

NEPHROS INC
Form 10-Q
November 13, 2014

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: **September 30, 2014**

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

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

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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) September 30, 2014	(Audited) December 31, 2013
ASSETS		
Current assets:		
Cash	\$ 1,047	\$ 579
Accounts receivable	179	122
Inventory, less allowances of \$84 at September 30, 2014 and \$365 at December 31, 2013	108	162
Prepaid expenses and other current assets	33	125
Total current assets	1,367	988
Property and equipment, net	1	7
Other assets, net of accumulated amortization	1,737	1,894
Total assets	\$ 3,105	\$ 2,889
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Senior secured notes, net of debt discount of \$146 at September 30, 2014 and \$142 at December 31, 2013	\$ 1,604	\$ 1,358
Accounts payable	908	1,073
Accrued expenses	300	365
Deferred revenue	245	703
Total current liabilities	3,057	3,499
Long-term portion of deferred revenue	434	-
Total liabilities	3,491	3,499

Commitments and Contingencies (Note 13)

Stockholders' deficit:

Preferred stock, \$.001 par value; 5,000,000 shares authorized at September 30, 2014 and December 31, 2013; no shares issued and outstanding at	-	-
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September 30, 2014 and December 31, 2013

Common stock, \$.001 par value; 90,000,000 shares authorized at September 30, 2014 and December 31, 2013; 25,249,054 and 18,082,043 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	25		18	
Additional paid-in capital	102,864		100,526	
Accumulated other comprehensive income	73		74	
Accumulated deficit	(103,348)	(101,228)
Total stockholders' deficit	(386)	(610)
Total liabilities and stockholders' deficit	\$ 3,105		\$ 2,889	

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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net revenues:				
Product revenues	\$298	\$242	\$765	\$979
License revenues	193	176	641	535
Total net revenues	491	418	1,406	1,514
Cost of goods sold	175	189	423	610
Gross margin	316	229	983	904
Operating expenses:				
Research and development	178	204	521	687
Depreciation and amortization	54	55	164	169
Selling, general and administrative	765	578	2,177	2,293
Total operating expenses	997	837	2,862	3,149
Loss from operations	(681)	(608)	(1,879)	(2,245)
Interest expense	(65)	(5)	(277)	(256)
Gain on sale of equipment	-	1	-	3
Other income (expense)	40	1	36	(25)
Net loss	(706)	(611)	(2,120)	(2,523)
Other comprehensive income(loss), foreign currency translation adjustments	1	-	(1)	(2)
Total comprehensive loss	\$(705)	\$(611)	\$(2,121)	\$(2,525)
Net loss per common share, basic and diluted	\$(0.03)	\$(0.03)	\$(0.09)	\$(0.17)
Weighted average common shares outstanding, basic and diluted	25,238,412	17,787,356	23,094,457	14,805,395

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

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(In Thousands, Except Share Amounts)

(Unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income(Loss)	Accumulated Deficit	Total
	Shares	Amount	Capital			
Balance, December 31, 2013	18,082,043	\$ 18	\$ 100,526	\$ 74	\$ (101,228)	\$(610)
Net loss					(2,120)	(2,120)
Net unrealized losses on foreign currency translation				(1)		(1)
Shareholder rights offering (March 2014), net	7,140,823	7	2,006			2,013
Exercise of warrants	26,188		11			11
Noncash stock-based compensation			321			321
Balance, September 30, 2014	25,249,054	\$ 25	\$ 102,864	\$ 73	\$ (103,348)	\$(386)

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)

	Nine Months Ended September	
	30,	2013
	2014	
Operating activities:		
Net loss	\$ (2,120) \$ (2,523
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	6	7
Amortization of other assets	158	162
Noncash stock-based compensation	321	401
Noncash warrant inducement	-	14
Amortization of debt discount	173	204
Inventory reserve	31	5
(Gain)loss on foreign currency transactions	(40) 17
Gain on sale of equipment	-	(3
(Increase) decrease in operating assets:		
Accounts receivable	(57) 831
Inventory	24	16
Prepaid expenses and other current assets	92	71
Decrease in operating liabilities:		
Accounts payable and accrued expenses	(229) (45
License and supply agreement fee payable	-	(1,318
Deferred revenue	(23) (535
Net cash used in operating activities	(1,664) (2,696
Investing activities:		
Proceeds from sale of equipment	-	3
Net cash provided by investing activities	-	3
Financing activities:		
Proceeds from issuance of common stock, net of equity issuance costs of \$128 and \$229, respectively	2,013	2,771
Proceeds from issuance of senior secured note	1,610	1,300
Proceeds from exercise of warrants	11	248
Payment of senior secured note	(1,500) (1,300
Payment of financing costs	-	(204
Net cash provided by financing activities	2,134	2,815
Effect of exchange rates on cash and cash equivalents	(2) (1

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Net increase in cash	468	121
Cash, beginning of period	579	47
Cash, end of period	\$ 1,047	\$ 168
Supplemental disclosure of cash flow information		
Cash paid for income taxes	\$ 6	\$ 2
Cash paid for interest	\$ 70	\$ -
Restricted stock issued to settle liability	\$ -	\$ 116

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

1. Organization and Nature of Operations

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

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

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 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 28, 2014. 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 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, 2013 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 interim condensed consolidated financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. Certain reclassifications were made to the prior year's amounts to conform to the 2014 presentation. All significant 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. The more significant estimates used by management relate to the valuation of inventory reserves and the measurement of deferred revenue. Actual results could differ materially from those estimates.

Going Concern and Management's Response

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

The Company has incurred significant losses in operations in each quarter since inception. For the nine months ended September 30, 2014 and 2013, the Company has incurred net losses of \$2,120,000 and \$2,523,000, respectively. To become profitable, the Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, its results of operations and financial condition will be materially and adversely affected.

In October 2013, the Company announced the voluntary recalls of its point of use ("POU") and DSU in-line ultrafilters used in hospital water treatment applications. As a result, the Company recalled all production lots of its POU filters, and also requested that customers remove and discard certain labeling/promotional materials for the products. In addition, the Company also requested, for the DSU in-line ultrafilter, that customers remove and discard certain labeling/promotional materials for the product. These voluntary recalls did not affect the Company's dialysis products. The Company is working towards a resolution of the issues raised by the Food and Drug Administration ("FDA") and is unable to predict at this time what additional effect this recall might have on its business, financial condition, future prospects or reputation or whether it may be subject to future actions from the FDA. On March 20, 2014, the Company requested termination of its product recall from the FDA. As of the date of this filing, there has been no additional communication from the FDA regarding the product recall. The voluntary recalls of POU and DSU ultrafilters used in hospital water treatment applications and the related circumstances could subject the Company to

claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact the Company's sales and revenues.

NEPHROS, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

2. Basis of Presentation and Going Concern (continued)

On August 29, 2014, the Company issued a senior secured note to Lambda Investors LLC (“Lambda”) in the principal amount of \$1.75 million. The note bears interest at the rate of 12% per annum and is scheduled to mature on February 28, 2015, at which time all principal and accrued interest will be due. In addition, the Company is planning a \$3 million rights offering, which will enable the Company to pay the principal and interest prior to the maturity date. For a more detailed discussion of the terms of the senior secured note, see Note 11, Senior Secured Notes.

On March 21, 2014, the Company completed a rights offering which resulted in gross proceeds of \$2.1 million. See Note 12, Stockholders’ Equity, for a more detailed discussion of the rights offering. The Company repaid the November 12, 2013 senior secured note issued to Lambda in the principal amount of \$1.5 million with a portion of the proceeds from the rights offering. For a more detailed discussion of the terms of the senior secured note, see Note 11, Senior Secured Notes.

On February 19, 2014, the Company entered into the First Amendment to License Agreement (the “First Amendment”), by and between the Company and Bellco S.r.l. (“Bellco”), which amends the License Agreement, entered into as of July 1, 2011 by and between the Company and Bellco. Pursuant to the First Amendment, the Company and Bellco agreed to extend the term of the License Agreement through December 31, 2021. 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 other half of which was received on April 4, 2014. See Note 13, Commitments and Contingencies, for further discussion of, and additional terms related to, the First Amendment.

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.

3. Concentration of Credit Risk

For the nine months ended September 30, 2014 and 2013, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2014	2013
A	46 %	36 %
B	25 %	31 %
C	9 %	16 %

As of September 30, 2014 and December 31, 2013, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2014	2013
A	61 %	69 %
B	15 %	- %
C	13 %	- %
D	- %	28 %

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

NEPHROS, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

4. Revenue Recognition (continued)

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 September 30, 2014 condensed consolidated balance sheet is approximately \$679,000 and is related to the License Agreement with Bellco, which is being deferred through December 31, 2021, the remainder of the expected obligation period. The Company has recognized approximately \$2,396,000 of revenue related to the License Agreement to date and approximately \$641,000 for the nine months ended September 30, 2014. See Note 13, Commitments and Contingencies, for further discussion of the Bellco License Agreement.

5. Stock-Based Compensation

Stock Options

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

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

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The Company granted 302,519 stock options during the nine months ended September 30, 2014 to employees, non-employees, directors and consultants. These stock options vest over a two-year or four-year period and will be expensed over the applicable vesting period. The fair value of all stock-based awards granted during the nine months ended September 30, 2014 was approximately \$127,000.

The following assumptions were used for options granted for the nine months ended September 30, 2014:

Assumptions for Option Grants	Nine Months	
	Ended	September 30, 2014
Risk-free interest rate	1.76 - 1.91	%
Volatility	129.2 - 133.4	%
Expected dividend yield	0	%
Expected term	5.75 - 6.25 yrs	

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 \$318,000 and \$300,000 for the nine months ended September 30, 2014 and 2013, respectively. For the nine months ended September 30, 2014, approximately \$302,000 and approximately \$16,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations. For the nine months ended September 30, 2013, approximately \$275,000 and approximately \$25,000 are included in Selling, General and Administrative expenses and Research and Development expenses, respectively, on the accompanying condensed consolidated statement of operations.

There was no tax benefit related to expense recognized in the nine months ended September 30, 2014 and 2013, as the Company is in a net operating loss position. As of September 30, 2014, there was approximately \$580,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans, which will be amortized over the weighted average remaining requisite service period of 1.9 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the approximately \$580,000 of total unrecognized compensation cost, the Company expects to recognize approximately 16% in the remaining interim periods of 2014, approximately 64% in 2015, approximately 17% in 2016 and approximately 3% in 2017.

NEPHROS, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

5. Stock-Based Compensation (continued)

Restricted Stock

Total stock-based compensation expense for the restricted stock grants was approximately \$3,000 for the nine months ended September 30, 2014 and is included in Selling, General and Administrative expenses on the accompanying condensed consolidated interim statement of operations. As of September 30, 2014, all compensation expense related to the restricted stock awards has been recognized.

6. Warrants