NEPHROS INC
Form 10QSB
May 16, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-QSB

(MARK ONE)

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

For the quarterly period ended March 31, 2005

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	13-3971809
(State or Other Jurisdiction of Incorporation or Organization)	(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 [X] NO [ ]

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

Class	Outstanding at April
Common Stock, $.001 par value	12,304,498

Transitional Small Business Disclosure Format: YES [ ] NO [X]

NEPHROS, INC. AND SUBSIDIARY

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PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements.

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	March 31, 2005	Dec
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,315,093	$
Short-term investments	5,995,380	
Accounts receivable	221,312	
Inventory	586,877	
Prepaid expenses and other current assets	508,834	
Total current assets	11,627,496	1

Property and equipment, at cost less accumulated depreciation of $653,348 and $584,130 at March 31, 2005 and December 31, 2004, respectively	1,230,145	
Other assets	5,322	
Total assets	$ 12,862,963	$ 1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 549,245	$
Accrued expenses	432,386	
Deferred revenue	40,395	
Accrued liabilities	1,500,000	
Total current liabilities	2,522,026	
Stockholders' equity:		
Preferred stock, $.001 par value, 31,000,000 shares authorized at March 31, 2005 and December 31, 2004; no shares issued and outstanding at March 31, 2005 and December 31, 2004	--	
Common stock, $.001 par value; 49,000,000 shares authorized at March 31, 2005 and December 31, 2004; 12,304,498 and 12,120,248 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	12,304	
Additional paid-in capital	54,739,869	5
Deferred compensation	(2,311,987)	(
Accumulated other comprehensive income - foreign currency translation	72,964	
Accumulated other comprehensive loss - unrealized losses on available-for-sale securities	(4,620)	
Accumulated deficit	(42,167,593)	(4
Total stockholders' equity	10,340,937	
Total liabilities and stockholders' equity	$ 12,862,963	$ 1

See accompanying notes to the condensed consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended March 31,	
	2005	2004
Net contract revenues	$ 1,750,000	$ --

Net product revenues	151,665	--
Net revenues	1,901,665	--
Operating costs and expenses:		
Cost of product revenue	135,368	12,618
Research and development	462,701	690,024
Selling, general and administrative	1,752,488	1,316,435
Total operating expenses	2,350,557	2,019,077
Loss from operations	(448,892)	(2,019,077)
Other income:		
Interest income	56,005	1,345
Total other income	56,005	1,345
Net loss	(392,887)	(2,017,732)
Dividends and accretion to redemption value of redeemable convertible preferred stock	--	(2,071,500)
Net loss attributable to common stockholders	$ (392,887)	$ (4,089,232)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.03)	$ (2.57)
Shares used in computing basic and diluted net loss attributable to common stockholders per common share	12,150,956	1,593,659

See accompanying notes to the condensed consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,	
	2005	2004
Operating activities		
Net loss	$ (392,887)	$(2,017,732)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	73,775	31,935

Noncash stock-based compensation	167,330	417,608
(Increase) decrease in operating assets		
Accounts receivable	(46,515)	(21,559)
Prepaid expenses and other current assets	(40,479)	(565,685)
Inventory	66,474	37,853
Other assets	(1,500)	(3,000)
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	(10,972)	(22,430)
Deferred revenue	(23,663)	21,559
Net cash used in operating activities	(208,437)	(2,121,451)
Investing activities		
Purchase of property and equipment	(112,064)	(213,478)
Net cash used in investing activities	(112,064)	(213,478)
Financing activities		
Proceeds from issuance of preferred stock, net	--	3,811,538
Proceeds from private placement issuance of common stock subsequent to the initial public offering	955,521	--
Adjustment to proceeds from initial public offering of common stock	44,361	--
Net cash provided by financing activities	999,882	3,811,538
Effect of exchange rates on cash	(83,469)	(30,877)
Net increase in cash and cash equivalents	595,912	1,445,732
Cash and cash equivalents, beginning of period	3,719,181	4,121,263
Cash and cash equivalents, end of period	$ 4,315,093	$ 5,566,995
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 11,630	$ 723

See accompanying notes to the condensed consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DE

(unaudited)

	Series A Preferred Stock		Common Stock		St Subsc
	Shares	Amount	Shares	Amount	Rece
Balance, January 1, 2004	4,000,000	$ 4,000	1,593,659	$ 1,594	$

Comprehensive loss:					
Net loss	--	--	--	--	
Net unrealized gains on foreign currency translation	--	--	--	--	
Net unrealized losses on available-for-sale securities	--	--	--	--	
Comprehensive loss					
Noncash stock-based compensation	--	--	--	--	
Beneficial conversion recognized in connection with issuance of preferred stock	--	--	--	--	
Amortization of deferred compensation	--	--	--	--	
Cumulative preferred dividend and accretion	--	--	--	--	
Exercise of warrants	87,500	88	--	--	
Issuance of common stock in connection with initial public offering	--	--	2,100,000	2,100	
Conversion of preferred stock into common stock upon initial public offering	(4,087,500)	(4,088)	8,426,589	8,426	
Balance, December 31, 2004	--	--	12,120,248	12,120	
Comprehensive loss:					
Net loss	--	--	--	--	
Net unrealized losses on foreign currency translation	--	--	--	--	
Net unrealized losses on available-for-sale securities	--	--	--	--	
Comprehensive loss					
Amortization of deferred compensation	--	--	--	--	
Issuance of common stock in connection with initial public offering	--	--	--	--	
Issuance of common stock in connection with private placement	--	--	184,250	184	
Balance, March 31, 2005	--	$ --	12,304,498	$ 12,304	$

	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
Balance, January 1, 2004	$ 19,005,356	$ 100,337	$(22,443,693)	$ (5,382,346)
Comprehensive loss:				

Net loss	--	--	(7,596,480)	(7,596,480)
Net unrealized gains on foreign currency translation	--	56,096	--	56,096
Net unrealized losses on available-for-sale securities	--	(4,060)	--	(4,060)
Comprehensive loss				(7,544,444)
Noncash stock-based compensation	1,223,133	--	--	--
Beneficial conversion recognized in connection with issuance of preferred stock	3,811,538	--	--	3,811,538
Amortization of deferred compensation	--	--	--	793,756
Cumulative preferred dividend and accretion	--	--	(11,734,533)	(11,734,533)
Exercise of warrants	87,412	--	--	87,500
Issuance of common stock in connection with initial public offering	10,732,486	--	--	10,734,586
Conversion of preferred stock into common stock upon initial public offering	18,880,246	--	--	18,884,584
Balance, December 31, 2004	53,740,171	152,373	(41,774,706)	9,650,641
Comprehensive loss:				
Net loss	--	--	(392,887)	(392,887)
Net unrealized losses on foreign currency translation	--	(83,469)	--	(83,469)
Net unrealized losses on available-for-sale securities	--	(560)	--	(560)
Comprehensive loss				(476,916)
Amortization of deferred compensation	--	--	--	167,330
Issuance of common stock in connection with initial public offering	44,361	--	--	44,361
Issuance of common stock in connection with private placement	955,337	--	--	955,521
Balance, March 31, 2005	$ 54,739,869	$ 68,344	$(42,167,593)	$ 10,340,937

See accompanying notes to the condensed consolidated financial statements.

(unaudited)

1. Basis of Presentation

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 as of and for the year ended December 31, 2004 included in the Company's Annual Report on Form 10-KSB filed with the Securities and Exchange Commission (the "SEC") on March 31, 2005. The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("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 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.

Effective January 1, 2005, as a result of the product sales generated to date from the Company's OLpurTM MD190 dialyzer, as well as the license agreement signed on March 2, 2005 between the Company and Asahi Kasei Medical Co., Ltd. ("Asahi") (see Note 2), management has determined that the Company is no longer in the development stage as defined in Financial Accounting Standards Board ("FASB") Statement No. 7, Accounting and Reporting for Development Stage Companies. All references to cumulative statement of operations, stockholder's equity (deficit), and statements of cash flows have been eliminated in the accompanying financial statements.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Revenue Recognition

Revenue is recognized in accordance with SEC Staff Accounting Bulletin ("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.

The Company's sales history does not yet provide a basis from which to reasonably estimate rates of product return, and therefore revenues from certain shipments during the three months ended March 31, 2005 were deferred. Product sales are recognized thirty days after the date of shipment, when the right of product return expires. In addition, cost of revenue to the extent of amount billed was deferred and will be recognized when the revenue is recognized.

On March 2, 2005, the Company entered into an agreement with Asahi, a business unit of Asahi Kasei Corporation, granting Asahi exclusive rights to manufacture and distribute filter products based on the Company's OLpur MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, the Company received an up

front license fee in the amount of $1,750,000, and the Company is entitled to receive additional royalties and milestone payments based on the future sales of products in Japan, which sales are subject to Japanese regulatory approval. Because (i) the license agreement requires no continuing involvement in the manufacture and delivery of the licensed product in the covered territory of Japan, (ii) the criteria of SAB 104 have been met and (iii) the license fee received is non-refundable, the Company recognized $1,750,000 in contract revenue on the effective date of the license agreement.

Stock-based Compensation

The Company accounts for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued in accordance with the Emerging Issues Task Force ("EITF") 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services."

The Company accounts for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and discloses the effect of the differences which would result had the Company applied the fair-value-based method of accounting on a pro forma basis, as required by Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation." Had compensation expense for stock options granted under the Nephros 2000 Equity Incentive Plan (the "2000 Plan") and the 2004 Stock Incentive Plan (the "2004 Plan") been determined based on fair value at the grant dates, the Company's net loss and net loss per share for the three months ended March 31, 2005 and 2004 would have been as follows:

	Three Months Ended March 31,	
	2005	2004
Net loss attributable to common stockholders:		
As reported	$ (392,887)	$(4,089,232)
Less - compensation recognized under the intrinsic-value method	167,330	417,608
Add - compensation under the fair value method	(249,362)	(362,096)
Pro forma	$ (474,919)	$(4,033,720)
Net loss per share:		
As reported	$ (0.03)	$ (2.57)
Pro forma	$ (0.04)	$ (2.53)

Comprehensive Loss

The Company complies with the provisions of SFAS No. 130, "Reporting Comprehensive Income," which requires companies to report all changes in equity during a period, except those resulting from investment by owners and distributions to owners, for the period in which they are recognized. Comprehensive income (loss) is the total of net income (loss) and all other non-owner changes in equity (or other comprehensive income (loss)) such as unrealized gains or losses on securities classified as available-for-sale and

foreign currency translation adjustments. For the three months ended March 31, 2005 and 2004, the comprehensive loss was $476,916 and $2,048,609, respectively.

Income (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 attributable to common stockholders by the weighted-average number of common shares outstanding and excluding any potential dilution. Net loss per common share amounts assuming dilution ("diluted EPS") is generally computed by reflecting potential dilution from conversion of convertible securities and the exercise of stock options and warrants. However, because their effect is antidilutive, the Company has excluded stock options and warrants exercisable to purchase in the aggregate 2,249,857 and 9,491,397 common shares from the computation of diluted EPS for the three months ended March 31, 2005 and 2004, respectively.

3. Stockholders' Equity and Redeemable Convertible Preferred Stock

On March 2, 2005, the Company entered into a Subscription Agreement with Asahi pursuant to which Asahi purchased 184,250 shares of the Company's common stock at an aggregate purchase price of $955,521 (see Note 2). The Subscription Agreement contains certain transfer restrictions with respect to the shares purchased thereunder.

4. Commitments and Contingencies

In August 2002, the Company entered into a subscription agreement with Lancer Offshore, Inc ("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 installments, consisting of $1,500,000 principal amount of the notes and 34,092 of the warrants, 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.

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-CV-20547, pending in the U.S. District Court for the Southern District of Florida (the "Ancillary Proceeding"). That action is ancillary to a proceeding captioned Securities and Exchange Commission v. Michael Lauer, et. al., Case No.03-CV-80612, also pending in the U.S. District Court for the Southern District of Florida, in which the court has appointed a Receiver to manage Lancer and various related entities (the "Receivership"). In the Ancillary Proceeding, the Receiver seeks 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 effected by the Company on September 10, 2004 pursuant to the antidilution provisions of such warrant, as amended), that the Receiver alleges are due as a result of the Company's settlement agreement with Lancer. The Company believes that it has valid defenses to the Receiver's claims, and it intends to continue to contest them vigorously. Additionally, the Company has asserted claims for damages against Lancer that exceed the amount sought in the Ancillary Proceeding by submitting a proof of claim in the Receivership. Subsequent to March 31, 2005, both the Company and the Receiver filed motions for summary judgment in the Ancillary Proceeding. The Company has discussed the potential settlement of all claims with the Receiver, however, there can be no assurance that the Company will settle or that the outcome of any of these proceedings will be successful.

5. Reverse Stock Split

On September 10, 2004, the Company effected a reverse stock split pursuant to which each share of its common stock then outstanding was converted into 0.2841 of one share of its common stock. All share and per share amounts for all periods presented preceding September 10, 2004 have been retroactively restated to give effect to this reverse stock split.

Item 2. Management's Discussion and Analysis or Plan of Operation.

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this quarterly report on Form 10-QSB (this "Quarterly Report") and the audited financial statements and notes thereto as of and for the year ended December 31, 2004 included in our Annual Report on Form 10-KSB filed with the SEC on March 31, 2005. Operating results are not necessarily indicative of results that may occur in future periods.

Business Overview

We were founded in 1997 by health professionals, scientists and engineers to develop hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190, a dialyzer, OLpurTM H2H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines, and the OLpurTM NS2000 system, a stand-alone HDF machine with associated filter technology. We began selling our OLpur MD190 dialyzer in some or all of Cyprus, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom (our "Target European Market") in March 2004. We have also developed prototypes for our OLpur H2H product and are developing our OLpur NS2000 product in conjunction with an established machine manufacturer in Italy. We are working with this manufacturer to modify an existing HDF platform they currently offer for sale in parts of our Target European Market, incorporating our proprietary H2H technology.

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 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 which exceed our per unit costs; and

(5) the consolidation of dialysis clinics into larger clinical groups.

To the extent we are unable to succeed in accomplishing (1) through (4), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (5), the impact could either be positive, in the case where dialysis clinics

consolidate into independent chains, or negative, in the case where competitors acquire these dialysis clinics and use their own products, as competitors have historically tended to use their own products in clinics they have acquired.

Financial Operations Overview

Revenue

We began sales of our first product in March 2004. Accordingly, our sales history does not yet provide a basis from which to reasonably estimate rates of product return, if any. Consequently, and until we are able to estimate rates of return, if any, more effectively, we do not recognize revenue from these sales until the rights of return have expired.

On March 2, 2005, we entered into an agreement with Asahi, granting Asahi exclusive rights to manufacture and distribute filter products based on our OLpur MD190 hemodiafilter in Japan for 10 years commencing when the first such product receives Japanese regulatory approval. In exchange for these rights, we received an up front license fee in the amount of $1,750,000, and we are entitled to receive additional royalties and milestone payments based on the future sales of products in Japan, which sales are subject to Japanese regulatory approval. Because (i) the license agreement requires no continuing involvement in the manufacture and delivery of the licensed product in the covered territory of Japan, (ii) the criteria of SAB 104 have been met and (iii) the license fee received is non-refundable, the Company recognized $1,750,000 in contract revenue on the effective date of the license agreement.

Cost of Product Revenue

Cost of product revenue represents our acquisition cost for the products we purchase from our third party manufacturers, as well as damaged and obsolete inventory written off. Since our sales history does not yet provide a basis from which to reasonably estimate rates of product return, we defer cost of goods sold to the extent of amounts billed to customers until rights of return of expired.

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 personnel and related costs for general corporate functions, including finance, accounting, legal, human resources, facilities and information systems expense.

We expect our expense from sales, marketing and customer service activities, including costs of distributing samples and expenses related to marketing clinical trials, to increase in future periods. These increases are a result of our plan to seek greater market penetration with our OLpur MD190 within our Target European Market and to enter additional markets and introduce additional products once we obtain the requisite regulatory approvals. We also anticipate increases in general and administrative expenses for insurance, professional services, investor relations and other activities associated with operating as a publicly-traded company.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires application of management's subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to consolidated financial statements included in this Quarterly Report and in our Annual Report on Form 10-KSB, we believe that the following accounting policies require the application of significant judgments and estimates.

Revenue Recognition

Revenue is recognized in accordance with 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. We began sales of our first product in March 2004. Accordingly, our sales history does not yet provide a basis from which to reasonably estimate rates of product return, if any. Consequently, and until we can estimate rates of return, if any, more effectively, we do not recognize revenue from these sales until the rights of return have expired.

We enter into licensing arrangements with other parties whereby we receive contract revenue based on the terms of the agreement. The timing of revenue recognition is dependent on the level of our continuing involvement in the manufacture and delivery of licensed products. If we have continuing involvement, the revenue is deferred and recognized on a straight-line basis over the period of continuing involvement. In addition, if the licensing arrangements require no continuing involvement and payments are merely based on

the passage of time, we will assess such payments for revenue recognition under the collectibility criteria of SAB 104.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves identifying services which have been performed on our behalf, and the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for the preclinical development of our products, the manufacturing of clinical materials, and clinical trials, as well as legal and accounting services provided by professional organizations. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-Based Compensation

We accounted for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued in accordance with the EITF 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services."

During December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment," which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants. We grant options to purchase common stock to our employees and directors under various plans at prices equal to the fair market value of the stock on the dates the options were granted. SFAS No. 123R is effective for small business issuers the first interim reporting period beginning after December 15, 2005. Accordingly, we will adopt SFAS No. 123R commencing with the quarter ending March 31, 2006.

We account for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by APB Opinion No. 25, "Accounting for Stock Issued to Employees," and disclose the effect of the differences which would result had we applied the fair-value-based method of accounting on a pro forma basis, as required by SFAS No. 123, "Accounting for Stock-Based Compensation."

We have elected to follow APB Opinion No. 25 and related interpretations in accounting for our employee stock options because the alternative fair value accounting provided for under SFAS No. 123, Accounting for Stock-Based Compensation, or SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation--Transition and Disclosure," requires use of option valuation models that were not developed for use in valuing employee stock options. Employee stock compensation expense, which is a non-cash charge, is measured as the excess, if any, of the fair value of our underlying common stock at the date of grant over the amount an employee must pay to acquire such stock. This compensation cost is either amortized over the related vesting periods, or expensed upon the reaching of certain Company milestones.

Plan of Operation

Based on our cash flow projections, we expect that our existing cash resources will be sufficient to satisfy our cash needs, with no further financing required, to obtain positive cash flow. However, if our sales do not meet our projections or our expenses exceed our expectations, then we may need to raise additional funds through additional public or private offerings of our securities. In such event, if we are unable to raise additional funds on a timely basis or at all, any progress with respect to our products, and, therefore, our potential revenues, would be adversely affected. Even if we generate no revenues, we believe our existing cash resources will be sufficient to satisfy our cash needs, with no further financing required through the second quarter of 2006.

We intend to focus our research and development efforts during the next 12 months on:

- advancing our OLpur H2H product development in order to eventually apply for regulatory approval for the OLpur H2H product in the European Community which we have targeted for the first quarter of 2006;

- advancing our OLpur H2H product development in order to eventually apply for regulatory approval for the OLpur H2H and the OLpur MD190 in the United States which we have targeted for the second half of 2006; and

- advancing our OLpur NS2000 product development in conjunction with our dialysis machine manufacturer in order to eventually obtain regulatory approval in the European Community and in the United States in 2006.

We intend to focus our sales and marketing efforts over the next 12 months primarily on expanding our marketing of OLpur MD190 in our Target European Market, and on continuing our clinical studies on the OLpur MD190 to provide definitive demonstration of the OLpur MD190's efficacy, including four such studies we have already initiated in our Target European Market. Furthermore, we anticipate initiating marketing of OLpur H2H in our Target European Market once we obtain the requisite regulatory approvals.

Over the next 12 months, we currently expect to spend approximately: $500,000 to continue our product engineering to complete our clinical grade OLpur H2H product; $1.3 million for the marketing and sales of our OLpur MD190 product, including marketing clinical studies, product sampling and exhibiting at trade shows; $500,000 to complete clinical studies and pursue regulatory approvals with respect to our OLpur H2H product in Europe; $650,000 in costs associated with operating as a publicly traded company, such as professional and insurance fees; and $800,000 to conduct clinical studies and pursue U.S. regulatory approvals with respect to both our OLpur MD190 and our OLpur H2H products, unless we make arrangements whereby collaborative partners finance such activities.

If and when the volume-discount pricing provisions of our agreement with our fiber supplier, Membrana GmbH, become applicable, for each period we will record inventory and cost of goods sold for our fiber orders pursuant to our agreement with Membrana GmbH based 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.

In August 2003, we established a European customer service and financial operations center in Dublin, Ireland. Our sales staffs are based in various parts of our Target European Market. We have a clinical services staff that provides customer support and training. We intend to add one to three members to our sales staff as well as one to two members to our administrative or our clinical services staff in our Target European Market. We intend to make these staff additions as we expand our presence in our Target European Market and such expansion is currently in process.

Results of Operations

Fluctuations in Operating Results

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

Three Months Ended March 31, 2005 Compared to the Three Months Ended March 31, 2004

Revenues

Revenues increased to $1,901,665 for the three months ended March 31, 2005 from $0 for the three months ended March 31, 2004. Revenues for the three months ended March 31, 2005 represented licensing revenues of $1,750,000 resulting from our agreement with Asahi and $151,665 in receivables with respect to shipments of our OLpur MD190 product to customers in our Target European Market where the rights of return have expired. Although we began shipping our product during the three months ended March 31, 2004, revenues related to such shipments were deferred since rights of return on our product had not yet expired.

Cost of Product Revenue

Cost of product revenue increased to $135,368 for the three months ended March 31, 2005 from $12,618 for the three months ended March 31, 2004. Cost of product revenue represented the cost of our OLpur MD190 product shipped to customers in our Target European Market where the rights of return have expired as well as obsolete inventory written-off due to the incorporation of improved fiber into our dialyzers. Cost of product revenue increased because of increased product revenues from shipments of our OLpur MD190 product during the three months ended March 31, 2005.

Research and Development

Research and development expenses decreased to $462,701 for the three months ended March 31, 2005 from $690,024 for the three months ended March 31, 2004. This $227,323 decrease was primarily due to a decrease in development expenses related to our OLpur H2H product of approximately $190,000 due to timing of the project. We anticipate increases to research and development expenses in future periods as we plan to complete the development of our OLpur H2H and OLpur NS2000 products, make them available for clinical testing and seek regulatory approval

for introduction in our Target European Market and the United States.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $1,752,488 for the three months ended March 31, 2005 from $1,316,435 for the three months ended March 31, 2004. This $436,053 increase was primarily due to an increase of approximately $227,000 in expenses related to the marketing of our OLpur MD190, including increased salaries of approximately $143,000 due to the hiring of additional sales and clinical support staff and increased product sampling of approximately $96,000 in our Target European Market. Other contributors to the increase include $159,000 in expenses associated with being a public company, including legal, accounting and insurance expenses, and approximately $41,000 in expenses related to the improvement of the manufacturing of our OLpur MD190. We anticipate increases to selling, general and administrative expenses in future periods as we plan to seek greater market penetration with our OLpur MD190 within our Target European Market and to enter additional markets and introduce additional products once we obtain the requisite regulatory approvals. We also expect to continue to incur costs for insurance and professional fees associated with operating as a public company that we did not have prior to our initial public offering in September 2004.

Other Income (Expense), net

Our other income increased to $56,005 for the three months ended March 31, 2005 from $1,345 for the three months ended March 31, 2004. This $54,660 increase represents increased interest income earned on cash deposits and short-term investments as a result of higher balances of our cash and cash equivalents and short-term investments at March 31, 2005.

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock

Dividends and Accretion to Redemption Value of Redeemable Convertible Preferred Stock decreased to $0 for the three months ended March 31, 2005 from $2,071,500 for the three months ended March 31, 2004. This decrease is due to the conversion of our redeemable convertible preferred stock into common stock in conjunction with the completion of our initial public offering in September 2004.

Liquidity and Capital Resources

At March 31, 2005, we had a deficit accumulated of $42.2 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 and our initial public offering.

At March 31, 2005, we had $4.3 million in cash and cash equivalents. Net cash used in operating activities was $0.2 million for the three months ended March 31, 2005 compared to $2.1 million for the three months ended March 31, 2004. The $1.9 million decrease in net cash used in operating activities during the three months ended March 31, 2005 was primarily due to a smaller net loss of approximately $1.6 million in the three months ended March 31, 2005, mainly due to the $1,750,000 license fee earned pursuant to the license agreement entered into with Asahi.

Net cash used in investing activities was $112,064 for the three months ended March 31, 2005 compared to $213,478 for the three months ended March 31, 2004. This decrease was due to a decreased amount of fixed asset purchases, mainly manufacturing equipment, in the three months ended March 31, 2005.

Net cash provided by financing activities was $1.0 million for the three months ended March 31, 2005 compared to $3.8 million for the three months ended March 31, 2004. The net cash provided by financing activities in the three months ended March 31, 2005 was primarily due to the net proceeds of approximately $956,000 from Asahi in exchange for 184,250 shares of our common stock pursuant to a Subscription Agreement dated March 2, 2005. The net cash provided by financing activities in the three months ended March 31, 2004 was due to the net proceeds raised from the issuance of Series D convertible preferred stock.

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 products;
- to continue our product engineering;
- to pay a former supplier, Plexus Services Corp., amounts due under our settlement agreement; and
- for working capital purposes, including for additional salaries and wages as our organization grows and as we expand our presence in our Target European Market and establish operations in the United States and other markets, and for additional professional fees and expenses and other operating costs.

We have consumed substantial amounts of capital since our inception. We currently expect our long-term future liquidity source to be gross margins generated from sales of our products. Nonetheless, we believe our existing resources would be sufficient to fund our currently planned operations through the first half of 2006, even if we were not to generate any gross revenues from sales of our products. 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 timing and costs associated with obtaining the Conformite Europeene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MD190, for which the CE mark was obtained in July of 2003), or United States regulatory approval;
- the continued progress in and the costs of clinical studies and other research and development programs;
- the costs associated with manufacturing scale-up;
- 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 actual, current and threatened litigation.

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 anticipated sales of our products, otherwise prove to be insufficient to fund our operations, we could be required to seek additional financing. We have no current arrangements with respect to sources of additional financing.

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:

- potential products that appeared promising in early research or clinical trials to us may not demonstrate efficacy or safety in subsequent pre-clinical or clinical trials;
- we may not obtain appropriate or necessary governmental approvals;
- product orders may be cancelled, patients currently using our products may cease to do so and patients expected to begin using our products may not;

- we may not be able to obtain funding if and when needed;
- 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 our target markets;
- we may not be able to sell our products at competitive prices or profitably; and
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products.

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 filed with the SEC for the fiscal year ended December 31, 2004. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a

result of new information, future events or otherwise.

Item 3. Controls and Procedures.

Prior to the filing of this Quarterly Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report. In conjunction with our preparation toward compliance with Section 404 of the Sarbanes-Oxley Act of 2002, we are in the process of implementing certain enhancements with respect to our internal controls over financial reporting. These matters are being discussed with our independent accountants and with the Audit Committee of our Board of Directors. Management, including the Chief Executive Officer and Chief Financial Officer, expects that these enhancements will be in place by June 30, 2006.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

There have been no material developments in the pending legal proceedings as described in our Form 10-KSB for the fiscal year ended December 31, 2004.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Recent Sales of Unregistered Securities

On March 2, 2005, we entered into a Subscription Agreement with Asahi Kasei Medical Co., Ltd. ("Asahi"), a business unit of Asahi Kasei Corporation, pursuant to which Asahi purchased 184,250 shares of our common stock at an aggregate purchase price of $955,521. The purchased shares were not registered

at the time of their issuance because the issuance was conducted pursuant to Section 4(2) of the Securities Act of 1933, as amended, or Regulation D promulgated thereunder.

(b) Use of Proceeds from Registered Securities

The initial public offering of our common stock, par value $.001 (the "Offering"), was effected through a Registration Statement on Form S-1 (File No. 333-116162) that was declared effective by the Securities and Exchange Commission on September 20, 2004. Since September 20, 2004 through March 31, 2005, of the net $10.8 million of proceeds from the Offering, we had used: approximately $1.2 million for the marketing and sales of our products; approximately $750,000 on product engineering; approximately $400,000 for capital expenditures; approximately $350,000 on payments of preferred dividends; and approximately $500,000 for working capital and other purposes. As of March 31, 2005, we held approximately $6.0 million of the remaining proceeds from the Offering in short term investments and approximately $1.6 million in cash and cash equivalents. None of the expenses, or application of the net proceeds from the Offering, were paid, directly or indirectly, to any of our directors or officers (or their associates), to persons owning 10 percent or more of our common stock or to any of our affiliates (other than directors' compensation and salaries to officers arising out of normal operating activities, and payments of dividends to former holders of shares of our series B, series C and series D convertible preferred stocks).

Item 6. Exhibits.

3.1 Third Amended and Restated Certificate of Incorporation of the Registrant (1)

3.2 Certificate of Retirement of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock of the Registrant

10.1 License Agreement dated as of March 2, 2005 between Asahi Kasei Medical Co., Ltd and the Registrant (2)

10.2 Subscription Agreement dated as of March 2, 2005 between Asahi Kasei Medical Co., Ltd and the Registrant (2)

10.3 Non-employee Director Compensation Summary

10.4 Named Executive Officer Summary of Changes to Compensation

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

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(1) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-1, File No. 333-116162.

(2) Incorporated by reference to Nephros, Inc.'s Report on Form 8-K filed with the Securities and Exchange Commission on March 3, 2005.

SIGNATURES

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

NEPHROS, INC.

Date: May 16, 2005

By /s/ NORMAN J. BARTA

Norman J. Barta
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 16, 2005

By /s/ MARC L. PANOFF

Marc L. Panoff
Chief Financial Officer
(Principal Financial and Accounting Officer)

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