of delivery, such as ice machines, 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 these requirements. We believe that these CMS regulations may have a positive impact on the sale of our HAI-inhibiting ultrafilters.

We currently have FDA 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 a hospital setting.

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 a 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 feeding sinks and showers. The S100 has an up to 3 month product life when used in a hospital setting.

Edgar Filing: NEPHROS INC - Form 10-Q

The HydraGuard™ and HydraGuard™ - Flush are 0.005 micron cartridge ultrafilters that provide single-stage protection from water borne pathogens. The HydraGuard™ ultrafilters are 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 and the HydraGuard™ - Flush has an up to 12 month product life when used in a hospital setting.

We received FDA 510(k) clearance to market the HydraGuard™ in December 2016 and began shipping it in July 2017. We began shipping the HydraGuard™ - Flush in September 2017. The DSU, SSU, and S100 products were 510(k)-cleared in prior years.

The complete hospital infection control product line, including in-line, point-of-use, and cartridge filters, can be viewed on our website at <http://www.nephros.com/infection-control/>. We are not including the information on our website as a part of, nor incorporating it by reference, into this Quarterly Report on Form 10-Q.

Dialysis Centers - Water/Bicarbonate. 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 United States. 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 FDA 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.

The 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. More specifically, the EndoPur is used primarily to filter water in large RO systems designed to provide ultrapure water to an entire dialysis clinic. The EndoPur is available in 10”, 20”, and 30” configurations.

The EndoPur is a cartridge-based, “plug and play” market entry that requires no plumbing at installation or replacement. In March 2017, we received FDA 510(k) clearance to market the EndoPur filter. We began shipping the EndoPur 10” filter in July 2017 and the 20” and 30” versions in September 2017.

Commercial and Industrial Facilities. 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.

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. This partnership is in the early stages of market roll-out.

In the fourth quarter of 2017, we released a lead filtration system that addresses both soluble and particulate lead in potable water, with the ability to treat up to 9,000 gallons of water between filter change-outs. This system is in the early stages of market roll-out.

Military and Outdoor Recreation. 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 freshwater source. This enables the soldier to remain hydrated, to help maintain mission effectiveness and unit readiness, and to extend mission reach. Our IWTD has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by the U.S. Army Public Health Command and the 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.

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 treatments 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.

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 prevalent in Europe and is performed for 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 HD, HDF can be resource-intensive and can require a significant amount of time to deliver one course of treatment.

We originally developed a medical device that enabled a standard HD machine to perform HDF. We refer to our approach as an on-line mid-dilution hemodiafiltration (“mid-dilution HDF”) system. Our original solution included a OLpür H2H Hemodiafiltration Module (“H2H Module”), a OLpür MD 220 Hemodiafilter (“HDF Filter”) and a H2H Substitution Filter (“Dialysate Filter”).

Our H2H Module attaches to a standard HD machine to perform on-line HDF 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 connects 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 original HDF system conformed with current ANSI/AAMI/ISO standards and was cleared by the FDA for the treatment of patients with chronic renal failure in 2012. To date, our HDF system is the only HDF system cleared by the FDA.

Over the last four years, DaVita Healthcare Partners, the Renal Research Institute (a research division of Fresenius Medical Care), and Vanderbilt University conducted post-market evaluations of our HDF system in their clinics. We gathered direct feedback from these evaluations to develop a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm. The ultimate goal of the evaluations was to better understand the potential for HDF, in the U.S. clinical setting, to (a) improve the quality of life for the patient, (b) reduce overall expenditure compared to other dialysis modalities, (c) minimize the impact on nurse work flow at the clinic, and (d) demonstrate the pharmacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. The last evaluation was concluded at Vanderbilt in the first quarter of 2018. When practical, we will work with Vanderbilt to publish observational findings.

Leveraging the learnings from our evaluations, we have initiated the development of the 2nd generation HDF system. We believe that the 2nd generation system, as currently designed, incorporates new features that could enable us to better manufacture at scale, to reduce the per treatment cost of performing HDF, and to better align with current work flow practices, versus our 1st generation HDF system. We filed a provisional patent on our new system design in June 2017. We are funding the 2nd generation HDF system as cash flow is available, and have announced plans to form a new subsidiary, Specialty Renal Products, Inc., to drive the development of this 2nd generation HDF system.

Critical Accounting Policies

For the three-month period ended March 31, 2018, there were no significant changes to our critical accounting policies as identified in our Annual Report on Form 10-K for the year ended December 31, 2017.

Recent Accounting Pronouncements

We are subject to recently issued accounting standards, accounting guidance and disclosure requirements. For a description of these new accounting standards, see Note 9, “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.

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 annual 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, marketing expenses related to product launches, timing of regulatory approval of our various products and market acceptance of our products. 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, 2018 Compared to the Three Months Ended March 31, 2017

Revenues

Total revenues for the three months ended March 31, 2018 were approximately \$985,000 compared to approximately \$734,000 for the three months ended March 31, 2017. The increase of approximately \$251,000, or 34%, was primarily driven by an increase in water filter product revenue in 2018 versus in 2017, 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. This product revenue increase was offset by an approximately \$17,000 decrease in license and royalty revenues due to the change in revenue recognition discussed in Note 4 of the Notes to our Unaudited Condensed Consolidated Interim Financial Statements.

Cost of Goods Sold

Cost of goods sold was approximately \$518,000 for the three months ended March 31, 2018 compared to approximately \$279,000 for the three months ended March 31, 2017. The increase of approximately \$239,000, or 86%, was primarily composed of approximately \$100,000 in increased direct product costs in support of increased sales, \$50,000 in the effects of foreign exchange rates, \$50,000 in inventory reserves for expiring items, and \$30,000 in physical count inventory adjustments.

Gross Margins

Gross margins were approximately 47% for the three months ended March 31, 2018, compared to approximately 62% for the three months ended March 31, 2017. The decrease of approximately 15% was due to the combined effects of reduced license and royalty revenues and the increased cost of goods sold, as described in preceding paragraphs.

Research and Development

Research and development expenses were approximately \$289,000 and \$231,000 for the three months ended March 31, 2018 and March 31, 2017, respectively. This increase of approximately \$58,000, or 25%, reflects an increase due to costs associated with the 2nd generation HDF development during the three months ended March 31, 2018 compared to the three months ended March 31, 2017.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately \$41,000 for the three months ended March 31, 2018 compared to approximately \$59,000 for the three months ended March 31, 2017. The decrease of approximately \$18,000, or 31%, is due to lower amortization expense for the three months ended March 31, 2018 as a result of an amendment to our license and supply agreement with Medica, which extended the term from December 31, 2022 to December 31, 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$1,260,000, for the three months ended March 31, 2018 compared to approximately \$770,000 for the three months ended March 31, 2017, representing an increase of \$490,000, or 64%. The increase was primarily due to an increase in personnel-related expenses of approximately \$277,000 due to increased headcount, an increase in share-based compensation of approximately \$57,000 due to increased headcount, and an increase in professional services expenses of approximately \$83,000 due to the implementation of a new ERP system and increased legal expenses.

Loss on Extinguishment of Debt

During the three months ended March 31, 2018, we recorded a loss on extinguishment of debt of approximately \$199,000 as a result of the repayment of our outstanding unsecured long term note payable.

Interest Expense

Edgar Filing: NEPHROS INC - Form 10-Q

The table below summarizes interest expense for the three months ended March 31, 2018 and 2017:

	2018	2017
Interest related to unsecured long-term note payable	\$30,000	\$33,000
Amortization of debt discount - unsecured long-term note payable	34,000	26,000
Interest - outstanding payables due to a vendor	10,000	7,000
Interest related to secured note payable	6,000	-
Interest on secured revolving credit facility	6,000	-
Total interest expense	\$86,000	\$66,000

Interest Income

Interest income of approximately \$1,000 for each of the three months ended March 31, 2018 and 2017, respectively, is as result of interest income recognized on a lease receivable.

Other Income/Expense

Other expense for the three months ended March 31, 2018 and 2017 of approximately \$22,000 and \$10,000, respectively, is related to foreign currency losses.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2018 and December 31, 2017 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	March 31, 2018	December 31, 2017
Cash	\$1,819	\$ 2,194
Other current assets	1,695	1,615
Working capital surplus	1,766	1,938
Stockholders' equity	1,898	1,950

At March 31, 2018, we had an accumulated deficit of approximately \$122,257,000 and we expect to incur additional operating losses over the next several quarters. On April 10, 2018, we completed a private placement transaction whereby we sold 6,540,669 shares of our common stock for aggregate net proceeds of approximately \$2.9 million. We believe that our cash and cash equivalents, together with the proceeds from this private placement, will be sufficient to fund our current operating plan through at least the next twelve months.

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

- 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, 2018, we had cash totaling approximately \$1,819,000 and total assets of approximately \$3,594,000, excluding other intangible assets (related to the license and supply agreement with Medica) of approximately \$1,038,000.

We have also continued to pursue different sources of additional financing. In the first quarter of 2018, we entered into a Secured Promissory Note with Tech Capital, LLC for a principal amount of \$1,187,000. We used these proceeds to repay the 11% unsecured promissory notes issued pursuant to the Note and Warrant Agreement dated June 2016.

Net cash used in operating activities was approximately \$669,000 for the three months ended March 31, 2018 compared to approximately \$659,000 for the three months ended March 31, 2017. Our net loss was approximately \$1,429,000 for the three months ended March 31, 2018 compared to a net loss of approximately \$680,000 for the three months ended March 31, 2017, an increase of approximately \$749,000.

The most significant items classified as cash used in operating activities that serve to offset the increase in net loss of approximately \$749,000 are highlighted below:

our accounts receivable decreased by approximately \$158,000 during the 2018 period compared to an increase of approximately \$185,000 during the 2017 period primarily as a result of improved management focus on receivable collections;

our loss on extinguishment of debt of approximately \$199,000 during the 2018 period as a result of the repayment of our outstanding unsecured long term note payable;

our stock-based compensation was approximately \$242,000 during the 2018 period compared to approximately \$199,000 during the 2017 period, primarily due to increased headcount; and

our accounts payable increased approximately \$190,000 during the 2018 period compared to a decrease of approximately \$226,000 during the 2017 period primarily as a result of increased purchases required for our higher sales volume.

The above changes are partially offset by:

our inventory increased by approximately \$304,000 during the 2018 period compared to a decrease of approximately \$78,000 during the 2017 period primarily as a result of managing inventory levels to support increased sales volume.

There was no cash used in investing activities for the three months ended March 31, 2018 or 2017.

Net cash provided by financing activities of approximately \$293,000 for the three months ended March 31, 2018 resulted from net proceeds from the issuance of common stock of approximately \$854,000 and proceeds from the issuance of a secured note payable of approximately \$1,187,000, offset partially by net payments on our secured revolving credit facility of approximately \$561,000 and payments of approximately \$1,187,000 on our unsecured long-term note payable.

Net cash provided by financing activities for the three months ended March 31, 2017 resulted from net proceeds of approximately \$1,187,000 from the issuance of common stock.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2018 or December 31, 2017.

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 and strategy for bringing such products to market, the timeline for regulatory review and approval of our products, the availability of funding sources for continued development of such products, and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

- we 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 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, 2017 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. 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 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 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 6. Exhibits

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.1	<u>Secured Promissory Note dated March 27, 2018, between the Registrant and Tech Capital, LLC, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on March 30, 2018.</u>
10.2	<u>Form of Stock Purchase Agreement, dated April 10, 2018, among the Registrant and the Purchasers identified therein, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 11, 2018.</u>
31.1	<u>Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</u>
31.2	<u>Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</u>
32.1	<u>Certifications by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *</u>
32.2	<u>Certifications by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *</u>
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 9, 2018 By: */s/ Daron Evans*
Name: Daron Evans
Title: President, Chief Executive Officer (Principal Executive Officer)

Date: May 9, 2018 By: */s/ Andrew Astor*
Name: Andrew Astor
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

