

NEPHROS INC  
Form 10-Q  
November 14, 2008

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended: **September 30, 2008**

OR

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32288

**NEPHROS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**DELAWARE**

**13-3971809**

(State or Other Jurisdiction of Incorporation or Organization)

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

**3960 Broadway**

**New York, New York**

(Address of Principal Executive Offices)

**10032**

(Zip Code)

**(212) 781-5113**

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

As of November 14, 2008, 38,165,380 shares of issuer's common stock, with \$0.001 par value per share, were outstanding.

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):

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Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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**PART I - FINANCIAL INFORMATION****Item 1. Financial Statements.****NEPHROS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands)****(Unaudited)****September 30,  
2008****December 31,  
2007****ASSETS**

## Current assets:

|  |    |       |    |        |
|--|----|-------|----|--------|
| Cash and cash equivalents  | \$ | 3,745 | \$ | 3,449  |
| Short-term investments   |    | 7     |    | 4,700  |
| Accounts receivable, less allowances of \$0 and \$7,<br>respectively |    | 322   |    | 419    |
| Inventory, less allowances of \$28 and \$30, respectively            |    | 337   |    | 336    |
| Prepaid expenses and other current assets                            |    | 336   |    | 392    |
| Total current assets   |    | 4,747 |    | 9,296  |
| Property and equipment, net  |    | 554   |    | 762    |
| Other assets   |    | 27    |    | 27     |
| Total assets   | \$ | 5,328 | \$ | 10,085 |

**LIABILITIES AND STOCKHOLDERS' EQUITY**

## Current liabilities:

|                           |    |       |    |       |
|---------------------------|----|-------|----|-------|
| Accounts payable          | \$ | 856   | \$ | 488   |
| Accrued expenses          |    | 1,066 |    | 841   |
| Total current liabilities |    | 1,922 |    | 1,329 |

## Stockholders' equity:

Preferred stock, \$.001 par value; 5,000,000 shares  
authorized at September 30, 2008 and December 31, 2007;  
no shares issued and outstanding at September 30, 2008  
and December 31, 2007.

Common stock, \$.001 par value; 60,000,000 shares  
authorized at September 30, 2008 and December 31, 2007;  
38,165,380 shares issued and outstanding at September 30,  
2008 and December 31, 2007.

|  |    |          |    |          |
|--|----|----------|----|----------|
| Additional paid-in capital                 |    | 90,317   |    | 90,220   |
| Accumulated other comprehensive income     |    | 93       |    | 110      |
| Accumulated deficit                        |    | (87,042) |    | (81,612) |
| Total stockholders' equity                 |    | 3,406    |    | 8,756    |
| Total liabilities and stockholders' equity | \$ | 5,328    | \$ | 10,085   |

*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<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|--|-------------------------------------|------------|------------------------------------|------------|
|  | 2008                                | 2007       | 2008                               | 2007       |
| Net product revenues   | \$ 393                              | \$ 112     | \$ 1,033                           | \$ 755     |
| Cost of goods sold   | 254                                 | 131        | 654                                | 581        |
| Gross margin   | 139                                 | (19)       | 379                                | 174        |
| Operating expenses:  |                                     |            |                                    |            |
| Research and development   | 191                                 | 298        | 2,072                              | 1,102      |
| Depreciation   | 84                                  | 86         | 255                                | 253        |
| Selling, general and administrative                              | 1,242                               | 1,408      | 3,830                              | 3,697      |
| Total operating expenses   | 1,517                               | 1,792      | 6,157                              | 5,052      |
| Loss from operations   | (1,378)                             | (1,811)    | (5,778)                            | (4,878)    |
| Interest income  | 27                                  | 2          | 185                                | 35         |
| Interest expense   |                                     | (149)      |                                    | (317)      |
| Impairment of auction rate securities                            |                                     |            | (114)                              |            |
| Unrealized holding gain - auction<br>rate securities             | (114)                               |            |                                    |            |
| Gain on sale of investments                                      | 114                                 |            | 114                                |            |
| Gain on exchange of debt   |                                     | 330        |                                    | 330        |
| Other income   | 5                                   | 166        | 163                                | 167        |
| Net loss   | (\$1,346)                           | (\$1,462)  | (\$5,430)                          | (\$4,663)  |
| Net loss per common share, basic<br>and diluted                  | (\$0.04)                            | (\$0.12)   | (\$0.14)                           | (\$0.38)   |
| Weighted average common shares<br>outstanding, basic and diluted | 38,165,380                          | 12,317,992 | 38,165,380                         | 12,317,992 |

*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)

**Nine Months Ended September 30,**  
**2008**                      **2007**

**Operating activities:**

|   |           |           |
|---|-----------|-----------|
| Net loss  | (\$5,430) | (\$4,663) |
| Adjustments to reconcile net loss to net cash used in operating activities: |           |           |
| Depreciation  | 255       | 253       |
| Amortization of research & development assets                               | 12        | 11        |
| Loss on disposal of equipment   | 3         | 2         |
| Impairment of auction rate securities                                       | 114       |           |
| Gain on sale of investments   | (114)     |           |
| Amortization of debt discount   |           | 32        |
| Loss on change in valuation of derivative liability                         |           | 7         |
| Stock-based compensation  | 97        | 265       |
| Gain on exchange of debt  |           | (330)     |
| (Increase) decrease in operating assets:                                    |           |           |
| Accounts receivable   | 93        | 124       |
| Inventory   | (1)       | (11)      |
| Deferred cost - insurance   |           | (4)       |
| Prepaid expenses and other current assets                                   | 48        | 197       |
| Increase (decrease) in operating liabilities:                               |           |           |
| Accounts payable and accrued expenses                                       | 594       | (205)     |
| Accrued interest-convertible notes  |           | 277       |
| Other liabilities   |           | (192)     |
| Net cash used in operating activities                                       | (4,329)   | (4,237)   |
| Investing activities:   |           |           |
| Purchase of property and equipment  | (63)      | (2)       |
| Purchase of short-term investments  |           | (4,000)   |
| Proceeds from sale of short-term investments                                | 4,100     |           |
| Maturities of short-term investments  | 593       | 2,800     |
| Net cash provided by (used in) investing activities                         | 4,630     | (1,202)   |
| Financing activities:   |           |           |
| Deferred financing costs  |           | (992)     |
| Proceeds from private placement of convertible securities                   |           | 12,677    |
| Net cash provided by financing activities                                   |           | 11,685    |
| Effect of exchange rates on cash  | (5)       | 14        |
| Net increase (decrease) in cash and cash equivalents                        | 296       | 6,260     |
| Cash and cash equivalents, beginning of period                              | 3,449     | 253       |

|  |    |       |    |       |
|--|----|-------|----|-------|
| Cash and cash equivalents, end of period | \$ | 3,745 | \$ | 6,513 |
|--|----|-------|----|-------|

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Supplemental disclosure of cash flow information:

|                     |    |   |    |   |
|---------------------|----|---|----|---|
| Cash paid for taxes | \$ | 8 | \$ | 3 |
|---------------------|----|---|----|---|

Supplemental disclosure of noncash investing and financing activities:

|   |  |    |       |
|---|--|----|-------|
| Convertible note issued on debt exchange              |  | \$ | 5,300 |
| Fair value of warrants issued as placement agent fees |  |    | 1,047 |
|   |  | \$ | 6,347 |

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

## Notes to the Unaudited Condensed Consolidated Interim Financial Statements

### 1. Basis of Presentation and Liquidity

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 2007 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission (the “SEC”) on March 31, 2008. The Company filed Amendment No. 1 to its 2007 Annual Report Form 10-KSB/A with the SEC on October 9, 2008. The amendment added certain language regarding internal control over financial reporting to paragraphs 4 and 4(b) of the certifications of the Company’s Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. The accompanying 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 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, 2007 was derived from the Company’s audited financial statements but does not include all disclosures required by GAAP. In the opinion of management, the interim financial statements reflect all adjustments consisting of normal, recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the condensed consolidated interim periods presented. Interim results are not necessarily indicative of results for a full year. All significant inter-company transactions and balances have been eliminated in consolidation.

The Company has incurred significant losses in its operations in each quarter since inception. For the three and nine months ended September 30, 2008, the Company incurred a net loss of approximately \$1.3 million and \$5.4 million, respectively. In addition, the Company has not generated positive cash flow from operations in any quarter since inception. The Company expects to continue to incur losses for at least the short-term. 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.

### 2. Concentration of Credit Risk

For the nine months ended September 30, 2008 and 2007, the following customers accounted for the following percentages of the Company’s sales, respectively.

| Customer | 2008 | 2007 |
|----------|------|------|
| A        | 84 % | 92 % |
| B        | 10 % | 0 %  |

As of September 30, 2008 and December 31, 2007, the following customers accounted for the following percentages of the Company’s accounts receivable, respectively.

| Customer | 2008 | 2007 |
|----------|------|------|
| A        | 77 % | 0 %  |
| B        | 16 % | 0 %  |

**3. Revenue Recognition**

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin (“SAB”) No. 104, “*Revenue Recognition*” (“SAB 104”). SAB 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 and determinable and (iv) collectability is reasonably assured.

The Company recognizes revenue related to product sales when its external logistics provider confirms delivery and the other criteria of SAB 104 are met. All costs and duties relating to delivery are absorbed by the Company. All shipments are currently received directly by the Company’s customers. Sales made on a returned basis are recorded net of a provision for estimated returns. These estimates are revised as necessary, to reflect actual experience and market conditions. The returns provision is based on historical unit return levels and valued relative to debtors at the end of each quarter. There were no returns for the nine months ended September 30, 2008 and 2007.

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**4. Stock-Based Compensation**

The Company complies with the accounting and reporting requirements of Statement of Financial Accounting Standards (“SFAS”) No. 123 (Revised 2004), “*Share-Based Payment*” (“SFAS 123R”), using a modified prospective transition method. For the three months ended September 30, 2008, stock-based compensation expense was approximately \$33,000, as compared to approximately \$30,000 of stock-based compensation for the comparable period in 2007. For the nine months ended September 30, 2008 and 2007, stock-based compensation expense was approximately \$97,000 and \$265,000, respectively.

There was no tax benefit related to expense recognized in the nine months ended September 30, 2008 and 2007, as the Company is in a net operating loss position. As of September 30, 2008, there was approximately \$706,000, 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 \$706,000 will be amortized over the weighted-average remaining requisite service period of 3.4 years. Of the total \$706,000, the Company expects to recognize approximately 8.3% in the remaining interim periods of 2008, approximately 35.2% in 2009, approximately 30.0% in 2010, approximately 15.0% in 2011 and approximately 11.6% in 2012.

**5. Comprehensive Income**

The Company accounts for comprehensive income in accordance with SFAS No. 130, “*Reporting Comprehensive Income*” (“SFAS 130”), which requires comprehensive income (loss) and its components to be reported when a company has items of other comprehensive income (loss). Comprehensive income (loss) includes net income plus other comprehensive income (loss) (i.e., certain revenues, expenses, gains and losses reported as separate components of stockholders’ equity (deficit) rather than in net income (loss)).

The Company accounts for certain transactions with a foreign affiliate in a currency other than U.S. dollars. For the purposes of presenting the condensed consolidated interim financial statements in conformity with GAAP, the transactions must be converted into U.S. dollars in accordance with SFAS No. 52, “*Foreign Currency Translation*” (“SFAS 52”). Since these transactions are of a long-term investment nature and settlement is not planned or anticipated in the foreseeable future, the offsetting foreign currency adjustment is accounted for as an other comprehensive income item in the unaudited condensed consolidated balance sheets.

**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 14,339,324 and 38,546,992 from the computation of diluted EPS for the three and nine month periods ended September 30, 2008 and 2007, respectively.

**7. Recently Adopted Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”). This Standard defines fair value, establishes a framework for measuring fair value, and

expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, "*Effective Date of FASB Statement No.157*" ("FSP 157-2"), which delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The Company adopted SFAS 157 for financial assets and liabilities on January 1, 2008. The disclosures required under SFAS 157 are set forth in Note 9. The Company is currently in the process of evaluating the effect, if any, that the adoption of FSP 157-2 will have on its results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, *“The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 155”* (“SFAS 159”). This statement permits entities to choose to measure selected assets and liabilities at fair value. The Company adopted SFAS 159 on January 1, 2008 resulting in no material impact to the Company’s financial condition, results of operation or cash flows.

On October 10, 2008, the FASB issued FSP FAS No. 157-3, *“Fair Value Measurements”* (FSP FAS 157-3), which clarifies the application of SFAS No. 157 in an inactive market and provides an example to demonstrate how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP FAS 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The adoption of this standard as of September 30, 2008 did not have a material impact on the Company’s results of operations, cash flows or financial positions.

## **8. New Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *“Business Combinations”* (“SFAS 141R”). SFAS 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. SFAS 141R determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting SFAS 141R on its consolidated results of operations and financial condition and plans to adopt it as required in the first quarter of fiscal 2009.

In December 2007, the FASB issued SFAS No. 160, *“Noncontrolling Interests in Consolidated Financial Statements”* (“SFAS 160”), an amendment of Accounting Research Bulletin (“ARB”) No. 51, *“Consolidated Financial Statements”* (“ARB 51”). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Minority interests will be recharacterized as noncontrolling interests and will be reported as a component of equity separate from the parent’s equity, and purchases or sales of equity interests that do not result in a change in control will be accounted for as equity transactions. In addition, net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement and upon a loss of control, the interest sold, as well as any interest retained, will be recorded at fair value with any gain or loss recognized in earnings. This pronouncement is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of adopting SFAS 160 on its consolidated results of operations and financial condition and plans to adopt it as required in the first quarter of fiscal 2009.

In March 2008, the FASB issued SFAS No. 161, *“Disclosures about Derivative Instruments and Hedging Activities”* (“SFAS 161”). SFAS 161 requires enhanced disclosures about an entity’s derivative and hedging activities and thereby improves the transparency of financial reporting. The objective of the guidance is to provide users of financial statements with an enhanced understanding of how and why an entity uses derivative instruments: how an entity accounts for derivative instruments and related hedged items and how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years beginning after November 15, 2008. Management has evaluated SFAS 161 and has determined that it will have no impact on the Company’s consolidated financial statements.

In December 2007, the SEC issued SAB No. 110, *“Share-Based Payment”* (“SAB 110”). SAB 110 establishes the continued use of the simplified method for estimating the expected term of equity based compensation. The simplified method was intended to be eliminated for any equity based compensation arrangements granted after December 31, 2007. SAB 110 is being published to help companies that may not have adequate exercise history to estimate expected terms for future grants. The Company does not expect the adoption of SAB 110 to have a material effect on its consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, “*The Hierarchy of Generally Accepted Accounting Principles*” (SFAS 162”). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. SFAS 162 is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “*The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.*” The adoption of this statement is not expected to have a material effect on the Company’s financial statements.

In May 2008, the FASB issued SFAS No. 163, “*Accounting for Financial Guarantee Insurance Contracts - An interpretation of FASB Statement No. 60*” (“SFAS 163”). SFAS 163 requires that an insurance enterprise recognize a claim liability prior to an event of default when there is evidence that credit deterioration has occurred in an insured financial obligation. It also clarifies how SFAS No. 60 “*Accounting and Reporting by Insurance Enterprises*” (“SFAS 60”) applies to financial guarantee insurance contracts, including the recognition and measurement to be used to account for premium revenue and claim liabilities, and requires expanded disclosures about financial guarantee insurance contracts. SFAS 163 is effective for financial statements issued for fiscal years beginning after December 15, 2008, except for some disclosures about the insurance enterprise’s risk-management activities. SFAS 163 requires that disclosures about the risk-management activities of the insurance enterprise be effective for the first period beginning after issuance. Except for the disclosures identified above, earlier application is not permitted. The adoption of this statement is not expected to have a material effect on the Company’s financial statements.

## **9. Fair Value of Financial Instruments**

As described in Note 7, the provisions of SFAS 157 were adopted by the Company on January 1, 2008 for financial assets and liabilities, and will be adopted by the Company on January 1, 2009 for non-financial assets and liabilities.

SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. SFAS 157 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

The Company invested in auction rate securities (“ARS”), which are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction “fails” and the holders of the ARS are unable to liquidate their investment through such auction. With the liquidity issues experienced in global credit and capital markets, the ARS held by the Company have experienced multiple failed auctions since February 2008, and as a result, the Company did not consider these affected ARS liquid in the first quarter of 2008. Accordingly, while the Company had classified its ARS as current assets at December 31, 2007, the Company reclassified them as noncurrent assets at March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, the Company wrote down ARS with an original par value of approximately \$4.4 million to an estimated fair value of \$4.3 million as of March 31, 2008. The Company reviewed impairments associated with the above in accordance with Emerging Issues Task Force (EITF) 03-1 and FSP SFAS 115-1/124-1, “*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.”

The Company determined the ARS classification to be “other-than-temporary,” and charged an impairment loss of approximately \$114,000 on the ARS to its results of operations for the three months ended March 31, 2008.

During the three months ended June 30, 2008 approximately \$300,000 of principal on the Company’s ARS had been paid back by the debtor, resulting in the Company’s investment in ARS having decreased from \$4.4 million to \$4.1 million (par value) at June 30, 2008. The net book value of the Company’s ARS at June 30, 2008 was \$3.986 million, due to the approximate \$114,000 impairment recorded at March 31, 2008. On July 22, 2008 the Company sold its ARS to a third party at 100% of par value, for proceeds of \$4.1 million. The Company reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with SFAS No. 115, “*Accounting for Certain Investments in Debt and Equity Securities,*” (“SFAS 115”) the ARS, classified as Trading Securities, were valued at their fair value of \$4.1 million at June 30, 2008. The adjustment



of the investment's carrying value from \$3.986 million net book value to \$4.1 million fair value resulted in an Unrealized Holding Gain of approximately \$114,000 which is included in the Company's Statement of Operations for the three and six months ended June 30, 2008.

The Company sold its ARS to a third party at 100% of par value, for proceeds of \$4.1 million on July 22, 2008. The Unrealized Holding Gain of approximately \$114,000 which was included in the Company's Statement of Operations for the three and six months ended June 30, 2008 was reversed and a realized Gain on Sale of Investments of approximately \$114,000 is included in the Company's Statement of Operations for the three and nine months ended September 30, 2008.

The underlying assets of the Company's ARS were comprised primarily of student loans and their fair value at March 31, 2008 was measured using Level 3 inputs due to the failure of the auction market. Due to the subsequent sale of the investments at par, the fair value of the securities was measured using Level 1 inputs as the proceeds redeemed in July 2008 were placed in a money market account with observable market sources.

## 10. Inventory, net

Inventory is stated at the lower of cost or market using the first-in first-out method. The Company's inventory as of September 30, 2008 and December 31, 2007 was approximately as follows:

|                         | <b>Unaudited</b> |                          |
|-------------------------|------------------|--------------------------|
|                         | <b>September</b> |                          |
|                         | <b>30, 2008</b>  | <b>December 31, 2007</b> |
| Raw Materials           | \$ 25,000        | \$ 62,000                |
| Finished Goods          | 340,000          | 304,000                  |
| Total Gross Inventory   | \$ 365,000       | \$ 366,000               |
| Less: Inventory reserve | 28,000           | 30,000                   |
| Total Inventory         | \$ 337,000       | \$ 336,000               |

## 11. Commitments and Contingencies

As of September 15, 2008, Norman J. Barta resigned from the Company's Board of Directors and as the Company's Chairman of the Board, President, Chief Executive Officer, Secretary and Treasurer. Effective immediately upon Mr. Barta's resignation, the Board of Directors appointed Ernest A. Elgin III as the Company's President and Chief Executive Officer, appointed the Company's Chief Financial Officer, Gerald Kochanski, to the additional offices of Secretary and Treasurer, and elected Mr. James Scibetta, an independent Director of the Company and the Chairman of Audit Committee, to serve as Chairman of the Board of Directors.

### *Separation Agreement*

On September 15, 2008, the Company entered into a separation agreement and release with Mr. Barta, pursuant to which the employment agreement between the Company and Mr. Barta, dated as of July 1, 2007, was terminated. Pursuant to the separation agreement, Mr. Barta agreed to remain employed by the Company and to consult with the Company's officers, directors and agents and otherwise provide assistance in the Company's transition to a new chief executive officer until October 10, 2008 ("Separation Date"). The separation agreement provides, among other things, that:

- The Company will pay Mr. Barta his base salary and any accrued but unused vacation through the Separation Date;
- Within five days following the Separation Date, the Company will pay Mr. Barta an \$18,000 bonus in connection with certain operational milestones that had been met; and
- Mr. Barta will continue to receive his base salary for a period of six months following the Separation Date.

The Separation Agreement also stated that, in accordance with their respective terms, the options granted to Mr. Barta on January 24, 2000, December 14, 2004 and November 8, 2007 - to the extent vested prior to the Separation Date - shall remain exercisable until three months after the Separation Date, and the options granted to Mr. Barta on January 30, 2003 shall remain exercisable until nine months after the Separation Date. A number of the options that were granted to Mr. Barta on November 8, 2007 remained unvested and were cancelled and forfeited by Mr. Barta as of the

Separation Date. The separation agreement also contains mutual releases and other customary provisions.

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### ***Employment Agreement***

The Company entered into an employment agreement with Mr. Elgin, dated as of September 15, 2008, having a term of three years. Pursuant to such employment agreement, Mr. Elgin's initial annual base salary is \$240,000. The employment agreement also provides that the Company shall establish a target discretionary bonus of 30% of Mr. Elgin's base salary, the amount of which, if any, that Mr. Elgin is awarded will be determined by the Compensation Committee of the Company's Board in its sole discretion, based in part on attainment of certain performance objectives to be identified by Mr. Elgin and the Compensation Committee. The Company agreed to provide Mr. Elgin with a guaranteed bonus of \$35,000 for the period from September 15, 2008 through December 31, 2008. Pursuant to the employment agreement, on September 15, 2008, the Company's Compensation Committee granted Mr. Elgin an option to purchase 750,000 shares of common stock under the Company's 2004 Equity Incentive Plan. The option will vest in four equal annual installments of 187,500 shares on each of September 15, 2009, September 15, 2010, September 15, 2011 and September 15, 2012, provided that Mr. Elgin remains employed by the Company at such time, and provided further that all options shall vest and become exercisable in full immediately upon the occurrence of a Change of Control (as defined in the employment agreement).

Mr. Elgin's employment agreement provides that, upon termination by the Company for Cause or Disability (as such terms are defined in the agreement) or by Mr. Elgin for any reason other than his exercise of the Change of Control Termination Option (as defined in the agreement), the Company shall pay him only his earned but unpaid base salary and bonuses for services rendered through the date of termination. If Mr. Elgin's employment is terminated by his death or by his voluntary resignation or retirement other than upon his exercise of the Change of Control Termination Option, then the Company shall pay him only his earned but unpaid base salary for services rendered through the date of termination. If the Company terminates Mr. Elgin's employment for any other reason or if he terminates his employment pursuant to his Change of Control Termination Option, then, provided he continues to abide by certain confidentiality and non-compete provisions of his agreement and executes a release, he shall be entitled to: (1) any accrued but unpaid base salary for services rendered through the date of termination; and (2) the continued payment of his base salary, in the amount as of the date of termination, for a period of either three months or, if he has been employed under the agreement for at least one year, six months subsequent to the termination date or until the end of the remaining term of the agreement if sooner, such payments to be made at the times such base salary would have been paid had his employment not been terminated. Upon termination of Mr. Elgin's employment for any reason, his unvested options shall immediately be cancelled and forfeited and his vested options shall remain exercisable for 90 days after such termination.

Upon any Change of Control (as defined in the employment agreement), Mr. Elgin shall have a period of time in which to discuss, negotiate and confer with any successor entity regarding the terms and conditions of his continued employment. If Mr. Elgin, acting reasonably, is unable to timely reach an agreement through good faith negotiations with such successor, then he may elect (the "Change of Control Termination Option") to terminate his employment with the Company and receive the payments and bonuses described above with respect to such a termination.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

### **Overview**

The following discussion and analysis of our condensed consolidated interim financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated interim financial statements and related notes, as well as the other sections of this quarterly report on Form 10-Q (the "Quarterly Report") and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2007 included in our Annual Report on Form 10-KSB filed with the SEC on March 31, 2008 (the "Annual Report") as well as the rest of such Annual Report, including the "Certain Risks and Uncertainties" and "Description of Business" sections thereof. Operating results are not necessarily indicative of results that may occur in future periods. 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 throughout this Quarterly Report and in our Annual Report. 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**

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLPur MD190 and MD220, which are dialyzers (our "OLPur MDHDF Filter Series"), OLPur H2H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines, and the OLPur NS2000 system, a stand-alone HDF machine with associated filter technology. We began selling our OLPur MD190 dialyzer in some parts of our Target European Market (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) in March 2004, and have developed units suitable for clinical evaluation for our OLPur H2H product. We are developing our OLPur NS2000 product in conjunction with an established machine manufacturer in Italy. We are working with this manufacturer to modify an existing HDF platform they currently offer for sale in parts of our Target European Market, incorporating our proprietary H2H technology.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval for our ESRD products, establishing manufacturing and marketing relationships and establishing our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European Market and the United States upon their approval by appropriate regulatory authorities.

In the first quarter of 2007, we received approval from the U.S. Food and Drug Administration (the "FDA") for our Investigational Device Exemption ("IDE") application for the clinical evaluation of our OLPur H2H module and OLPur MD 220 filter. We have also received the approval from the Institutional Review Board ("IRB") associated with the clinics at which the trials will take place. We obtained approval from Western IRB, Inc. to conduct a clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008.

We have also applied our filtration technologies to water filtration and in 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. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, Ebola virus, ricin toxin, legionella, fungi and e-coli.

We currently have pilot installations of the DSU at several hospitals in the United States. We are actively qualifying distributors nationwide to sell the DSU and they are in the process of completing product evaluations.

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 \$103,000 during the nine months ended September 30, 2008. 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 September 30, 2008.

Since our inception, we have incurred annual net losses. As of September 30, 2008 we had an accumulated deficit of approximately \$87,042,000, and we expect to incur additional losses in the foreseeable future. We recognized net losses of approximately \$5,430,000 for the nine month period ended September 30, 2008, and approximately \$4,663,000 for the nine-month period ended September 30, 2007.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through September 30, 2008, we received net-offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately \$52.0 million in the aggregate. An additional source of financing was our license agreement with Asahi, pursuant to which we received an up front license fee of \$1.75 million in March 2005.

The following trends, events and uncertainties may have a material impact on our potential sales, revenue and income from operations:

- (1) achieving regulatory approval for use of our ESRD therapy products in the United States;
- (2) the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
- (3) our ability to effectively and efficiently manufacture, market and distribute our products;
- (4) our ability to sell our products at competitive prices which exceed our per unit costs; and
- (5) the consolidation of dialysis clinics into larger clinical groups.

To the extent we are unable to succeed in accomplishing (1) through (4), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (5), the impact could either be positive, in the case where dialysis clinics consolidate into independent chains, or negative, in the case where competitors acquire these dialysis clinics and use their own products, as competitors have historically tended to use their own products in clinics they have acquired.

#### **Compliance with the Listing Standards of the NYSE Amerinext U.S. (f/k/a the American Stock Exchange)**

During 2006, we received notices from the American Stock Exchange (together with NYSE Amerinext U.S., following NYSE Euronext's acquisition of the American Stock Exchange, the "AMEX") that we were not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted our failure to comply with Section 1003(a)(i) of the AMEX Company Guide relating to shareholders' equity of less than \$2,000,000 and losses from continuing operations and/or net losses in two out of our three most recent fiscal years; Section 1003(a)(ii) of the AMEX Company Guide relating to shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three out of our four most recent fiscal years; and Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders' equity of less than \$6,000,000 and losses from continuing operations and/or net losses in our five most recent fiscal years. We submitted a plan in August 2006 to advise AMEX of the steps we had taken, and proposed to take, to regain compliance with the applicable listing standards.

On November 14, 2006, we received notice that the AMEX staff had reviewed our plan of compliance to meet the AMEX's continued listing standards and that AMEX would continue our listing while we sought to regain compliance



with the continued listing standards during the period ending January 17, 2008. During the plan period, we were required to provide the AMEX staff with updates regarding initiatives set forth in our plan of compliance. On November 14, 2007, all of our Series A 10% Secured Convertible Notes Due 2008 and our Series B 10% Secured Convertible Notes due 2008 (collectively, the "Notes"), representing an aggregate principal amount of \$18 million, were converted into shares of our common stock and warrants, resulting in an increase in our stockholders' equity. As a result, and notwithstanding our loss during the fourth quarter of 2007, our stockholders' equity at December 31, 2007 was approximately \$8,756,000 and in excess of the \$6,000,000 required by the AMEX rules.

On March 5, 2008, we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiencies referenced in the AMEX's letters dated July 17, 2006 and November 14, 2006.

At June 30, 2008, our stockholders' equity was \$4,814,000, which is less than the applicable AMEX continued listing standard.

On September 12, 2008 we received notice from the AMEX that we were not in compliance with certain conditions of the continued listing standards of Part 10 of the AMEX Company Guide. Specifically, the AMEX noted our failure to comply with Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years. We submitted a plan on October 13, 2008 to advise AMEX of the steps we had taken, and proposed to take, to regain compliance with the applicable listing standards. We have not yet received a response to the compliance plan that we submitted.

Management is considering various approaches to regaining compliance; however, there can be no assurance that we will be successful. In accordance with Section 1009(h) of the AMEX Company Guide, the AMEX may evaluate the relationship between our failures to meet its continued listing standards and truncate its evaluation process or immediately initiate delisting proceedings. If our plan of compliance to meet the AMEX continued listing standards is not accepted by the AMEX, or if we are unable to show progress consistent with our plan of compliance or otherwise unable to timely regain compliance with the AMEX listing standards, then we may be delisted from the AMEX. Furthermore, there can be no assurance that we will not fail to comply with the AMEX rules regarding minimum stockholders' equity or other continued listing standards in the future. If we fail to meet any of these standards, then our common stock may be delisted from the AMEX.

### **Critical Accounting Policies**

We adopted several changes to our critical accounting policies during the first nine months of 2008 as set forth below. 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 unaudited 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-KSB for the year ended December 31, 2007.

In September 2006, the FASB issued SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, the FASB issued FSP 157-2, which delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We adopted SFAS 157 for financial assets and liabilities on January 1, 2008. The disclosures required under SFAS 157 are set forth in Note 9 to our condensed financial statements set forth in Item 1 of this quarterly report. We are currently in the process of evaluating the effect, if any, that the adoption of FSP 157-2 will have on our results of operations or financial position.

### **Results of Operations**

#### *Fluctuations in Operating Results*

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

***Three Months Ended September 30, 2008 Compared to the Three Months Ended September 30, 2007***

*Net Product Revenues*

Net product revenues were approximately \$393,000 for the three months ended September 30, 2008 compared to approximately \$112,000 for the three months ended September 30, 2007, an increase of 251%. The \$281,000 increase in net product revenues is primarily due to an increase of approximately \$231,000 or 206% in sales of the OLpūr MD190 and MD220 Dialyzers in Europe and approximately \$50,000 in revenue generated from the U.S. Defense Department project in the United States which did not begin until 2008.

*Cost of Goods Sold*

Cost of goods sold was approximately \$254,000 for the three months ended September 30, 2008 compared to approximately \$131,000 for the three months ended September 30, 2007. The increase of approximately \$123,000 or 94% in cost of goods sold is primarily due to the 206% increase in sales of the OLpūr MD190 and MD220 Dialyzers in Europe for the 2008 period.

*Research and Development*

Research and development expenses were approximately \$191,000 for the three months ended September 30, 2008 compared to approximately \$298,000 for the three months ended September 30, 2007, a decrease of 36%. This \$107,000 decrease is primarily due to a decrease of approximately \$213,000 in Clinical Trial Expense, which was caused by a reduction during the three months ended September 30, 2008 in a previously accrued related expenditure. This reduction in Clinical Trial Expense was offset by increases of \$43,000 in Salaries, \$59,000 in Supplies, and \$4,000 in Product Development/Testing.

*Depreciation Expense*

Depreciation expense was approximately \$84,000 for the three months ended September 30, 2008 compared to approximately \$86,000 for the three months ended September 30, 2007, a decrease of approximately \$2,000.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$1,242,000 for the three months ended September 30, 2008 compared to approximately \$1,408,000 for the three months ended September 30, 2007, a decrease of approximately \$166,000 or 12%. The decrease is due primarily to reduced Legal Expenses of approximately \$321,000. Legal Expenses were higher in the 2007 period due to the exchange of New Notes for Old Notes and the private placement of additional New Notes that took place in September 2007. The savings in Legal Expenses were partially offset by increases of \$100,000 in Marketing Expenses and \$55,000 in Recruiting Expenses.

*Interest Income*

Interest income was approximately \$27,000 for the three months ended September 30, 2008, compared to approximately \$2,000 for the three months ended September 30, 2007. The increase of approximately \$25,000 is a result of our having in excess of \$3 million in a savings account generating interest income during the three months ended September 30, 2008, compared to none during the comparable period in 2007.

*Interest Expense*

We incurred no interest expense for the three months ended September 30, 2008 because we had no debt during this period. Interest expense totaled approximately \$149,000 for the three months ended September 30, 2007. The prior period interest expense primarily represents approximately \$72,000 for accrued interest liability associated with our 6% Secured Convertible Notes due 2012 (the "Old Notes"), approximately \$50,000 for the accrued interest liability associated with the our 10% Secured Convertible Notes due 2008 (the "New Notes"), approximately \$24,000 associated with the amortization of the debt discount on the New Notes that we issued in exchange for Old Notes on September 19, 2007, and approximately \$3,000 associated with amortization of debt discount on the Old Notes through September 18, 2007. In the fourth quarter of 2007, all of our debt securities, including the New Notes, were converted into equity. For further information regarding the conversion of these debt securities, please refer to Note 7 to our Consolidated Financial Statements in our Annual Report on Form 10-KSB for the year ended December 31, 2007.

*Unrealized Holding Gain - Auction Rate Securities(ARS) and Gain on Sale of Investments*

On July 22, 2008 the Company sold its ARS to a third party at 100% of par value, for proceeds of \$4.1 million. The Company, at June 30, 2008, reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," ("SFAS 115"), the ARS, classified as Trading Securities, were valued at their fair value of \$4.1 million at June 30, 2008. The adjustment of the investment's carrying value from \$3.986 million net book value to \$4.1 million fair value resulted in an Unrealized Holding Gain of approximately \$114,000 which is included in the Company's Statement of Operations for the three and six months ended June 30, 2008.

The Company sold its ARS to a third party at 100% of par value, for proceeds of \$4.1 million on July 22, 2008. The Unrealized Holding Gain of approximately \$114,000 which was included in the Company's Statement of Operations for the three and six months ended June 30, 2008 was reversed and a realized Gain on Sale of Investments of approximately \$114,000 is included in the Company's Statement of Operations for the three and nine months ended September 30, 2008.

#### *Gain on Exchange of Debt*

For the three months ended September 30, 2007, the gain on exchange of debt in the amount of approximately \$330,000 resulted from a gain of approximately \$254,000 on exchange of the Old Notes and a gain of approximately \$76,000 on the cancellation of the warrants that could have been issued upon certain prepayments of the Old Notes by the Company. There was no gain or loss on exchange of debt in the three months ended September 30, 2008.

#### *Other Income and Expenses*

Other income was approximately \$5,000 for the three months ended September 30, 2008 compared to approximately \$166,000 of other income for the three months ended September 30, 2007. The \$166,000 is the net result of approximately \$261,000 for refunds received from New York State for Qualified Emerging Technology Credits ("QETC") and other expenses of approximately \$95,000 for the three months ended September 30, 2007. The prior year other expenses are comprised of the impact of the change in valuation of the derivative liability of approximately \$8,000 and approximately \$87,000 in expenses associated with the collection of the QETC tax refund reported in other income.

#### ***Nine Months Ended September 30, 2008 Compared to the Nine Months Ended September 30, 2007***

#### *Net Product Revenues*

Total net product revenues for the nine months ended September 30, 2008 were approximately \$1,033,000 compared to approximately \$755,000 for the nine months ended September 30, 2007, an increase of 37%. The \$278,000 or 37% increase is primarily due to an increase of approximately \$165,000 or 22% in sales of the OLPur MD190 and MD220 Dialyzers in Europe and revenues in the United States of \$9,000 from the sale of the Dual Stage Ultrafilter (the "DSU") water filtration system. Our DSU represents a new and complementary product line and the Company had no revenues generated from it during the comparable time period in 2007. Approximately \$103,000 in revenue was generated from the U.S. Defense Department project in the United States which did not begin until 2008.

#### *Cost of Goods Sold*

Cost of goods sold was approximately \$654,000 for the nine months ended September 30, 2008 compared to approximately \$581,000 for the nine months ended September 30, 2007. The \$73,000 or 13% increase in cost of goods sold is primarily due to the \$165,000 increase in sales of the OLPur MD190 and MD220 Dialyzers in Europe for the 2008 period.

#### *Research and Development*

Research and development expenses were approximately \$2,072,000 for the nine months ended September 30, 2008 compared to approximately \$1,102,000 for the nine months ended September 30, 2007, an increase of \$970,000 or 88%. This \$970,000 increase is primarily due to the cost of the clinical trial that took place during the nine months ended September 30, 2008. There was no similar clinical trial in 2007.

*Depreciation Expense*

Depreciation expense was approximately \$255,000, for the nine months ended September 30, 2008 compared to approximately \$253,000 for the nine months ended September 30, 2007.. The \$2,000 increase is primarily due to an increase in purchases of long-term assets in the amount of \$63,000 during the nine months ended September 30, 2008.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were approximately \$3,830,000 for the nine months ended September 30, 2008 compared to approximately \$3,697,000 for the nine months ended September 30, 2007, an increase of \$133,000 or 4%. The increase of \$133,000 reflects the Company's investment in Marketing during the 2008 period in order to establish corporate identity, improve the company's website, and advertise the merits of the Dual Stage Ultrafilter (the "DSU") water filtration system. The Company also hired a Vice President of Marketing during the 2008 period and will hire a Vice President of Sales in 2008.

*Interest Income*

Interest income was approximately \$185,000 for the nine months ended September 30, 2008 compared to approximately \$35,000 for the nine months ended September 30, 2007. The increase of approximately \$150,000 resulted from our having cash on hand during the 2008 period that we invested in interest generating investments. We had no excess cash during the comparable period in 2007.

*Interest Expense*

We incurred no interest expense for the nine months ended September 30, 2008 because we had no debt during this period. The interest expense of approximately \$317,000 for the nine months ended September 30, 2007 primarily represents approximately \$228,000 for the accrued interest liability associated with our Old Notes, approximately \$50,000 for the accrued interest liability associated with the New Notes, approximately \$24,000 associated with the amortization of the debt discount on the New Notes that we issued in exchange for New Notes, approximately \$8,000 associated with the amortization of the debt discount on the Old Notes and approximately \$6,000 for the interest portion of the present value of payments we made to the Receiver for Lancer Offshore, Inc. pursuant to certain settlement arrangements. In the fourth quarter of 2007, all of our debt securities, including the New Notes, were converted into equity. We made the final payment under our settlement with the Receiver for Lancer Offshore, Inc. in October 2007.

*Impairment of Auction Rate Securities and Gain on Sale of Investments*

At December 31, 2007 we held \$4.1 million in ARS as a short-term investment. We sold our ARS to a third party on July 22, 2008 for \$4.1 million. We recorded an Unrealized Holding Gain through earnings for the three months ended June 30, 2008 of approximately \$114,000 (the difference between fair value and book value) 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 July 2008 when the sale transaction was executed.

*Gain on Exchange of Debt*

There was no gain or loss on exchange of debt in the nine months ended September 30, 2008. For the nine months ended September 30, 2007, the gain on exchange of debt includes approximately \$330,000 for the gain realized on debt extinguishment which includes a gain on exchange of the Old Notes of approximately \$254,000 and a gain of approximately \$76,000 on the cancellation of the warrants that could have been issued upon certain prepayments of the Old Notes by us.



*Other Income and Expenses*

Other income in the amount of approximately \$163,000 for the nine months ended September 30, 2008 resulted from our receipt of QETC tax refunds. This amount was approximately \$4,000, or 2%, less than other income of approximately \$167,000 for the nine months ended September 30, 2007, which also includes the impact of refunds received from New York State for QETC.

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## Liquidity and Capital Resources

We have incurred losses in our operations in each quarter since inception. We expect to continue to incur losses for at least the short-term. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

As of September 30, 2008, we had approximately \$3.7 million in cash and cash equivalents and approximately \$7,000 in short term investments. We do not currently generate enough revenue through the sale of our products or licensing revenues to meet our expenditure needs on an ongoing basis. There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our indebtedness and to meet our other commitments, then we may be required to adopt alternatives, such as seeking to raise additional debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

Net cash used in operating activities was approximately \$4.3 million for the nine months ended September 30, 2008 compared to approximately \$4.2 million for the nine months ended September 30, 2007. Approximately \$92,000 more cash was used in operating activities during the nine months ended September 30, 2008 than in the nine months ended September 30, 2007. This was primarily due to:

- During the 2008 period, our net loss increased by approximately \$767,000;
- During the 2008 period, adjustments to net loss were approximately \$127,000 higher than during the 2007 period;
- During the 2008 period, our decrease in current assets was approximately \$166,000 lower than during the 2007 period; and
- During the 2008 period, our increase in current liabilities was approximately \$714,000 higher than during the 2007 period due to higher operating expenses in the 2008 period as compared to the 2007 period.

Net cash provided by investing activities was approximately \$4,630,000 for the nine months ended September 30, 2008, compared to net cash used in investing activities of approximately \$1,202,000 for the nine months ended September 30, 2007. Our net cash provided by investing activities for the nine months ended September 30, 2008 reflects the proceeds from the sales of auction rate securities of approximately \$4,100,000 plus maturities of short-term investments net of purchases in the amount of approximately \$593,000 partially offset by approximately \$63,000 for purchases of computer equipment. For the nine months ended September 30, 2007, our \$1,202,000 net cash used in investing activities reflects purchases of \$4,000,000 of auction rate securities and purchases of \$2,000 of equipment, partially offset by the maturities of short-term investments in the amount of approximately \$2,800,000.

## Certain Risks and Uncertainties

Our Annual Report on Form 10-KSB for the year ended December 31, 2007 includes a detailed discussion of our risk factors under the heading "Certain Risks and Uncertainties." The information presented below updates and should be read in conjunction with the risk factors and information disclosed in such Form 10-KSB.

***We may not be able to meet the continued listing standards of the NYSE Amerinext U.S. (f/k/a the American Stock Exchange) and as a result, our Common Stock may be delisted from such exchange.***

During 2006, we received notices from the American Stock Exchange (together with NYSE Amerinext U.S., following NYSE Euronext's acquisition of the American Stock Exchange, the "AMEX") that we are not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted our failure to comply with Section 1003(a)(i) of the AMEX Company Guide relating to minimum shareholders' equity requirements. We submitted a plan in August 2006 to advise AMEX of the steps we had taken, and would take, to regain compliance with the applicable listing standards. On November 14, 2006, we received notice that the AMEX staff had reviewed our plan of compliance to meet the AMEX's continued listing standards and that AMEX will continue our listing while we seek to regain compliance with the continued listing standards during the period ending January 17, 2008.

On November 14, 2007, all of our Series A 10% Secured Convertible Notes Due 2008 and our Series B 10% Secured Convertible Notes due 2008 (collectively, the "Notes"), representing an aggregate principal amount of \$18 million, were converted into shares of our common stock and warrants, resulting in an increase in our stockholders' equity. As a result, and notwithstanding our loss during the fourth quarter of 2007, our stockholders' equity at December 31, 2007 was approximately \$8,756,000 and in excess of the \$6,000,000 required by the AMEX rules. On March 5, 2008, we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiencies referenced in the AMEX's letters dated July 17, 2006 and November 14, 2006.

At June 30, 2008, our stockholders' equity was \$4,814,000, which is less than the applicable AMEX continued listing standard. On September 12, 2008 we received notice from the AMEX that we were not in compliance with certain conditions of the continued listing standards of Part 10 of the AMEX Company Guide. Specifically, AMEX noted our failure to comply with Section 1003(a)(iii) of the AMEX Company Guide relating to shareholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years. We submitted a plan on October 13, 2008 to advise AMEX of the steps we had taken, and proposed to take, to regain compliance with the applicable listing standards. We have not yet received a response to the submitted plan.

In accordance with Section 1009(h) of the AMEX Company Guide, the AMEX may evaluate the relationship between our failures to meet its continued listing standards and truncate its evaluation process or immediately initiate delisting proceedings. Furthermore, there can be no assurance that we will not fail to comply with the AMEX rules regarding minimum stockholders' equity or other continued listing standards in the future. If we fail to meet any of these standards, then our common stock may be delisted from the AMEX.

If our plan of compliance to meet the AMEX continued listing standards is not accepted by the AMEX, or if we are unable to show progress consistent with our plan of compliance or otherwise unable to timely regain compliance with the AMEX listing standards, then we may be delisted from the AMEX. If our Common Stock is delisted by the AMEX, then the market liquidity for our Common Stock would likely be negatively affected, which may make it more difficult for holders of our Common Stock to sell their securities in the open market and we could face difficulty raising capital necessary for our continued operation. Investors may find it more difficult to dispose of or obtain accurate quotations as to the market value of our securities.

In addition, our Common Stock, if delisted by the AMEX, may constitute "penny stock" (as defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934, as amended) if we fail to meet certain criteria set forth in such Rule. Various practice requirements are imposed on broker-dealers who sell "penny stocks" to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transactions prior to sale. Consequently, if our Common Stock were to become "penny stock," then the Rule may deter broker-dealers from recommending or selling our Common Stock, which could further negatively affect the liquidity of our Common Stock.

### **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," "p," "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 be unable to maintain compliance with the AMEX's continued listing standards and, as a result, we may be delisted from the AMEX;
- 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-KSB for the fiscal year ended December 31, 2007 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](http://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 and nine month periods ended September 30, 2008 and 2007.

#### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Due to our status as a smaller reporting company, this Item is not required.

#### **Item 4T. Controls and Procedures.**

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end

of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures have not been operating effectively as of the end of the period covered by this report.

In connection with the preparation of our Annual Report of Form 10-KSB, 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. Due to the pervasive effect of the lack of resources, including a lack of resources that are appropriately qualified in the areas of U.S. GAAP and SEC reporting, and the potential impact on the financial statements and disclosures and the importance of the annual and interim financial closing and reporting process, in the aggregate, there is more than a remote likelihood that a material misstatement of the annual financial statements would not have been prevented or detected.

*Remediation Plans*

Management is in the process of remediating the above-mentioned weakness in our internal control over financial reporting and is implementing the following steps:

- Develop procedures to implement a formal monthly closing process and hold monthly meetings to address the monthly closing process;
- Establish a detailed timeline for review and completion of financial reports to be included in our Forms 10-Q and 10-K;
- Enhance the level of service provided by outside accounting service providers to further support and supplement our internal staff in accounting and related areas; and
- Employ 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.

The implementation of these remediation plans has been initiated and will continue during the remainder of fiscal 2008. The material weakness will not be considered remediated until the applicable remedial procedures are tested and management has concluded that the procedures are operating effectively. Management recognizes that use of our financial resources will be required not only for implementation of these measures, but also for testing their effectiveness.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



**PART II - OTHER INFORMATION**

**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 September 30, 2008.

**Item 6. Exhibits.**

**EXHIBIT INDEX**

- 10.1 Separation Agreement and Release, dated as of September 15, 2008, between Nephros, Inc. and Norman J. Barta.
- 10.2 Employment Agreement, dated as of September 15, 2008, between Nephros, Inc. and Ernest A. Elgin III.
- 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: November 14, 2008

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

Date: November 14, 2008

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

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