

NEPHROS INC
Form 10-Q
August 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: **June 30, 2016**

OR

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

For the transition period from: _____ to _____

Commission File Number: 001-32288

NEPHROS, INC.

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(Exact name of Registrant as Specified in Its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation or Organization)

13-3971809

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

41 Grand Avenue

River Edge, NJ

(Address of Principal Executive Offices)

07661

(Zip code)

(201) 343-5202

Registrant's Telephone Number, Including Area Code

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

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

YES NO

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

YES NO

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

Large accelerated filer

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

Accelerated filer

Smaller reporting company

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

YES NO

As of August 3, 2016, 48,825,461 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

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

	(Unaudited) June 30, 2016	(Audited) December 31, 2015
ASSETS		
Current assets:		
Cash	\$ 1,602	\$ 1,248
Accounts receivable, net	346	397
Investment in lease, net-current portion	26	-
Inventory, net	413	591
Prepaid expenses and other current assets	67	228
Total current assets	2,454	2,464
Property and equipment, net	84	12
Investment in lease, net-less current portion	68	-
Other assets, net	1,389	1,494
Total assets	\$ 3,995	\$ 3,970
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 838	\$ 652
Accrued expenses	310	237
Deferred revenue, current portion	70	70
Total current liabilities	1,218	959
Unsecured long-term note payable, net of debt issuance costs and debt discount of \$396	791	-
Long-term portion of deferred revenue	313	347
Total liabilities	2,322	1,306
Commitments and Contingencies		
Stockholders' equity:		
	-	-

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Preferred stock, \$.001 par value; 5,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued and outstanding at June 30, 2016 and December 31, 2015

Common stock, \$.001 par value; 90,000,000 shares authorized at June 30, 2016 and December 31, 2015; 48,825,461 and 48,580,355 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	49	49
Additional paid-in capital	120,477	119,797
Accumulated other comprehensive income	71	71
Accumulated deficit	(118,924)	(117,253)
Total stockholders' equity	1,673	2,664
Total liabilities and stockholders' equity	\$ 3,995	\$3,970

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

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2016	2015	June 30, 2016	2015
Net revenues:				
Product revenues	\$452	\$ 521	\$ 997	\$ 1,049
License, royalty and other revenues	57	46	102	63
Total net revenues	509	567	1,099	1,112
Cost of goods sold	212	209	507	471
Gross margin	297	358	592	641
Operating expenses:				
Research and development	254	164	523	355
Depreciation and amortization	56	53	111	106
Selling, general and administrative	804	735	1,582	1,578
Total operating expenses	1,114	952	2,216	2,039
Loss from operations	(817)	(594)	(1,624)	(1,398)
Change in fair value of warrant liability	-	(1,196)	-	(188)
Interest expense	(30)	(9)	(44)	(21)
Interest income	1	-	3	-
Other income (expense)	11	(16)	(6)	35
Net loss	(835)	(1,815)	(1,671)	(1,572)
Other comprehensive loss, foreign currency translation adjustments	(1)	(1)	-	(1)
Total comprehensive loss	\$(836)	\$(1,816)	\$(1,671)	\$(1,573)
Net loss per common share, basic and diluted	\$(0.02)	\$(0.06)	\$(0.03)	\$(0.05)
Weighted average common shares outstanding, basic and diluted	48,545,720	31,190,714	48,359,620	30,727,840

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

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2015 (audited)	48,580,355	\$ 49	\$ 119,797	\$ 71	\$(117,253)	\$2,664
Net loss		-			(1,671)	(1,671)
Issuance of restricted stock	244,200	-	16	-		16
Issuance of warrants, net of issuance costs of \$4	-	-	389	-	-	389
Exercise of warrants	906	-	1	-		1
Noncash stock-based compensation	-	-	274	-		274
Balance, June 30, 2016	48,825,461	\$ 49	\$ 120,477	\$ 71	\$(118,924)	\$1,673

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

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net loss	\$(1,671)	\$(1,572)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	6	1
Amortization of other assets	105	105
Noncash stock-based compensation, including stock options and restricted stock	233	119
Non-employee stock-based compensation	41	-
Amortization of debt discount	6	-
Change in fair value of warrant liability	-	188
Inventory reserve	27	-
Allowance for doubtful accounts reserve	15	-
Loss on foreign currency transactions	3	1
(Increase) decrease in operating assets:		
Accounts receivable	36	(185)
Inventory	169	(233)
Prepaid expenses and other current assets	17	43
Increase (decrease) in operating liabilities:		
Accounts payable	178	153
Accrued expenses	75	(36)
Deferred revenue	(34)	(35)
Net cash used in operating activities	(794)	(1,451)
Investing activities:		
Purchase of property and equipment	(40)	-
Net cash used in investing activities	(40)	-
Financing activities:		
Proceeds from issuance of unsecured note	1,187	-
Proceeds from issuance of common stock	-	1,205
Proceeds from exercise of warrants	1	1
Net cash provided by financing activities	1,188	1,206
Effect of exchange rates on cash	-	(2)
Net increase (decrease) in cash	354	(247)
Cash, beginning of period	1,248	1,284
Cash, end of period	\$1,602	\$1,037
Supplemental disclosure of cash flow information		
Cash paid for interest	\$26	\$25

Cash paid for income taxes	\$2	\$2
Supplemental disclosure of noncash investing and financing activities		
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	\$-
Reclassification of inventory from prepaid expenses and other current assets	\$18	\$-
Reclassification of property and equipment from prepaid expenses and other current assets	\$124	\$-
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.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 1 - Organization and Nature of Operations

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

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

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

Note 2 - Basis of Presentation and Going Concern

Interim Financial Information

The accompanying unaudited condensed consolidated interim financial statements of Nephros, Inc. and its wholly owned subsidiary, Nephros International Limited should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 30, 2016. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”)

for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying condensed consolidated interim financial statements do not include all of the information and notes required by GAAP for a complete financial statement presentation. The condensed consolidated balance sheet as of December 31, 2015 was derived from the Company's audited consolidated financial statements but does not include all disclosures required by GAAP. In the opinion of management, the condensed consolidated interim financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

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

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

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

Going Concern

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

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

Based on the Company's current projections, the Company expects that its existing cash balances and projected increase in product sales from the launch of new products, will allow the Company to fund its operations at least into the first quarter of 2017, if not longer, depending on the timing and market uptake of our new products. This assumption excludes the impact of future cash receipts from recurring operations. There can be no assurance that the Company's future cash flow will be sufficient to meet its obligations and commitments. If the Company is unable to generate sufficient cash flow from operations in the future to service its commitments, the Company will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing its planned activities or ceasing its operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable the Company to continue to satisfy its capital requirements.

Recently Adopted Accounting Pronouncement

In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-03, “Interest - Imputation of Interest (Subtopic 2015-03): Simplifying the Presentation of Debt Issuance Costs” related to the presentation requirements for debt issuance costs and debt discount and premium. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 is effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU 2015-03 during the three months ended June 30, 2016.

Note 3 – Major Customers and Concentration of Credit Risk

For the three months ended June 30, 2016 and 2015, the following customers accounted for the following percentages of the Company’s revenues, respectively.

Customer	2016	2015
A	19 %	3 %
B	10 %	31 %
C	2 %	23 %

For the six months ended June 30, 2016 and 2015, the following customers accounted for the following percentages of the Company’s revenues, respectively.

Customer	2016	2015
A	24 %	26 %
B	14 %	25 %
C	10 %	16 %

NEPHROS, INC.**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 3 – Major Customers and Concentration of Credit Risk (continued)**

As of June 30, 2016 and December 31, 2015, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2016	2015
A	35 %	37 %
B	12 %	11 %
C	10 %	- %
D	4 %	23 %

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was approximately \$30,000 and \$15,000 as of June 30, 2016 and December 31, 2015, respectively.

Note 4 - Revenue Recognition

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

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

Deferred revenue on the accompanying June 30, 2016 condensed consolidated balance sheet is approximately \$383,000 and is related to the Company's License Agreement with Bellco (see Note 12), which is being deferred over the remainder of the expected obligation period. The Company has recognized approximately \$2,640,000 of revenue related to the Bellco License Agreement to date and approximately \$17,000 and \$34,000, respectively, for the three and six months ended June 30, 2016. The Company recognized approximately \$17,000 and \$35,000, respectively, of revenue related to this License Agreement for the three and six months ended June 30, 2015. Revenue recognized in the three and six months ended June 30, 2015 and 2016 relates to the upfront payment received in February 2014. Approximately \$35,000 of revenue will be recognized in the remaining six months of fiscal year 2016 and approximately \$69,000 of revenue will be recognized in each of the years ended December 31, 2017 through 2021. In addition, beginning on January 1, 2015, Bellco pays the Company a royalty based on the number of units of certain products sold per year due one fiscal quarter in arrears. For the three and six months ended June 30, 2016, the Company recognized approximately \$29,000 and \$57,000, respectively. For the three months ended June 30, 2015, the Company recognized approximately \$28,000. See Note 12, 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 fair value guidance requires fair value measurements be classified and disclosed in one of the following three categories:

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

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

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

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 5 - Fair Value of Financial Instruments (continued)

Fair Value of Investment in Lease, net, and Unsecured Long-Term Note Payable

The carrying amounts of the investment in lease, net, and the unsecured long-term note payable approximate fair value as of June 30, 2016 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit quality.

Warrant Liability

The Company had outstanding warrants originally issued in 2007 (the “2007 Warrants”) that were accounted for as a derivative liability until they were fully exercised on September 29, 2015. The 2007 Warrants were classified as a liability because the transactions that would trigger the anti-dilution adjustment provision in the 2007 Warrants were not inputs to the fair value of the 2007 Warrants. The 2007 Warrants were recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in changes in fair value of warrant liability in the Company’s consolidated statement of operations and comprehensive income (loss) in each subsequent period. The Company utilized a binomial options pricing model to value the 2007 Warrants at each reporting period.

The estimated fair value of the 2007 Warrants as of June 30, 2015 was determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimated the volatility of its common stock based on historical volatility that matched the expected remaining life of the 2007 Warrants. The risk-free interest rate was based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the 2007 Warrants. The expected life of the 2007 Warrants was assumed to be equivalent to their remaining contractual term. The dividend rate was based on the historical rate, which the Company anticipated to remain at zero.

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On the condensed consolidated statement of operations and comprehensive loss for the three month period ended June 30, 2015, the Company recorded expense of \$1,196,000 as a result of the change in fair value of the warrant liability. On the condensed consolidated statement of operations and comprehensive loss for the six month period ended June 30, 2015, the Company recorded expense of \$188,000 as a result of the change in fair value of the warrant liability. A reconciliation of the warrant liability for the three and six month periods ended June 30, 2015 is as follows:

	2007
	Warrants
Balance at March 31, 2015	\$6,378,000
Increase in fair value of warrant liability	1,196,000
Balance at June 30, 2015	\$7,574,000

	2007
	Warrants
Balance at December 31, 2014	\$7,386,000
Increase in fair value of warrant liability	188,000
Balance at June 30, 2015	\$7,574,000

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

	June 30,	
	2015	
Calculated aggregate value	\$7,574,000	
Weighted average exercise price	\$0.30	
Closing price per share of common stock	\$0.71	
Volatility	135.0	%
Weighted average remaining expected life (years)	4.5	
Risk-free interest rate	1.6	%
Dividend yield	-	

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 5 - Fair Value of Financial Instruments (continued)

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

Note 6 – Stock Plans and Share-Based Payments

Stock Options

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

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

The Company granted 30,000 stock options to a consultant during the three and six months ended June 30, 2016. The fair value of the stock options will be expensed over the one year vesting period. The grant date fair value of the stock options as of June 30, 2016 was approximately \$7,000. In accordance with ASC 505-50, the stock options granted to the consultant will be remeasured at each reporting period until vested.

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

Stock-based compensation expense was approximately \$194,000 and \$110,000 for the six months ended June 30, 2016 and 2015, respectively. 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 statement of operations and comprehensive loss. For the six months ended June 30, 2015, approximately \$100,000 and approximately \$10,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statements of operations and comprehensive income (loss).

Stock-based compensation expense was approximately \$92,000 and \$90,000 for the three months ended June 30, 2016 and 2015, respectively. 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 statement of operations and comprehensive loss. For the three months ended June 30, 2015, approximately \$84,000 and approximately \$6,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statements of operations and comprehensive income (loss).

There was no tax benefit related to expense recognized in the six months ended June 30, 2016 and 2015, as the Company is in a net operating loss position. As of June 30, 2016, there was approximately \$1,003,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately \$158,000 of the \$1,003,000 total unrecognized compensation will be recognized at the time that certain performance conditions are met. The remaining approximately \$845,000 will be amortized over the weighted average remaining requisite service period of 2.6 years. Such amount does not include the effect of future grants of equity compensation, if any.

Restricted Stock

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

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 6 – Stock Plans and Share-Based Payments (continued)

During the six months ended June 30, 2016, the Company issued 154,527 shares of restricted stock as payment for non-employee services to be rendered. The grant date fair value of the outstanding restricted stock awards was approximately \$46,000 and was based on the fair value of the common stock on the date of grant. Of the total grant date fair value of approximately \$46,000, approximately \$21,000 and \$41,000, respectively, was recorded during the three and six months ended June 30, 2016.

Additionally, stock-based compensation expense of approximately \$14,000 and \$38,000, respectively, was recorded during the three and six months ended June 30, 2016 related to shares of restricted stock issued to employees during the year ended December 31, 2015.

Total stock-based compensation expense for the restricted stock grants was approximately \$79,000 and \$9,000 for the six months ended June 30, 2016 and 2015, respectively, and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations and comprehensive income (loss).

Total stock-based compensation expense for the restricted stock grants was approximately \$35,000 and \$3,000 for the three months ended June 30, 2016 and 2015, respectively, and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated statements of operations and comprehensive income (loss).

As of June 30, 2016, there was approximately \$5,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next three or six months, dependent upon the respective restricted stock agreements.

Note 7 - Warrants

During 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. There were no warrants exercised during the three months ended June 30, 2016.

During the three months ended June 30, 2015, 25,112 warrants were exercised, resulting in proceeds of approximately \$500 and the issuance of 1,160 shares of common stock. During the six months ended June 30, 2015, 46,039 warrants were exercised, resulting in proceeds of approximately \$1,000 and the issuance of 2,127 shares of 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. If applicable for a given period, 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.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

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

	For the three months		For the six months	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Income (loss) per share - Basic:				
Numerator for basic income (loss) per share	\$ (835,000)	\$ (1,815,000)	\$ (1,671,000)	\$ (1,572,000)
Denominator for basic income (loss) per share	48,545,720	31,190,714	48,359,620	30,727,840
Basic income (loss) per common share	\$ (0.02)	\$ (0.06)	\$ (0.03)	\$ (0.05)
Income (loss) per share - Diluted:				
Numerator for diluted income (loss) per share	\$ (835,000)	\$ (1,815,000)	\$ (1,671,000)	\$ (1,572,000)
Adjust: Change in fair value of dilutive warrants outstanding	-	1,196,000	-	188,000
Numerator for diluted income (loss) per share	\$ (835,000)	\$ (619,000)	\$ (1,671,000)	\$ (1,384,000)
Denominator for basic income (loss) per share	48,545,720	31,190,714	48,359,620	30,727,840
Plus: Incremental shares underlying warrants outstanding	-	-	-	-
Denominator for diluted income (loss) per share	48,545,720	31,190,714	48,359,620	30,727,840
Diluted income (loss) per common share	\$ (0.02)	\$ (0.06)	\$ (0.03)	\$ (0.05)

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,	
	2016	2015
Shares underlying warrants outstanding	3,291,149	17,667,937
Shares underlying options outstanding	4,222,640	3,634,502
Unvested restricted stock	128,234	-

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 9 - Recent Accounting Pronouncements

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 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 2015-14, "Revenue from Contracts with Customers: Deferral of the Effective Date". The amendment in this ASU defers the effective date of ASU 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. Early adoption is permitted only for fiscal years beginning after December 31, 2016, including interim reporting periods within that fiscal year. The Company is currently reviewing the revised guidance and assessing the potential impact on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and sets rules for how this information should be disclosed in the financial statements. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating any impact the adoption of ASU 2014-15 might have on its consolidated financial statements.

In July 2015, the FASB issued ASU 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 to be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. The Company does not believe that the adoption of ASU 2015-11 will have a significant impact on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, “Balance Sheet Classification of Deferred Taxes,” that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. The Company does not believe that the adoption of ASU 2015-17 will have a significant impact on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities,” that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases”, that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity that is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is evaluating the impact of adopting this guidance on our consolidated financial statements.

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 currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 9 - Recent Accounting Pronouncements (continued)

In March 2016, the FASB issued ASU 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2017. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, “Identifying Performance Obligations and Licensing,” which clarifies the implementation guidance performance obligations and licensing. The amendments in this update do not change the core principle of ASU 2014-09. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of ASU 2014-09. As discussed above, ASU 2015-14 defers the effective date of ASU 2014-09 by one year. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements.

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 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 evaluating the impact of adopting this guidance on its consolidated financial statements.

Note 10 - Inventory, net

Inventory is stated at the lower of cost or market using the first-in first-out method and consists entirely of finished goods. The Company's inventory as of June 30, 2016 and December 31, 2015 was as follows:

	June 30, 2016 (Unaudited)	December 31, 2015 (Audited)
Total Gross Inventory, Finished Goods	\$ 469,000	\$ 634,000
Less: Inventory reserve	(56,000)	(43,000)
Total Inventory	\$ 413,000	\$ 591,000

Note 11 - Unsecured Promissory Notes and Warrants

On June 7, 2016, the Company entered into a Note and Warrant Agreement (the "Agreement") with new creditors as well as existing shareholders under which the Company issued unsecured promissory notes ("Notes") and warrants ("Warrants") resulting in total gross proceeds to the Company during June 2016 of approximately \$1,187,000. 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 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 to the investors in the Agreement. The warrants have an exercise price of \$0.30 per share and are exercisable for 5 years from the issuance date. The Warrants issued under the Agreement are indexed to the Company's common stock, therefore, the Company is accounting for the Warrants as a component of equity. In connection with the Agreement, the Company incurred approximately \$13,000 in legal fees.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 11 - Unsecured Promissory Notes and Warrants (continued)

The approximately \$1,187,000 in gross proceeds from the 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 proceeds, including fees, 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 proceeds of approximately \$794,000, including fees, 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 Agreement. As of 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. As of June 30, 2016, approximately \$10,000 of interest expense has been accrued. As of June 30, 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. There were no unsecured long-term notes payable outstanding as of December 31, 2015.

Note 12 - Commitments and Contingencies

Manufacturing and Suppliers

The Company has not and does not intend in the near future to manufacture any of its products and components. With regard to the OLpur MD190 and MD220, on June 27, 2011, the Company entered into a license agreement (the "License Agreement"), effective July 1, 2011, with Belco 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 Belco 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 Sweden, Denmark, Norway, Finland, Korea, Mexico, Brazil, China and the Netherlands. The First Amendment further provides new minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. The Company has agreed to reduce the fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021. Beginning on January 1, 2015 through and including December 31, 2021, Bellco will pay the Company a royalty based on the number of units of Products sold per year in the Territory as follows: for the first 125,000 units sold in total, €1.75 (estimated at approximately \$1.95 using current exchange rates) per unit; thereafter, €1.25 (estimated at approximately \$1.40 using current exchange rates) per unit. 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. See Note 4 for further discussion of the licensing revenue recognized by the Company related to the upfront fees.

In addition to the licensing revenue, the Company recognized royalty revenue related to the First Amendment with Bellco. For the three and six months ended June 30, 2016, the Company recognized approximately \$29,000 and \$57,000, respectively. For the three months ended June 30, 2015, the Company recognized approximately \$28,000.

NEPHROS, INC.**NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS****Note 12 - Commitments and Contingencies (continued)**License and Supply Agreement

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

As further consideration for the license and other rights granted to the Company, the Company granted Medica options to purchase 300,000 shares of the Company’s common stock. The fair market value of these stock options was approximately \$273,000 as of April 23, 2012, calculated as described in Note 6 under Stock Options. Together with the total installment payments described above, the fair market value of the options has been capitalized as a long-term intangible asset. The gross value of the intangible asset capitalized was approximately \$2,250,000. Included in other long-term assets on the consolidated balance sheet is approximately \$1,368,000 and \$1,473,000, as of June 30, 2016 and December 31, 2015, respectively, related to the License and Supply Agreement. Accumulated amortization is approximately \$882,000 and \$777,000 as of June 30, 2016 and December 31, 2015, respectively. The asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately \$53,000 and \$105,000 has been charged to amortization expense for the three and six months ended June 30, 2016 and 2015, respectively on the condensed consolidated statement of operations and comprehensive loss. Approximately \$105,000

of amortization expense will be recognized in the remainder of 2016 and approximately \$210,000 will be recognized in each of the years ended December 31, 2017 through 2022. In addition, for the period beginning April 23, 2014 through December 31, 2022, the Company will pay Medica a royalty rate of 3% of net sales of the Filtration Products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. Royalty expense of approximately \$14,000 was included in accrued expenses as of June 30, 2016 and December 31, 2015. 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, 2016, approximately \$14,000 and \$26,000 of interest, respectively, was paid to Medica. For the three and six months ended June 30, 2015, approximately \$11,000 and \$25,000 of interest, respectively, was paid to Medica.

Contractual Obligations

The Company has an operating lease that expires on November 30, 2018 for the rental of its U.S. office and research and development facilities with a monthly cost of approximately \$9,000. Included in other assets, net, on the condensed consolidated balance sheet as of June 30, 2016 is approximately \$21,000 related to a security deposit for the U.S. office facility. Rent expense was approximately \$38,000 and \$28,000 for the three months ended June 30, 2016 and 2015, respectively. Rent expense was approximately \$67,000 and \$66,000 for the six months ended June 30, 2016 and 2015, respectively.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Note 12 - Commitments and Contingencies (continued)

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 sales-type 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, 2016, approximately \$2,000 and \$3,000, respectively, was recognized in interest income. As of June 30, 2016, investment in lease, current is approximately \$26,000, net of unearned interest of \$5,000. As of June 30, 2016, investment in lease, noncurrent, is approximately \$68,000, net of unearned interest of \$7,000.

As of June 30, 2016, scheduled maturities of minimum lease payments receivable were as follows:

2016	\$ 19,000
2017	17,000
2018	18,000
2019	19,000
2020	21,000
	94,000
Less: Current portion	(26,000)
Investment in sales-type lease, noncurrent	\$ 68,000

The Company also invoiced Biocon 1, LLC approximately \$11,000 related to consulting services provided during the three and six months ended June 30, 2016 and is included in license, royalty and other revenue on the condensed consolidated statement of operations and comprehensive loss. Approximately \$11,000 is also included in accounts

receivable as of June 30, 2016.

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

This discussion should be read in conjunction with our consolidated financial statements included in this Quarterly Report on Form 10-Q and the notes thereto, as well as the other sections of this Quarterly Report on Form 10-Q, including the “Forward-Looking Statements” section hereof, and our Annual Report on Form 10-K for the year ended December 31, 2015, including the “Risk Factors” and “Business” sections thereof. This discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015. Our actual results may differ materially.

Financial Operations Overview

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

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

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

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

Overview

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

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

Our OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease (“ESRD”). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

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

Going Concern

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

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

Based on our current cash flow projections, we expect that our existing cash balances and our projected increases in product sales from the launch of new products will allow us to fund our operations at least into the first quarter of fiscal year 2017, depending on the timing and market up-take of our new products. This assumption excludes the impact of future cash receipts from recurring operations. There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our commitments, we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

Our Products

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

HDF Systems

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

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

Enhanced clearance of middle and large molecular weight toxins

Improved survival - up to a 35% reduction in mortality risk

Reduction in the occurrence of dialysis-related amyloidosis

Reduction in inflammation

Reduction in medication such as EPO and phosphate binders

Improved patient quality of life

Reduction in number of hospitalizations and overall length of stay

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

We have developed a modified approach to HDF that we believe is more patient-friendly, less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration (“mid-dilution HDF”) system and it consists of our OLpūr H2H Hemodiafiltration Module (“H2H Module”), our OLpūr MD 220 Hemodiafilter (“HDF Filter”) and our H2H Substitution Filter (“Dialysate Filter”).

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

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

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

Our HDF System is cleared by the FDA to market for use with an ultrafiltration controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States. Our on-line mid-dilution HDF system is the only on-line mid-dilution HDF system of its kind to be cleared by the FDA to date.

In May 2014, DaVita Healthcare Partners initiated an evaluation of our HDF System to treat patients at DaVita's North Colorado Springs Clinic. In February 2015, we announced that, in the course of the evaluation, DaVita informed Nephros that they would require additional validation of the system. Nephros and DaVita agreed upon a protocol for the additional validation work which was completed in March 2015. We do not believe that DaVita will restart the evaluation in the near term.

In March 2015, we announced that the Renal Research Institute ("RRI"), a research division of Fresenius Medical Care, was conducting an ongoing evaluation of our hemodiafiltration system in its clinic. As of June 2016, our HDF Systems had performed over 1,200 patient treatments. Over the last 18 months of commercial use, we have gathered direct feedback from users of our HDF System to help improve our system and our training methodology. In January 2016, we updated our training procedures and rolled out a software update, which was focused on improving the system's alignment with nurse work flow. In June 2016, after approximately 5 months of successfully completed patient treatments with the updated software, we concluded the evaluation project with RRI.

We expect to deploy our HDF Systems at a highly respected academic institution in the fourth quarter of fiscal year 2016. We are currently working through the final stages of contracting and planning for the deployment. 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.

Ultrafiltration Products

Our ultrafiltration products target a number of markets.

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

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

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

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

Our Target Markets

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

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

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

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

On October 27, 2015, we announced that we had submitted the S100 Point of Use filter to the FDA for 510(k) clearance. In late December 2015, the FDA requested additional information. On April 14, 2016, we announced that we received 510(k) clearance from the FDA to market our S100 Point of Use filter.

On May 27, 2016, we submitted the PathoGuard™ 10" cartridge filter to the FDA for 510(k) under the Special 510(k): Device Modification process. In late June 2016, the FDA sent us a request for additional information. On July 7, 2016, we provided the FDA with additional information. We have a meeting with the FDA scheduled for August 15, 2016 to further discuss our PathoGuard™ and EndoPur™ submissions.

The complete hospital infection control product line, including in-line and point of use 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, or incorporating it by reference into, this report.

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

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

Published studies have shown t