

NEPHROS INC
Form 10-Q
November 14, 2011

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, 2011

OR

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

For the transition period from: _____ to _____

Commission File Number: 001-32288

NEPHROS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

13-3971809
(I.R.S. Employer
Identification No.)

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

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

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

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

As of November 7, 2011, 10,473,134 shares of issuer’s common stock, with \$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) September 30, 2011	(Audited) December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,117	\$ 240
Accounts receivable	203	326
Inventory, less allowances of \$18	396	726
Prepaid expenses and other current assets	132	190
Total current assets	2,848	1,482
Property and equipment, net	37	108
Total assets	\$ 2,885	\$ 1,590
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Short-term borrowings	\$ -	\$ 500
Accounts payable	427	441
Accrued expenses	105	481
Deferred revenue	500	33
Total current liabilities	1,032	1,455
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at September 30, 2011 and December 31, 2010; no shares issued and outstanding at September 30, 2011 and December 31, 2010	-	-
Common stock, \$.001 par value; 90,000,000 authorized at September 30, 2011 and December 31, 2010; 10,065,118 and 2,090,552 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	10	2
Additional paid-in capital	95,398	92,019
Accumulated other comprehensive income	75	22
Accumulated deficit	(93,630)	(91,908)
Total stockholders' equity	1,853	135
Total liabilities and stockholders' equity	\$ 2,885	\$ 1,590

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

NEPHROS, INC. AND SUBSIDIARY

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenues:				
Product revenues	\$ 220	\$ 622	\$ 1,538	\$ 2,421
Licensing revenues	187	-	187	-
Total net revenues	407	622	1,725	2,421
Cost of goods sold	98	319	1,014	1,446
Gross margin	309	303	711	975
Operating expenses:				
Research and development	131	116	335	259
Depreciation and amortization	23	30	71	98
Selling, general and administrative	580	550	1,974	1,903
Total operating expenses	734	696	2,380	2,260
Loss from operations	(425)	(393)	(1,669)	(1,285)
Interest income	2	-	3	1
Interest expense	-	-	(12)	-
Amortization of debt issuance costs	-	-	(40)	-
Other income (expense)	10	18	(4)	16
Net loss	\$ (413)	\$ (375)	\$ (1,722)	\$ (1,268)
Net loss per common share, basic and diluted	\$ (0.04)	\$ (0.18)	\$ (0.21)	\$ (0.61)
Weighted average common shares outstanding, basic and diluted	10,065,118	2,090,552	8,071,476	2,085,889

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,
2011 2010

Operating activities		
Net loss	\$ (1,722)	\$ (1,268)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	71	98
Non-cash stock-based compensation	197	70
Deferred revenue	484	67
Amortization of debt issuance costs	40	-
Noncash interest	12	-
Decrease in operating assets:		
Accounts receivable	137	168
Inventory	350	28
Prepaid expenses and other current assets	58	67
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(306)	129
Net cash used in operating activities	(679)	(641)
Investing activities		
Purchase of property and equipment	-	(6)
Net cash provided by (used in) investing activities	-	(6)
Financing activities		
Repayment of debt	(500)	-
Payment of financing costs	(140)	-
Proceeds from stock options exercised	-	72
Proceeds from issuance of common stock	3,190	-
Net cash provided by financing activities	2,550	72
Effect of exchange rates on cash	6	(8)
Net increase (decrease) in cash	1,877	(583)
Cash, beginning of period	240	1,004
Cash, end of period	\$ 2,117	\$ 421
Supplemental disclosure of cash flow information		
Cash paid for taxes	\$ 4	\$ 2

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

1. Basis of Presentation and Going Concern

Reverse Stock Split

On January 10, 2011, the Company's stockholders voted to implement a 1:20 reverse stock split of the Company's common stock. The reverse split became effective on March 11, 2011. All of the share and per share amounts discussed in these condensed consolidated interim financial statements on Form 10-Q have been adjusted to reflect the effect of this reverse split.

Interim Financial Information

The accompanying unaudited condensed consolidated interim financial statements of Nephros, Inc. and its wholly owned subsidiary, Nephros International Limited (collectively, the "Company") should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's 2010 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 29, 2011 and Form 10-K/A filed with the SEC on April 28, 2011. 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, 2010 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. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amount of revenues and expenses, during the reporting period. Actual results could differ materially from those estimates.

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, 2011 and 2010, the Company has incurred net losses of \$1,722,000 and \$1,268,000, respectively. In

addition, the Company has not generated positive cash flow from operations for the nine months ended September 30, 2011 and 2010. 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.

On October 1, 2010, the Company issued a senior secured note to Lambda Investors LLC, its largest stockholder, in the principal amount of \$500,000. The note bore interest at the rate of 12% per annum and was to mature on April 1, 2011, at which time all principal and accrued interest was due. However, the Company agreed to and did prepay, without penalty, amounts due under the note with the cash proceeds from its rights offering prior to the maturity date. The note was secured by a first priority lien on all of the Company's property, including its intellectual property.

On March 10, 2011 the Company completed its rights offering and a private placement that together resulted in gross proceeds of approximately \$3.2 million. The aggregate net proceeds were approximately \$2.3 million, after deducting the estimated aggregate expenses of these transactions which approximated \$200,000, the repayment of the \$500,000 note issued to Lambda Investors, LLC, plus \$26,650 of accrued interest thereon, the payment of an 8% sourcing/transaction fee of \$40,000 in respect of the note and an aggregate of \$100,000 for reimbursement of Lambda Investors' legal fees incurred in connection with the loan and the rights offering.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

1. Basis of Presentation and Going Concern (continued)

After giving effect to the 1:20 reverse stock split on March 11, 2011, the Company's stockholders subscribed for 4,964,854 units in the rights offering and the Company accepted all basic subscription rights and oversubscription privileges. The units were sold at a per unit purchase price of \$0.40. Gross proceeds to the Company from the sale of these units in the rights offering were approximately \$2.0 million. The Company issued an aggregate of 4,964,854 shares of common stock and warrants to purchase an aggregate of approximately 4.6 million shares of its common stock to stockholders who subscribed.

Simultaneously with the closing of the rights offering, Lambda Investors, LLC purchased in a private placement 3,009,711 units at the same per unit purchase price of \$0.40, pursuant to a purchase agreement between the Company and Lambda Investors. The Company issued to Lambda Investors an aggregate of 3,009,711 shares of common stock and warrants to purchase an aggregate of 2,782,579 shares of common stock. Of the \$3.2 million in gross proceeds from the rights offering and the private placement, the Company received approximately \$1.2 million in gross proceeds from the sale of units to Lambda Investors.

The Company effected a reverse stock split, in which every 20 shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:00 p.m. on March 11, 2011, were converted into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to \$0.04 per pre-split share for such fractional interests. The number of shares of common stock issued and outstanding was reduced from approximately 201,300,000 pre-split to approximately 10,100,000 post-split. The reverse stock split was effected in connection with the rights offering and private placement.

The reverse stock split was approved by the Company's stockholders at the annual meeting held on January 10, 2011. The number of shares of common stock subject to outstanding stock warrants and options, and the exercise prices and conversion ratios of those securities, were automatically proportionately adjusted for the 1-for-20 ratio provided for by the reverse stock split.

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters. This Agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. These fixed payments of €1,850,000 or approximately \$2,600,000, take place over the next fifteen months. The first fixed payment was received in July 2011. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to Nephros a royalty based on the number of units of products sold in the territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. Anticipated payments from this License Agreement will be a positive source of cash flow to the Company.

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.

2. Concentration of Credit Risk

For the nine months ended September 30, 2011 and 2010, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2011	2010
A	53%	49%
B	21%	31%

As of September 30, 2011 and December 31, 2010, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

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NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Customer	2011	2010
A	-	72%
B	39%	12%
C	22%	-

The Company's OLpur MDHDF filter series and Dual Stage Ultrafilter water filtration system products are manufactured by the same vendor.

3. 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 of 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 Nephros. Shipments for all products are currently received directly by the Company's customers.

On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters. This Agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. The Company recognizes the fixed licensing revenue on a straight line basis over the forty-two month period which they cover. Any difference between payments and recognized revenue is reported as deferred revenue.

4. Stock-Based Compensation

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 through the vesting period.

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

The Company granted 612,500 stock options during the nine months ended September 30, 2011 to employees, non-employee directors and consultants. These stock options vest 40% immediately and the remaining 60% annually over a three-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, 2011 was approximately \$267,000.

The following assumptions were used for options granted for the nine months ended September 30, 2011.

	Nine Months Ended September 30, 2011
Assumptions for Option Grants	
Risk-free interest rate	2.31 - 2.42%
Volatility	122%
Expected dividend yield	—
Expected term	5.5 yrs

The Company calculates expected volatility for a stock-based grant based on historic monthly stock price observations of common stock 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 at 5.8% as a part of the estimate of expense as of the grant date. The Company has used historical data to estimate expected employee behaviors related to forfeitures. 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.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Stock-based compensation expense was approximately \$197,000 and \$70,000 for the nine months ended September 30, 2011 and 2010, respectively. This expense is presented as part of the operating results in Selling, General and Administrative expenses on the accompanying condensed consolidated statement of operations.

There was no tax benefit related to expense recognized in the three and nine months ended September 30, 2011 and 2010, as the Company is in a net operating loss position. As of September 30, 2011, there was approximately \$193,000 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 2.2 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the total \$193,000, the Company expects to recognize approximately 16% in the remaining interim periods of 2011, approximately 41% in 2012, approximately 36% in 2013 and approximately 7% in 2014.

5. Comprehensive Income (Loss)

Comprehensive income (loss), as defined in ASC 220, is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)) such as unrealized gains or losses on securities classified as available-for-sale and foreign currency translation adjustments. As of September 30, 2011 and December 31, 2010, accumulated other comprehensive income was approximately \$75,000 and \$22,000, respectively.

6. Loss per Common Share

In accordance with ASC 260-10, net loss per common share amounts (“basic EPS”) are computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution (“diluted EPS”) is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. However, because their effect is anti-dilutive, the Company has excluded stock options and warrants aggregating 17,546,200 and 454,255 shares, respectively, from the computation of diluted EPS for the nine-month periods ended September 30, 2011 and 2010, respectively.

7. Recently Adopted Accounting Pronouncements

In April 2010, the FASB issued an ASU, Revenue Recognition – Milestone Method, to provide guidance on (i) defining a milestone, and (ii) determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The guidance becomes effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010, with early adoption and retrospective application permitted. The adoption of this amendment did not impact the Company’s consolidated financial statements.

In February 2010, the FASB issued an amendment which requires that an SEC filer, as defined, evaluate subsequent events through the date that the financial statements are issued. The update also removed the requirement for an SEC filer to disclose the date through which subsequent events have been evaluated. The adoption of this guidance on January 1, 2010 did not have a material effect on the Company’s consolidated financial statements.

In January 2010, the FASB issued an amendment to ASC Topic 820- Improving Disclosures about Fair Value Measurements, which amends the existing fair value measurement and disclosure guidance currently included in ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value

measurements. Specifically, the amendment to ASC Topic 820 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, this amendment also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This amendment is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of this amendment did not impact the Company's consolidated financial statements.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

8. New Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income," ("ASU 2011-05") which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after Dec. 15, 2011 with early adoption permitted. The Company does not believe that the adoption of ASU 2011-05 will have a material impact on the Company's consolidated results of operation and financial condition.

9. Fair Value of Financial Instruments

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

The Company had no financial assets held at fair value at September 30, 2011 or December 31, 2010.

10. Inventory, net

Inventory is stated at the lower of cost or market using the first-in first-out method. The Company's inventory as of September 30, 2011 and December 31, 2010 was approximately as follows:

	Unaudited September 30, 2011	Audited December 31, 2010
Raw Materials	\$ -	\$ 264,000
Finished Goods	414,000	480,000
Total Gross Inventory	414,000	744,000
Less: Inventory reserve	(18,000)	(18,000)
Total Inventory	\$ 396,000	\$ 726,000

11. Commitments and Contingencies

Suppliers

The Company entered into an agreement in December 2003, and amended in June 2005, with a fiber supplier ("FS"), a manufacturer of medical and technical membranes for applications like dialysis, to continue to produce the fiber for the OLpur MDHDF filter series. Pursuant to the agreement, FS is the Company's exclusive provider of the fiber for the OLpur MDHDF filter series in the European Union as well as certain other territories. On January 18, 2010, the FS notified the Company that it exercised its right to terminate the supply agreement. Termination of the supply agreement was effective on July 18, 2010. On June 27, 2011, the Company entered into a License Agreement, effective July 1, 2011, with Bellco S.r.l., as licensee ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters. The Company does not need to procure fiber for the OLpur MDHDF filter series as a result of this License

Agreement.

12. Subsequent Events

On October 18, 2011, Nephros, Inc. issued a press release announcing that its Post-Effective Amendment No. 2 to Registration Statement on Form S-1 (Registration Number 333-169728) was declared effective on October 18, 2011 by the Securities and Exchange Commission.

As of November 7, 2011, shareholders have exercised 8,828,471 warrants resulting in the issuance of 408,016 common shares.

On November 10, 2011 the Company announced that it has received the initial review by the Food and Drug Administration (“FDA”) of the 510(k) application for marketing clearance of the company’s hemodiafiltration system. On August 11, 2011 the Company submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. As the next step, the Company will respond to the FDA’s request for more information. The Company intends to provide its response within 30 days or request an extension of time to respond, if necessary.

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 "Certain Risks and Uncertainties" section hereof, and our Annual Report for the year ended December 31, 2010 on Form 10-K and Form 10-K/A, including the "Certain Risks and Uncertainties" and "Description of 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 and our Annual Report for the year ended December 31, 2010 on Form 10-K. 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 of 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 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.

Business Overview

Founded in 1997, we are a Delaware corporation that has been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. In January 2006, we introduced our Dual Stage Ultrafilter (the "DSU") water filtration system, which represented a new and complementary product line to our existing ESRD therapy business.

We currently have three products in various stages of development in the HDF modality to deliver improved therapy to ESRD patients:

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); we believe that it is the only filter designed expressly for HDF therapy and employs our proprietary Mid-Dilution Diafiltration technology;
- OLpur H2H, our add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy; and
- OLpur NS2000 system, our stand-alone HDF machine and associated filter technology.

We have also developed our OLpur HD 190 high-flux dialyzer cartridge, which incorporates the same materials as our OLpur MD series but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLpur HD190 was designed for use with either hemodialysis or hemodiafiltration machines, and received its approval from the U.S. Food and Drug Administration, or FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act, in June 2005.

OLpur and H2H are among our trademarks for which U.S. registrations are pending. H2H is a registered European Union trademark. We have assumed that the reader understands that these terms are source-indicating. Accordingly, such terms appear throughout the remainder of this report without trademark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

We believe that products in our OLpur MDHDF filter series are more effective than any products currently available for ESRD therapy because they are better at removing certain larger toxins (known in the industry as “middle molecules” because of their heavier molecular weight) from blood. The accumulation of middle molecules in the blood has been related to such conditions as malnutrition, impaired cardiac function, carpal tunnel syndrome, and degenerative bone disease in the ESRD patient. We also believe that OLpur H2H will, upon introduction, expand the use of HDF as a cost-effective and attractive alternative for ESRD therapy.

We believe that our products will reduce hospitalization, medication and care costs as well as improve patient health (including reduced drug requirements and improved blood pressure profiles), and therefore, quality of life, by removing a broad range of toxins through a more patient-friendly, better-tolerated process. In addition, independent studies in Europe have indicated that, when compared with dialysis as it is currently offered in the United States, HDF can reduce the patient's mortality risk by up to 35%. We believe that the OLPur MDHDF filter series and the OLPur H2H will provide these benefits to ESRD patients at competitive costs and without the need for ESRD treatment providers to make significant capital expenditures in order to use our products. We also believe that the OLPur NS2000 system, if successfully developed, will be the most cost-effective stand-alone hemodiafiltration system available.

In the first quarter of 2007, we received approval from the FDA for our Investigational Device Exemption ("IDE") application for the clinical evaluation of our OLPur H2H module and OLPur MD 220 filter. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA requested additional information from us. We replied to the FDA inquiries on March 13, 2009.

On June 30, 2010, we received a final decision letter from the FDA for our 510(k) submission which stated that the FDA could not reach a substantial equivalence determination for our hemodiafiltration (HDF) system. On August 11, 2011, Nephros filed a new 510(k) application with the FDA for clearance of the Company's hemodiafiltration (HDF) system for end-stage renal disease. Upon issuance of a 510(k) application tracking number, the application is subject to the FDA's standard 90-day review period. Nephros believes that, if approved, its technology would be the first FDA-approved on-line HDF therapy available in the U.S. The prior decision by the U.S. FDA with regard to our HDF system does not impact our ability to market and sell our mid-dilution (MD) filters for hemodiafiltration procedures outside of the U.S.

On June 27, 2011, the Company entered into a license agreement, effective as of July 1, 2011, with Bellco S.r.l. as licensee, an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products. Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon the written approval of Nephros, other European countries where Nephros does not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by Nephros, Bellco will be required to sell the Products to Nephros' distributors in the Territory.

We currently have multiple products in various stages of development for the ultrafiltration of water and other fluids:

- DSU, our Dual Stage Ultrafilters for use in hospital infection control, hemodialysis, and other applications;
- SSU, our SafeSpout Ultrafilter for endpoint use on sinks;
- MSU, our large capacity Ultrafilter for commercial applications; and
- UF-40, our compact Ultrafilter for use in military applications and outdoor activities, such as hiking.

In January 2006, we introduced our DSU water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter

architecture and is, to our knowledge, the only water filter that allows the user to sight-verify that the filter is properly performing its cleansing function. Our research and development work on the OLpur H2H and MD Mid-Dilution filter technologies for ESRD therapy provided the foundations for a proprietary multi-stage water filter that we believe is cost effective, extremely reliable, and long-lasting. We believe our DSU can offer a robust solution to a broad range of contaminated water and disease prevention issues. Hospitals are particularly stringent in their water quality requirements; transplant patients and other individuals whose immune systems are compromised can face a substantial infection risk in drinking or bathing with standard tap water that would generally not present a danger to individuals with normal immune function. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli. With over 5,800 registered hospitals in the United States alone (as reported by the American Hospital Association in Fast Facts of November 11, 2009), we believe the hospital shower and faucet market can offer us a valuable opportunity as a first step in water filtration.

On October 7, 2008, we filed a 510(k) application for approval to market our DSU to dialysis clinics for in-line purification of dialysate water. On July 1, 2009, we received FDA approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

On May 10, 2011, we received approval from the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, to market our Dual Stage Ultrafilter (DSU) in Canada to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

On July 21, 2011 the Company announced that it received 510k clearance from the U.S. Food and Drug Administration to market its MSU and SSU ultrafilters to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

The Association for the Advancement of Medical Instruments' (AAMI) adoption of more stringent water purity standards for dialysis applications as well as observational studies showing a significant reduction in required erythropoietin dosing when the Nephros DSU is utilized during dialysis therapy has significantly increased interest in the product. We have filed a special 510(k) application for our SSU and MSU filters to enable these products to be used in dialysis applications. We expect to realize accelerating product sales to the U.S. dialysis market as a combined result of these driving factors. We also expect to realize initial sales of DSU products to dialysis markets outside the U.S. in 2012.

We have introduced product line extensions for the hospital infection control market which include a more durable filter design to withstand the higher pressures of hospital plumbing, filter covers to improve the aesthetics of the filters in hospital showers, and the SafeSpout Filter as a convenient endpoint filter to address acute outbreak scenarios. We are investigating a range of additional commercial, industrial, and military opportunities for our DSU technology.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra-filter. In connection with this Federal appropriation of approximately \$1 million, we worked on the development of a personal potable water purification system for use by warfighters. Work on this project was completed in August 2009 and we billed approximately \$900,000 during the twenty months ended August 2009. In August 2009, we were awarded a new \$1.8 million research contract from the Office of Naval Research (ONR) for continued development of a potable dual-stage military water purifying filter. The research contract is an expansion of our former ONR contract and is being performed as part of the Marine Corps Advanced Technology Demonstration (ATD) project. The primary objective of this expanded research program is to select concepts and functional prototype filter/pump units which were developed during the first phase of the project, and further develop them into smaller field-testable devices that can be used for military evaluation purposes. An advantage of our ultrafilter is the removal of viruses which are not removed with commercially available off-the-shelf microfilter devices. Such devices generally rely on a secondary chemical disinfection step to make the water safe to drink. The expanded contract also includes research geared toward improving membrane performance, improving device durability, developing larger squad-level water purifier devices, and investigating desalination filter/pump devices for emergency-use purposes. Approximately \$1,625,000 of revenue has been recognized on this new project since September 2009 of which approximately \$356,000 was recognized on this project during the nine months ended September 30, 2011.

During 2010, in response to a Request For Information (RFI) from the U.S. Army, we submitted its UF-40 ultrafilter for consideration as part of the standard issue hydration pack for soldiers in the field. We have been informed by the U.S. Army Public Health Command that its UF-40 filter has been validated to meet the military's NSF P248 standard for emergency military operations as a microbiological water purifier. We believe that our UF-40 filter is the only stand-alone filter to date to have met the performance criteria of the NSF P248 standard without secondary disinfection steps. The Army has not to date issued a Request For Proposal (RFP), and we have no information regarding when or if an RFP applicable to the UF-40 ultrafilter may be put forth by the U.S. Army.

We have also introduced the DSU to various government agencies as a solution to providing potable water in certain emergency response situations. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology.

In March 2010, we entered into a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. We received an initial payment upon entering into the agreement of \$40,000 and were eligible to receive additional payments upon successful completion of product development milestones.

During 2010, we completed the initial milestone under the joint collaboration agreement with STERIS Corporation and completed the remaining milestones under the agreement during the first three quarters of 2011. Completion of these milestones resulted in aggregate payments to us of \$100,000.

On June 27, 2011, the Company entered into a license agreement, effective July 1, 2011, with Bellco S.r.l., as licensee, an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of Nephros' patented mid-dilution dialysis filters (MD 190, MD 220), referred to herein as the Products.

Under the agreement, Nephros granted Bellco a license to manufacture, market and sell the Products under its own name, label and CE mark in Italy, France, Belgium, Spain and Canada on an exclusive basis, and to do the same on a non-exclusive basis in the United Kingdom and Greece and, upon the written approval of Nephros, other European countries where Nephros does not sell the Products as well as non-European countries, all such countries herein referred to as the Territory. In addition, if requested by Nephros, Bellco will be required to sell the Products to Nephros' distributors in the Territory.

In exchange for the rights granted to it under the agreement through December 31, 2014, Bellco agreed to pay Nephros installment payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. The first payment was received in July 2011. Such installment payments, herein referred to as the Installment Payments, are Bellco's sole financial obligations through December 31, 2014. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to Nephros a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, Bellco will pay €4.50 per unit; thereafter, Bellco will pay €4.00 per unit. Bellco must meet minimum sales targets of 15,000 units in each quarter of 2015 and 2016. If Bellco fails to meet a quarterly minimum, the license in Italy, France, Belgium, Spain and Canada will, at the discretion of Nephros, convert to a non-exclusive one. All sums payable under the agreement will be paid in Euros, as adjusted to account for currency exchange fluctuations between the Euro and the U.S. dollar that occur between July 1, 2011, the effective date of the agreement, and the date of payment.

In the case where Nephros desires to pursue a Change in Control transaction (as defined in the agreement), Bellco will have a 30-day right of first offer with respect to such acquisition, and where either party pursues a change in control transaction, it will require the acquirer to assume such party's obligations under the agreement.

If there is an infringement of any of the patents underlying the Products, Nephros will have the first right to decide whether to act to protect such patents. Where Nephros decides not to act, Bellco, upon the written consent of Nephros, will be allowed to act to protect the patents and Nephros will reimburse Bellco the reasonable expenses sustained by Bellco as a credit against royalties due under the agreement.

The term of the agreement is from July 1, 2011 through December 31, 2016, or until earlier terminated by either party as follows. Either party may terminate immediately after giving notice of a breach of any material obligation or upon the insolvency or bankruptcy of the other party, in each case that remains uncured after the expiration of a 30-day cure period. In addition, in the event the agreement is terminated by Bellco on or prior to December 31, 2014 due to a material breach by Nephros that causes any of the patents underlying the Products to lapse, Nephros will be required to reimburse Bellco any of the Installment Payments paid by Bellco prior to the date of termination. Finally, Nephros may terminate the agreement immediately for the following reasons: Bellco's failure to cure a monetary default within 30 days of being provided notice of such default; in the event any required permit of Bellco expires, is not approved, is not issued, or is terminated, revoked, withdrawn or deactivated; and in respect of any calendar year commencing January 1, 2015, if aggregate royalties payable to Nephros fall below €270,000.

The parties are subject to standard indemnification obligations.

On June 27, 2011, Nephros issued a press release announcing its entry into the license agreement. The description of the license agreement set forth above is not complete and is qualified in its entirety by reference to the agreement, which is attached as Exhibit 10.1 to this report and is incorporated by reference.

On July 21, 2011 the Company announced that it received 510(k) clearance from the U.S. Food and Drug Administration to market its MSU and SSU ultrafilters to filter out biological contaminants from water and bicarbonate solution used in hemodialysis procedures.

The Nephros DSU, MSU, and SSU are FDA cleared devices for the filtration of biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. Within the U.S., there are approximately 4,500 clinics providing over 50 million dialysis treatments to 350,000 patients annually. To perform hemodialysis, ultrapure water is crucial to the production of dialysate. Dialysis clinics have water purification systems; however, microbial contaminants can originate from the water treatment system, the water distribution loop, or the dialysate concentrates. Nephros ultrafilters filter out substances down to the 0.005 micron level and address dialysate contamination at crucial points: after the reverse osmosis module and at the dialysis machine entrance from the water distribution loop.

Nephros ultrafilters can be used as the last step in the water purification process to ensure that ultrapure water is used for dialysis procedures. Regular use of Nephros ultrafilters offers an affordable safety measure when utilized with modern water treatment systems and optimally maintained hemodialysis machines. Recent data have shown that the Nephros DSU, when used as part of the water purification system for dialysis systems, may reduce the required dosage of erythropoietin stimulating agents, which we believe will provide a unique benefit to patients.

On July 25, 2011, Nephros, Inc. entered into a letter agreement with DHR International, Inc., an international executive search firm, whereby DHR International will conduct a search to recruit a chief executive officer for Nephros.

Under the agreement, Nephros will pay DHR International a retainer consisting of \$100,000 in cash and equity worth \$25,000. The cash retainer is due in three equal installments. The first retainer payment was due and paid on execution of the agreement. The second retainer was due and paid when Nephros began the first round of interviews during the third quarter and the third retainer is due upon a candidate's acceptance of an offer from Nephros. The stock portion of the retainer is in the form of an option for 20,000 shares of common stock with an exercise price of \$1.25 per share, which was the closing price of our common stock on July 25, 2011 as reported on the Over-the-Counter Bulletin Board. The option is fully vested and has a term of 10 years.

In addition to the payments discussed above, Nephros will reimburse DHR International for indirect out-of-pocket expenses related to the executive search, such as administrative, database management and reproduction costs, which are estimated to run 12% of the aggregate retainer, and are payable in three equal installments to be billed at the same time as the three retainer installments. Nephros also must reimburse DHR International for any direct out-of-pocket expenses, such as travel and lodging, which will be billed monthly as incurred.

In the event that Nephros hires a candidate provided by DHR International for any position other than chief executive officer, Nephros will be obligated to pay DHR International a fee equal to 33% of the individual's projected first year total cash compensation.

DHR International anticipates the search to be completed in three months. If the search is not completed by that time, DHR International will continue the search without charge for a period not to exceed six months.

Nephros may cancel the agreement at any time. If Nephros cancels within 60 days of execution of the agreement, the second and third cash retainers and the reimbursable indirect costs will be prorated through the date of cancellation.

If Nephros hires a candidate presented by DHR International and that individual is terminated, either voluntarily or involuntarily, within two years from the hiring date, DHR International will, at Nephros' option, refill the position for no additional fee.

On July 26, 2011, Nephros issued a press release announcing, among other things, its entry into the letter agreement.

On July 26, 2011, Nephros issued a press release that reported, among other things, the amount of revenue Nephros has received for the first six months of 2011 from the Office of Naval Research for work related to an advanced water purification system for military field use that Nephros is developing using its proprietary dual stage cold sterilization ultrafilter as the basis of the portable system. For 2011, Nephros has generated approximately \$356,000 of revenue through September 30 from its U.S. Defense Department project.

On July 26, 2011, Nephros issued a press release that provided a corporate update on its operations and strategy.

On August 11, 2011 Nephros submitted a new 510(k) application to market its leading-edge hemodiafiltration (HDF) system for end-stage renal disease. The application will be subject to the FDA's standard 90-day review period. The application details Nephros's OLpur MD220 diafilter and Nephros's OLpur H 2 H Hemodiafiltration module. Nephros's OLpur MD220 is a dialyzer designed expressly for HDF therapy that employs Nephros's proprietary Mid-Dilution diafiltration technology. Nephros's OLpur H 2 H Hemodiafiltration module enables the most common types of standard dialysis machines to perform HDF therapy. Nephros believes that, if approved, its technology would be the first approved on-line HDF therapy available in the U.S.

Critical Accounting Policies

The discussion and analysis of our consolidated financial condition and results of operations are based upon our condensed consolidated financial statements. These condensed consolidated financial statements have been prepared following the requirements of accounting principles generally accepted in the United States ("GAAP") and Rule 8-03 of Regulation S-X for interim periods and require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to potential impairment of investments and share-based compensation expense. As these are condensed consolidated financial statements, you should also read expanded information about our critical accounting policies and estimates provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in our Form 10-K for the year ended December 31, 2010. There have been no material changes to our critical accounting policies and estimates from the information provided in our Form 10-K and Form 10-K/A for the year ended December 31, 2010.

New Accounting Pronouncements

See Note 8 to our condensed consolidated financial statements set forth in Item 1 of this quarterly report for information regarding new accounting pronouncements.

Results of Operations

Fluctuations in Operating Results

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

Three Months Ended September 30, 2011 Compared to the Three Months Ended September 30, 2010

Revenues

Total revenues for the three months ended September 30, 2011 were approximately \$407,000 compared to approximately \$622,000 for the three months ended September 30, 2010. Total revenues decreased approximately \$215,000. The decrease of approximately 35% is due to decreased revenue of approximately \$330,000 in direct sales of our MD filters in our Target European Market, approximately \$19,000 less DSU sales, and decreased revenue of approximately \$73,000 related to the STERIS project. These decreases were partially offset by approximately \$20,000 higher sales related to our contract with the Office of U.S. Naval Research and \$187,000 of Bellco licensing revenue for the three months ended September 30, 2011 compared to the same period in 2010.

Cost of Goods Sold

Cost of goods sold was approximately \$98,000 for the three months ended September 30, 2011 compared to approximately \$319,000 for the three months ended September 30, 2010. The decrease of approximately \$221,000, or 69%, in cost of goods sold is primarily related to a \$242,000 reduction in cost of direct sales of our MD filters in our Target European Market, which have been replaced by licensed sales which carried no cost of goods sold for the three months ended September 30, 2011, and a decrease in cost of goods sold related to the STERIS project of approximately \$40,000 for the three months ended September 30, 2011 compared to the same period in 2010. This reduction was partially offset by our contract with the Office of U.S. Naval Research, where cost of goods sold increased by approximately \$19,000, and a \$42,000 increase in cost of sales related to DSU sales for the three months ended September 30, 2011 compared to the same period in 2010.

Research and Development

Research and development expenses were approximately \$131,000 and \$116,000 respectively, for the three months ended September 30, 2011 and September 30, 2010. This increase of approximately \$15,000 or 13% is primarily due to an increase in research and development outside testing, computer hardware, and water costs of approximately \$41,000, partially offset by a decrease in research and development personnel costs of approximately \$10,000 and a decrease in military materials expense of approximately \$16,000 during the three months ended September 30, 2011 compared to the same period in 2010.

Depreciation Expense

Depreciation expense was approximately \$23,000 for the three months ended September 30, 2011 compared to approximately \$30,000 for the three months ended September 30, 2010, a decrease of 23%. The decrease of approximately \$7,000 is primarily due to several assets having been fully depreciated as of year-end 2010 resulting in no depreciation expense for those assets during the three months ended September 30, 2011. There were no disposals of assets during the three months ended September 30, 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$580,000 for the three months ended September 30, 2011 compared to approximately \$550,000 for the three months ended September 30, 2010, an increase of \$30,000 or 5%. The increase is primarily due to \$78,000 of recruiting fees during the three months ended September 30, 2011 and an increase of approximately \$11,000 of compensation expense related to stock options during the three months ended September 30, 2011 compared to the same period in 2010. These increases were partially offset by a reduction in legal and other professional service fees in the U.S. of approximately \$29,000 during the three months ended

September 30, 2011 compared to the same period in 2010.

Interest Income

Interest income was approximately \$2,000 for the three months ended September 30, 2011. There was no interest income for the three months ended September 30, 2010.

Interest Expense

There was no interest expense for the three months ended September 30, 2011 or the three months ended September 30, 2010.

Other income

Other income in the amount of approximately \$10,000 for the three months ended September 30, 2011 was a foreign currency gain on invoices paid to an international supplier. Other income for the three months ended September 30, 2010 of approximately \$18,000 resulted from the reversal of a prior year's accrual determined to no longer be necessary.

Nine Months Ended September 30, 2011 Compared to the Nine Months Ended September 30, 2010

Revenues

Total revenues for the nine months ended September 30, 2011 were approximately \$1,725,000 compared to approximately \$2,421,000 for the nine months ended September 30, 2010. Total revenues decreased approximately \$696,000. The decrease of approximately 29% is due to decreased revenue of approximately \$400,000, or 53%, during the nine months ended September 30, 2011 over the same period in 2010, related to our contract with the Office of U.S. Naval Research, a \$478,000 reduction in sales of our MD filters in our Target European Market, and a \$40,000 reduction in STERIS project sales. These decreases were partially offset by approximately \$35,000 more DSU sales, or 9%, and \$187,000 in revenue related to the Bellco license agreement for the nine months ended September 30, 2011 compared to the same period in 2010.

Cost of Goods Sold

Cost of goods sold was approximately \$1,014,000 for the nine months ended September 30, 2011 compared to approximately \$1,446,000 for the nine months ended September 30, 2010. The decrease of approximately \$432,000, or 30%, in cost of goods sold is primarily related to our contract with the Office of U.S. Naval Research, where the cost of goods sold decreased by approximately \$203,000, a \$309,000 reduction in cost of sales of our MD filters in our Target European Market, and a \$19,000 reduction in costs related to the STERIS project. These decreases were partially offset by increased cost of goods sold of approximately \$99,000 related to DSU sales for the nine months ended September 30, 2011 compared to the same period in 2010.

Research and Development

Research and development expenses were approximately \$335,000 and \$259,000 respectively, for the nine months ended September 30, 2011 and September 30, 2010. This increase of approximately \$76,000 or 29% is primarily due to an increase in research and development personnel related costs of approximately \$48,000 and an increase in outside testing costs of approximately \$23,000 during the nine months ended September 30, 2011 compared to the same period in 2010.

Depreciation Expense

Depreciation expense was approximately \$71,000 for the nine months ended September 30, 2011 compared to approximately \$98,000 for the nine months ended September 30, 2010, a decrease of 28%. The decrease of approximately \$27,000 is primarily due to several assets having been fully depreciated as of year-end 2010 resulting in no depreciation expense for those assets during the nine months ended September 30, 2011. There were no disposals of assets during the nine months ended September 30, 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$1,974,000 for the nine months ended September 30, 2011 compared to approximately \$1,903,000 for the nine months ended September 30, 2010, an increase of \$71,000 or 4%. The increase is primarily due to a \$79,000 bonus expense, an increase in stock compensation expense of \$127,000, a \$23,000 increase in investor relations costs, and \$78,000 of recruiting fees during the nine months ended September 30, 2011 compared to the same period in 2010. These increases were partially offset by a reduction in U.S. salary expense of \$99,000 and a reduction in legal and other professional service fees in the U.S. of approximately \$134,000 during the nine months ended September 30, 2011 compared to the same period in 2010.

Interest Income

Interest income was approximately \$3,000 for the nine months ended September 30, 2011 compared to approximately \$1,000 for the nine months ended September 30, 2010.

Interest Expense

Interest expense was approximately \$12,000 for the nine months ended September 30, 2011. This interest relates to interest accrued on the \$500,000 senior secured note issued to Lambda Investors LLC, which was paid in March 2011. We had no interest expense for the nine months ended September 30, 2010.

Amortization of Debt Issuance Costs

Amortization of debt issuance costs of \$40,000 for the nine months ended September 30, 2011 is associated with the senior secured note issued to Lambda Investors LLC and paid in March 2011. These capitalized costs have been fully amortized as of September 30, 2011. There was no amortization of debt issuance costs in the nine months ended September 30, 2010 as there was no debt during that period.

Other income/expense

Other expense in the amount of approximately \$4,000 for the nine months ended September 30, 2011 was a foreign currency loss on invoices paid to an international supplier. Other income in the amount of approximately \$16,000 for the nine months ended September 30, 2010 resulted from the reversal of a prior year's accrual determined to no longer be necessary.

Liquidity and Capital Resources

At September 30, 2011, we had an accumulated deficit of approximately \$93,630,000 and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering, licensing revenue and, most recently, the March 2011 rights offering and concurrent private placement.

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

- receipt of scheduled payments per the Bellco S.r.l. license agreement;
- the cost, timing and results of our efforts to obtain regulatory approval of our products, including specifically our 510(k) application for our HDF system;
- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;
- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the timing and costs associated with obtaining United States regulatory approval or the Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory pre requisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MDHDF filter series, for which the CE mark was obtained in July 2003);
- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

- for the marketing and sales of our products;
- to obtain appropriate regulatory approvals and expand our research and development with respect to our ESRD therapy products;
- to continue our ESRD therapy product engineering;
- to pursue business opportunities with respect to our DSU water-filtration product; and

for working capital purposes.

At September 30, 2011, we had cash and cash equivalents totaling approximately \$2,117,000 and tangible assets of approximately \$2,885,000.

The Company entered into a License Agreement with Bellco, as licensee, which is discussed in the Business Overview. This Agreement provides the Company with payments of €500,000, €750,000, and €600,000 on July 1, 2011, January 15, 2012 and January 15, 2013, respectively. These fixed payments of €1,850,000 or approximately \$2,600,000, take place over the next fifteen months. Beginning on January 1, 2015 through and including December 31, 2016, Bellco will pay to Nephros a royalty based on the number of units of Products sold in the Territory as follows: for the first 103,000 units sold, €4.50 per unit; thereafter, €4.00 per unit. The first fixed payment of €500,000 was received in July 2011. Anticipated payments from this License Agreement will be a positive source of cash flow to the Company.

As of the date of this report, we estimate that these cash flows would allow us to keep operating only into the second quarter of 2013. Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We must seek and obtain additional financing to fund our operations. If we cannot raise sufficient capital, we will be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in our Company. There can be no assurance that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately \$679,000 for the nine months ended September 30, 2011 compared to approximately \$641,000 for the nine months ended September 30, 2010. The most significant items contributing to this increase of approximately \$38,000 in cash used in operating activities during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 are highlighted below:

- during the 2011 period, our net loss increased by approximately \$454,000, compared to the 2010 period;
- during the 2011 period, depreciation expense decreased by approximately \$27,000, compared to the 2010 period;
- our accounts receivable decreased by approximately \$137,000 during the 2011 period compared to a decrease of approximately \$168,000 during the 2010 period;
- our accounts payable and accrued expenses decreased by approximately \$306,000 in the aggregate during the 2011 period compared to an increase of approximately \$129,000 during the 2010 period;
- our prepaid expenses and other assets decreased by approximately \$58,000 during the 2011 period compared to a decrease of approximately \$67,000 during the 2010 period: and
- our inventory decreased by approximately \$350,000 during the 2011 period compared to a decrease of approximately \$28,000 during the 2010 period.

Offsetting the above changes are the following items:

- during the 2011 period, our stock-based compensation expense, a non-cash expense, increased by approximately \$127,000;
- during the 2011 period, we recorded amortization of debt issuance costs of \$40,000, whereas there was no amortization of debt issuance costs in the 2010 period; and
- during the 2011 period, we recorded non-cash interest of \$12,000, whereas there was no non-cash interest in the 2010 period.

Net cash used in investing activities was approximately \$6,000 for the nine months ended September 30, 2010 and there was no net cash used in investing activities for the nine months ended September 30, 2011. Net cash used in investing activities for the nine months ended September 30, 2010 was for the purchase of tooling equipment.

Net cash provided by financing activities was approximately \$2,550,000 for the nine months ended September 30, 2011, resulting from the issuance of stock, providing cash of \$3,190,000, which was partially offset by the payment of debt of \$500,000 and the payment of deferred financing costs of \$140,000. Financing activities provided net cash of approximately \$72,000 for the nine months ended September 30, 2010 resulting from the issuance of common stock due to exercise of stock options.

Certain Risks and Uncertainties

Our Annual Report on Form 10-K for the year ended December 31, 2010 includes a detailed discussion of our risk factors under the heading “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operation - Certain Risks and Uncertainties.” The information presented below should be read in conjunction with the risk factors and information disclosed in such Form 10-K.

Safe Harbor for Forward-Looking Statements

This report contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for continued development of such products and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include the risks that:

- we may not be able to continue as a going concern;
- we may not be able to obtain funding if and when needed or on terms favorable to us in order to continue operations;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan or effectively market our products including, without limitation, FDA approval of our HDF system;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may encounter problems with our suppliers and manufacturers;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- HDF therapy may not be accepted in the United States and/or our technology and products may not be accepted in current or future target markets, which could lead to failure to achieve market penetration of our products;
- we may not be able to sell our ESRD therapy or water filtration products at competitive prices or profitably;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products; and
- we may not be able to achieve sales growth in Europe and Canada or expand into other key geographic markets.

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this Quarterly Report, is set forth in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as amended and our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC’s web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a result

of new information, future events or otherwise, except as required by law.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the nine month periods ended September 30, 2011 and 2010.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Required.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is designed to provide reasonable assurance that information required to be disclosed in our reports filed pursuant to the Exchange Act is accumulated and communicated to management in a timely manner. At the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our acting Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures pursuant to Securities and Exchange Act Rule 13a-15(b). Based upon that evaluation, our acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

Changes in Internal Control Over Financial Reporting

Our Management, with the participation of the acting Chief Executive Officer and Chief Financial Officer, has concluded that there were no changes in our internal control over financial reporting, that occurred during the quarter ended September 30, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Through the evaluation of the Sarbanes-Oxley internal control assessment, a more structured approach, including checklists, reconciliations and analytical reviews, has been implemented to reduce risk in the financial reporting process.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

There are no currently pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject.

Item 5. Other Information

On November 10, 2011 the Company announced that it has received the initial review by the Food and Drug Administration (“FDA”) of the 510(k) application for marketing clearance of the company’s hemodiafiltration system. On August 11, 2011 the Company submitted a new 510(k) application to market its hemodiafiltration (HDF) system for end-stage renal disease. On November 8, 2011 the Company received the initial FDA review of its new 510(k) application (K112314), which included a request for additional information. As the next step, the Company will respond to the FDA’s request for more information. The Company intends to provide its response within 30 days or request an extension of time to respond, if necessary.

Item 6. Exhibits

EXHIBIT INDEX

- 10.1 License Agreement between Nephros, Inc. and Bellco S.r.l. effective July 1, 2011. (1)
- 10.2 Letter Agreement, dated July 27, 2011, between Nephros, Inc. and DHR International, Inc., entered into as of July 25, 2011. (2)
- 31.1 Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications by the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 Interactive Data File
- (1) Incorporated by reference to Exhibit 10.62 to Nephros, Inc.’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2011.
- (2) Incorporated by reference to Exhibit 10.63 to Nephros, Inc.’s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2011.

SIGNATURES

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

NEPHROS, INC.

Date: November 14, 2011

By: /s/ Paul A. Mieyal
Name: Paul A. Mieyal
Title: Acting Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2011

By: /s/ Gerald J. Kochanski
Name: Gerald J. Kochanski
Chief Financial Officer (Principal
Financial and Accounting Officer)

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