

NEPHROS INC
Form 10-Q
May 15, 2009

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 2009

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

07661

(Address of Principal Executive Offices)

(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

Edgar Filing: NEPHROS INC - Form 10-Q

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 May 15, 2009, 38,165,380 shares of issuer's common stock, with \$0.001 par value per share, were outstanding.

Table of Contents

	Page No.
PART I – FINANCIAL INFORMATION	
Item 1.	Financial Statements
	Unaudited Condensed Consolidated Balance Sheets 1
	Unaudited Condensed Consolidated Statements of Operations 2
	Unaudited Condensed Consolidated Statements of Cash Flows 3
	Notes to Unaudited Condensed Consolidated Interim Financial Statements 4
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations 9
Item 4T.	Controls and Procedures 15
PART II – OTHER INFORMATION	
Item 1.	Legal Proceedings 16
Item 4.	Submission of Matters to a Vote of Security Holders 16
Item 6.	Exhibits 16
SIGNATURES 17	

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

NEPHROS, INC. AND SUBSIDIARY

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,651	\$ 2,306
Short-term investments	-	7
Accounts receivable, less allowances of \$0 and \$4, respectively	436	404
Inventory	589	724
Prepaid expenses and other current assets	147	162
Total current assets	2,823	3,603
Property and equipment, net	328	412
Other assets	21	21
Total assets	\$ 3,172	\$ 4,036
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,013	\$ 986
Accrued expenses	383	411
Accrued severance expense	15	105
Total current liabilities	1,411	1,502
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at March 31, 2009 and December 31, 2008; no shares issued and outstanding at March 31, 2009 and December 31, 2008.	-	-
Common stock, \$.001 par value; 60,000,000 shares authorized at March 31, 2009 and December 31, 2008; 38,165,380 shares issued and outstanding at March 31, 2009 and December 31, 2008.	38	38
Additional paid-in capital	90,386	90,375
Accumulated other comprehensive income	21	70
Accumulated deficit	(88,684)	(87,949)
Total stockholders' equity	1,761	2,534
Total liabilities and stockholders' equity	\$ 3,172	\$ 4,036

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)

	Three Months Ended March 31,	
	2009	2008
Product revenues	\$ 631	\$ 387
Cost of goods sold	452	238
Gross margin	179	149
Operating expenses:		
Research and development	58	723
Depreciation	72	88
Selling, general and administrative	789	1,114
Total operating expenses	919	1,925
Loss from operations	(740)	(1,776)
Interest income	5	92
Impairment of auction rate securities	-	(114)
Other income	-	158
Net loss	\$ (735)	\$ (1,640)
Net loss per common share, basic and diluted	\$ (0.02)	\$ (0.04)
Weighted average common shares outstanding, basic and diluted	38,165,380	38,165,380

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

NEPHROS, INC. AND SUBSIDIARY

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Three Months Ended March 31,	
	2009	2008
Operating activities:		
Net loss	\$ (735)	\$ (1,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	72	88
Amortization of research & development assets	-	4
Impairment of auction rate securities	-	114
Stock-based compensation	11	32
(Increase) decrease in operating assets:		
Accounts receivable	(51)	40
Inventory	105	5
Prepaid expenses and other current assets	15	(55)
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	13	235
Accrued severance expense	(90)	(62)
Net cash used in operating activities	(660)	(1,239)
Investing activities:		
Purchase of property and equipment	-	(10)
Purchase of short-term investments	-	(100)
Maturities of short-term investments	7	400
Net cash provided by investing activities	7	290
Effect of exchange rates on cash	(2)	5
Net decrease in cash and cash equivalents	(655)	(944)
Cash and cash equivalents, beginning of period	2,306	3,449
Cash and cash equivalents, end of period	\$ 1,651	\$ 2,505
Supplemental disclosure of cash flow information:		
Cash paid for taxes	\$ 2	\$ 9

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 2008 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 31, 2009. 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, 2008 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 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 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 before the end of 2009. 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.

The Company has incurred significant losses in its operations in each quarter since inception. For the three months ended March 31, 2009 and 2008, the Company has incurred net losses of approximately \$735,000 and \$1,640,000, respectively. In addition, the Company has not generated positive cash flow from operations for the three months ended March 31, 2009 and 2008. 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 market, organizational changes necessary to begin the commercialization of the Company's water filtration business and the completion of current year milestones which 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, talking to various potential investors who could provide financing. 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 three months ended March 31, 2009 and 2008, the following customers accounted for the following percentages of the Company's sales, respectively.

Customer	2009	2008
A	42%	90%
B	53%	6%

As of March 31, 2009 and December 31, 2008, the following customers accounted for the following percentages of the Company's accounts receivable, respectively.

Customer	2009	2008
A	64%	66%
B	29%	23%

The Company's MD and DSU products are manufactured under agreement with the same vendor.

3. Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104 "Revenue Recognition" ("SAB No. 104"). SAB No. 104 requires that 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) collectibility 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 SAB No. 104 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 under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004) "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. 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 March 31, 2009, stock-based compensation expense was approximately \$11,000, as compared to approximately \$32,000 of stock-based compensation for the comparable period in 2008.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

4. Stock-Based Compensation – (continued)

There was no tax benefit related to expense recognized in the three months ended March 31, 2009 and 2008, as the Company is in a net operating loss position. As of March 31, 2009, there was approximately \$288,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Such amount does not include the effect of future grants of equity compensation, if any. Of this amount, approximately \$288,000 will be amortized over the weighted-average remaining requisite service period of 3.3 years. Of the total \$288,000, the Company expects to recognize approximately 25% in the remaining interim periods of 2009, approximately 30% in 2010, approximately 30% in 2011 and approximately 15% in 2012.

5. Comprehensive Income

The Company complies with the provisions of SFAS No. 130 "Reporting Comprehensive Income," which requires companies to report all changes in equity during a period, except those resulting from investment by owners and distributions to owners, for the period in which they are recognized. Comprehensive income is the total of net income 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 March 31, 2009 and December 31, 2008, accumulated other comprehensive income was approximately \$21,000 and \$70,000 respectively.

6. Loss per Common Share

In accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"), net loss per common share amounts ("basic EPS") are computed by dividing net loss by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution ("diluted EPS") are 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 13,748,165 and 13,214,324, respectively, from the computation of diluted EPS for the three month periods ended March 31, 2009 and 2008, respectively.

7. Recently Adopted Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("No. 157"). This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements and was effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position No. 157-2 ("FSP No. 157-2"). FSP No. 157-2 delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. These nonfinancial items include assets and liabilities such as reporting units measured at a fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. Effective January 1, 2008, we adopted SFAS No. 157 for financial assets and liabilities recognized at fair value on a recurring basis, and on January 1, 2009, we fully adopted SFAS No. 157. Upon full adoption, SFAS

No. 157 had no effect on our financial position, results of operations and cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations ("No. 141R"). This statement establishes requirements for (i) recognizing and measuring in an acquiring company's financial statements the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree, (ii) recognizing and measuring the goodwill acquired in the business combination or a gain from a bargain purchase and (iii) determining what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The provisions of SFAS No. 141R are effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Upon adoption, SFAS No. 141R had no effect on our financial position, results of operations and cash flows.

NEPHROS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

8. New Accounting Pronouncements

In April 2009, the Financial Accounting Standards Board (“FASB”) issued FASB Staff Position (“FSP”) FAS 157-4, Determining Fair Value when the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions that are not Orderly (“FSP 157-4”), which is effective for the Company for interim and annual reporting periods ending after June 15, 2009, and shall be applied prospectively. FSP 157-4 affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. The FSP provides guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. This FSP applies to all fair value measurements when appropriate. The Company does not expect that the adoption of this statement will have a significant impact on its financial statements based on current market conditions.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments (“FSP 115-2”), which is effective for the Company for interim and annual reporting periods ending after June 15, 2009. FSP 115-2 amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity’s management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The Company has not determined the impact of the adoption of FSP 115-2 on its financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments (“FSP 107-1”), which is effective for the Company for the quarterly period beginning April 1, 2009. FSP 107-1 requires an entity to provide the annual disclosures required by FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments, in its interim financial statements. The Company will provide the additional disclosures required by FSP 107-1 in its quarterly report on Form 10-Q for the period ended June 30, 2009.

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 following table details the fair value measurements within the fair value hierarchy of the Company's financial assets at December 31, 2008:

	Total Fair Value at December 31, 2008	Fair Value Measurements at Reporting Date Using		
		Level 1	Level 2	Level 3
Certificate of deposit	\$ 7,000	\$ 7,000	\$ —	\$ —
Total	\$ 7,000	\$ 7,000	\$ —	\$ —

The Company had no financial assets held at fair value at March 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 March 31, 2009 and December 31, 2008 was approximately as follows:

	Unaudited	
	March 31, 2009	December 31, 2008
Raw Materials	\$ 264,000	\$ 382,000
Finished Goods	325,000	342,000
Total Gross Inventory	\$ 589,000	\$ 724,000
Less: Inventory reserve	-	-
Total Inventory	\$ 589,000	\$ 724,000

11. Subsequent Events

As a result of the Company's noncompliance with the NYSE Alternext US LLC's (formerly, the American Stock Exchange or "AMEX") listing standards, the Company, in a letter dated April 13, 2009, was provided a copy of the AMEX application to strike the Company's common stock from the AMEX.

The listing standards to which the Company was in noncompliance of are as follows:

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;

- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and

- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

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 "Risk Factors" section hereof, and our Annual Report for the year ended December 31, 2008 on Form 10-K, 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, 2008 on Form 10-K. Our actual results may differ materially.

Financial Operations Overview

Revenue Recognition: Revenue is recognized in accordance with SAB 101, "Revenue Recognition in Financial Statements" ("SAB 101"), as amended by SAB 104. SAB 101 requires that 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:

- OLpur MDHDF filter series (which we sell in various countries in Europe and currently consists of our MD190 and MD220 diafilters); to our knowledge, the only filter designed expressly for HDF therapy and employing 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 Quarterly 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, and that, if approved by the FDA in 2009, our OLPur H2H and MDHDF filters will be the first, and only, HDF therapy, approved by the FDA, available in the United States at that time.

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 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 5,000 registered hospitals in the United States (as reported by the American Hospital Association in Fast Facts of October 20, 2006), 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. Following its review of the application, the FDA requested additional information from us. On February 24, 2009, we provided a formal response to the FDA. Per FDA guidelines, the FDA has 90 days to review the additional information.

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 are developing a personal potable water purification system for use by warfighters. Work on this project commenced in January 2008 and we have billed approximately \$530,000 during the fifteen months ended March 31, 2009. In December 2007, the U.S. Department of Defense Appropriations Act appropriated an additional \$2 million to

continue the development of a dual stage ultra reliable personal water filtration system. Although it is our intention to execute an agreement with the U.S. Department of Defense to utilize this appropriation before it expires in September 2009, such an agreement has not been executed as of March 31, 2009. We have defined the project scope and objectives in connection with this appropriation and submitted a proposal to the Office of Naval Research in February 2009. 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.

NYSE Alternext US LLC (formerly, the American Stock Exchange or "AMEX") Issues

On January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan of compliance regarding the following listing standards to which we were in noncompliance of:

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;

- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than \$4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and
- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

The AMEX further stated that the AMEX intended to strike our common stock from the AMEX by filing a delisting application with the SEC pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we decided not to seek an appeal of the AMEX's intention to delist our common stock.

On January 22, 2009, we were informed by the AMEX that the AMEX had suspended trading in our common stock effective immediately. Immediately following the notification, our common stock was no longer traded on the AMEX.

Effective February 4, 2009, our common stock was quoted on the Over the Counter Bulletin Board under the symbol "NEPH.OB".

In a letter dated April 13, 2009, we received a copy of the AMEX's application to strike our common stock from the AMEX.

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, one 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, 2008. 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, 2008.

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 March 31, 2009 Compared to the Three Months Ended March 31, 2008

Revenues

Total revenues for the three months ended March 31, 2009 were approximately \$631,000 compared to approximately \$387,000 for the three months ended March 31, 2008. Total revenues increased approximately \$244,000. The increase of almost 63% is due to increased revenue of approximately \$311,000 during the three months ended March 31, 2009 over the same period in 2008, related to our contract with the Office of U.S. Naval Research and \$24,000 in sales of our DSU in the United States for the three months ended March 31, 2009 whereas we had no DSU revenue in the same period in 2008. Sales of our MD filters in our Target European Market were \$91,000 lower in the three months ended March 31, 2009 compared to the same period in 2008. Approximately \$51,000 of the European revenue reduction was due to less units sold and the remaining \$40,000 was due to foreign currency exchange rate fluctuation. Unit sales in Europe decreased approximately 13% for the three months ended March 31, 2009 compared to the same period in 2008. The decrease in unit sales was not the result of decreased customer orders, but rather due to production delays resulting in deferment of shipments.

Cost of Goods Sold

Cost of goods sold was approximately \$452,000 for the three months ended March 31, 2009 compared to approximately \$238,000 for the three months ended March 31, 2008. The increase of approximately \$214,000, or 90%, in cost of goods sold is primarily due to increased costs of approximately \$240,000 during the three months ended March 31, 2009 over the same period in 2008 related to our contract with the Office of U.S. Naval Research and \$8,000 in costs related to sales of our DSU in the United States for the three months ended March 31, 2009 whereas we had no DSU revenue in the same period in 2008. Costs related to Sales of our MD filters in our Target European Market were \$35,000 lower in the three months ended March 31, 2009 compared to the same period in 2008. Approximately \$5,000 of the European revenue reduction was due to less units sold and the remaining \$30,000 was due to foreign currency exchange rate fluctuation. Unit sales decreased approximately 13% for the three months ended March 31, 2009 compared to the same period in 2008.

Research and Development

Research and development expenses were approximately \$58,000 and \$723,000 respectively, for the three months ended March 31, 2009 and March 31, 2008. This decrease of approximately \$665,000 or 92% is primarily due to the fact that there was no clinical trial being conducted in the three months ended March 31, 2009 compared to the same period in 2008. The decreased spending for the clinical trials relates to the 2008 US trials for the H2H which were completed in the second quarter of 2008. Of the \$58,000 of research and development expense incurred during the three months ended March 31, 2009 approximately \$21,000 was related to development work on the DSU, approximately \$15,000 was related to regulatory support and the remaining \$22,000 related to other research.

Depreciation Expense

Depreciation expense was approximately \$72,000 for the three months ended March 31, 2009 compared to approximately \$88,000 for the three months ended March 31, 2008, a decrease of 18%. The decrease of approximately \$16,000 is primarily due to several assets having been fully depreciated as of year end 2008 resulting in no depreciation expense for those assets during the three months ended March 31, 2009. There was not a significant disposition of assets during the three months ended March 31, 2009 compared to the same period in 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$789,000 for the three months ended March 31, 2009 compared to approximately \$1,114,000 for the three months ended March 31, 2008, a decrease of \$325,000 or 29%. The decrease reflects a reduction in salaries and fringe benefit costs of approximately \$145,000 during the three months ended March 31, 2009 compared to the same period in 2008 due to reductions in staff, a reduction in recruiting service fees of \$78,000 since no such fees were incurred during the three months ended March 31, 2009, a reduction in legal fees of approximately \$144,000 during the three months ended March 31, 2009 compared to the same period in 2008 and a reduction of approximately \$45,000 in insurance premiums during the three months ended March 31, 2009 compared to the same period in 2008 even though coverage was increased. These reductions were partially offset by an increase in marketing spending primarily for the DSU product. Marketing expenditures increased by approximately \$89,000 during the three months ended March 31, 2009 compared to the same period in 2008.

Interest Income

Interest income was approximately \$5,000 for the three months ended March 31, 2009 compared to approximately \$92,000 for the three months ended March 31, 2008. The decrease of approximately \$87,000 is due to the

decreased investments that we had in the three months ended March 31, 2009 compared to the first three months ended March 31, 2008.

Impairment loss of Auction Rate Securities

Effective January 1, 2008, we adopted fair value measurements under SFAS No. 157 which applied to our financial assets such as available-for-sale marketable securities (included as part of investments in the Unaudited Condensed Consolidated Balance Sheet). These items were to be marked-to-market at each reporting period; however, the definition of fair value used for these mark-to-markets is now applied using SFAS No. 157. Our available-for-sale marketable securities consisted of auction rate securities (ARS) at March 31, 2008.

During the first three months of 2008, our ARS failed at auction due to sell orders exceeding buy orders. Based upon an analysis of other-than-temporary impairment factors, ARS with an original par value of approximately \$4.4 million were written-down to an estimated fair value of \$4.3 million as of March 31, 2008. We reviewed impairments associated with the above in accordance with Emerging Issues Task Force (EITF) 03-1 and FSP SFAS 115-1 and 124-1, "The Meaning of Other-Than-Temporary-Impairment and Its Application to Certain Investments," to determine the classification of the impairment as "temporary" or "other-than-temporary."

An impairment loss of approximately \$114,000 on ARS was charged to our results of operations for the three months ended March 31, 2008. Approximately \$300,000 of ARS were redeemed at par during the three months ended June 30, 2008 thereby reducing the total par value from \$4.4 million at March 31, 2008 to \$4.1 million as of June 30, 2008.

We sold, at par value, our remaining ARS to a third party on July 22, 2008 for \$4.1 million. We recorded an Unrealized Holding Gain in the second quarter of 2008 of approximately \$114,000 when we adjusted such investment to fair value, as a result of our reclassification of such investment from Available-for-Sale to Trading Securities. We subsequently reversed the Unrealized Holding Gain and recorded a Realized Gain on Sale of Investments of approximately \$114,000 in the third quarter of 2008 when the sale transaction was executed.

There was no impact on our operations for the three month period ended March 31, 2009 because the ARS investment was sold in 2008.

Other income and expenses

Other income in the amount of approximately \$158,000 for the three months ended March 31, 2008 resulted primarily from receipt of New York State Qualified Emerging Technology Company ("QETC") tax refunds. There was no other income for the three months ended March 31, 2009.

Liquidity and Capital Resources

Net cash used in operating activities was approximately \$660,000 for the three months ended March 31, 2009 compared to approximately \$1,239,000 for the three months ended March 31, 2008. The \$579,000 decrease was primarily due to a decrease in our net loss adjusted for noncash items of approximately \$750,000, a \$79,000 increase in cash provided by our current assets and offset partially by a decrease of \$250,000 in cash used in accounts payable and accrued expenses. The most significant items contributing to this decrease of approximately \$579,000 cash used in operating activities during the three months ended March 31, 2009 compared to the three months ended March 31, 2008 are highlighted below:

- During the 2009 period, our net loss decreased by approximately \$905,000;
- During the 2009 period, our stock-based compensation expense decreased by approximately \$21,000;
-

Edgar Filing: NEPHROS INC - Form 10-Q

During the 2008 period, we recognized an expense of approximately \$114,000 due to an impairment of ARS;

- Our accounts receivable increased by approximately \$51,000 during the 2009 period compared to a decrease of approximately \$40,000 during the 2008 period;
- Our inventory decreased by approximately \$105,000 during the 2009 period compared to a decrease of approximately \$5,000 during the 2008 period;
- Our prepaid expenses and other assets decreased by approximately \$15,000 in the 2009 period compared to an increase of approximately \$55,000 in the 2008 period;
- Our accounts payable and accrued expenses increased by approximately \$13,000 in the aggregate in the 2009 period compared to an increase of approximately \$235,000 in the 2008 period; and

- Our accrued severance expenses decreased by approximately \$90,000 in the aggregate in the 2009 period compared to a decrease of approximately \$62,000 in the 2008 period.

Net cash provided by investing activities was approximately \$7,000 for the three months ended March 31, 2009, compared to net cash provided by investing activities of approximately \$290,000 for the three months ended March 31, 2008. Our net cash provided by investing activities for the three months ended March 31, 2008 reflects the maturities of short-term investments in the amount of approximately \$400,000 partially offset by purchases of approximately \$100,000 in short-term investments and approximately \$10,000 for purchases of computer equipment at our office in Ireland.

Certain Risks and Uncertainties

Our Annual Report on Form 10-K for the year ended December 31, 2008 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,” “pursues,” “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;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may not obtain appropriate or necessary regulatory approvals to achieve our business plan or effectively market our products;
- 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 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, 2008 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 three month periods ended March 31, 2009 and 2008.

Item 4T. 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 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 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

In connection with the preparation of our Annual Report of Form 10-KSB for the year ended December 31, 2007, management identified a material weakness, due to an insufficient number of resources in the accounting and finance department, resulting in (i) an ineffective review, monitoring and analysis of schedules, reconciliations and financial statement disclosures and (ii) the misapplication of U.S. GAAP and SEC reporting requirements. Throughout fiscal year 2008 and as reported in our Form 10-Qs filed during the year, we initiated and implemented the following measures:

- Developed procedures to implement a formal quarterly closing calendar and process and held quarterly meetings to address the quarterly closing process;
- Established a detailed timeline for review and completion of financial reports to be included in our Forms 10-Q and 10-K;
- Enhanced the level of service provided by outside accounting service providers to further support and provide additional resources for internal preparation and review of financial reports and supplemented our internal staff in accounting and related areas; and
- Employed the use of appropriate supplemental SEC and U.S. GAAP checklists in connection with our closing process and the preparation of our Forms 10-Q and 10-K.

As a result of the implementation of the above items, the material weakness was remediated in the fourth quarter of 2008.

Other than the matters discussed above, there were no other significant 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

A former employee in France filed a claim in October 2008 stating that the individual is due 30,000 Euro or approximately \$42,000 in back wages. The individual left our employment four years ago and signed a Separation Agreement which stated we had no further liability to the individual. Our attorney has advised us that the Separation Agreement is valid and should preclude us from having any liability. The matter is scheduled to be heard before a French court on June 18, 2009.

A former employee in the United States filed a claim in March 2009 against us and our CEO alleging breach of the individual's employment agreement and fraud. The individual was employed with us from April 2008 through January 8, 2009. Our loss is limited to \$10,000, which is the deductible under our Employment Practices Liability insurance. An accrual of \$10,000 has been recorded as of March 31, 2009.

There are no other 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 March 31, 2009.

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: May 15, 2009

By: /s/ Ernest A. Elgin III
Name: Ernest A. Elgin III
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2009

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

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.