

NEPHROS INC
Form 10-Q
August 16, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: June 30, 2010

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 August 13, 2010, 41,811,048 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) June 30, 2010	(Audited) December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 344	\$ 1,004
Accounts receivable	652	629
Inventory, less allowances of \$18	697	653
Prepaid expenses and other current assets	90	135
Total current assets	1,783	2,421
Property and equipment, net	138	210
Other assets	21	21
Total assets	\$ 1,942	\$ 2,652
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 585	\$ 455
Accrued expenses	182	239
Deferred revenue	100	-
Total current liabilities	867	694
Total liabilities	867	694
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at June 30, 2010 and December 31, 2009; no shares issued and outstanding at June 30, 2010 and December 31, 2009.	-	-
Common stock, \$.001 par value; 90,000,000 authorized at June 30, 2010 and December 31, 2009; 41,811,048 and 41,604,798 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively.	42	42
Additional paid-in capital	91,936	91,815
Accumulated other comprehensive income (loss)	(34)	76
Accumulated deficit	(90,869)	(89,975)
Total stockholders' equity	1,075	1,958
Total liabilities and stockholders' equity	\$ 1,942	\$ 2,652

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

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30		Six Months Ended June 30	
	2010	2009	2010	2009
Product revenue	\$ 809	\$ 527	\$ 1,799	\$ 1,158
Cost of goods sold	527	336	1,127	788
Gross margin	282	191	672	370
Operating expenses:				
Research and development	71	92	143	150
Depreciation and amortization	32	65	68	137
Selling, general and administrative	545	628	1,353	1,417
Total operating expenses	648	785	1,564	1,704
Loss from operations	(366)	(594)	(892)	(1,334)
Interest income	1	1	1	6
Interest expense	-	(2)	-	(2)
Other income (expense)	-	182	(2)	182
Net loss	\$ (365)	\$ (413)	\$ (893)	\$ (1,148)
Net loss per common share, basic and diluted	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.03)
Weighted average common shares outstanding, basic and diluted	41,735,423	38,264,462	41,670,111	38,214,921

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

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

Six Months Ended
June 30,
2010 2009

Operating activities

Net loss	\$	(893)	\$	(1,148)
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Adjustments to reconcile net loss to net cash used in operating activities:

Depreciation of property and equipment	68	137
Noncash stock-based compensation	49	35

(Increase) decrease in operating assets:

Accounts receivable	(78)	77
Inventory	(101)	(48)
Prepaid expenses and other current assets	44	87

Increase (decrease) in operating liabilities:

Accounts payable and accrued expenses	92	(570)
Deferred revenue	100	-
Net cash used in operating activities	(719)	(1,430)

Investing activities

Maturities of short-term investments	-	7
Net cash provided by investing activities	-	7

Financing activities

Proceeds from stock options exercised	72	-
Net cash provided by financing activities	72	-

Effect of exchange rates on cash	(13)	7
Net decrease in cash	(660)	(1,416)
Cash, beginning of year	1,004	2,306
Cash, end of year	\$ 344	\$ 890

Supplemental disclosure of cash flow information

Cash paid for interest	\$	-	\$	2
Cash paid for taxes		2		3

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

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 2009 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on April 2, 2010. 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 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, 2009 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 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 U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the Company’s condensed consolidated financial statements and accompanying notes. 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 condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on the Company’s current cash flow projections, it will need to raise additional funds through either the licensing or sale of its technologies or additional public or private offerings of its securities. The Company continues to investigate strategic funding opportunities as they are identified. However, there is no guarantee that the Company will be able to obtain further financing. If it is unable to raise additional funds on a timely basis or at all, the Company would not be able to continue its operations.

On May 21, 2010, the Company filed a Form S-1 in which the Company offered up to 500,000 units, each unit consisting of 25 shares of our common stock and warrants to purchase an additional 25 shares of our common stock. The warrants are exercisable at any time after the closing date of the offering and on or before the five year anniversary of their initial exercise date. Units will not be issued or certificated. The units will separate immediately

and the common stock and warrants will be issued separately and the common stock and warrants will trade separately. As of the date of this Form 10-Q, the SEC has not declared the Form S-1 effective and, as a result, the Company has not sold any units.

The Company has incurred significant losses in its operations in each quarter since inception. For the six months ended June 30, 2010 and 2009, the Company has incurred net losses of approximately \$893,000 and \$1,148,000, respectively. In addition, the Company has not generated positive cash flow from operations for the three and six months ended June 30, 2010 and 2009. 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, the Company's results of operations and financial condition will be materially and adversely affected.

The Company's current operating plans primarily include the continued development and support of the Company's business in the European and Canadian markets, organizational changes necessary to expand the commercialization of the Company's water filtration business and the completion of current year milestones that are included in the Office of Naval Research appropriation.

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.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

1. Basis of
Presentation
and Going
Concern
(continued)

The Company continues to investigate additional funding opportunities. However, there can be no assurance that the Company will be able to obtain further financing, do so on reasonable terms or do so on terms that would not substantially dilute the equity interests in the Company. If the Company is unable to raise additional funds on a timely basis, or at all, the Company will not be able to continue its operations.

2.
Concentration
of Credit
Risk

For the six months ended June 30, 2010 and 2009, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2010	2009
A	49%	41%
B	37%	49%

As of June 30, 2010 and December 31, 2009, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2010	2009
A	61%	44%
B	19%	34%

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 the Company. All shipments are currently received directly by the Company's customers.

4. Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718 by recognizing the fair value of stock-based compensation in the statement of operations. The fair value of the Company's stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that the Company estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock-based awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

For the three months ended June 30, 2010 and 2009, stock-based compensation expense was approximately \$22,000 and \$24,000, respectively. For the six months ended June 30, 2010 and 2009, stock-based compensation expense was approximately \$49,000 and \$35,000, respectively.

There was no tax benefit related to expense recognized in the three and six months ended June 30, 2010 and 2009, as the Company is in a net operating loss position. As of June 30, 2010, there was approximately \$170,000 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 2.4 years. Such amount does not include the effect of future grants of equity compensation, if any. Of the total \$170,000, the Company expects to recognize approximately 24% in the remaining interim periods of 2010, approximately 46% in 2011, approximately 18% in 2012 and approximately 12% in 2013.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

5. Comprehensive Income (Loss)

Comprehensive income (loss), as defined in ASC Topic 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 June 30, 2010, accumulated other comprehensive loss was approximately \$34,000. As of December 31, 2009, accumulated other comprehensive income was approximately \$76,000.

6. Loss per Common Share

In accordance with ASC Topic 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 antidilutive, the Company has excluded stock options and warrants aggregating 9,335,109 and 12,399,475 shares, respectively, from the computation of diluted EPS for the six month periods ended June 30, 2010 and 2009, respectively.

7. Recently Adopted Accounting Pronouncements

In December 2009, the Financial Accounting Standards Board (“FASB”) issued an amendment to ASC Topic 810-Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities. This amendment to ASC Topic 810 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. The amendment, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under the amendment to ASC Topic 810 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. The Company adopted the pronouncement on January 1, 2010 resulting in no impact to the Company's consolidated balance sheets, statements of income and cash flows. .

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 or results of operations.

8. New Accounting Pronouncements

In April 2010, the FASB issued an Accounting Standards Update which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The amendments in this standard provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This standard is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. This standard is effective for the Company on January 1, 2011. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's consolidated financial condition, results of operations, and disclosures.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

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 June 30, 2010 or December 31, 2009.

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 June 30, 2010 and December 31, 2009 was approximately as follows:

	Unaudited June 30, 2010	Audited December 31, 2009
Raw Materials	\$ 254,000	\$ 257,000
Finished Goods	461,000	414,000
Total Gross Inventory	\$ 715,000	\$ 671,000
Less: Inventory reserve	(18,000)	(18,000)
Total Inventory	\$ 697,000	\$ 653,000

11. Commitments and Contingencies

On March 30, 2010, Ernest Elgin, III resigned as the Company's President and Chief Executive Officer and also resigned from the Board of Directors. In connection with Mr. Elgin's resignation, the Company entered into a separation, release and consulting agreement with Mr. Elgin, pursuant to which the Company paid Mr. Elgin his current salary through April 16, 2010, paid his applicable COBRA premiums through April 30, 2010 and, during any time that his COBRA coverage is in effect in 2010, will reimburse him for out-of-pocket payments made in 2010 under his healthcare coverage up to \$5,000, which is the deductible under the healthcare coverage. Mr. Elgin was available to consult with the Company for up to 15 hours a week until May 31, 2010, for which the Company paid Mr. Elgin at the rate of 50% of his current salary from April 16 to May 31, 2010. The Company has extended the consulting period for four months during which Mr. Elgin has and will be available to consult with the Company for up to 7.5 hours a week and during which the Company paid and will pay Mr. Elgin 25% of his current salary. The agreement contains customary release and confidentiality terms. The maximum value of the severance pay was approximately \$55,000. As of June 30, 2010, the remaining unpaid but accrued balance is approximately \$22,000.

Gerald Kochanski, our Chief Financial Officer, served as the acting Chief Executive Officer from March 30, 2010 until April 5, 2010. As of April 6, 2010, Paul Mieyal, a member of the Board of Directors, has served as the acting Chief Executive Officer. Dr. Mieyal is a Vice President of Wexford Capital LP, the managing member of Lambda Investors LLC, which is the beneficial owner of approximately 44.2% of the Company's outstanding stock based on common stock and warrants held at June 30, 2010.

Suppliers

The Company entered into an agreement in December 2003, as amended in June 2005, with a fiber supplier (“FS”), a manufacturer of medical and technical membranes for applications such as dialysis, to continue to produce the fiber for the OLpur MDHDF filter series. Pursuant to the agreement, the 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 is exercising its right to terminate the supply agreement. Termination of the supply agreement was effective on July 18, 2010. The Company has an adequate supply of fiber inventory on hand. The FS noted its desire to negotiate and execute a new supply agreement with the Company. Negotiations on terms of a new supply agreement are ongoing.

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 on Form 10-K for the year ended December 31, 2009, 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 on Form 10-K for the year ended December 31, 2009. Our actual results may differ materially.

Immediate Need for Capital

We have incurred significant losses in our operations in each quarter since inception. In addition, we have not generated positive cash flow from operations for the year ended December 31, 2008 or 2009 or for the three or six months ended June 30, 2010. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. We need to raise operating funds through either the licensing or sale of our technologies or public or private offerings of our securities. While we are investigating strategic funding opportunities, we might not be able to raise funds on a timely basis or on acceptable terms or at all. If we fail to raise capital, we expect our funds will be depleted in the fourth quarter of 2010, and we might not be able to continue our operations.

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 new Dual Stage Ultrafilter (the "DSU") water filtration system, which represents 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:

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- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); to our knowledge, 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 Annual 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. An in-person meeting with the FDA has been scheduled for September 10, 2010, to discuss the issues raised in the current FDA letter as well as the process for moving forward. Based upon the meeting with the FDA reviewers, we will determine the appropriate course of action, which could include filing a new 510(k) application or filing an appeal related to the current application. We have engaged King & Spalding LLP as regulatory counsel to advise us in our interactions with the FDA. We also intend to utilize the FDA’s Ombudsman process, as applicable. The current 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.

In January 2006, we introduced our new Dual Stage Ultrafilter (the “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.

Due to the ongoing concerns of maintaining water quality, 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.

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 that 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 \$1,093,000 of revenue has been recognized on this new project since September 2009 of which approximately \$670,000 was recognized on this project during the six months ended June 30, 2010.

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

On March 23, 2010, we announced that Nephros signed a development agreement with STERIS Corporation to jointly develop filtration-based products for medical device applications. Under the terms of the contract Nephros received a \$100,000 payment from STERIS Corporation during the second quarter of 2010. This \$100,000 is accounted for as Deferred Revenue on the Balance Sheet at June 30, 2010 since the work performed in Q2 was preparatory in nature. The contract has several milestones identified that, if reached, will result in additional cumulative \$100,000 in payments to Nephros. We expect we will achieve the milestones during the remainder of 2010 and in early 2011.

Critical Accounting Policies

The discussion and analysis of our consolidated financial condition and results of operations are based upon our condensed financial statements. These condensed 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, 2009. There have been no material changes to our critical accounting policies and estimates from the information provided in our Form 10-K for the year ended December 31, 2009.

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 June 30, 2010 Compared to the Three Months Ended June 30, 2009

Revenues

Total revenues for the three months ended June 30, 2010 were approximately \$809,000 compared to approximately \$527,000 for the three months ended June 30, 2009. Total revenues increased approximately \$282,000. The increase of approximately 54% is due to increased revenue of approximately \$62,000 in sales of our DSU in the United States for the three months ended June 30, 2010 over the same period in 2009. Sales of our MD filters in our Target European Market were approximately \$237,000 higher in the three months ended June 30, 2010 compared to the same

period in 2009. Approximately \$268,000 of the European revenue increase was due to more units sold offset partially by a decrease of approximately \$31,000 due to foreign currency exchange rate fluctuation. Unit sales in Europe increased approximately 120% for the three months ended June 30, 2010 compared to the same period in 2009. The increases were partially offset by a decrease of approximately \$17,000 during the three months ended June 30, 2010 over the same period in 2009, related to our contract with the Office of U.S. Naval Research.

Cost of Goods Sold

Cost of goods sold was approximately \$527,000 for the three months ended June 30, 2010 compared to approximately \$336,000 for the three months ended June 30, 2009. The increase of approximately \$191,000, or 57%, in cost of goods sold is primarily due to increased costs related to higher sales of our MD filters in our Target European Market of approximately \$164,000 and an increase of approximately \$58,000 in costs related to higher sales of our DSU in the United States for the three months ended June 30, 2010 over the same period in 2009. Approximately \$186,000 of the European cost of goods sold increase was due to more units sold offset partially by a decrease of approximately \$23,000 was due to foreign currency exchange rate fluctuation. Costs related to the contract with the Office of U.S. Naval Research were approximately \$31,000 lower for the three months ended June 30, 2010 compared to the same period in 2009. The reduced costs were related to use of a subcontractor on the contract and not internal personnel.

Research and Development

Research and development expenses were approximately \$71,000 and \$92,000 respectively, for the three months ended June 30, 2010 and June 30, 2009. This decrease of approximately \$21,000 or 23% is primarily due to a decrease in research and development personnel related costs of approximately \$17,000. Although the number of personnel dedicated to research and development did not change, their percentage of time spent on the contract with the Office of U.S. Naval Research increased during the three months ended June 30, 2010 compared to the same period in 2009. Travel expenses of research and development personnel decreased by approximately \$4,000 during the three months ended June 30, 2010 compared to the same period in 2009.

Depreciation Expense

Depreciation expense was approximately \$32,000 for the three months ended June 30, 2010 compared to approximately \$65,000 for the three months ended June 30, 2009, a decrease of 51%. The decrease of approximately \$33,000 is primarily due to several assets having been fully depreciated as of year end 2009 resulting in no depreciation expense for those assets during the three months ended June 30, 2010. There were no disposals of assets during the three months ended June 30, 2010.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$545,000 for the three months ended June 30, 2010 compared to approximately \$628,000 for the three months ended June 30, 2009, a decrease of \$83,000 or 13%. The decrease is primarily due to a decrease in personnel related expenses of approximately \$101,000, a decrease in marketing expenses of approximately \$27,000 and a decrease in travel expenses of approximately \$10,000. These decreases were partially offset by increases of approximately \$36,000 in professional services expenses, including legal and accounting fees, and other business expenses of approximately \$19,000.

Interest Income

Interest income was approximately \$1,000 for the three months ended June 30, 2010 and 2009, respectively.

Interest Expense

There was no interest expense for the three months ended June 30, 2010. We incurred approximately \$2,000 of interest expense for the three months ended June 30, 2009. This interest relates primarily to financing of premiums for product liability insurance.

Other income (expense)

There was no other income (expense) incurred for the three months ended June 30, 2010. Other income in the amount of approximately \$182,000 for the three months ended June 30, 2009 resulted primarily from receipt of 2007 New York State Qualified Emerging Technology Company tax refunds.

Six Months Ended June 30, 2010 Compared to the Six Months Ended June 30, 2009

Revenues

Total revenues for the six months ended June 30, 2010 were approximately \$1,799,000 compared to approximately \$1,158,000 for the six months ended June 30, 2009. Total revenues increased approximately \$641,000. The increase

of approximately 55% is due to increased revenue of approximately \$105,000 during the six months ended June 30, 2010 over the same period in 2009, related to our contract with the Office of U.S. Naval Research and an increase of approximately \$160,000 in sales of our DSU in the United States for the six months ended June 30, 2010 over the same period in 2009. Sales of our MD filters in our Target European Market were approximately \$376,000 higher in the six months ended June 30, 2010 compared to the same period in 2009. Approximately \$379,000 of the European revenue increase was due to more units sold offset partially by \$3,000 due to foreign currency exchange rate fluctuation. Unit sales in Europe increased approximately 77% for the six months ended June 30, 2010 compared to the same period in 2009.

Cost of Goods Sold

Cost of goods sold was approximately \$1,127,000 for the six months ended June 30, 2010 compared to approximately \$788,000 for the six months ended June 30, 2009. The increase of approximately \$339,000, or 43%, in cost of goods sold is primarily due to increased costs related to higher sales of our MD filters in our Target European Market of approximately \$265,000 and an increase of approximately \$109,000 in costs related to higher sales of our DSU in the United States for the six months ended June 30, 2010 over the same period in 2009. Approximately \$267,000 of the European cost of goods sold increase was due to more units sold offset partially by \$2,000 due to foreign currency exchange rate fluctuation. Costs related to the contract with the Office of U.S. Naval Research were approximately \$35,000 lower for the six months ended June 30, 2010 compared to the same period in 2009.

Research and Development

Research and development expenses were approximately \$143,000 and \$150,000 respectively, for the six months ended June 30, 2010 and June 30, 2009. This decrease of approximately \$7,000 or 5% is primarily due to decreased water development expenses of approximately \$21,000 and decreased travel expenses of approximately \$5,000, offset partially by increases in other expenses of approximately \$19,000.

Depreciation Expense

Depreciation expense was approximately \$68,000 for the six months ended June 30, 2010 compared to approximately \$137,000 for the six months ended June 30, 2009, a decrease of 50%. The decrease of approximately \$69,000 is primarily due to several assets having been fully depreciated as of year end 2009 resulting in no depreciation expense for those assets during the six months ended June 30, 2010. There were no disposals of assets during the six months ended June 30, 2010.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$1,353,000 for the six months ended June 30, 2010 compared to approximately \$1,417,000 for the six months ended June 30, 2009, a decrease of \$64,000 or 5%. The decrease is due primarily to a decrease in personnel costs of approximately \$56,000, decreases in marketing related expenses of approximately \$112,000, decreases in business travel expenses of approximately \$12,000 and a decrease in investor relations expense of approximately \$9,000. These decreases were partially offset by increases in professional services fees, including legal expenses, of approximately \$115,000 and other expenses of approximately \$10,000.

Interest Income

Interest income was approximately \$1,000 for the six months ended June 30, 2010 compared to approximately \$6,000 for the six months ended June 30, 2009. The decrease of approximately \$5,000 is due to the decreased investments held during the six months ended June 30, 2010 compared to the six months ended June 30, 2009.

Interest Expense

There was no interest expense for the six months ended June 30, 2010. We incurred approximately \$2,000 of interest expense for the six months ended June 30, 2009. This interest relates primarily to financing of premiums for product liability insurance.

Other income (expense)

Other expense in the amount of approximately \$2,000 for the six months ended June 30, 2010 was a currency loss related to an international funds transfer. Other income in the amount of approximately \$182,000 for the six months ended June 30, 2009 resulted primarily from receipt of 2007 New York State Qualified Emerging Technology Company tax refunds.

Liquidity and Capital Resources

Net cash used in operating activities was approximately \$719,000 for the six months ended June 30, 2010 compared to approximately \$1,430,000 for the six months ended June 30, 2009. The most significant items contributing to this decrease of approximately \$711,000 cash used in operating activities during the six months ended June 30, 2010 compared to the six months ended June 30, 2009 are highlighted below:

- during the 2010 period, our net loss decreased by approximately \$255,000;
- during the 2010 period, we recorded deferred revenue of \$100,000, whereas there was no deferred revenue in the 2009 period;
- during the 2010 period, our stock-based compensation expense increased by approximately \$14,000;

- our accounts payable and accrued expenses increased by approximately \$37,000 in the aggregate in the 2010 period compared to a decrease of approximately \$660,000 in the 2009 period; and
- our accrued severance expense was approximately \$55,000 in the aggregate in the 2010 period compared to a reversal of expense of approximately \$90,000 in the 2009 period.

Offsetting the above changes are the following items:

- during the 2010 period, depreciation expense decreased by approximately \$69,000;
- our accounts receivable increased by approximately \$78,000 during the 2010 period compared to a decrease of approximately \$77,000 during the 2009 period;
- our inventory increased by approximately \$101,000 during the 2010 period compared to an increase of approximately \$48,000 during the 2009 period;
- our prepaid expenses and other assets decreased by approximately \$44,000 in the 2010 period compared to a decrease of approximately \$87,000 in the 2009 period.

There were no investing activities for the six months ended June 30, 2010. Net cash provided by investing activities was approximately \$7,000 for the six months ended June 30, 2009 and resulted from the maturities of short-term investments.

Financing activities provided net cash of approximately \$72,000 for the six months ended June 30, 2010 resulting from the issuance of common stock due to the exercise of stock options. There were no financing activities for the six months ended June 30, 2009.

Certain Risks and Uncertainties

Our Annual Report on Form 10-K for the year ended December 31, 2009 includes a detailed discussion of our risk factors under the heading “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 obtain funding if and when needed or on terms favorable to us in order to continue operations;

- we may not be able to continue as a going concern;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan or effectively market our products;
- 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 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, 2009 and in this Quarterly Report on Form 10-Q. 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.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the six month periods ended June 30, 2010 and 2009.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Securities and Exchange Act Rule 13a-15(e), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended, 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, of the effectiveness of the design and operation 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

There were no changes in our internal control over financial reporting or in other factors 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 4. Submission of Matters to a Vote of Security Holders

There were no matters submitted to a vote of security holders during the three months ended June 30, 2010.

Item 6. Exhibits

EXHIBIT INDEX

- 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.

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: August 16, 2010

By: /s/ Paul A. Mieyal

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

Date: August 16, 2010

By: /s/ Gerald J. Kochanski

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

Exhibit Index

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