

NEPHROS INC  
Form 10QSB  
November 15, 2006

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

**FORM 10-QSB**

(Mark One)

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

For the quarterly period ended September 30, 2006  
OR

TRANSITION REPORT UNDER 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 Small Business Issuer as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

13-397 1809

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

3960 Broadway

New York, NY 10032

(Address of Principal Executive Offices)

(212) 781-5113

(Registrant's telephone number,  
including area code)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

| <b>Class</b>                   | <b>Outstanding at<br/>November 14, 2006</b> |
|--------------------------------|---|
| Common Stock, \$.001 par value | 12,317,992                                  |

Transitional Small Business

Disclosure Format: YES [ ] NO [X]

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**NEPHROS, INC. AND SUBSIDIARY**

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements.

**NEPHROS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(unaudited)

|  | September 30,<br>2006 | December 31,<br>2005 |
|--|-----------------------|----------------------|
| <b>ASSETS</b>  |                       |                      |
| Current assets:  |                       |                      |
| Cash and cash equivalents  | \$ 923,957            | \$ 746,581           |
| Short-term investments   | 3,800,000             | 4,500,000            |
| Accounts receivable, less allowances: 2006: \$37,157; 2005: \$18,697 | 472,944               | 244,100              |
| Inventory  | 463,442               | 814,548              |
| Prepaid expenses and other current assets                            | 380,905               | 358,306              |
| Total current assets   | 6,041,248             | 6,663,535            |
| Property and equipment, net  | 943,061               | 1,143,309            |
| Other assets   | 17,732                | 17,731               |
| Total assets   | \$ 7,002,041          | \$ 7,824,575         |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                          |                       |                      |
| Current liabilities:   |                       |                      |
| Accounts payable   | \$ 762,260            | \$ 766,158           |
| Accrued expenses   | 273,020               | 451,109              |
| Accrued severance expense  | -                     | 318,250              |
| Note payable - short-term portion                                    | 379,751               | 295,838              |
| Total current liabilities  | 1,415,032             | 1,831,355            |
| Convertible notes payable  | 5,210,860             | -                    |
| Accrued interest - convertible notes                                 | 103,430               | -                    |
| Note payable - long-term portion                                     | 184,025               | 613,727              |
| Total liabilities  | 6,913,347             | 2,445,082            |
| Stockholders' equity:  |                       |                      |
| Common stock   | 12,318                | 12,313               |
| Additional paid-in capital   | 53,114,329            | 54,848,711           |
| Deferred compensation  | -                     | (2,189,511)          |
| Accumulated other comprehensive loss                                 | (36,694)              | (49,137)             |
| Accumulated deficit  | (53,001,259)          | (47,242,883)         |
| Total stockholders' equity   | 88,694                | 5,379,493            |
| Total liabilities and stockholders' equity                           | \$ 7,002,041          | \$ 7,824,575         |

See accompanying notes to the condensed consolidated financial statements



## NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(unaudited)

|   | Three Months Ended<br>September 30 |                | Nine Months Ended<br>September 30 |                |
|---|------------------------------------|----------------|-----------------------------------|----------------|
|   | 2006                               | 2005           | 2006                              | 2005           |
| Contract revenues   | \$ -                               | \$ -           | \$ -                              | \$ 1,750,000   |
| Net product revenues  | 164,699                            | 225,248        | 641,115                           | 603,339        |
| Net revenues  | 164,699                            | 225,248        | 641,115                           | 2,353,339      |
| Cost of goods sold  | 202,839                            | 151,646        | 810,677                           | 400,695        |
| Gross (loss) profit   | (38,140)                           | 73,602         | (169,562)                         | 1,952,644      |
| Operating expenses:   |                                    |                |                                   |                |
| Research and development  | 544,505                            | 401,873        | 1,444,281                         | 1,415,584      |
| Depreciation expense  | 64,223                             | 75,345         | 224,250                           | 230,050        |
| Selling, general and administrative                                     | 1,256,354                          | 1,404,660      | 3,965,817                         | 4,658,975      |
| Total operating expenses  | 1,865,082                          | 1,881,878      | 5,634,348                         | 6,304,609      |
| Loss from operations  | (1,903,222)                        | (1,808,276)    | (5,803,910)                       | (4,351,965)    |
| Interest income   | 116,014                            | 60,394         | 163,855                           | 178,863        |
| Interest expense  | 113,494                            | -              | 113,494                           | -              |
| Other expense   | 4,826                              | -              | 4,826                             | -              |
| Net loss  | \$ (1,905,528)                     | \$ (1,747,882) | \$ (5,758,375)                    | \$ (4,173,102) |
| Basic and diluted net loss per<br>common shares                         | \$ (0.15)                          | \$ (0.14)      | \$ (0.47)                         | \$ (0.34)      |
| Shares used in computing basic and<br>diluted net loss per common share | 12,317,992                         | 12,307,089     | 12,316,773                        | 12,254,753     |

See accompanying notes to the condensed consolidated financial statements

## NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(unaudited)

|   | <b>Nine Months Ended September 30,</b> |                |
|---|--|----------------|
|   | <b>2006</b>                            | <b>2005</b>    |
| Operating activities:   |  |                |
| Net loss  | \$ (5,758,375)                         | \$ (4,173,102) |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |                |
| Depreciation  | 224,250                                | 229,828        |
| Loss on disposal of equipment   | 24,293                                 | -              |
| Amortization of debt discount   | 3,939                                  | -              |
| Noncash stock-based compensation  | 453,693                                | 326,458        |
| (Increase) decrease in operating assets:                                    |  |                |
| Accounts receivable   | (181,076)                              | (54,813)       |
| Inventory   | 387,087                                | 184,445        |
| Prepaid expenses and other current assets                                   | (490)                                  | (248,800)      |
| Increase (decrease) in operating liabilities:                               |  |                |
| Accounts payable and accrued expenses                                       | (614,736)                              | 267,987        |
| Accrued severance expense   | (335,402)                              | -              |
| Accrued interest-convertible notes  | 103,430                                | -              |
| Deferred revenue  | -                                      | (64,058)       |
| Net cash used in operating activities                                       | (5,693,387)                            | (3,532,055)    |
| Investing activities  |  |                |
| Purchase of property and equipment  | (32,776)                               | (228,990)      |
| Purchase of short-term investments  | (3,000,000)                            | -              |
| Maturities of short-term investments  | 3,700,000                              | -              |
| Net cash provided by (used in) investing activities                         | 667,224                                | (228,990)      |
| Financing activities  |  |                |
| Proceeds from private placement of common stock                             | -                                      | 955,521        |
| Proceeds from private placement of convertible notes                        | 5,206,921                              | -              |
| Adjustment to proceeds from IPO of common stock                             | -                                      | 44,361         |
| Proceeds from exercise of stock options                                     | 1,441                                  | 1,439          |
| Net cash provided by financing activities                                   | 5,208,362                              | 1,001,321      |
| Effect of exchange rates on cash  | (4,824)                                | (130,514)      |
| Net increase (decrease) in cash and cash equivalents                        | 177,375                                | (2,890,238)    |
| Cash and cash equivalents, beginning of period                              | 746,581                                | 3,719,181      |
| Cash and cash equivalents, end of period                                    | \$ 923,957                             | \$ 828,943     |

Supplemental disclosure of cash flow information

|                     |    |        |    |        |
|---------------------|----|--------|----|--------|
| Cash paid for taxes | \$ | 32,283 | \$ | 11,630 |
|---------------------|----|--------|----|--------|

See accompanying notes to the condensed consolidated financial statements



## NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
(unaudited)

|   | Common Stock |           | Additional         | Deferred       | Accumulated<br>Other<br>Comprehensive | Accumulated     | Total        |
|---|--------------|-----------|--------------------|----------------|---------------------------------------|-----------------|--------------|
|   | Shares       | Amount    | Paid-in<br>Capital | Compensation   | Loss                                  | Deficit         |              |
| Balance, December 31, 2005                            | 12,313,494   | \$ 12,313 | \$ 54,848,711      | \$ (2,189,511) | \$ (49,137)                           | \$ (47,242,883) | \$ 5,379,493 |
| Comprehensive loss:                                   |              |           |                    |                |                                       |                 |              |
| Net loss  |              |           |                    |                |                                       | (5,758,375)     | (5,758,375)  |
| Net unrealized losses on foreign currency translation |              |           |                    |                | 12,443                                |                 | 12,443       |
| Comprehensive loss                                    |              |           |                    |                |                                       |                 | (5,745,932)  |
| Reclassification of deferred compensation             |              |           | (2,189,511)        | 2,189,511      |                                       |                 | -            |
| Noncash stock-based compensation                      |              |           | 453,693            |                |                                       |                 | 453,693      |
| Exercise of stock options                             | 4,498        | 5         | 1,436              |                |                                       |                 | 1,441        |
| Balance, September 30, 2006                           | 12,317,992   | \$ 12,318 | \$ 53,114,329      | \$ -           | \$ (36,694)                           | \$ (53,001,259) | \$ 88,694    |

See accompanying notes to the condensed consolidated financial statements

**NEPHROS, INC. AND SUBSIDIARY**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the periods ended September 30, 2006 and 2005**  
**(unaudited)**

**1. Basis of Presentation and Going Concern**

The accompanying unaudited condensed consolidated financial statements of Nephros, Inc. and its wholly owned subsidiary, Nephros International, Limited, (together the "Company") should be read in conjunction with the audited financial statements and notes thereto included in the Company's 2005 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission (the "SEC") on April 20, 2006. 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-QSB. 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. 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 interim periods presented. Interim results are not necessarily indicative of results for a full year. All inter-company transactions have been eliminated in consolidation. Accrued severance expense as of December 31, 2005 was reclassified from total accrued expenses and presented separately on the balance sheet to be consistent with the current period presentation.

For the nine months ended September 30, 2006 and 2005, the following customers accounted for the following percentages of the Company's sales, respectively. The Company believes that the loss of any of these customers could have a material adverse effect on the Company's product sales, at least temporarily, while the Company seeks to replace such customers and/or self-distribute in the territories currently served by such customers.

| <b>Customer</b> | <b>2006</b> | <b>2005</b> |
|-----------------|-------------|-------------|
| <b>A</b>        | 63%         | 41%         |
| <b>B</b>        | 20%         | 3%          |

As of September 30, 2006 and 2005, the following customers accounted for the following percentages of the Company's accounts receivable, respectively. The Company believes that the loss of these customers could have a material adverse effect on the Company's product sales, at least temporarily, while the Company seeks to replace such customers and/or self-distribute in the territories currently served by such customers.

| <b>Customer</b> | <b>2006</b> | <b>2005</b> |
|-----------------|-------------|-------------|
| <b>A</b>        | 71%         | 65%         |
| <b>C</b>        | 12%         | 11%         |

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 raises substantial doubt about its ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on the Company's current cash flow projections, and in order to comply with the American Stock Exchange's continued listing standards, the Company will need to raise additional funds through either the licensing of its technologies or the additional public or private offerings of its securities. However, there is no guarantee that the

Company will be able to obtain further financing. If the Company is unable to raise additional funds on a timely basis or at all, the Company would be adversely affected. The Company is exploring various options in respect of raising additional funds.

## **2. Stock Based Compensation**

The Company has adopted Statement of Financial Accounting Standards (“SFAS”) No. 123 (Revised 2004), “Share-Based Payment” (“SFAS 123R”), effective January 1, 2006. SFAS 123R requires the recognition of

compensation expense in an amount equal to the fair value of all share-based payments granted to employees. The Company has elected the modified prospective transition method and therefore adjustments to prior periods are not required as a result of adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted after the date of adoption and to any unrecognized expense of awards unvested at the date of adoption based on the grant date fair value. SFAS 123R also amends SFAS No. 95, "Statement of Cash Flows," to require that excess tax benefits that had been reflected as operating cash flows be reflected as financing cash flows. Deferred compensation of \$2,189,511 related to the awards granted in periods prior to January 1, 2006 were reclassified against additional paid-in capital, as required by SFAS 123R.

Prior to the Company's initial public offering, options were granted to employees, non-employees and non-employee directors at exercise prices which were lower than the fair market value of the Company's stock on the date of grant. After the date of the Company's initial public offering, stock options are granted to employees, non-employees and non-employee directors at exercise prices equal to the fair market value of the Company's stock on the date of grant. Stock options granted have a life of 10 years and vest upon a combination of the following: immediate vesting; straight line vesting of two, three, or four years; and upon the achievement of certain milestones.

Expense is recognized, net of expected forfeitures, over the vesting period of the options. For options that vest upon the achievement of certain milestones, expense is recognized when it is probable that the condition will be recognized. Stock based compensation expense recognized for the three and nine months ended September 30, 2006 was approximately \$80,616 or \$0.01 per share and \$453,693 or \$0.04 per share, respectively.

Fair values for the first nine months of 2006 and 2005 were estimated using the Black-Scholes option-pricing model, based on the following assumptions:

|                                     | <b>Nine Months Ended</b> |             |
|-------------------------------------|--------------------------|-------------|
|                                     | <b>September 30,</b>     |             |
|                                     | <b>2006</b>              | <b>2005</b> |
| Expected volatility                 | 65% to 92%               | 80%         |
| Risk-free interest rate             | 4.3% to<br>5.0%          | 4.0%        |
| Expected life of options (in years) | 5.8 to 6.0               | 7.0         |

There is no expected dividend yield. Expected volatility is based on historical volatility of the Company's common stock at the time of grant. The risk-free interest rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected life of the options. For the expected life, the Company is using the simplified method as described in the SEC Staff Accounting Bulletin 107. This method assumes that stock option grants will be exercised based on the average of the vesting periods and the grant's life.

Stock-based employee compensation for the three and nine months ended September 30, 2005 was determined using the intrinsic value method. The following table provides supplemental information for the three and nine months ended September 30, 2005 as if stock-based compensation had been computed under SFAS 123:

|  | <b>Three Months<br/>Ended<br/>September 30,<br/>2005</b> | <b>Nine Months<br/>Ended<br/>September 30,<br/>2005</b> |
|--|--|---|
| Net loss as reported   | \$ (1,747,882)   | \$ (4,173,102)  |
| Add back: compensation expense recorded under the intrinsic method | 35,566   | 326,458   |

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|  |    |             |    |             |
|--|----|-------------|----|-------------|
| Deduct: compensation expense under the fair value method |    | (161,862)   |    | (675,728)   |
| Pro forma net loss using the fair value method           | \$ | (1,874,178) | \$ | (4,522,372) |
| Net loss per share:                                      |    |             |    |             |
| As reported  | \$ | (0.14)      | \$ | (0.34)      |
| Pro forma  | \$ | (0.15)      | \$ | (0.37)      |

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The Company granted stock options to purchase an aggregate of 650,500 shares of common stock during the nine-month period ended September 30, 2006. The weighted average fair value per share of the stock options granted in the nine-month period ended September 30, 2006 was \$1.14. The Company granted stock options to purchase an aggregate of 450,000 share of common stock in the three-month period ended September 30, 2006. The weighted average fair value per share of the stock options granted in the three-month period ended September 30, 2006 was \$0.97. The Company granted 65,000 stock options in the nine-month period ended September 30, 2005. The weighted average fair value per share of the stock options granted in the nine-month period ended September 30, 2005 was \$2.00. The Company did not grant any stock options in the three-month period ended September 30, 2005.

The total fair value of options vested during the three and nine-month periods ended September 30, 2006, was \$54,563 and \$389,036 respectively. Such amounts are recorded in selling, general and administrative expense and research and development. As of September 30, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$1,887,304. Of this amount, \$640,643 will be amortized over the weighted-average remaining requisite service period of 1.7 years and \$1,246,661 will be recognized upon the attainment of related milestones.

The following table summarizes stock option activity for the nine-month period ended September 30, 2006:

|                                   | <b>Number of<br/>options</b> |    | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
|-----------------------------------|------------------------------|----|--|
| At January 1, 2006                | 1,884,537                    | \$ | 1.91   |
| Granted                           | 650,500                      |    | 1.14   |
| Exercised                         | (4,498)                      |    | 0.32   |
| Canceled or expired               | (202,573)                    |    | 2.65   |
| Outstanding at September 30, 2006 | 2,327,966                    | \$ | 1.75   |
| Exercisable at September 30, 2006 | 1,387,611                    | \$ | 1.54   |

The aggregate intrinsic value of stock options outstanding at September 30, 2006 was \$355,591. The aggregate intrinsic value of stock options currently exercisable at September 30, 2006 was \$355,591. Intrinsic value for stock options is calculated based on the exercise price of the underlying awards as compared to the quoted price of the Company's common stock as of the reporting date. There were no tax benefits recognized related to stock-based compensation and related cash flow impacts during the first nine months of 2006, as the Company is in a net operating loss position.

### 3. Loss per Common Share

In accordance with SFAS No. 128, "Earnings Per Share," net loss per common share amounts ("basic EPS") were 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 where basic EPS is negative, the Company has excluded stock options and warrants exercisable to purchase in the aggregate 2,719,732 common shares from the computation of diluted EPS for each of the three and nine month periods ended September 30, 2006 and 2,310,359 common shares for each of the three and nine month periods ended September 30, 2005.



**NEPHROS, INC. AND SUBSIDIARY****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****For the periods ended September 30, 2006 and 2005 (unaudited)****(continued)****4. Inventory**

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, 2006 and December 31, 2005 was as follows:

|                 | <b>September<br/>30, 2006</b> | <b>December<br/>31, 2005</b> |
|-----------------|-------------------------------|------------------------------|
| Raw Materials   | \$ 187,006                    | \$ 153,299                   |
| Finished Goods  | 276,436                       | 661,249                      |
| Total Inventory | \$ 463,442                    | \$ 814,548                   |

**5. Convertible Notes due 2012**

In June 2006, the Company entered into subscription agreements with certain investors who purchased an aggregate of \$5,200,000 principal amount of 6% Secured Convertible Notes due 2012 (the "Notes") issued by the Company for the face value thereof. The Company closed on the sale of the first tranche of Notes, in an aggregate principal amount of \$5,000,000, on June 1, 2006 (the "First Tranche") and closed on the sale of the second tranche of Notes, in an aggregate principal amount of \$200,000, on June 30, 2006 (the "Second Tranche"). The Notes are secured by substantially all of the Company's assets.

The Notes accrue interest at a rate of 6% per annum, compounded annually and payable in arrears at maturity. Subject to certain restrictions, principal and accrued interest on the Notes are convertible at any time at the holder's option into shares of the Company's common stock, at an initial conversion price of \$2.10 per share (subject to anti-dilution adjustments upon the occurrence of certain events). There is no cap on any increases to the conversion price. The conversion price may not be adjusted to an amount less than \$0.001 per share, the current par value of the Company's common stock. The Company may cause the Notes to be converted at their then effective conversion price, if the common stock achieves average last sales prices of at least 240% of the then effective conversion price and average daily volume of at least 35,000 shares (subject to adjustment) over a prescribed time period. In the case of an optional conversion by the holder or a compelled conversion by the Company, the Company has 15 days from the date of conversion to deliver certificates for the shares of common stock issuable upon such conversion. As further described below, conversion of the Notes is restricted, pending stockholder approval.

The Company may prepay outstanding principal and interest on the Notes at any time. Any prepayment requires the Company to pay each holder a premium equal to 15% of the principal amount of the Notes held by such holder receiving the prepayment if such prepayment is made on or before June 1, 2008, and 5% of the principal amount of the Notes held by such holder receiving prepayment in connection with prepayments made thereafter. In addition to the applicable prepayment premium, upon any prepayment of the Notes occurring on or before June 1, 2008, the Company must issue the holder of such Notes warrants ("Prepayment Warrants") to purchase a quantity of common stock equal to three shares for every \$20 principal amount of Notes prepaid at an exercise price of \$0.01 per share (subject to adjustment). Upon issuance, the Prepayment Warrants would expire on June 1, 2012.





**NEPHROS, INC. AND SUBSIDIARY**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**For the periods ended September 30, 2006 and 2005 (unaudited)**

**(continued)**

Unless and until its stockholders approve the issuance of shares of common stock in excess of such amount, the number of shares of common stock issuable upon conversion of the First Tranche of Notes and exercise of the Prepayment Warrants related thereto, in the aggregate, is limited to 2,451,280 shares, which equals approximately 19.9% of the number of shares of common stock outstanding immediately prior to the issuance of the Notes. The Company will not issue any shares of common stock upon conversion of the Second Tranche of Notes or exercise of any Prepayment Warrants that may be issued pursuant to such Notes until its stockholders approve the issuance of shares of common stock upon conversion of the Notes and exercise of the Prepayment Warrants as may be required by the applicable rules and regulations of the American Stock Exchange (the "AMEX").

In connection with the sale of the Notes, the Company has entered into a registration rights agreement with the investors pursuant to which the Company granted the investors two demand registration rights and unlimited piggy-back and short-form registration rights with respect to the shares of common stock issuable upon conversion of the Notes or exercise of Prepayment Warrants, if any.

Subject to terms and conditions set forth in the Notes, the outstanding principal of and accrued interest on the Notes may become immediately due and payable upon the occurrence of any of the following events of default: the Company's failure to pay principal or interest on the Notes when due; certain bankruptcy-related events with respect to the Company; material breach of any representation, warranty or certification made by the Company in or pursuant to the Notes, or under the registration rights agreement or the subscription agreements; its incurrence of Senior Debt (as defined in the Notes); the acceleration of certain of the Company's other debt; or the rendering of certain judgments against the Company.

The Notes contain a prepayment feature that requires the Company to issue common stock purchase warrants to the Note holders for partial consideration of certain Note prepayments that the Note holders may demand under certain circumstances. Pursuant to the Notes, the Company must offer the Note holders the option (the "Holder Prepayment Option") of prepayment (subject to applicable premiums) of their Notes, if the Company completes an asset sale in excess of \$250,000 outside the ordinary course of business (a "Major Asset Sale"), to the extent of the net cash proceeds of such Major Asset Sale. Paragraph 12 of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", ("SFAS 133"), provides that an embedded derivative shall be separated from the host contract and accounted for as a derivative instrument if and only if certain criteria are met. In consideration of SFAS 133, the Company has determined that the Holder Prepayment Option is an embedded derivative to be bifurcated from the Notes and carried at fair value in the financial statements. At June 1, 2006 the value of the embedded derivative was a liability of approximately \$71,000. The Company reassesses the valuation of the Holder Prepayment Option quarterly.

At September 30, 2006, the value of the embedded derivative was a liability of approximately \$78,000. The change in value was recorded as other expense during the quarter. Also, the debt discount, of approximately \$71,000, created by bifurcating the Holder Prepayment Option, is being amortized over the term of the debt. During the quarter ended September 30, 2006, the Company recorded interest expense of approximately \$4,000.

**6. Commitments and Contingencies**

**Settlement Agreements**

In April 2002, the Company entered into a letter agreement with Hermitage Capital Corporation (“Hermitage”), as placement agent, the stated term of which was from April 30, 2002 through September 30, 2004. As of February 2003, the Company entered into a settlement agreement with Hermitage pursuant to which, among

other things: the letter agreement was terminated; the parties gave mutual releases relating to the letter agreement, and the Company agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between the Company and Lancer Offshore, Inc. (“Lancer”), warrants exercisable until February 2006 to purchase an aggregate of 60,000 shares of common stock for \$2.50 per share (or 17,046 shares of the Company’s common stock for \$8.80 per share, adjusted for the reverse stock split effected by the Company on September 10, 2004, pursuant to the antidilution provisions of such warrant, as amended.) Because Lancer never satisfied the closing conditions and, consequently, a closing has not been held, the Company has not issued any warrants to Hermitage in connection with the Company’s settlement with them. In June 2004, Hermitage threatened to sue the Company for warrants it claimed were due to it under its settlement agreement with the Company as well as a placement fee and additional warrants it claimed were, or would be, owed in connection with the Company’s initial public offering completed on September 24, 2004, as compensation for allegedly introducing the Company to one of the underwriters. The Company had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. The Company has not heard from Hermitage since then. As of September 30, 2006, no loss amount has been accrued because a loss is not considered probable or estimable.

In June 2002, the Company entered into a settlement agreement with one of its suppliers. The Company had an outstanding liability to such supplier in the amount of approximately \$1,900,000. Pursuant to this settlement agreement, the Company and the supplier agreed to release each other from any and all claims or liabilities, whether known or unknown, that each had against the other as of the date of the settlement agreement, except for obligations arising out of the settlement agreement itself. The settlement agreement required the Company to grant to the supplier (i) warrants to purchase 170,460 shares of common stock of the Company at an exercise price of approximately \$10.56 per share that expire in June 2007 and (ii) cash payments of an aggregate amount of \$650,000 in three installments. The warrants were valued at \$400,000 using the Black-Scholes model. Accordingly, the Company recorded a gain of approximately \$850,000 based on such settlement agreement. On June 19, 2002, the Company issued the warrant to the supplier, and on August 7, 2002, the Company satisfied the first \$300,000 installment of the agreement. The second installment of \$100,000 was due on February 7, 2003, and the Company paid \$75,000 towards the installment. On November 11, 2004, after the successful closing of its initial public offering, the Company paid an additional \$25,000 and agreed with the supplier to pay the remaining \$250,000 over time. The outstanding balance at September 30, 2006 was \$100,000 and is included in “Accounts Payable” on the condensed consolidated balance sheet. As agreed with the supplier, the Company will retire the remaining balance by making four quarterly payments each in the amount of \$25,000.

In August 2002, the Company entered into a subscription agreement with Lancer. The subscription agreement provided, among other things, that Lancer would purchase, in several installments, (1) \$3,000,000 principal amount of secured notes due March 15, 2003 convertible into 340,920 shares of the Company’s common stock and (2) warrants to purchase until December 2007 an aggregate of 68,184 shares of the Company’s common stock at an exercise price of approximately \$8.80 per share. In accordance with the subscription agreement, the first installment of securities, consisting of \$1,500,000 principal amount of the notes and 34,092 of the warrants (which 34,092 warrants had nominal value at such time), were tendered. However, Lancer failed to fund the remaining installments. Following this failure, the Company entered into a settlement agreement with Lancer dated as of January 31, 2003, pursuant to which, (i) the parties terminated the subscription agreement; (ii) Lancer agreed to surrender 12,785 of the original 34,092 warrants issued to it; (iii) the warrants that were not surrendered were amended to provide that the exercise price per share and the number of shares issuable upon exercise thereof would not be adjusted as a result of a 0.2248318-for one reverse stock split of the Company’s common stock that was contemplated at such time but never consummated; and (iv) the secured convertible note in the principal amount of \$1,500,000 referred to above was cancelled. Lancer agreed, among other things, to deliver to the Company at or prior to a subsequent closing the cancelled note and warrants and to reaffirm certain representations and warranties and, subject to the satisfaction of these and other conditions, the Company agreed to issue to Lancer at such subsequent closing an unsecured note in the principal amount of \$1,500,000 bearing no interest, not convertible into common stock and due on January 31, 2004 or earlier under certain circumstances. Lancer never fulfilled the conditions to the subsequent closing and,

accordingly, the Company never issued the \$1,500,000 note that the settlement agreement provided would be issued at such closing.

**NEPHROS, INC. AND SUBSIDIARY**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**For the periods ended September 30, 2006 and 2005 (unaudited)**

**(continued)**

The above transaction resulted in the Company becoming a defendant in an action captioned Marty Steinberg, Esq. as Receiver for Lancer Offshore, Inc. v. Nephros, Inc., Case No. 04-C V-20547, that was commenced on March 8, 2004, in the U.S. District Court for the Southern District of Florida (the "Ancillary Proceeding"). That action was ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No.03-CV-80612, pending in the U.S. District Court for the Southern District of Florida, in which the court had appointed a Receiver to manage Lancer and various related entities (the "Receivership"). In the Ancillary Proceeding, the Receiver sought payment of \$1,500,000, together with interest, costs and attorneys' fees, as well as delivery of a warrant evidencing the right to purchase until December 2007 an aggregate of 75,000 shares of the Company's common stock for \$2.50 per share (or 21,308 shares of the Company's common stock for \$8.80 per share, if adjusted for the 0.2841-for-one reverse stock split the Company effected on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended). On or about April 29, 2004, the Company served an answer in which it denied liability for, and asserted numerous defenses to, the Receiver's claims. In addition, on or about March 30, 2004, the Company asserted claims for damages against Lancer Offshore, Inc. that exceeded the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership.

On December 19, 2005, the U.S. District Court for the Southern District of Florida approved the Stipulation of Settlement with respect to the Ancillary Proceeding dated November 8, 2005 (the "Settlement"). Pursuant to the terms of the Settlement, the Company agreed to pay the Receiver an aggregate of \$900,000 under the following payment terms: \$100,000 paid on January 5, 2006; and four payments of \$200,000 each at six month intervals thereafter. In addition, any warrants previously issued to Lancer were cancelled, and, on January 18, 2006, the Company issued to the Receiver warrants to purchase 21,308 shares of the Company's common stock at \$1.50 per share exercisable until January 18, 2009.

The Company had reserved for the Ancillary Proceeding on its balance sheet as of December 31, 2004 as a \$1,500,000 accrued liability. As a result of the above Settlement the Company has adjusted such accrued liability and recorded a note payable to the Receiver to reflect the present value, as of September 30, 2006, of the above amounts due to the Receiver of \$563,727, of which \$379,702 is reflected as short-term note payable and \$184,025 reflected as a long-term note payable. Additionally, the Company recorded the issuance of the warrants issued at their fair market value of \$17,348 based on a Black-Scholes calculation. Such Settlement resulted in a gain of \$623,087 recorded in the fourth quarter of 2005.

**Employee Severance Agreement**

During the year ended December 31, 2005, the Company expensed \$318,250 for severance costs associated with the termination of the employment of Jan Rehnberg, our former Senior Vice President, Marketing and Sales. These severance expenses were reported within accrued expenses and presented as accrued severance expenses at December 31, 2005. In accordance with the terms and provisions of his employment agreement, the Company paid a lump sum severance payment of \$253,856 of the balance to Mr. Rehnberg on April 19, 2006. During the three months ended September 30, 2006, the Company reversed the \$64,394 residual portion of the severance accrual as it was determined during the quarter that this liability was no longer required.

**7. Notification from the American Stock Exchange**

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On July 17, 2006, the Company received notice from the staff of the AMEX that, based on AMEX's review of the Company's Form 10-QSB for the quarter ended March 31, 2006, the Company is not in compliance with certain conditions of the continued listing standards of Section 1003 of the AMEX Company Guide. Specifically, AMEX noted the Company's failure to comply with Section 1003(a)(ii) relating to shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of the Company's four most recent fiscal years and Section 1003(a)(iii) relating to shareholders' equity of less than \$6,000,000 and losses from continuing operations and/or net losses in the Company's five most recent fiscal years.

**NEPHROS, INC. AND SUBSIDIARY**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**For the periods ended September 30, 2006 and 2005 (unaudited)**

**(continued)**

In order to maintain listing of the Company's common stock on AMEX, the Company submitted a plan on August 23, 2006 advising AMEX of the actions the Company has taken, or will take, that would bring the Company into compliance with the applicable listing standards by January 17, 2008. On November 14, 2006, the AMEX notified the Company that the AMEX will continue the Company's listing, subject to certain conditions which are substantially as follows. First, the Company must make a public announcement through the news media by November 21, 2006, disclosing the fact that it is not in compliance with the AMEX's continued listing standards and that its listing is being continued pursuant to an extension. Second, during the plan period, the Company must continue to provide the AMEX Staff with updates regarding initiatives set forth in its plan of compliance. Finally, if the Company is not in compliance with the continued listing standards at January 17, 2008 or the Company does not make progress consistent with the plan during the plan period, then the AMEX may initiate immediate delisting proceedings.

As of the date of this filing, the Company's common stock continues to trade on AMEX under the symbol NEP.

**8. Appointment of Executive Chairman**

On August 2, 2006, the Company entered into an employment agreement (the "Employment Agreement") with William J. Fox, engaging Mr. Fox to serve as the Company's Executive Chairman, effective as of July 1, 2006, for a term of two years ending on June 30, 2008 (the "Initial Term"). After the Initial Term, the Employment Agreement will automatically be extended for one or more additional annual periods unless Mr. Fox or the Company gives the other party written notice at least 60 days prior to the end of the Initial Term or any extension thereof (the "Term") of such party's election not to renew the Employment Agreement. The Employment Agreement provides that Mr. Fox will receive a starting base salary of \$277,500 per year (subject to annual adjustment beginning with July 1, 2007, based on the New York area Consumer Price Index), and will be eligible to receive an annual bonus based on the extent to which individual and Company-wide performance goals established by the Board of Directors for each year have been met. The Company also granted Mr. Fox an option to purchase 450,000 shares of the Company's common stock at an exercise price equal to \$1.36 (the closing share price of the Company's common stock on the AMEX on the date of grant), pursuant to the Company's 2004 Stock Incentive Plan and a Non-Qualified Stock Option Agreement (the "Option Agreement"). Pursuant to the Option Agreement, the option will vest in equal quarterly installments of 56,250 shares each beginning on September 30, 2006 until the option fully vests on June 30, 2008, subject to certain conditions.



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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-QSB (the "Quarterly Report") and the audited financial statements and notes thereto as of and for the year ended December 31, 2005 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission ("SEC") on April 20, 2006. Operating results are not necessarily indicative of results that may occur in future periods.

### Financial Operations Overview

*Revenue Recognition:* Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104 Revenue Recognition. 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 and determinable; and (iv) collectibility 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 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

We are a Delaware corporation founded in 1997 by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease, or ESRD, therapy technology and products that would address both patient treatment needs and the clinical and financial needs of the treatment provider. Beginning in 2006, we diversified beyond ESRD therapy technologies into high-performance water filtration systems.

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

- OLPur MDHDF filter series (currently consisting of our MD 190 and MD220 diafilters) designed expressly for HDF therapy and employing our proprietary Mid-Dilution Diafiltration technology;
- OLPur H<sub>2</sub>H, 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 HD190 high-flux dialyzer cartridge, which incorporates the same materials as our OLPur MDHDF series but does not employ our proprietary Mid-Dilution Diafiltration technology. Our OLPur HD190 is designed for use with either hemodialysis or hemodiafiltration machines, and received its approval from the U.S. Food and Drug Administration, or the FDA, under Section 510(k) of the Food, Drug and Cosmetic Act, or the FDC Act, in

June 2005. We filed an Investigational Device Exemption with the FDA for our OLpūr H2H module earlier this year and received questions from the FDA in June 2006.

Our OLpūr HD190 cartridge, as well as our OLpūr MDHDF filter series, have each received Conformité Européene, or CE, markings which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking. TUV Rheinland of North America, Inc., a worldwide testing and certification agency

(also referred to as a notified body), has reviewed technical files and approved our use of the CE mark as well as certified that our quality management system meets the requirements of EN ISO 13485 / 2003. We are certified to sell our MD 190 and MD220 hemodiafilters in the European Union.

In January 2006, we introduced our new Dual Stage Ultrafilter (the “DSU”) water filtration system. Our DSU represents a new and complimentary 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 OLpūr H2H and 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 problems. 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, anthrax, HIV, Ebola virus, ricin toxin, legionella, fungi and e - coli. During January 2006, we received our first purchase order for the shower filtration system version of our DSU, known as the MediWash<sup>TM</sup> filter, from a major hospital in New York City that is using it initially in the hospital’s patient showers. We expect to work with the United States Marine Corps in developing a potable personal water purification system for warfighters, and a Federal appropriation totaling \$1 million was recently approved for this purpose. We have also begun investigating a range of commercial, industrial and retail opportunities for our DSU technology. However, there can be no assurance that our efforts to market the DSU to hospitals will be successful, that the Federal appropriation for our water system will actually be spent or that we will be able to successfully apply the DSU to any other markets.

#### **Notification from the American Stock Exchange**

On July 17, 2006, we received notice from the staff of the American Stock Exchange (the “AMEX”) that, based on AMEX’s review of our Form 10-QSB for the quarter ended March 31, 2006, 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) (ii) relating to shareholders’ equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of our four most recent fiscal years and Section 1003(a) (iii) 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.

In order to maintain listing of our common stock on AMEX, we submitted a plan on August 23, 2006, advising AMEX of the actions we have taken, or will take, that would bring us into compliance with the applicable listing standards by January 17, 2008. On November 14, 2006, the AMEX notified us that the AMEX will continue our listing, subject to certain conditions which are substantially as follows. First, we must make a public announcement through the news media by November 21, 2006, disclosing the fact that we are not in compliance with the AMEX’s continued listing standards and that our listing is being continued pursuant to an extension. Second, during the plan period, we must continue to provide the AMEX Staff with updates regarding initiatives set forth in our plan of compliance. Finally, if we are not in compliance with the continued listing standards at January 17, 2008 or we do not make progress consistent with the plan during the plan period, then the AMEX may initiate immediate delisting proceedings.

As of the date of this filing, our common stock continues to trade on AMEX under the symbol NEP.

#### **Liquidity and Going Concern**

The financial statements included in this Quarterly Report on Form 10-QSB and in our Annual Report on Form 10-KSB have been prepared assuming that we will continue as a going concern, however, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections, and in order to comply with the AMEX's continued listing standards, we will need to raise additional funds through either the licensing of our technologies or the additional public or private offerings of our securities. We are exploring various options in respect of raising additional funds. However, there can be no assurance that we will be able to obtain further financing, do so on reasonable terms or do so on terms that will satisfy continued listing standards. If we are unable to raise additional funds on a timely basis, or at all, we would be adversely affected and may be de-listed from the AMEX.

### **Certain Plans and Expected Uses of Capital**

We anticipate focusing our research and development efforts during the next nine months on:

- advancing our OLpūr H2H product development in order to apply for regulatory approval for the OLpūr H2H and OLpūr MDHDF filter series products in the United States which we have targeted for the fourth quarter of 2007;
  - advancing our OLpūr H2H product development in order to apply for regulatory approval for the OLpūr H2H product in the European Community which we have targeted for the first half of 2007;
- developing alternative configurations using our proprietary water filtration technology to address a growing range of market opportunities; and
- advancing our OLpūr NS2000 product development in conjunction with a European dialysis machine manufacturer in order to eventually obtain regulatory approval in the European Community and in the United States in 2007.

We anticipate focusing our sales and marketing efforts during the next nine months on:

- our OLpūr MD 190 and MD220 products principally in France, Germany, Ireland, Italy, and the United Kingdom as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland (collectively, our “Target European Market”).
- our ultrapure water filtration systems in the U.S. in the health care and other commercial markets, primarily our MediWash shower in the U.S. medical community.

We are also working to develop relationships with one or more distributors in the U.S. for our water filtration systems.

Over the next nine months, we currently expect to spend approximately: \$1,117,000 for the marketing and sales of our OLpūr MD filter products, including direct personnel costs, marketing clinical studies, product sampling and exhibiting at trade shows; \$650,000 to conduct clinical studies and pursue U.S. regulatory approvals with respect to both our OLpūr MDHDF filter series products and our OLpūr H2H products; \$75,000 in settlement payments to the Plexus Technology Group and \$200,000 in settlement payments to the Receiver.

Our forecasts of future operations and expenditures are forward-looking statements that involve risks and uncertainties. In the event that our plans change, our assumptions change or prove inaccurate, and/or we do not successfully raise additional funds on a timely basis, we may be required to curtail our planned activities.

On December 19, 2005, the U.S. District Court for the Southern District of Florida approved the Stipulation of Settlement, dated November 8, 2005 (the “Settlement”), with respect to the action captioned Marty Steinberg, Esq. as Receiver for Lancer Offshore, Inc. v. Nephros, Inc., Case No. 04-CV-20547, that was commenced on March 8, 2004, in the U.S. District Court for the Southern District of Florida (the “Ancillary Proceeding”), which is further described herein and in our Annual Report on Form 10-KSB. Pursuant to the terms of the Settlement, we agreed to pay the Receiver an aggregate of \$900,000 under the following payment terms: \$100,000 paid on January 5, 2006; and four payments of \$200,000 each at six month intervals thereafter. In addition, any warrants previously issued to Lancer were cancelled, and, on January 18, 2006, we issued to the Receiver warrants to purchase 21,308 shares of our common stock at \$1.50 per share exercisable until January 18, 2009.

In June 2005, we renewed our supply agreement with our fiber supplier, Membrana GmbH. Pursuant to the agreement, Membrana will be our exclusive provider of the fiber for the OLpūr MDHDF filter series in the European Union as well as certain other territories through September 2009. Notwithstanding the exclusivity provisions, we may

purchase membranes from other providers if Membrana is unable to timely satisfy our orders, or if Membrana cannot offer us a price that is competitive with offers from other providers. If and when the volume-discount pricing provisions of our agreement with Membrana become applicable, for each period we will record inventory and cost of goods sold for our fiber requirements pursuant to our agreement with Membrana GmbH based

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on the volume-discounted price level applicable to the actual year-to-date cumulative orders at the end of such period. If, at the end of any subsequent period in the same calendar year, actual year-to-date cumulative orders entitle us to a greater volume-discount for such calendar year, then we will adjust inventory and cumulative cost of goods sold amounts quarterly throughout the calendar year to reflect the greater volume-discount.

On August 2, 2006, we entered into an employment agreement (the "Employment Agreement") with William J. Fox, engaging Mr. Fox to serve as our Executive Chairman, effective as of July 1, 2006, for a term of two years ending on June 30, 2008 (the "Initial Term"). After the Initial Term, the Employment Agreement will automatically be extended for one or more additional annual periods unless either party gives the other written notice at least 60 days prior to the end of the Initial Term or any extension thereof (the "Term") of such party's election not to renew the Employment Agreement. The Employment Agreement provides that Mr. Fox will receive a starting base salary of \$277,500 per year (subject to annual adjustment beginning with July 1, 2007, based on the New York area Consumer Price Index), and will be eligible to receive an annual bonus based on the extent to which individual and company-wide performance goals established by the Board of Directors for each year have been met. We also granted Mr. Fox an option to purchase 450,000 shares of our common stock at an exercise price equal to \$1.36 (the closing share price of the Company's common stock on the AMEX on the date of grant), pursuant to our 2004 Stock Incentive Plan. Pursuant to the Non-Qualified Stock Option Agreement entered into in connection with such grant, the option will vest in eight equal quarterly installments of 56,250 shares each, beginning on September 30, 2006 until the option fully vests on June 30, 2008, subject to certain conditions.

### **Critical Accounting Policies**

Refer to "Management's Discussion and Analysis or Plan of Operation" in the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005 for disclosures regarding the Company's critical accounting policies. There were no changes to these accounting policies, other than the adoption of SFAS No. 123R as further described in Note 2 to the Condensed Consolidated Financial Statements, during the nine months ended September 30, 2006.

### **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.

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

- (1) the completion and success of additional clinical trials and of our regulatory approval processes for each of our ESRD therapy products in our target territories;
- (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 that 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.



***Three Months Ended September 30, 2006 Compared to the Three Months Ended September 30, 2005***

*Revenues*

Product revenues decreased to \$164,699 for the three months ended September 30, 2006 from \$225,248 for the three months ended September 30, 2005. The \$60,549 decrease in product revenues is due to lower unit sales in our European market because of tighter inventory controls at one of our significant European customers.

*Cost of Goods Sold*

Cost of goods sold increased to \$202,839 for the three months ended September 30, 2006 compared to \$151,646 for the three months ended September 30, 2005. The \$51,193 increase in cost of goods sold reflects the impact of an inventory write off of \$93,594 for expiring inventory offset by lower unit sales and resulting lower cost of goods sold.

*Research and Development*

Research and development expenses increased to \$544,505 for the three months ended September 30, 2006 from \$401,873 for the three months ended September 30, 2005. The increase of \$142,632 is primarily due to increases in outside test expense of \$47,221, increases in clinical trial expense of \$39,589, and increases in payroll of \$40,700.

*Depreciation Expense*

Depreciation expenses decreased to \$64,223 for the three months ended September 30, 2006 from \$75,345 for the three months ended September 30, 2005, a net decrease of \$11,122. Depreciation expenses were previously classified as selling, general and administrative expenses and have been reclassified to conform to current year presentation.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased to \$1,256,354 the three months ended September 30, 2006 from \$1,404,660 for the three months ended September 30, 2005. The decrease of \$148,306 is substantially due to lower expenses associated with European based marketing salaries, lower product sampling of our OLPür MD190 product within our Target European Market and lower travel-related expenses.

*Interest Income*

Interest income increased to \$116,014 for the three months ended September 30, 2006 from \$60,394 for the three months ended September 30, 2005. The \$55,620 increase represents the impact of higher average balances of our cash and cash equivalents and short-term investments during the quarter ended September 30, 2006.

*Interest Expense*

Interest expense increased to \$113,494 for the three months ended September 30, 2006. There was no interest expense for the three months ended September 30, 2005. The current period interest increase primarily represents the accrued interest liability associated with the 6% convertible Notes. For additional information about the Notes, please see the section "Liquidity and Capital Resources" below.

*Other expense*

Other expense of \$4,826 includes the impact of \$6,921 related to debt discount amortization being partially offset by \$2,094 of other miscellaneous income items for the three months ended September 30, 2006.

***Nine Months Ended September 30, 2006 Compared to the Nine Months Ended September 30, 2005***

*Revenues*

Total revenues for the nine months ended September 30, 2006 were \$641,115 compared to \$2,353,339 for the prior year period. Product revenues increased from \$603,339 for the nine months ended September 30, 2005 to \$641,115 for the nine months ended September 30, 2006, an increase of 6%. This \$37,776 increase in product revenues is primarily due to increased sales of our OLpūr MDHDF filter series product in our Target European Market, which was partially offset by lower average realized prices. The sales of our DSU product contributed \$10,000 to the increase in product revenues. Results for the nine months ended September 30, 2005 included the licensing revenues of \$1,750,000 resulting from our agreement with Asahi Kasei Medical Co., Ltd. (“Asahi”).

*Cost of Goods Sold*

Cost of goods sold increased to \$810,677 for the nine months ended September 30, 2006 from \$400,695 for the nine months ended September 30, 2005. The \$409,982 increase in cost of goods sold is primarily due to the following: \$153,303 related to an increase in the number of units sold; adjustments of \$141,074 to revalue to market pricing specific inventory lots to reflect the competitive pricing environment in the German market; and the write-off of expired inventory in the amount of \$154,621. During the nine months ended September 30, 2006, cost of goods sold for the DSU was \$9,975.

*Research and Development*

Research and development expenses increased to \$1,444,281 for the nine months ended September 30, 2006 from \$1,415,584 for the nine months ended September 30, 2005. The \$28,697 increase in expenses is primarily due to expenses associated with outside testing and clinical trial expenses.

*Depreciation Expense*

Depreciation expense decreased to \$224,250 for the nine months ended September 30, 2006 from \$230,050 for the nine months ended September 30, 2005, a decrease of \$5,800. Depreciation expenses were previously classified as selling, general and administrative expenses and have been reclassified to conform to current year presentation.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased to \$3,965,817 for the nine months ended September 30, 2006 from \$4,658,975 for the nine months ended September 30, 2005. The decrease of \$693,158 reflects a decrease in selling expenses of \$888,367 offset by an increase in general and administrative expenses of \$194,276. Selling expenses decreased to \$912,395 for the nine months ended September 30, 2006 from \$1,800,762 for the nine months ended September 30, 2005 primarily due to a reduction in European marketing expenses reflecting \$220,000 in lower sampling expense, \$289,000 in lower payroll due to the termination of our Senior Vice President of Marketing and Sales and lower travel expenses. General and administrative expenses increased to \$3,052,490 for the nine months ended September 30, 2006 from \$2,858,216 for the nine months ended June 30, 2005 primarily due to an increase in U.S. expenses associated with fees for professional services associated with investor relations and financial services of approximately \$300,000 and asset disposal expense of \$23,360 related to the relocation of our Dublin offices to a new Dublin location and incurred net of accumulated depreciation.

*Interest Income*

Interest income decreased to \$113,494 for the nine months ended September 30, 2006 from \$178,863 for the nine months ended September 30, 2005. The \$15,008 decrease reflects lower average balances of our cash and cash equivalents and short term investments during the first six months of 2006.

*Interest Expense*

Interest expense totaled \$109,333 for the nine months ended September 30, 2006. There was no interest expense for the nine months ended September 30, 2005. The current period interest increase primarily represents the accrued interest liability associated with the 6% Convertible Notes. For additional information about the Notes, please see the section "Liquidity and Capital Resources" below.

## Other expense

Other expense of \$4,826 includes the impact of \$6,921 related to debt discount amortization being partially offset by \$2,094 of other miscellaneous income items for the nine months ended September 30, 2006.

## Liquidity and Capital Resources

In June 2006, we entered into subscription agreements with certain investors who purchased an aggregate of \$5,200,000 principal amount of our 6% Secured Convertible Notes due 2012 (the "Notes") for the face value thereof. We closed on the sale of the first tranche of Notes, in an aggregate principal amount of \$5,000,000, on June 1, 2006 (the "First Tranche") and closed on the sale of the second tranche of Notes, in an aggregate principal amount of \$200,000, on June 30, 2006 (the "Second Tranche"). The Notes are secured by substantially all of the Company's assets.

The Notes accrue interest at a rate of 6% per annum, compounded annually and payable in arrears at maturity. Subject to certain restrictions, principal and accrued interest on the Notes are convertible at any time at the holder's option into shares of our common stock, at an initial conversion price of \$2.10 per share (subject to anti-dilution adjustments upon the occurrence of certain events). We may cause the Notes to be converted at their then effective conversion price, if the common stock achieves average last sales prices of at least 240% of the then effective conversion price and average daily volume of at least 35,000 shares (subject to adjustment) over a prescribed time period. As further described below, conversion of the Notes is restricted, pending stockholder approval.

We may prepay outstanding principal and interest on the Notes at any time. Any prepayment requires us to pay each holder a premium equal to 15% of the principal amount of the Notes held by such holder receiving the prepayment if such prepayment is made on or before June 1, 2008, and 5% of the principal amount of the Notes held by such holder receiving prepayment in connection with prepayments made thereafter. In addition to the applicable prepayment premium, upon any prepayment of the Notes occurring on or before June 1, 2008, we must issue the holder of such Notes warrants ("Prepayment Warrants") to purchase a quantity of common stock equal to three shares for every \$20 principal amount of Notes prepaid at an exercise price of \$0.01 per share (subject to adjustment). Upon issuance, the Prepayment Warrants would expire on June 1, 2012.

Unless and until our stockholders approve the issuance of shares of common stock in excess of such amount, the number of shares of common stock issuable upon conversion of the First Tranche of Notes and exercise of the Prepayment Warrants related thereto, in the aggregate, is limited to 2,451,280 shares, which equals approximately 19.9% of the number of shares of common stock outstanding immediately prior to the issuance of the Notes. We will not issue any shares of common stock upon conversion of the Second Tranche of Notes or exercise of any Prepayment Warrants that may be issued pursuant to such Notes until our stockholders approve the issuance of shares of common stock upon conversion of the Notes and exercise of the Prepayment Warrants as may be required by the applicable rules and regulations of the AMEX.

In connection with the sale of the Notes, we have entered into a registration rights agreement with the investors pursuant to which we granted the investors two demand registration rights and unlimited piggy-back and short-form registration rights with respect to the shares of common stock issuable upon conversion of the Notes or exercise of Prepayment Warrants, if any.

Subject to terms and conditions set forth in the Notes, the outstanding principal of and accrued interest on the Notes may become immediately due and payable upon the occurrence of any of the following events of default: our failure to pay principal or interest on the Notes when due; certain bankruptcy-related events with respect to us; material breach of any representation, warranty or certification made by us in or pursuant to the Notes, or under the registration rights agreement or the subscription agreements; our incurrence of Senior Debt (as defined in the Notes); the acceleration of certain of our other debt; or the rendering of certain judgments against us.

The Notes contain a prepayment feature that requires us to issue common stock purchase warrants to the Note holders for partial consideration of certain Note prepayments that the Note holders may demand under certain circumstances. Pursuant to the Notes, we must offer the Note holders the option (the “Holder Prepayment Option”) of prepayment (subject to applicable premiums) of their Notes, if we

completes an asset sale in excess of \$250,000 outside the ordinary course of business (a "Major Asset Sale"), to the extent of the net cash proceeds of such Major Asset Sale. Paragraph 12 of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", ("SFAS 133"), provides that an embedded derivative shall be separated from the host contract and accounted for as a derivative instrument if and only if certain criteria are met. In consideration of SFAS 133, we have determined that the Holder Prepayment Option is an embedded derivative to be bifurcated from the Notes and carried at fair value in the financial statements. At June 1, 2006 the value of the embedded derivative was a liability of approximately \$71,000. We reassesses the valuation of the Holder Prepayment Option quarterly.

At September 30, 2006, the value of the embedded derivative was a liability of approximately \$78,000. The change in value was recorded as other expense during the quarter. Also, the debt discount, of approximately \$71,000, created by bifurcating the Holder Prepayment Option, is being amortized over the term of the debt. During the quarter ended September 30, 2006, the Company recorded interest expense of approximately \$4,000.

Our financial statements have been prepared on a basis which assumes that we will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

At September 30, 2006, we had an accumulated deficit of approximately \$53.0 million and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we manufacture and market our products profitably. We have financed our operations since inception primarily through the private placements of equity and debt securities, our initial public offering and from licensing revenue received from Asahi in March 2005.

At September 30, 2006, we had approximately \$0.9 million in cash and cash equivalents and \$3.8 million in short-term investments. Currently, we believe that these funds and our anticipated cash flows will be sufficient to fund our currently planned operations through the end of the second quarter of 2007. This time frame estimate includes the costs associated with our clinical trials in the United States for our OLP<sub>ur</sub> MDHDF filters and H<sub>2</sub>H module. In order to remain listed on the AMEX, we will need to raise additional funds through either the licensing of our technologies or the additional public or private offerings of our securities to comply with the AMEX continued listing standards as discussed above. We are currently considering what actions we may take to regain compliance. However, there is no guarantee that we will be able to obtain further financing on reasonable terms or at all, or that we will be able to regain compliance with the continued listing standards.

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

- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the availability of additional financing, through the sale of equity securities or otherwise, on commercially reasonable terms or at all;
- the timing and costs associated with obtaining the CE mark for products other than our OLP<sub>ur</sub> MDHDF filter series, for which the CE mark was obtained in July 2003, or United States regulatory approval;
  - our ability to maintain the listing of our common stock on the AMEX;
- the continued progress in and the costs of clinical studies and other research and development programs;
  - the costs involved in filing and enforcing patent claims and the status of competitive products; and
  - the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

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



- to pay the Receiver of Lancer Offshore, Inc. amounts due under the settlement with respect to the Ancillary Proceeding between us and the Receiver (see Note 6 to our Condensed Consolidated Financial Statements for additional information regarding such payment);
- to pay a former supplier, Plexus Services Corp., amounts due under our settlement agreement; and
- for working capital purposes and for additional professional fees and expenses and other operating costs.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In the event that our plans change, our assumptions change or prove inaccurate, or if our existing cash resources, together with other funding resources including increased sales of our products, otherwise prove to be insufficient to fund our operations, we could be required to seek additional financing sooner than anticipated and/or reduce our planned activities in order to conserve capital.

Net cash used in operating activities was approximately \$5.7 million for the nine months ended September 30, 2006 compared to approximately \$3.5 million for the nine months ended September 30, 2005. Included in the prior year amounts is the impact of the Asahi contract revenue of \$1.75 million offset by cash used in operating activities in the nine months ended September 30, 2005 of approximately \$5.3 million.

Net operating assets in the nine months ended September 30, 2006 decreased by \$645,346 compared to an increase of \$84,761 for the nine months ended September 30, 2005. The principle factors contributing to the change are a \$268,945 decrease in current liabilities and accrued expenses in the current period compared to a \$267,987 increase in the nine months ended September 30, 2005, a \$335,402 decrease in the severance accrual in the nine months ended September 30, 2006, a \$349,950 reduction in short term notes payable being partially offset by a \$103,430 increase in convertible notes accrued interest in the nine months ended September 30, 2006.

Net cash provided by investing activities was \$667,224 for the nine months ended September 30, 2006 compared to net cash used of \$228,990 for the nine months ended September 30, 2005. The current year provision of cash reflects \$700,000 in net repayments of short term securities as repayments of \$3,700,000 are partially offset by \$3,000,000 of purchases of short term securities and \$32,776 of purchases of property and equipment. In the prior period, net cash used reflects fixed asset purchases, mainly manufacturing equipment.

Net cash provided by financing activities was approximately \$5.2 million for the nine months ended September 30, 2006 compared to approximately \$1.0 million for the nine months ended September 30, 2005. The net cash provided in the current period reflects the sale of an aggregate of approximately \$5.2 million of our Notes and \$1,441 from the exercise of options to purchase of our common stock. Financing activities in the nine months ended September 30, 2005 included net proceeds of \$955,521 from Asahi from the sale of 184,250 shares of our common stock pursuant to a Subscription Agreement dated March 2, 2005.

### **Certain Risks and Uncertainties**

Our Annual Report on Form 10-KSB for the year ended December 31, 2005 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 American Stock Exchange's continued listing standards and as a result, we may be delisted from the American Stock Exchange.*

On July 17, 2006, we received notice from the staff of the AMEX that, based on AMEX's review of our Form 10-QSB for the quarter ended March 31, 2006, 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)(ii) relating to shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of our four most recent fiscal years and Section 1003(a)(iii) 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.

In order to comply with the AMEX's continued listing standards, we will need to raise additional funds through either the licensing of our technologies or the additional public or private offerings of our securities. There can be no assurance, however, that we will be able to obtain further financing, do so on reasonable terms or do so on terms that will satisfy the AMEX's continued listing standards. If we are unable to raise additional funds on a timely basis, then we may be delisted from the AMEX.

If our common stock is delisted by the AMEX, trading of our common stock would thereafter likely be conducted on the OTC Bulletin Board. In such case, 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 affect the liquidity of our common stock.

***Our existing and future debt obligations could impair our liquidity and financial condition.***

As of September 30, 2006, we had \$5.2 million aggregate principal amount of secured convertible notes outstanding. We may incur additional debt in the future to fund all or part of our capital requirements. Our outstanding debt and future debt obligations could impair our liquidity and could:

- make it more difficult for us to satisfy our other obligations;
- require us to dedicate a substantial portion of any cash flow we may generate to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- impede us from obtaining additional financing in the future for working capital, capital expenditures and general corporate purposes; and
  - make us more vulnerable in the event of a downturn in our business prospects and limit our flexibility to plan for, or react to, changes in our industry.

***We may not have sufficient cash flows from operating activities and cash on hand to service our indebtedness and meet our cash needs.***

Our ability to make payments on our indebtedness will depend on our ability to generate cash in the future. This, to some extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control.

We cannot assure you 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, we will be required to adopt alternatives, such as seeking to raise additional debt or equity capital and/or to curtail our planned activities. We cannot assure you 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.

*Several customers individually account for a large portion of our product sales, the loss of any of these customers could have a material adverse effect on our sales.*

For the nine months ended September 30, 2006, one of our customers accounted for 63% of our product sales. Also, this customer represented 71% of our accounts receivable as of September 30, 2006. We believe that the

loss of this customer could have a material adverse effect on our product sales, at least temporarily, while we seek to replace such customer and/or self-distribute in the territories currently served by such customer.

### **Safe Harbor for Forward-Looking Statements**

This report contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines for bringing such products to market and the availability of funding sources for continued development of such products and other statements that are not historical facts, including statements which may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include the risks that:

- products that appeared promising in research or clinical trials to us may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may not obtain appropriate or necessary governmental or regulatory approvals to achieve our business plan;
- product orders may be cancelled, patients currently using our products may cease to do so, patients expected to begin using our products may not and we may not be able to bring on new patients at the rate originally anticipated;
  - we may not be able to obtain funding if and when needed or on terms favorable to the Company;
- 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;
- FDA approval relating to our OLpūr HD190 filter may not facilitate or have any effect on the regulatory approval process for our other products;
  - we may not be able to achieve sales growth in Europe or expand into other key geographic markets;
    - we may not be able to satisfy our debt obligations when they become due and payable;
      - we may not be able to continue as a going concern; and
- we may not be able to meet the AMEX’s continued listing standards and as a result, we may be delisted from the AMEX.

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, 2005. 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.

### **Item 3. 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 Company's effectiveness of 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. Based on that evaluation, the 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.

On October 17, 2006, we filed an amendment to our Form 10-QSB for the period ended March 31, 2006, which restated our previously issued condensed consolidated financial statements for such period. We have considered the effect of the restatement of our previously issued consolidated financial statements in our assessment of disclosure controls and procedures and of internal control over financial reporting. We have concluded that the material weaknesses identified in section 1 below existed in our internal control over financial reporting as of December 31, 2005 and the material weakness identified in section 2 below existed as of March 31, 2006, June 30, 2006 and September 30, 2006. A material weakness, as defined by the Public Company Accounting Oversight Board, is a significant deficiency, or a combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

#### *Description of Material Weaknesses in Internal Control over Financial Reporting*

##### **1. Accounting for accrued severance expense**

In connection with the audit of our 2005 annual financial statements, our auditors identified a material adjustment to accrued severance expense for the recognition of employee severance relating to the financial closing process with respect to the termination of one of our employees and a number of other adjustments relating to the financial closing process that were immaterial. Our management concluded that our failure to book these severance and other adjustments prior to our auditors bringing them to our attention evidenced a material weakness in our internal control over financial reporting with respect to our financial closing and review and analysis process.

##### **2. Financial close process**

Subsequent to the initial issuance of its condensed consolidated financial statements for the period ended March 31, 2006, the Company identified the following errors in such financial statements as included in the Company's Form 10-QSB filed with the SEC on May 22, 2006:

- i. An error related to stock-based compensation expense recorded in the previously reported financial statements for the period ended March 31, 2006. The error, which occurred during the process of adopting the new standard of accounting for stock options under SFAS 123R, resulted in the overstatement of \$368,197 in the non-cash stock-based compensation expense for the three months ended March 31, 2006. Additionally, the Company determined it had not properly allocated such non-cash compensation expense among the research and development and selling, general and administrative expense categories;
- ii. An error related to the classification of an interest bearing cash account. The error, which occurred during the process of preparing the Condensed Consolidated Statement of Cash Flows for the period ended March 31, 2006

resulted in a reclassification adjustment of \$405,264 from short-term investments to cash and cash equivalents; and

iii. An error related to the presentation of depreciation expense and the effect of exchange rates on cash on the Condensed Consolidated Statement of Cash Flows for the period ended March 31, 2006 resulted in a reclassification adjustment of \$29,325 between depreciation expense and the effect of exchange rates on cash.



The Company reviewed these matters with its Audit Committee. The Audit Committee accepted management's recommendation that the Company restate its condensed consolidated financial statements for the First Quarter 2006 to correct for these errors. Notwithstanding the material weaknesses described above, management has concluded that the Company's condensed consolidated financial statements for the periods covered by and included in this report are fairly stated in all material respects in accordance with U.S. GAAP for each of the periods presented herein. Management's conclusion as to the fairness of the presentation of the financial statements included in this report is based in part on the substantial work performed by management during the restatement process.

*Changes in Internal Control over Financial Reporting*

Management is in the process of remediating the above-mentioned weakness in our internal control over financial reporting with respect to accounting and has taken the following measures:

- Monthly meetings to address all expense and accrual activity focusing on analysis of budget variances. Meetings are led by the Chief Financial Officer and attended by the Chief Executive Officer and other functional departmental executives; and
- Engaging outside accounting services to support and supplement our internal staff and enhance our internal controls over accounting and related areas.

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 6. Exhibits**

- 10.1 Employment Agreement between Nephros, Inc. and William J. Fox, entered into on August 2, 2006 (incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 4, 2006)
- 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 Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification by the 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**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NEPHROS, INC.**

Date: November 14, 2006

By: By: /s/ Mark W. Lerner

By: /s/ Mark W. Lerner

Mark W. Lerner

Chief Financial Officer

(Principal Financial and Accounting Officer)

**Exhibit Index**

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