CONTINENTAL RESOURCES, INC
Form 10-K
February 21, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-32886

CONTINENTAL RESOURCES, INC.
(Exact name of registrant as specified in its charter)

Oklahoma	73-0767549
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20 N. Broadway, Oklahoma City, Oklahoma	73102
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (405) 234-9000
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.01 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2017 was approximately $2.8 billion, based upon the closing price of $32.33 per share as reported by the New York Stock Exchange on such date.

375,215,902 shares of our $0.01 par value common stock were outstanding on January 31, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement of Continental Resources, Inc. for the Annual Meeting of Shareholders to be held in May 2018, which will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year, are incorporated by reference into Part III of this Form 10-K.

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Glossary of Crude Oil and Natural Gas Terms

The terms defined in this section may be used throughout this report:

“basin” A large natural depression on the earth’s surface in which sediments generally brought by water accumulate.

“Bbl” One stock tank barrel, of 42 U.S. gallons liquid volume, used herein in reference to crude oil, condensate or natural gas liquids.

“Bcf” One billion cubic feet of natural gas.

“Boe” Barrels of crude oil equivalent, with six thousand cubic feet of natural gas being equivalent to one barrel of crude oil based on the average equivalent energy content of the two commodities.

“Btu” British thermal unit, which represents the amount of energy needed to heat one pound of water by one degree Fahrenheit and can be used to describe the energy content of fuels.

“completion” The process of treating a drilled well followed by the installation of permanent equipment for the production of crude oil and/or natural gas.

“conventional play” An area believed to be capable of producing crude oil and natural gas occurring in discrete accumulations in structural and stratigraphic traps.

“DD&A” Depreciation, depletion, amortization and accretion.

“de-risked” Refers to acreage and locations in which the Company believes the geological risks and uncertainties related to recovery of crude oil and natural gas have been reduced as a result of drilling operations to date. However, only a portion of such acreage and locations have been assigned proved undeveloped reserves and ultimate recovery of hydrocarbons from such acreage and locations remains subject to all risks of recovery applicable to other acreage.

“developed acreage” The number of acres allocated or assignable to productive wells or wells capable of production.

“development well” A well drilled within the proved area of a crude oil or natural gas reservoir to the depth of a stratigraphic horizon known to be productive.

“dry gas” Refers to natural gas that remains in a gaseous state in the reservoir and does not produce large quantities of liquid hydrocarbons when brought to the surface. Also may refer to gas that has been processed or treated to remove all natural gas liquids.

“dry hole” Exploratory or development well that does not produce crude oil and/or natural gas in economically producible quantities.

“enhanced recovery” The recovery of crude oil and natural gas through the injection of liquids or gases into the reservoir, supplementing its natural energy. Enhanced recovery methods are sometimes applied when production slows due to depletion of the natural pressure.

“exploratory well” A well drilled to find crude oil or natural gas in an unproved area, to find a new reservoir in an existing field previously found to be productive of crude oil or natural gas in another reservoir, or to extend a known reservoir beyond the proved area.

“field” An area consisting of a single reservoir or multiple reservoirs all grouped on, or related to, the same individual geological structural feature or stratigraphic condition. The field name refers to the surface area, although it may refer to both the surface and the underground productive formations.

“formation” A layer of rock which has distinct characteristics that differs from nearby rock.

“fracture stimulation” A process involving the high pressure injection of water, sand and additives into rock formations to stimulate crude oil and natural gas production. Also may be referred to as hydraulic fracturing.

“gross acres” or “gross wells” Refers to the total acres or wells in which a working interest is owned.

“held by production” or “HBP” Refers to an oil and gas lease continued into effect into its secondary term for so long as a producing oil and/or gas well is located on any portion of the leased premises or lands pooled therewith.

“horizontal drilling” A drilling technique used in certain formations where a well is drilled vertically to a certain depth and then drilled horizontally within a specified interval.

“MBbl” One thousand barrels of crude oil, condensate or natural gas liquids.

"MBoe" One thousand Boe.
"Mcf" One thousand cubic feet of natural gas.
"MMBo" One million barrels of crude oil.
"MMBoe" One million Boe.
"MMBtu" One million British thermal units.
"MMcf" One million cubic feet of natural gas.
"net acres" or "net wells" Refers to the sum of the fractional working interests owned in gross acres or gross wells.
"NYMEX" The New York Mercantile Exchange.
"pad drilling" or "pad development" Describes a well site layout which allows for drilling multiple wells from a single pad resulting in less environmental impact and lower per-well drilling and completion costs.
"play" A portion of the exploration and production cycle following the identification by geologists and geophysicists of areas with potential crude oil and natural gas reserves.
"productive well" A well found to be capable of producing hydrocarbons in sufficient quantities such that proceeds from the sale of the production exceed production expenses and taxes.
"prospect" A potential geological feature or formation which geologists and geophysicists believe may contain hydrocarbons. A prospect can be in various stages of evaluation, ranging from a prospect that has been fully evaluated and is ready to drill to a prospect that will require substantial additional seismic data processing and interpretation.
"proved reserves" The quantities of crude oil and natural gas, which, by analysis of geoscience and engineering data, can be estimated with reasonable certainty to be economically producible from a given date forward, from known reservoirs and under existing economic conditions, operating methods, and government regulations prior to the time at which contracts providing the right to operate expire, unless evidence indicates renewal is reasonably certain.
"proved developed reserves" Reserves expected to be recovered through existing wells with existing equipment and operating methods.
"proved undeveloped reserves" or "PUD" Proved reserves expected to be recovered from new wells on undrilled acreage or from existing wells where a relatively major expenditure is required for completion.
"PV-10" When used with respect to crude oil and natural gas reserves, PV-10 represents the estimated future gross revenues to be generated from the production of proved reserves using a 12-month unweighted arithmetic average of the first-day-of-the-month commodity prices for the period of January to December, net of estimated production and future development and abandonment costs based on costs in effect at the determination date, before income taxes, and without giving effect to non-property-related expenses, discounted to a present value using an annual discount rate of 10% in accordance with the guidelines of the Securities and Exchange Commission ("SEC"). PV-10 is not a financial measure calculated in accordance with generally accepted accounting principles ("GAAP") and generally differs from Standardized Measure, the most directly comparable GAAP financial measure, because it does not include the effects of income taxes on future net revenues. Neither PV-10 nor Standardized Measure represents an estimate of the fair market value of the Company's crude oil and natural gas properties. The Company and others in the industry use PV-10 as a measure to compare the relative size and value of proved reserves held by companies without regard to the specific tax characteristics of such entities.
"reservoir" A porous and permeable underground formation containing a natural accumulation of producible crude oil and/or natural gas that is confined by impermeable rock or water barriers and is separate from other reservoirs.
"resource play" Refers to an expansive contiguous geographical area with prospective crude oil and/or natural gas reserves that has the potential to be developed uniformly with repeatable commercial success due to advancements in horizontal drilling and completion technologies.
"royalty interest" Refers to the ownership of a percentage of the resources or revenues produced from a crude oil or natural gas property. A royalty interest owner does not bear exploration, development, or operating expenses associated with drilling and producing a crude oil or natural gas property.
"SCOOP" Refers to the South Central Oklahoma Oil Province, a term used to describe properties located in the Anadarko basin of Oklahoma in which we operate. Our SCOOP acreage extends across portions of Garvin, Grady, Stephens, Carter, McClain and Love counties of Oklahoma and has the potential to contain hydrocarbons from a variety of conventional and unconventional reservoirs overlying and underlying the Woodford formation.

"STACK" Refers to Sooner Trend Anadarko Canadian Kingfisher, a term used to describe a resource play located in the Anadarko Basin of Oklahoma characterized by stacked geologic formations with major targets in the Meramec, Osage and Woodford formations. A significant portion of our STACK acreage is located in over-pressured portions of Blaine, Dewey and Custer counties of Oklahoma.

"spacing" The distance between wells producing from the same reservoir. Spacing is often expressed in terms of acres (e.g., 640-acre spacing) and is often established by regulatory agencies.

"Standardized Measure" Discounted future net cash flows estimated by applying the 12-month unweighted arithmetic average of the first-day-of-the-month commodity prices for the period of January to December to the estimated future production of year-end proved reserves. Future cash inflows are reduced by estimated future production and development costs based on period-end costs to determine pre-tax net cash inflows. Future income taxes, if applicable, are computed by applying the statutory tax rate to the excess of pre-tax cash inflows over the tax basis in the crude oil and natural gas properties. Future net cash inflows after income taxes are discounted using a 10% annual discount rate.

"step-out well" or "step outs" A well drilled beyond the proved boundaries of a field to investigate a possible extension of the field.

"three dimensional (3D) seismic" Seismic surveys using an instrument to send sound waves into the earth and collect data to help geophysicists define the underground configurations. 3D seismic provides three-dimensional pictures. We typically use 3D seismic testing to evaluate reservoir presence and/or continuity. We also use 3D seismic to identify sub-surface hazards to assist in steering, avoiding hazards and determining where to perform optimized completions.

"unconventional play" An area believed to be capable of producing crude oil and natural gas occurring in accumulations that are regionally extensive, but may lack readily apparent traps, seals and discrete hydrocarbon-water boundaries that typically define conventional reservoirs. These areas tend to have low permeability and may be closely associated with source rock, as is the case with oil and gas shale, tight oil and gas sands and coalbed methane, and generally require horizontal drilling, fracture stimulation treatments or other special recovery processes in order to achieve economic production. In general, unconventional plays require the application of more advanced technology and higher drilling and completion costs to produce relative to conventional plays.

"undeveloped acreage" Lease acreage on which wells have not been drilled or completed to a point that would permit the production of commercial quantities of crude oil and/or natural gas.

"unit" The joining of all or substantially all interests in a reservoir or field, rather than a single tract, to provide for development and operation without regard to separate property interests. Also, the area covered by a unitization agreement.

"well bore" The hole drilled by the bit that is equipped for crude oil or natural gas production on a completed well. Also called a well or borehole.

"working interest" The right granted to the lessee of a property to explore for and to produce and own crude oil, natural gas, or other minerals. The working interest owners bear the exploration, development, and operating costs on either a cash, penalty, or carried basis.

Cautionary Statement for the Purpose of the “Safe Harbor” Provisions of the Private Securities Litigation Reform Act of 1995

This report and information incorporated by reference in this report include “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical fact, including, but not limited to, forecasts or expectations regarding the Company’s business and statements or information concerning the Company’s future operations, performance, financial condition, production and reserves, schedules, plans, timing of development, rates of return, budgets, costs, business strategy, objectives, and cash flows, included in this report are forward-looking statements. The words “could,” “may,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “project,” “budget,” “plan,” “continue,” “potential,” “guidance,” “strate
expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words.

Forward-looking statements may include, but are not limited to, statements about:

- our strategy;
- our business and financial plans;
- our future operations;
- our crude oil and natural gas reserves and related development plans;
- technology;
- future crude oil, natural gas liquids, and natural gas prices and differentials;
- the timing and amount of future production of crude oil and natural gas and flaring activities;
- the amount, nature and timing of capital expenditures;
- estimated revenues, expenses and results of operations;
- drilling and completing of wells;
- competition;
- marketing of crude oil and natural gas;
- transportation of crude oil, natural gas liquids, and natural gas to markets;
- property exploitation, property acquisitions and dispositions, or joint development opportunities;
- costs of exploiting and developing our properties and conducting other operations;
- our financial position;
- general economic conditions;
- credit markets;
- our liquidity and access to capital;
- the impact of governmental policies, laws and regulations, as well as regulatory and legal proceedings involving us and of scheduled or potential regulatory or legal changes;
- our future operating and financial results;
- our future commodity or other hedging arrangements; and
- the ability and willingness of current or potential lenders, hedging contract counterparties, customers, and working interest owners to fulfill their obligations to us or to enter into transactions with us in the future on terms that are acceptable to us.

Forward-looking statements are based on the Company’s current expectations and assumptions about future events and currently available information as to the outcome and timing of future events. Although the Company believes these assumptions and expectations are reasonable, they are inherently subject to numerous business, economic, competitive, regulatory and other risks and uncertainties, most of which are difficult to predict and many of which are beyond the Company’s control. No assurance can be given that such expectations will be correct or achieved or that the assumptions are accurate or will not change over time. The risks and uncertainties that may affect the operations, performance and results of the business and forward-looking statements include, but are not limited to, those risk factors and other cautionary statements described under Part I, Item 1A. Risk Factors and elsewhere in this report, registration statements we file from time to time with the Securities and Exchange Commission, and other announcements we make from time to time.

Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which such statement is made. Should one or more of the risks or uncertainties described in this report occur, or should underlying assumptions prove incorrect, the Company's actual results and plans could differ materially from those expressed in any forward-looking statements. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

Except as expressly stated above or otherwise required by applicable law, the Company undertakes no obligation to publicly correct or update any forward-looking statement whether as a result of new information, future events or circumstances after the date of this report, or otherwise.

Part I

You should read this entire report carefully, including the risks described under Part I, Item 1A. Risk Factors and our consolidated financial statements and the notes to those consolidated financial statements included elsewhere in this report. Unless the context otherwise requires, references in this report to "Continental Resources," "Continental," "we," "us," "our," "ours" or "the Company" refer to Continental Resources, Inc. and its subsidiaries.

Item 1. Business

General

We are an independent crude oil and natural gas company with properties in the North, South and East regions of the United States. The North region consists of properties north of Kansas and west of the Mississippi River and includes North Dakota Bakken, Montana Bakken, and the Red River units. The South region includes all properties south of Nebraska and west of the Mississippi River including various plays in the SCOOP (South Central Oklahoma Oil Province) and STACK (Sooner Trend Anadarko Canadian Kingfisher) areas of Oklahoma. The East region is primarily comprised of undeveloped leasehold acreage east of the Mississippi River with no significant drilling or production operations.

We were formed in 1967 to explore for, develop and produce crude oil and natural gas properties. Through the 1980s, our activities and growth remained focused primarily in Oklahoma. In the 1980s, we expanded our activity into the North region. The North region comprised approximately 59% of our crude oil and natural gas production and approximately 69% of our crude oil and natural gas revenues for the year ended December 31, 2017. The Company's principal producing properties in the North region are located in the Bakken field of North Dakota and Montana. Approximately 50% of our estimated proved reserves as of December 31, 2017 are located in the North region. In recent years, we have significantly expanded our operations in our South region with our increased activity in the SCOOP and STACK plays. The South region comprised approximately 41% of our crude oil and natural gas production, 31% of our crude oil and natural gas revenues, and 50% of our estimated proved reserves as of and for the year ended December 31, 2017.

We focus our exploration activities in large new or developing crude oil and natural gas plays that provide us the opportunity to acquire undeveloped acreage positions for future drilling operations. We have been successful in targeting large repeatable resource plays where three dimensional seismic, horizontal drilling, geosteering technologies, advanced completion technologies (e.g., fracture stimulation) and enhanced recovery technologies allow us to develop and produce crude oil and natural gas reserves from unconventional formations. As a result of these efforts, we have grown substantially through the drill bit.

As of December 31, 2017, our estimated proved reserves were 1,331 MMBoe, with estimated proved developed reserves of 602 MMBoe, or 45% of our total estimated proved reserves. Crude oil represents approximately 48% of our estimated proved reserves as of December 31, 2017. The standardized measure of our discounted future net cash flows totaled approximately $10.5 billion at December 31, 2017.

For 2017, we generated crude oil and natural gas revenues of $2.98 billion and operating cash flows of $2.08 billion. Crude oil accounted for approximately 57% of our total production and approximately 78% of our crude oil and natural gas revenues for 2017. Production averaged 242,637 Boe per day for 2017, a 12% increase compared to average production of 216,912 Boe per day for 2016. Average daily production for the quarter ended December 31, 2017 increased 37% to 286,985 Boe per day compared to 209,861 Boe per day for the quarter ended December 31, 2016 due to increased drilling and completion activities.

The table below summarizes our total estimated proved reserves, PV-10 (non-GAAP) and net producing wells as of December 31, 2017, average daily production for the quarter ended December 31, 2017 and the reserve-to-production index in our principal operating areas. The PV-10 values shown below are not intended to represent the fair market value of our crude oil and natural gas properties. There are numerous uncertainties inherent in estimating quantities of crude oil and natural gas reserves. See Part I, Item 1A. Risk Factors and "Critical Accounting Policies and Estimates" in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this report for further discussion of uncertainties inherent in the reserve estimates.

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December 31, 2017				Average daily production for fourth quarter 2017 (Boe per day)	Annualized reserve/production index (2)
Proved reserves (MBoe)	Percent of total	PV-10 (1) (In millions)	7		

Competition

The dialyzer and renal replacement therapy market is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical needs of physicians and nephrologists, improve patient outcomes and remain cost-effective for payors.

We compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG, and Gambro AB, currently two of the primary machine manufacturers in hemodialysis. At present, Fresenius Medical Care AG and Gambro AB also manufacture HDF machines.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis products include Gambro AB, Baxter International Inc., Asahi Kasei Medical Co. Ltd., Bellco S.p.A., a subsidiary of the Sorin group, B. Braun Melsungen AG, Nipro Corporation Ltd., Nikkiso Co., Ltd., Terumo Corporation and Toray Medical Co., Ltd.

Other competitive considerations include pharmacological and technological advances in preventing the progression of ESRD in high-risk patients such as those with diabetes and hypertension, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants.

We are not aware of any other companies using technology similar to ours in the treatment of ESRD. Our competition would increase, however, if companies that currently sell ESRD products, or new companies that enter the market, develop technology that is more efficient than ours. We believe that in order to become competitive in this market, we will need to develop and maintain competitive products and take and hold sufficient market share from our competitors. Therefore, we expect our methods of competing in the ESRD marketplace to include:

- continuing our efforts to develop, have manufactured and sell products which, when compared to existing products, perform more efficiently and are available at prices that are acceptable to the market;
- displaying our products and providing associated literature at major industry trade shows in the United States, our Target European Market and Asia;
- initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;
- offering the OLpur H2H at a price that does not provide us with significant positive margins in order to encourage adoption of this product and associated demand for our dialyzers; and
- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities.

With respect to the water filtration market, we expect to compete with companies that are well entrenched in the water filtration domain. These companies include Pall Corporation, which manufactures end-point water filtration systems, as well as CUNO (a 3M Company) and US Filter (a Siemens business). Our methods of competition in the water filtration domain include:

- developing and marketing products that are designed to meet critical and specific customer needs more effectively than competitive devices;
- offering unique attributes that illustrate our product reliability, “user-friendliness,” and performance capabilities;
- selling products to specific customer groups where our unique product attributes are mission-critical; and
- pursuing alliance opportunities for joint product development and distribution.

Intellectual Property

Patents

We protect our technology and products through patents and patent applications. In addition to the United States, we are also applying for patents in other jurisdictions, such as the European Patent Office, Canada and Japan, to the extent we deem appropriate. We have built a portfolio of patents and applications covering our products, including their hardware design and methods of hemodiafiltration.

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge," have claims that cover the OLpur MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Although there are pending applications with claims to the present embodiments of the OLpur H 2 H and the OLpur NS2000 products, these products are still in the development stage and we cannot determine if the applications (or the patents that we may issue on them) will also cover the ultimate commercial embodiment of these products. In addition, technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have applied for patents on our DSU water filtration products to cover various applications in residential, commercial, and remote environments.

As of January 2009, we have fifteen issued U.S. patents; one issued Eurasian patent; three Mexican patents, four South Korean patents, three Russian patents, four Chinese patents, five French patents, five German patents, four Israeli patents, four Italian patents, one Spanish patent, five United Kingdom patents, six Japanese patents, two Hong Kong patents, and five Canadian patents. Our issued U.S. patents expire between 2018 and 2022. In addition, we have four pending U.S. patent applications, ten pending patent applications in Canada, eight pending patent applications in the European Patent Office, five pending patent applications in Brazil, three pending patent applications in China, nine pending patent applications in Japan, three pending patent applications in Mexico, one pending patent application in South Korea, one pending patent application in Hong Kong, two pending patent applications in India, two pending patent applications in Israel and one pending patent application in Australia.. Our pending patent applications relate to a range of dialysis technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance toxin removal. We also have pending patent applications on our DSU water filtration system.

We have filed U.S. and International patent applications for a redundant ultra filtration device that was jointly invented by onr of our employees and an employee of our CM. We and are CM are negotiating commercial arrangements pertaining to the invention and the patent applications.

Trademarks

As of December 31, 2008, we secured registrations of the trademarks CENTRAPUR, H2H, OLpur and the Arrows Logo in the European Union. Applications for these trademarks are pending registration in the United States. We also have applications for registration of a number of other marks pending in the United States Patent and Trademark Office.

Governmental Regulation

The research and development, manufacturing, promotion, marketing and distribution of our ESRD therapy products in the United States, our Target European Market and other regions of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and analogous agencies.

United States

The FDA regulates the manufacture and distribution of medical devices in the United States pursuant to the FDC Act. All of our ESRD therapy products are regulated in the United States as medical devices by the FDA under the FDC Act. Under the FDC Act, medical devices are classified in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

- Class I devices are medical devices for which general controls are deemed sufficient to ensure their safety and effectiveness. General controls include provisions related to (1) labeling, (2) producer registration, (3) defect notification, (4) records and reports and (5) quality service requirements, or QSR.
- Class II devices are medical devices for which the general controls for the Class I devices are deemed not sufficient to ensure their safety and effectiveness and require special controls in addition to the general controls. Special controls include provisions related to (1) performance and design standards, (2) post-market surveillance, (3) patient registries and (4) the use of FDA guidelines.
- Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before a new medical device can be introduced to the market, FDA clearance of a pre-market notification under Section 510(k) of the FDC Act or FDA clearance of a pre-market approval, or PMA, application under Section 515 of the FDC Act must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process. We understand that it generally takes four to 12 months from the date a Section 510(k) notification is accepted for filing to obtain Section 510(k) pre-market clearance and that it could take several years from the date a Section 515 application is accepted for filing to obtain Section 515 pre-market approval, although it may take longer in both cases.

We expect that all of our ESRD therapy products and our DSU will be categorized as Class II devices and that these products will not require clearance of pre-market approval applications under Section 515 of the FDC Act, but will be eligible for marketing clearance through the pre-market notification process under Section 510(k). We have determined that we are eligible to utilize the Section 510(k) pre-market notification process based upon our ESRD therapy and DSU products' substantial equivalence to previously legally marketed devices in the United States. However, we cannot assure you:

- that we will not need to reevaluate the applicability of the Section 510(k) pre-market notification process to our ESRD therapy and DSU products in the future;
- that the FDA will agree with our determination that we are eligible to use the Section 510(k) pre-market notification process; or
- that the FDA will not in the future require us to submit a Section 515 pre-market approval application, which would be a more costly, lengthy and uncertain approval process.

The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past and may request clinical data to support pre-market clearance. As a result, the FDA could refuse to accept for filing a Section 510(k) notification made by us or request the submission of additional information. The FDA may determine that any one of our proposed ESRD therapy products is not substantially equivalent to a legally marketed device or that additional information is needed before a substantial equivalence determination can be made. A "not substantially equivalent" determination, or request for additional data, could prevent or delay the market introduction of our products that fall into this category, which in turn could have a material adverse effect on our potential sales and revenues. Moreover, even if the FDA does clear one or all of our products under the Section 510(k) process, it may clear a product for some procedures but not others or for certain classes of patients and not others.

For any devices cleared through the Section 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require a new Section 510(k) pre-market notification submission. Accordingly, if we do obtain Section 510(k) pre-market clearance for any of our ESRD therapy and DSU products, we will need to submit another Section 510(k) pre-market notification if we significantly affect that product's safety or effectiveness through subsequent modifications or enhancements.

If human clinical trials of a device are required in connection with a Section 510(k) notification and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or distributor of the device) will need to file an IDE application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal testing and/or laboratory bench testing. If the IDE application is approved, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as specified in the IDE. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of subjects. We submitted our original IDE application to the FDA for our OLpur H 2 H hemodiafiltration module and OLpur MD220 filter in May 2006. The FDA answered our application with additional questions in June 2006, and we submitted responses to the FDA questions in December 2006. In January 2007, we received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We completed the patient treatment phase of our clinical trials during the second quarter of 2008 and filed our 510(k) applications with respect to the OLpur MDHDF filter series and the OLpur H 2 H module in November 2008. No IDE was required for our DSU product. We hope to achieve U.S. regulatory approval of all products during the first half of 2009. Following its review of our applications, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

The Section 510(k) pre-market clearance process can be lengthy and uncertain. It will require substantial commitments of our financial resources and management's time and effort. Significant delays in this process could occur as a result of factors including:

- our inability to timely raise sufficient funds;
- the FDA’s failure to schedule advisory review panels;
- changes in established review guidelines;
- changes in regulations or administrative interpretations; or
- determinations by the FDA that clinical data collected is insufficient to support the safety and effectiveness of one or more of our products for their intended uses or that the data warrants the continuation of clinical studies.

Delays in obtaining, or failure to obtain, requisite regulatory approvals or clearances in the United States for any of our products would prevent us from selling those products in the United States and would impair our ability to generate funds from sales of those products in the United States, which in turn could have a material adverse effect on our business, financial condition, and results of operations.

The FDC Act requires that medical devices be manufactured in accordance with the FDA’s current QSR regulations which require, among other things, that:

- the design and manufacturing processes be regulated and controlled by the use of written procedures;

- the ability to produce medical devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process;
- any deficiencies in the manufacturing process or in the products produced be investigated;
- detailed records be kept and a corrective and preventative action plan be in place; and
- manufacturing facilities be subject to FDA inspection on a periodic basis to monitor compliance with QSR regulations.

If violations of the applicable QSR regulations are noted during FDA inspections of our manufacturing facilities or the manufacturing facilities of our contract manufacturers, there may be a material adverse effect on our ability to produce and sell our products.

Before the FDA approves a Section 510(k) pre-market notification, the FDA is likely to inspect the relevant manufacturing facilities and processes to ensure their continued compliance with QSR. Although some of the manufacturing facilities and processes that we expect to use to manufacture our ESRD and DSU filters have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not all been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H 2 H have been inspected by the FDA, they have not all been inspected by any notified body. A "notified body" is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. Even after the FDA has cleared a Section 510(k) submission, it will periodically inspect the manufacturing facilities and processes for compliance with QSR. In addition, in the event that additional manufacturing sites are added or manufacturing processes are changed, such new facilities and processes are also subject to FDA inspection for compliance with QSR. The manufacturing facilities and processes that will be used to manufacture our products have not yet been inspected by the FDA for compliance with QSR. We cannot assure you that the facilities and processes used by us will be found to comply with QSR and there is a risk that clearance or approval will, therefore, be delayed by the FDA until such compliance is achieved.

In addition to the requirements described above, the FDC Act requires that:

- all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices which they distribute commercially;
- information be provided to the FDA on death or serious injuries alleged to have been associated with the use of the products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur; and
- certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported.

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive 93/42/EEC. The European Union directive applies to both the manufacturer's quality assurance system and the product's technical design and discusses the various ways to obtain approval of a device (dependent on device classification), how to properly CE Mark a device and how to place a device on the market. We have subjected our entire business in our Target European Market to the most comprehensive procedural approach in order to demonstrate the quality standards and performance of our operations, which we believe is also the fastest way to launch a new product in the European Community.

The regulatory approach necessary to demonstrate to the European Union that the organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices requires the certification of a full quality management system by a notified body. We engaged TÜV Rheinland of North America, Inc. ("TÜV Rheinland") as the notified body to assist us in obtaining certification to the International Organization for Standardization, or ISO, 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

European Union requirements for products are set forth in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. A company demonstrates conformity to these requirements, with respect to a product, by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

Once a manufacturer's full quality management system is determined to be in compliance with ISO 13485/2003 and other statutory requirements, and the manufacturer's products conform with harmonized European standards, the notified body will recommend and document such conformity. The manufacturer will receive a CE marking and ISO certifications, and then may place a CE mark on the relevant products. The CE mark, which stands for Conformité Européenne, demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported to, or sold or distributed within, the European Union.

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms with the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. As of the date of filing of this Annual Report, the manufacturing facilities and processes that we are using to manufacture our OLpur MDHDF filter series have been inspected and certified by a notified body.

Regulatory Authorities in Regions Outside of the United States and the European Union

We also plan to sell our ESRD therapy products in foreign markets outside the United States which are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. Other than the CE marking of our OLpur MDHDF filter products, we have not obtained any regulatory approvals to sell any of our products and there is no assurance that any such clearance or certification will be issued.

Reimbursement

In both domestic markets and markets outside of the United States, sales of our ESRD therapy products will depend in part, on the availability of reimbursement from third-party payors. In the United States, ESRD providers are reimbursed through Medicare, Medicaid and private insurers. In countries other than the United States, ESRD providers are also reimbursed through governmental and private insurers. In countries other than the United States, the pricing and profitability of our products generally will be subject to government controls. Despite the continually expanding influence of the European Union, national healthcare systems in its member nations, reimbursement decision-making included, are neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government.

Product Liability and Insurance

The production, marketing and sale of kidney dialysis products have an inherent risk of liability in the event of product failure or claim of harm caused by product operation. We have acquired product liability insurance for our products in the amount of $5 million. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products, our ability to generate revenues and our profitability.

Some of our existing and potential agreements with manufacturers of our products and components of our products do or may require us (1) to obtain product liability insurance or (2) to indemnify manufacturers against liabilities resulting from the sale of our products. If we are not able to maintain adequate product liability insurance, we will be in breach of these agreements, which could materially adversely affect our ability to produce our products. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

Employees

As of December 31, 2008, we employed a total of 11 employees, 9 of whom were full time and 2 who are employed on a part-time basis. We also engaged 2 consultants on an ongoing basis. Of the 13 total employees and consultants, 5 were employed in a sales/marketing/customer support capacity, 4 in general and administrative and 4 in research and development.

Recent Developments

In March 2007, we received full approval on our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We obtained approval from the IRBs and completed the clinical trial near the end of the second quarter in 2008. The clinical data was complied, analyzed, summarized and submitted with our FDA 510(k) in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009 Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

Item 2. Properties

Our U.S. facilities are located at 41 Grand Avenue, River Edge, New Jersey, 07661 and consist of approximately 4,688 square feet of space. The term of the rental agreement is for three years commencing December 2008 with a monthly cost of approximately $7,423. We use our facilities to house our corporate headquarters and research facilities.

Our facilities in our Target European Market are currently located at 6 Eaton House, Main Street, Rathcoole, Co. Dublin and consist of approximately 650 square feet of space. The lease agreement was entered into on November 30, 2008. The lease term is 6 months beginning March 1, 2009 and is renewable based on business views. Our monthly cost will be 735 Euro (approximately $1,000). We use our facilities to house our accounting, operations and customer service departments. We believe this space will be adequate to meet our needs. We do not own any real property for use in our operations or otherwise.

Item 3. Legal Proceedings

A former employee in France filed a claim in October 2008 stating that he is due 30,000 Euro or approximately $42,000 in back wages. The individual left the Company four years ago and signed a Separation Agreement which stated the Company had no further liability to the individual. Our attorney has advised us that the Separation Agreement is valid and should preclude us from having any liability. The matter will be heard before a French court sometime in 2009. No date has been set at this time.

There are no other currently pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject. Please refer to the "Risks Related to Our Company" section of this Report for a discussion of certain threatened litigation and please refer to "Note 12 to the Condensed Consolidated Financial Statements" for a discussion of certain settlement arrangements.

Item 4. Submission of Matters to a Vote of Security Holders

There were no matters submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this Report.

PART II

Item 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company was informed on January 22, 2009 that the AMEX had suspended trading of the Company's common stock effective immediately. Until such date, our common stock had been trading on the AMEX under the symbol NEP. The following table sets forth the high and low sales prices for our common stock as reported on the AMEX for each quarter within the years ended December 31, 2008 and 2007.

Quarter Ended	High	Low
March 31, 2007	$ 2.59	$ 1.40
June 30, 2007	$ 1.84	$ 1.05
September 30, 2007	$ 1.45	$ 0.45
December 31, 2007	$ 1.88	$ 0.45
March 31, 2008	$ 1.60	$ .33
June 30, 2008	$ .97	$ .50
September 30, 2008	$ .65	$ .24
December 31, 2008	$ .48	$ .05

Effective February 4, 2009, our common stock is now quoted on the OTC Bulletin Board under the symbol "NEPH.OB".

As of March 20, 2009, there were approximately 37 holders of record and approximately 850 beneficial holders of our common stock.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends on our common stock in the foreseeable future. We expect that any earnings which we may realize will be retained to finance our growth. There can be no assurance that we will ever pay dividends on our common stock. Our dividend policy with respect to the common stock is within the discretion of the Board of Directors and its policy with respect to dividends in the future will depend on numerous factors, including our earnings, financial requirements and general business conditions.

The information set forth in Part III, Item 12 of this Annual Report on Form 10-K relating to our equity compensation plans is hereby incorporated by reference to this Item 5.

Item 7. Management's Discussion and Analysis or Plan of Operation

Business Overview

Since our inception in April 1997, we have been engaged primarily in the development of hemodiafiltration, or HDF, products and technologies for treating patients with End Stage Renal Disease, or ESRD. Our products include the OLpur MD190 and MD220, which are dialyzers (our "OLpur MDHDF Filter Series"), OLpur H 2 H, an add-on module designed to enable HDF therapy using the most common types of hemodialysis machines. We began selling our OLpur MD190 dialyzer in some parts of our Target European Market (consisting of France, Germany, Ireland, Italy and the United Kingdom (U.K.), as well as Cyprus, Denmark, Greece, the Netherlands, Norway, Portugal, Spain, Sweden and Switzerland) in March 2004, and have developed units suitable for clinical evaluation for our OLpur H 2 H product. We are developing our OLpur NS2000 product by modifying an existing HDF platform and incorporating our proprietary H 2 H technology.

To date, we have devoted most of our efforts to research, clinical development, seeking regulatory approval for our ESRD products, establishing manufacturing and marketing relationships and establishing our own marketing and sales support staff for the development, production and sale of our ESRD therapy products in our Target European Market and the United States upon their approval by appropriate regulatory authorities. We submitted to the FDA for our 510(k) application in November 2008 for approval of our OLpūr H2H module and OLpūr MD 220 filter and expect to obtain approval in 2009. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

We have also applied our filtration technologies to water filtration and in 2006 we introduced our new Dual Stage Ultrafilter (the "DSU") water filtration system. Our DSU represents a new and complementary product line to our existing ESRD therapy business. The DSU incorporates our unique and proprietary dual stage filter architecture 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. The DSU is designed to remove a broad range of bacteria, viral agents and toxic substances, including salmonella, hepatitis, cholera, HIV, Ebola virus, ricin toxin, legionella, fungi and e-coli.

In the fourth quarter of 2008, we also filed a 510(k) with US FDA for approval to use DSU product with reverse osmosis (RO) water systems found within dialysis centers and hospitals. Due the nature of this application our DSU will be categorized as a medical device and therefore requires a 510(k). While waiting for both ESRD and DSU 510(k)s we redirected much of our resources to our sales and marketing efforts of our DSU product here in the US in its non-medical device applications. Our goal is to expand distribution to the hospital market and identify other short term applications. Following its review of the application, the FDA has requested additional information from us. On February 24, 2009, we provided a formal response to the FDA. Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

In 2006, the U.S. Defense Department budget included an appropriation for the U.S. Marine Corps for development of a dual stage water ultra filter. In connection with this Federal appropriation of approximately $1 million, we are developing a personal potable water purification system for use by warfighters. Work on this project commenced in January 2008 and we have billed $196,000 during the year ended December 31, 2008. In December 2007, the U.S. Department of Defense Appropriations Act appropriated an additional $2 million to continue the development of a dual stage ultra reliable personal water filtration system. Although it is our intention to execute an agreement with the U.S. Department of Defense to utilize this appropriation before it expires in September 2009, such an agreement has not been executed as of December 31, 2008. We have defined the project scope and objectives in connection with this appropriation and have submitted a proposal to the Office of Naval Research in February 2009.

Since our inception, we have incurred annual net losses. As of December 31, 2008, we had an accumulated deficit of $87,949,000, and we expect to incur additional losses in the foreseeable future. We recognized net losses of $6,337,000 and $26,356,000 for the years ended December 31, 2008 and 2007, respectively.

Since our inception, we have financed our operations primarily through sales of our equity and debt securities. From inception through December 31, 2008, we received net offering proceeds from private sales of equity and debt securities and from the initial public offering of our common stock (after deducting underwriters' discounts, commissions and expenses, and our offering expenses) of approximately $52.0 million in the aggregate. An additional source of finances was our license agreement with Asahi, pursuant to which we received an up front license fee of $1.75 million in March 2005.

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

1) the completion and success of additional clinical trials;
2) receiving regulatory approval for each of our ESRD therapy products and our DSU product in our target territories;
3) the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
4) our ability to effectively and efficiently manufacture, market and distribute our products;
5) our ability to sell our products at competitive prices which exceed our per unit costs;
6) the consolidation of dialysis clinics into larger clinical groups; and
7) the current U.S. healthcare plan is to bundle reimbursement for dialysis treatment which may force dialysis clinics to change therapies due to financial reasons.

To the extent we are unable to succeed in accomplishing (1) through (7), our sales could be lower than expected and dramatically impair our ability to generate income from operations. With respect to (6), 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.

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

On September 27, 2007, we received a warning letter from the AMEX stating that the staff of the AMEX Listing Qualifications Department had determined that we were not in compliance with Section 121B(2)(c) of the AMEX Company Guide requiring that at least 50% of the directors of our Company's board of directors are independent directors. This non-compliance was due to the fact that William J. Fox, Judy Slotkin, W. Townsend Ziebold and Howard Davis resigned from our board of directors on September 19, 2007, concurrently with the appointment of Paul Mieyal and Arthur Amron to the board of directors, in accordance with our September 2007 financing. Consequently, our board of directors consisted of five directors, two of whom were independent. The AMEX had given us until December 26, 2007 to regain compliance with the independence requirements. On November 16, 2007, James S. Scibetta was appointed to serve as an independent director on our board of directors. On December 5, 2007, we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiency identified in their September 27, 2007 letter.

On September 12, 2008, we received a letter from the AMEX notifying us of our noncompliance with certain continued listing standards. The following are the listing standards that we were in noncompliance of:

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;
- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and
- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

In response to that letter, we submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions we have taken, or will take, that would bring us into compliance with the continued listing standards by April 30, 2009.

Subsequent to December 31, 2008, on January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan. The AMEX further notified us that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we have decided not to seek an appeal of the AMEX's intention to delist our common stock.

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

Effective February 4, 2009, our common stock is now quoted on the Over the Counter ("OTC") Bulletin Board under the symbol "NEPH.OB".

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 157, “Fair Value Measurements” (“SFAS 157”). This Standard defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, “Effective Date of FASB Statement No.157” (“FSP 157-2”), which delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We adopted SFAS 157 for financial assets and liabilities on January 1, 2008. The disclosures required under SFAS 157 are set forth in Note 2 to the consolidated financial statements. We are currently in the process of evaluating the effect, if any, that the adoption of FSP 157-2 will have on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 155” (“SFAS 159”). This statement permits entities to choose to measure selected assets and liabilities at fair value. We adopted SFAS 159 on January 1, 2008 resulting in no material impact to our consolidated financial statements.

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

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS 141R"). SFAS 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. SFAS 141R determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is not permitted. The effect of SFAS 141R on our consolidated financial statements will be dependent on the nature and terms of any business combinations that occur after its effective date.

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

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

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

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

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 annual report on Form 10-K, we believe that the following accounting policies require the application of significant judgments and estimates.

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.

The Company recognizes revenue related to product sales when delivery is confirmed by its external logistics provider and the other criterion of SAB No. 104 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by the Company's customers.

Stock-Based Compensation

We account for stock-based compensation under the provisions of SFAS No. 123 (Revised 2004) "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

Accounts Receivable

We provide credit terms to our customers in connection with purchases of our products. We periodically review customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect our best estimate of potential losses.

Inventory Reserves

Our inventory reserve requirements are based on factors including the products' expiration date and estimates for the future sales of the product. If estimated sales levels do not materialize, we will make adjustments to its assumptions for inventory reserve requirements.

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.

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 annual 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, marketing expenses related to product launches, timing of regulatory approval of our various products and market acceptance of our products. 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 Fiscal Year Ended December 31, 2008 Compared to the Fiscal Year Ended December 31, 2007

Product Revenues

Total product revenues for the year ended December 31, 2008 were $1,473,000 compared to $1,196,000 for the year ended December 31, 2007. The $277,000, or 23.2%, increase is primarily due to $196,000 related to revenue generated from the Office of Naval Research project in the United States. The Company began work on this project in 2008. An increase of $33,000 or 3% was related to sales of the OLpūr MD190 and MD220 Dialyzers in Europe. Sales of the OLpūr MD190 and MD220 Dialyzers increased only 1.4% in number of units during 2008 in Europe however, a negative price variance of $42,000 was incurred due to the sale of reworked units at a discounted price. A favorable currency exchange contributed $75,000 to the change in 2008 revenue compared to 2007. In addition, revenues in the United States increased by $49,000 from sales of the Dual Stage Ultrafilter (the "DSU") water filter. The DSU represents a new and complementary product line introduced in 2008 and the Company had no revenues generated from it during 2007.

Cost of Goods Sold

Cost of goods sold was $1,064,000 for the year ended December 31, 2008 compared to $876,000 for the year ended December 31, 2007. The $188,000, or 21.5%, increase in cost of goods sold is primarily due to an increase of $141,000 related to the sales of the Dual Stage Ultrafilter (the "DSU") water filters in the United States. The DSU represents a new and complementary product line introduced in 2008. The Company did not recognize any revenue or related cost of goods sold for the year ended December 31, 2007. The cost of the OLpūr MD190 and MD220 Dialyzers sold in Europe for the year ended December 31, 2008 increased by $47,000, or 5.4%, over the comparable period in 2007. This increase was due to higher manufacturing costs of $50,000 primarily due to an unfavorable currency exchange offset by a reduction in freight costs of $3,000 due to the discontinued use of a public warehouse.

Research and Development

Research and development expenses were $1,977,000 for the year ended December 31, 2008 compared to $1,920,000 for the year ended December 31, 2007, an increase of $57,000 or 3.0%. This increase consists of $564,000 related to a clinical trial conducted during 2008 and $17,000 related to development spending for the DSU water filter offset by reductions of $287,000 in personnel costs and $241,000 in machine development expenditures during 2008 compared to 2007.

Depreciation and Amortization Expense

Depreciation expense was $447,000, for the year ended December 31, 2008 compared to $352,000 for the year ended December 31, 2007, an increase of $95,000, or 27.0%. This increase is due to the acquisition of a DSU Mold in 2008, which contributed $36,000 of depreciation for the year ended December 31, 2008. An additional $59,000 recorded in 2008 is related to depreciation on furniture and fixtures and tooling to reflect the assessed utility of these assets as of December 31, 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $4,702,000 for the year ended December 31, 2008 compared to $5,527,000 for the year ended December 31, 2007, a decrease of $825,000 or 14.9%. The decrease is primarily due to the following:

- Selling expenses were $624,000 for the year ended December 31, 2008 compared to $451,000 for the year ended December 31, 2007, an increase of $173,000, or 38.4%. The increase in personnel costs of $73,000 and $100,000 in marketing expenditures during 2008 compared to the comparable period in 2007 were the primary reasons. This increase reflects the Company' investment in Marketing during fiscal year 2008 in order to establish corporate identity, improve the Company's website and advertise the merits of the DSU water filtration system.

- General and administrative expenses were $4,078,000 for the year ended December 31, 2008 compared to $5,076,000 for the year ended December 31, 2007, a decrease of $998,000, or 19.7%, primarily due to factors impacting professional service fees and compensation expense. The decrease is due to the following reductions in 2008 spending compared to 2007: personnel costs reduced by $150,000; deferred compensation costs reduced by $433,000; audit and legal fees reduced by $524,000; underwriting fees reduced by $140,000. These decreases were offset by the following increases in 2008 spending compared to 2007: recruiting fees of $148,000; directors' fees of $46,000; regulatory fees of $34,000; insurance fees of $27,000; facility costs of $20,000 and moving costs of $16,000.

Interest Income

Interest income was $199,000 for the year ended December 31, 2008 compared to $138,000 for the year ended December 31, 2007. The increase of $61,000, or 44%, reflects the impact of having additional cash on hand during 2008 compared to 2007. The additional cash resulted from the private investment in public equity executed in September 2007.

Interest Expense

No interest expense was incurred during 2008 as a result of the Company not having any outstanding debt during the fiscal 2008. Interest expense totaled $535,000 for the year ended December 31, 2007. The related debt was converted to equity as a result of the private investment in public equity that was executed in September 2007.

Interest expense for the year ended December 31, 2007 consisted of:

- $498,000 in connection with the New Notes;
- $37,000 associated with the present value impact of $400,000 of payments made during such period under our settlement agreement with the Receiver for Lancer Offshore, Inc.;

Amortization of Beneficial Conversion Feature

There was no amortization of beneficial conversion feature for the year ended December 31, 2008.

Expense due to amortization of beneficial conversion feature for the year ended December 31, 2007 consisted of beneficial conversion features of $13,429,000 associated with the Series A and Series B 10% Secured Convertible Notes due 2008 (the "New Notes"). The beneficial conversion feature is the difference between the conversion price of the New Notes ($0.706 per share) and the market price of our common stock on the commitment date ($1.35 per share) multiplied by the number of shares to be received on conversion of the note. The beneficial conversion feature is amortized over the life of the note or expensed in total at the time the note is converted into stock. Since the New Notes were both issued and converted in full during fiscal 2007, we expensed the entire beneficial conversion feature associated with the New Notes during such period.

Amortization of Debt Discount

There was no amortization of debt discount for the year ended December 31, 2008.

Amortization of debt discount totaled $4,556,000 for the year ended December 31, 2007. Amortization of debt discount for the year ended December 31, 2007 consisted of amortization of the debt discounts on the New Notes of $4,548,000 and amortization of the debt discount on the 6% Secured Convertible Notes due 2012 (the "Old Notes") of $8,000. The value assigned to the warrants attached to the Series A notes is recorded as a discount on the notes they are attached to. The Series B note issued in exchange for the Old Notes was recorded at a discount to record the New Note at fair market value. The debt discounts are amortized over the life of the notes or expensed in total at the time the note is converted into stock. Since the New Notes were both issued and converted in full during fiscal 2007, we expensed the entire debt discount associated with the New Notes during such period.

Amortization of Deferred Financing Costs

There was no amortization of deferred financing costs for the year ended December 31, 2008.

Amortization of deferred financing costs totaled $992,000 for the year ended December 31, 2007.

Impairment of Auction Rate Securities and Gain on sale of investments

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

Based upon an analysis of other-than-temporary impairment factors, the Company wrote down ARS with an original par value of 4,400,000 to an estimated fair value of $4,286,000 as of March 31, 2008. The Company reviewed impairments associated with the above in accordance with Emerging Issues Task Force (EITF) 03-1 and FSP SFAS 115-1/124-1, "The Meaning of Other-Than-Temporary-Impairment and Its Application to Certain Investments," to determine the classification of the impairment as "temporary" or "other-than-temporary." The Company determined the ARS classification to be "other-than-temporary," and charged an impairment loss of $114,000 on the ARS to its results of operations for the three months ended March 31, 2008.

During the three months ended June 30, 2008, $300,000 of principal on the Company's ARS had been paid back by the debtor, resulting in the Company's investment in ARS having decreased from $4,400,000 to $4,100,000 (par value) at

June 30, 2008. The net book value of the Company's ARS at June 30, 2008 was $3,986,000 million, due to the approximate $114,000 impairment recorded at March 31, 2008. On July 22, 2008 the Company sold its ARS to a third party at 100% of par value, for proceeds of $4,100,000. The Company reclassified the ARS from Available-for-Sale to Trading Securities due to the sale of the investments in July 2008.

In accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," ("SFAS 115") the ARS, classified as Trading Securities, are valued at their fair value of $4,100,000 at June 30, 2008. The adjustment of the investment's carrying value from $3,986,000 net book value to $4,100,000 fair value resulted in an Unrealized Holding Gain of $114,000 which is included in the Company's Statement of Operations for the three and six months ended June 30, 2008.

We subsequently reversed the Unrealized Holding Gain and recorded a Realized Gain on Sale of Investments of $114,000 in July 2008 when the sale transaction was executed.

There was no impairment of auction rate securities or gain on sale of investments for the year ended December 31, 2007.

Gain on Exchange of Debt

There was no gain on exchange of debt for the year ended December 31, 2008.

For the year ended December 31, 2007, the gain on exchange of debt includes $330,000 for the gain realized on debt extinguishment which includes a gain on exchange of the Old Notes of $254,000 and a gain of $76,000 on the cancellation of the warrants that could have been issued upon certain prepayments of the Old Notes by the Company.

Other Income and Expenses

Other income of $181,000 was recorded for the year ended December 31, 2008 and includes the impact of $147,000 for refunds received from New York State for business credits as Nephros qualifies as a Qualified Emerging Technology Company (“QETC”) and $34,000 of additional other income.

Other income of $167,000 was recorded for the year ended December 31, 2007 and includes the impact of $261,000 for refunds received from New York State for business credits as Nephros qualifies as a QETC and other expenses of $94,000. The other expenses are comprised of the impact of the nine month gain on change in valuation of the derivative liability of $7,000 and $87,000 in expenses associated with the collection of the QETC tax credit.

Off-Balance Sheet Arrangements

We did not engage in any off-balance sheet arrangements during the periods ended December 31, 2008 and December 31, 2007.

Going Concern and Management’s Response

The financial statements included in this Annual Report on Form 10-K 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. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred significant losses in our operations in each year since inception. For the years ended December 31, 2008 and 2007, we have incurred a net loss of $6,337,000 and $26,356,000, respectively. In addition, we have not generated positive cash flow from operations for the year ended December 31, 2008 and 2007. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

At December 31, 2008, we had $2,306,000 in cash and cash equivalents. However there can be no assurance that our cash and cash equivalents will provide the liquidity we need to continue our operations. These operating plans primarily include the continued development and support of our business in the European market, organizational changes necessary to begin the commercialization of our water filtration business and the completion of current year milestones which are included in the Office of Naval Research appropriation.

There can be no assurance that 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 commitments we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

We continue to investigate additional funding opportunities, talking to various potential investors who could provide financing. 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 would not substantially dilute your equity interests in us.

In addition, on September 12, 2008, we received a letter from the NYSE Alternext US LLC (formerly, the American Stock Exchange or "AMEX") notifying us of our noncompliance with certain continued listing standards. The following are the listing standards that we were in noncompliance of:

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;
- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and
- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

In response to that letter, we submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions we have taken, or will take, that would bring us into compliance with the continued listing standards by April 30, 2009.

Subsequent to December 31, 2008, on January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan. The AMEX further notified us that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we have decided not to seek an appeal of the AMEX's intention to delist our common stock.

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

Effective February 4, 2009, our common stock is now quoted on the Over the Counter ("OTC") Bulletin Board under the symbol "NEPH.OB".

For additional information describing the risks concerning our liquidity, please see "Certain Risks and Uncertainties" below.

Liquidity and Capital Resources

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 Conformité Européene, or CE, mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory pre requisite for selling our ESRD therapy products in the European Union and certain other countries that recognize CE marking (for products other than our OLpur MDHDF filter series, for which the CE mark was obtained in July 2003), or United States regulatory approval;
- 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 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; and
- for working capital purposes.

In response to liquidity issues experienced with our auction rate securities, and in order to facilitate greater liquidity in our short-term investments, on March 27, 2008, our board of directors adopted an Investment, Risk Management and Accounting Policy. Such policy limits the types of instruments or securities in which we may invest our excess funds in the future to: U.S. Treasury Securities; Certificates of Deposit issued by money center banks; Money Funds by money center banks; Repurchase Agreements; and Eurodollar Certificates of Deposit issued by money center banks. This policy provides that our primary objectives for investments shall be the preservation of principal and achieving sufficient liquidity to meet our forecasted cash requirements. In addition, provided that such primary objectives are met, we may seek to achieve the maximum yield available under such constraints.

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 and we are unable to obtain additional financing, we will be required to adopt alternatives, such as curtailing our planned activities or ceasing our operations.

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 “Old Notes”). The Old Notes were secured by substantially all of our assets. However, as of September 19, 2007, the Old Notes were exchanged for New Notes as further described in the paragraphs below.

We entered into a Subscription Agreement (“Subscription Agreement”) with Lambda Investors LLC (“Lambda”) on September 19, 2007 (the “First Closing Date”), GPC 76, LLC on September 20, 2007, Lewis P. Schneider on September 21, 2007 and Enso Global Equities Partnership LP (“Enso”) on September 25, 2007 (collectively, the “New Investors”) pursuant to which the New Investors purchased an aggregate of $12,677,000 principal amount of our Series A 10% Secured Convertible Notes due 2008 (the “Purchased Notes”), for the face value thereof (the “Offering”). Concurrently with the Offering, we entered into an Exchange Agreement (the “Exchange Agreement”) with each of Southpaw Credit Opportunities Master Fund LP, 3V Capital Master Fund Ltd., Distressed/High Yield Trading Opportunities, Ltd., Kudu Partners, L.P. and LJHS Company (collectively, the “Exchange Investors” and together with the New Investors, the “Investors”), pursuant to which the Exchange Investors agreed to exchange the principal and accrued but unpaid interest in an aggregate amount of $5,600,000 under our Old Notes, for our new Series B 10% Secured Convertible Notes due 2008 in an aggregate principal amount of $5,300,000 (the “Exchange Notes”, and together with the Purchased Notes, the “New Notes”) (the “Exchange”, and together with the Offering, the “Financing”).

We obtained the approval of our stockholders representing a majority of our outstanding shares to the issuance of shares of our common stock upon conversion of our New Notes and exercise of our Class D Warrants (as defined below) issuable upon such conversion, as further described below. The stockholder approval became effective on November 13, 2007, and the New Notes converted into shares of our common stock on November 14, 2007.

All principal and accrued but unpaid interest (the "Conversion Amount") under our New Notes automatically converted into (i) shares of our common stock at a conversion price per share of our common stock (the "Conversion Shares") equal to $0.706 and (ii) in the case of our Purchased Notes, but not our Exchange Notes, Class D Warrants (the "Class D Warrants") for purchase of shares of our common stock (the "Warrant Shares") in an amount equal to 50% of the number of shares of our common stock issued to the New Investors in accordance with clause (i) above with an exercise price per share of our common stock equal to $0.90 (subject to anti-dilution adjustments). The Class D Warrants have a term of five years and are non-callable by us.

National Securities Corporation ("NSC") and Dinosaur Securities, LLC ("Dinosaur" and together with NSC, the "Placement Agent") acted as co-placement agents in connection with the Financing pursuant to an Engagement Letter, dated June 6, 2007 and a Placement Agent Agreement dated September 18, 2007. The Placement Agent received (i) an aggregate cash fee equal to 8% of the face amount of the Lambda Purchased Note and the Enso Purchased Note allocated and paid 6.25% to NSC and 1.75% to Dinosaur, and (ii) warrants ("Placement Agent Warrant") with a term of five years from the date of issuance to purchase 10% of the aggregate number of shares of our common stock issued upon conversion of the Lambda Purchased Note and the Enso Purchased Note with an exercise price per share of our common stock equal to $0.90.

In connection with the sale of the New Notes, we entered into a Registration Rights Agreement with the Investors, dated as of the First Closing Date (the "Registration Rights Agreement"), pursuant to which we agreed to file an initial resale registration statement ("Initial Resale Registration Statement") with the SEC no later than 60 days after we file a definitive version of our Information Statement on Schedule 14C with the SEC, and we filed such Initial Resale Registration Statement on December 20, 2007. We also agreed to use our commercially reasonable best efforts to have the Initial Resale Registration Statement declared effective within 240 days after filing of a definitive version of our Information Statement on Schedule 14C. The Initial Resale Registration Statement was declared effective on May 5, 2008.

At December 31, 2008, we had an accumulated deficit of $87,949,000, and we expect to incur additional losses in the foreseeable future at least until such time, if ever, that we are able to increase product sales or licensing revenue. We have financed our operations since inception primarily through the private placements of equity and debt securities and our initial public offering in September 2004, from licensing revenue received from Asahi Kasei Medical Co., Ltd. ("Asahi") in March 2005, a private placement of convertible debenture in June 2006 and a private investment in public equity in September 2007.

Net cash used in operating activities was $5,725,000 for the year ended December 31, 2008 compared to $6,442,000 for the year ended December 31, 2007.

During 2008, the net cash used in operating activities was $717,000 less than the net cash used in operating activities during 2007. The most significant items contributing to this increase in operating cash are highlighted below:

- During 2008, our net loss adjusted to reconcile net loss to net cash used in operating activities was $5,735,000 compared to $6,461,000 in 2007. This represents a improvement of $726,000 in operating cash in 2008. Noncash stock-based compensation was $155,000 and $885,000 in 2008 and 2007 respectively, a reduction of $730,000.
- During 2008, our accounts receivable, other current assets and other assets decreased by $236,000. This compares to an increase of $96,000 in 2007. This represents a $332,000 source of operating cash.

- During 2008, our inventory increased by $409,000. This compares to a decrease in inventory of $217,000 in 2007. This represents a $626,000 use of operating cash. Inventory increased due to the introduction of the DSU product in 2008.
- During 2008, accounts payable and accrued expenses increased by $183,000. This compares to a decrease in accounts payable and accrued expenses of $102,000 during 2007. This represents a $285,000 source of operating cash.

Net cash provided by investing activities was $4,599,000 for the year ended December 31, 2008 compared to net cash used by investing activities of $2,045,000 for the year ended December 31, 2007.

In 2008, $4,693,000 of the funds were provided by the sale of short-term investments. Approximately $97,000 of these funds were used to purchase property, plant and equipment. An additional $3,000 was provided by the sale of equipment.

In 2007, $2,800,000 of funds was provided by the sale of short-term investments. $145,000 of these funds was used to purchase property, plant and equipment. Approximately $4,700,000 of funds was used to purchase short-term investments during 2007.

There was no net cash provided by or used in financing activities for the year ended December 31, 2008. The cash provided by financing activities for the year ended December 31, 2007 reflects the September 2007 private placement which raised $12,677,000.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2008:

		Payments Due in Period			
Contractual Obligations	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years
Leases	$ 296,000	$ 115,000	$ 181,000	$ —	$ —
Employment Contracts	1,066,250	425,000	641,250		
Total	$ 1,362,250	$ 540,000	$ 822,250	$ —	$ —

Certain Risks and Uncertainties

Certain statements in this Annual Report on Form 10-K, including certain statements contained in “Description of Business” and “Management’s Discussion and Analysis,” constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases “can be,” “may,” “could,” “would,” “expects,” “believes,” “seeks,” “estimates,” “projects” and words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties, including those described on the following pages, and we caution you that any forward-looking information provided by us is not a guarantee of future performance. Our actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond our control. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Risks Related to Our Company

We have not obtained FDA approval for use of our DSU water filter in dialysis clinics as part of their water purification system.

Our business strategy depends in part on our ability to sell our DSU water filter into hospitals and other healthcare facilities which include dialysis clinics. We cannot sell our DSU water filter to dialysis clinics in the United States until we receive FDA clearance. We have filed an application for 510(k) approval and have answered questions put forth by the FDA in February 2009. Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

We may be further delayed in selling the DSU in the United States to the dialysis clinic market if the FDA has additional questions. We may not obtain FDA approval for use of our DSU water filter in dialysis clinics as we envisioned. Either of these events will have a negative financial impact on the Company through the delay or elimination of some of our potential DSU revenue.

We have a history of operating losses and a significant accumulated deficit, and we may not achieve or maintain profitability in the future.

We have not been profitable since our inception in 1997. As of December 31, 2008, we had an accumulated deficit of $87,949,000 primarily as a result of our research and development expenses and selling, general and administrative expenses. We expect to continue to incur additional losses for the foreseeable future as a result of a high level of operating expenses, significant up-front expenditures including the cost of clinical trials, production and marketing activities and very limited revenue from the sale of our products. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

- 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;
- the market acceptance of HDF therapy in the United States and of our technologies and products in each of our target markets;
- our ability to effectively and efficiently manufacture, market and distribute our products;
- our ability to sell our products at competitive prices which exceed our per unit costs; and

- the consolidation of dialysis clinics into larger clinical groups.

Our independent registered public accountants, in their audit report related to our financial statements for the year ended December 31, 2008, expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in their report on our financial statements included in this Annual Report on Form 10-K expressing doubt as to our ability to continue as a going concern. The accompanying financial statements 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, raises 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, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We have not met the NYSE Alternext US LLC (formerly, the American Stock Exchange or "AMEX") continued listing standards and as a result, we have not maintained our listing on AMEX.

On September 27, 2007, we received a warning letter from the AMEX stating that the staff of the AMEX Listing Qualifications Department had determined that we were not in compliance with Section 121B(2)(c) of the AMEX Company Guide requiring that at least 50% of the directors of our Company's board of directors are independent directors. This non-compliance was due to the fact that William J. Fox, Judy Slotkin, W. Townsend Ziebold and Howard Davis resigned from our board of directors on September 19, 2007, concurrently with the appointment of Paul Mieyal and Arthur Amron to the board of directors, in accordance with our September 2007 financing. Consequently, our board of directors consisted of five directors, two of whom were independent. The AMEX had given us until December 26, 2007 to regain compliance with the independence requirements. On November 16, 2007, James S. Scibetta was appointed to serve as an independent director on our board of directors. On December 5, 2007, we received a letter from the AMEX acknowledging that we had resolved the continued listing deficiency identified in their September 27, 2007 letter.

On September 12, 2008, we received a letter from the AMEX notifying us of our noncompliance with certain continued listing standards. The following are the listing standards that we were in noncompliance of:

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;
- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and
- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

In response to that letter, we submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions we have taken, or will take, that would bring us into compliance with the continued listing standards by April 30, 2009.

Subsequent to December 31, 2008, on January 8, 2009, we received a letter from the AMEX notifying us that it was rejecting our plan. The AMEX further notified us that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission pursuant to Rule 1009(d) of the AMEX

Company Guide. Given the turmoil in the capital markets, we have decided not to seek an appeal of the AMEX's intention to delist our common stock.

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

Effective February 4, 2009, our common stock is now quoted on the OTC Bulletin Board under the symbol "NEPH.OB".

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

Pursuant to the terms of our 2007 financing, had we failed to have the Initial Resale Registration Statement that we filed with the SEC declared effective in a timely manner as provided in the Registration Rights Agreement, then we may have been required to pay liquidated damages to Investors.

In connection with our sale in September 2007 (the "Financing") of an aggregate of $18 million aggregate principal amount of Series A and Series B 10% Secured Convertible Notes due 2008 (the "New Notes"), we entered into a Registration Rights Agreement with the investors in the Financing (the "Investors") pursuant to which we agreed to file an Initial Resale Registration Statement with the SEC no later than 60 days after we file a definitive Schedule 14C information statement with the SEC. The definitive Schedule 14C was filed with the SEC on October 24, 2007, and the Initial Resale Registration Statement was filed on December 20, 2007.

We have agreed to use our commercially reasonable best efforts to have the Initial Resale Registration Statement declared effective within 240 days after filing of the definitive Schedule 14C. The Initial Resale Registration Statement was declared effective on May 5, 2008.

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

For the year ended December 31, 2008, one of our customers accounted for 78% of our product sales. Also, this customer represented 66% of our accounts receivable as of December 31, 2008. We believe that the loss of this customer would 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.

We cannot sell our ESRD therapy products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. We have not obtained FDA approval for any of our ESRD therapy products, except for our HD190 filter, and cannot sell any of our other ESRD therapy products in the United States unless and until we obtain such approval. If we fail to receive, or experience a significant delay in receiving, such approvals and clearances then we may not be able to get our products to market and enhance our revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We obtained the Conformité Européene, 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 (collectively, "European Community"), for our OLpur MDHDF filter series product in 2003 and received CE marking in November 2006 for our water filtration product, the Dual Stage Ultrafilter ("DSU"). We have not yet obtained the CE mark for any of our other products. Similarly, we cannot sell our ESRD therapy products in the United States until we receive FDA clearance. Although we received approval of our IDE in March 2007 to begin clinical trials in the United States, until we complete the requisite U.S. human clinical trials and submit pre-market notification to the FDA pursuant to Section 510(k) of the FDC Act or otherwise comply with FDA requirements for a 510(k) approval, we will not be eligible for FDA approval for any of our products, except for our HD190 filter.

In addition to the pre-market notification required pursuant to Section 510(k) of the FDC Act, the FDA could require us to obtain pre-market approval of our ESRD therapy products under Section 515 of the FDC Act, either because of legislative or regulatory changes or because the FDA does not agree with our determination that we are eligible to use the Section 510(k) pre-market notification process. The Section 515 pre-market approval process is a significantly more costly, lengthy and uncertain approval process and could materially delay our products coming to market. If we do obtain clearance for marketing of any of our devices under Section 510(k) of the FDC Act, then any changes we wish to make to such device that could significantly affect safety and effectiveness will require clearance of a notification pursuant to Section 510(k), and we may need to submit clinical and manufacturing comparability data to obtain such approval or clearance. We could not market any such modified device until we received FDA clearance or approval. We cannot guarantee that the FDA would timely, if at all, clear or approve any modified product for which Section 510(k) is applicable. Failure to obtain timely clearance or approval for changes to marketed products would impair our ability to sell such products and generate revenues in the United States.

The clearance and/or approval processes in the European Community and in the United States can be lengthy and uncertain and each requires substantial commitments of our financial resources and our management's time and effort. We may not be able to obtain further CE marking or any FDA approval for any of our ESRD therapy products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals with respect to the European Community or the United States would prevent us from selling our affected products in these regions. If we cannot sell some of our products in these regions, or if we are delayed in selling while awaiting the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

If we are successful in our initial marketing efforts in some or all of our Target European Market and the United States, then we plan to market our ESRD therapy products in several countries outside of our Target European Market and the United States, including Korea and China, Canada and Mexico. Requirements pertaining to the sale of medical devices vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our ESRD therapy products in many of these countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our ESRD therapy products outside of our Target European Market and the United States, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

Clinical studies required for our ESRD therapy products are costly and time-consuming, and their outcome is uncertain.

Before obtaining regulatory approvals for the commercial sale of any of our ESRD therapy products in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective. We received conditional approval for our IDE application from the FDA to begin human clinical trials of our OLpur H 2 H hemodiafiltration module and OLpur MD220 hemodiafilter. We were granted this approval on the condition that, by March 5, 2007, we submit a response to two informational questions from the FDA. We have responded to these questions. We have obtained approval from Western IRB, Inc., which enables us to proceed with our clinical trial. We completed the patient treatment phase of our clinical trial during the second quarter of 2008. We have submitted our data to the FDA with our 510(k) application on these products in November 2008. Following its review of the application, the FDA has requested additional information from us. We replied to the FDA inquiries on March 13, 2009. Per FDA guidelines, the FDA has 90 days to review the additional information provided by us.

For products other than those for which we have already received marketing approval, if we do not prove in clinical trials that our ESRD therapy products are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our ESRD therapy products may not exhibit the expected medical benefits, may cause harmful side effects, may not be effective in treating dialysis patients or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

- slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;
- lower than expected retention rates of subjects in a clinical trial;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's review board, or other required approvals;
- longer treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the ESRD therapy product;
- adverse medical events or side effects in treated subjects; and
- lack of effectiveness of the ESRD therapy product being tested.

Even if we obtain positive results from clinical studies for our products, we may not achieve the same success in future studies of such products. Data obtained from clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for device approval during the period of product development and FDA regulatory review of each submitted new device application. We may encounter similar delays in foreign countries. Moreover, regulatory approval may entail limitations on the indicated uses of the device. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products. Additionally, we may be unable to complete our clinical trials if we are unable to obtain additional capital.

We may be required to design and conduct additional clinical trials.

We may be required to design and conduct additional clinical trials to further demonstrate the safety and efficacy of our ESRD therapy product, which may result in significant expense and delay. The FDA and foreign regulatory authorities may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials, a possible failure to conduct clinical trials in complete adherence to FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding the safety or efficacy of our ESRD therapy products. It is possible that the FDA or foreign regulatory authorities may not ultimately approve our products for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

We cannot assure you that our ESRD therapy products will be safe and we are required under applicable law to report any product-related deaths or serious injuries or product malfunctions that could result in deaths or serious injuries, and such reports could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.

We cannot assure you that our ESRD therapy products will be safe. Under the FDC Act, we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and product malfunctions that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following:

- information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications;
- because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and
- if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to gain market acceptance of our ESRD therapy products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our ESRD therapy products.

Product liability associated with the production, marketing and sale of our products, and/or the expense of defending against claims of product liability, could materially deplete our assets and generate negative publicity which could impair our reputation.

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance in the amount of $5,000,000 for our products, we may not be able to maintain or obtain this insurance on acceptable terms or at all. Because we may not be able to obtain insurance that provides us with adequate protection against all potential product liability claims, a successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, even if we are able to obtain adequate insurance, any claim against us could generate negative publicity, which could impair our reputation and adversely affect the demand for our products, our ability to generate sales and our profitability.

Some of the agreements that we may enter into with manufacturers of our products and components of our products may require us:

- To obtain product liability insurance; or
- To indemnify manufacturers against liabilities resulting from the sale of our products.

For example, the agreement with our CM requires that we obtain and maintain certain minimum product liability insurance coverage and that we indemnify our CM against certain liabilities arising out of our products that they manufacture, provided they do not arise out of our CM's breach of the agreement, negligence or willful misconduct. If we are not able to obtain and maintain adequate product liability insurance, then we could be in breach of these agreements, which could materially adversely affect our ability to produce our products and generate revenues. Even if we are able to obtain and maintain product liability insurance, if a successful claim in excess of our insurance coverage is made, then we may have to indemnify some or all of our manufacturers for their losses, which could materially deplete our assets.

If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our ESRD therapy products. If we violate the FDC Act or other regulatory requirements at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including:

- fines;
- injunctions;
- civil penalties;
- recalls or seizures of products;
- total or partial suspension of the production of our products;
- withdrawal of any existing approvals or pre-market clearances of our products;
- refusal to approve or clear new applications or notices relating to our products;
- recommendations by the FDA that we not be allowed to enter into government contracts; and
- criminal prosecution.

Any of the above could have a material adverse effect on our business, financial condition and results of operations.

Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales and revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. Any future laws, regulations, interpretations, applications or enforcements could delay or prevent regulatory approval or clearance of our products and our ability to market our products. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

Access to the appropriations from the U.S. Department of Defense regarding the development of a dual-stage water ultrafilter could be subject to unanticipated delays which could adversely affect our potential revenues.

Our business strategy with respect to our DSU products depends in part on the successful development of DSU products for use by the military. We have contracted with the U.S. Office of Naval Research to develop a personal potable water purification system for warfighters in an amount not to exceed $866,000 and have submitted a proposal for a second contract with a value not to exceed $2 million. These contracts would utilize the Federal appropriations from the U.S. Department of Defense in an aggregate amount of $3 million that have been approved for this purpose. If we are unsuccessful in being awarded the second contract or if there are unanticipated delays in receiving the appropriations from the U.S. Department of Defense, our operations and potential revenues may be adversely affected.

Protecting our intellectual property in our technology through patents may be costly and ineffective. If we are not able to adequately secure or enforce protection of our intellectual property, then we may not be able to compete effectively and we may not be profitable.

Our future success depends in part on our ability to protect the intellectual property for our technology through patents. We will only be able to protect our products and methods from unauthorized use by third parties to the extent that our products and methods are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our 13 granted U.S. patents will expire at various times from 2018 to 2022, assuming they are properly maintained.

The protection provided by our patents, and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. Numerous publications may have been disclosed by, and numerous patents may have been issued to, our competitors and others relating to methods and devices for dialysis of which we are not aware and additional patents relating to methods and devices for dialysis may be issued to our competitors and others in the future. If any of those publications or patents conflict with our patent rights, or cover our products, then any or all of our patent applications could be rejected and any or all of our granted patents could be invalidated, either of which could materially adversely affect our competitive position.

Litigation and other proceedings relating to patent matters, whether initiated by us or a third party, can be expensive and time-consuming, regardless of whether the outcome is favorable to us, and may require the diversion of substantial financial, managerial and other resources. An adverse outcome could subject us to significant liabilities to third parties or require us to cease any related development, product sales or commercialization activities. In addition, if patents that contain dominating or conflicting claims have been or are subsequently issued to others and the claims of these patents are ultimately determined to be valid, then we may be required to obtain licenses under patents of others in order to develop, manufacture, use, import and/or sell our products. We may not be able to obtain licenses under any of these patents on terms acceptable to us, if at all. If we do not obtain these licenses, we could encounter delays in, or be prevented entirely from using, importing, developing, manufacturing, offering or selling any products or practicing any methods, or delivering any services requiring such licenses.

If we file patent applications or obtain patents in foreign countries, we will be subject to laws and procedures that differ from those in the United States. Such differences could create additional uncertainty about the level and extent of our patent protection. Moreover, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be as favorable to us. Many non-U.S. jurisdictions, for example, prohibit patent claims covering methods of medical treatment of humans, although this prohibition may not include devices used for such treatment.

If we are not able to secure and enforce protection of our trade secrets through enforcement of our confidentiality and non-competition agreements, then our competitors may gain access to our trade secrets, we may not be able to compete effectively and we may not be profitable. Such protection may be costly and ineffective.

We attempt to protect our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. If these employees or other parties breach our confidentiality agreements and non-competition agreements or if these agreements are not sufficient to protect our technology or are found to be unenforceable, then our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Policing unauthorized use of our trade secrets is difficult and expensive, particularly because of the global nature of our operations. The laws of other countries may not adequately protect our trade secrets.

If our trademarks and trade names are not adequately protected, then we may not be able to build brand loyalty and our sales and revenues may suffer.

Our registered or unregistered trademarks or trade names may be challenged, cancelled, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build brand loyalty. Over the long term, if we are unable to establish a brand based on our trademarks and trade names, then we may not be able to compete effectively and our sales and revenues may suffer.

If we are not able to successfully scale-up production of our products, then our sales and revenues will suffer.

In order to commercialize our products, we need to be able to produce them in a cost-effective way on a large scale to meet commercial demand, while maintaining extremely high standards for quality and reliability. If we fail to successfully commercialize our products, then we will not be profitable.

We expect to rely on a limited number of independent manufacturers to produce our OLpur MDHDF filter series and our other products, including the DSU. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

We will not control the independent manufacturers of our products, which may affect our ability to deliver our products in a timely manner. If we are not able to ensure the timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.

Independent manufacturers of medical devices will manufacture all of our products and components. We have contracted with our CM to assemble and produce our OLpur MD190, MD220 and possibly other filters, including our DSU, and have an agreement with FS, a manufacturer of medical and technical membranes for applications like dialysis, to produce the fiber for the OLpur MDHDF filter series. As with any independent contractor, these manufacturers will not be employed or otherwise controlled by us and will be generally free to conduct their business at their own discretion. For us to compete successfully, among other things, our products must be manufactured on a timely basis in commercial quantities at costs acceptable to us. If one or more of our independent manufacturers fails to deliver our products in a timely manner, then we may not be able to find a substitute manufacturer. If we are not or if potential customers believe that we are not able to ensure timely delivery of our products, then potential customers may not order our products, and our sales and revenues would be adversely affected.

The loss or interruption of services of any of our manufacturers could slow or stop production of our products, which would limit our ability to generate sales and revenues.

Because we are likely to rely on no more than two contract manufacturers to manufacture each of our products and major components of our products, a stop or significant interruption in the supply of our products or major components by a single manufacturer, for any reason, could have a material adverse effect on us. We expect most of our contract manufacturers will enter into contracts with us to manufacture our products and major components and that these contracts will be terminable by the contractors or us at any time under certain circumstances. We have not made alternative arrangements for the manufacture of our products or major components and we cannot be sure that acceptable alternative arrangements could be made on a timely basis, or at all, if one or more of our manufacturers failed to manufacture our products or major components in accordance with the terms of our arrangements. If any such failure occurs and we are unable to obtain acceptable alternative arrangements for the manufacture of our products or major components of our products, then the production and sale of our products could slow down or stop and our cash flow would suffer.

If we are not able to maintain sufficient quality controls, then the approval or clearance of our ESRD therapy products by the European Union, the FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.

Approval or clearance of our ESRD therapy products could be delayed by the European Union, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The European Union imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by our manufacturers to comply with these requirements could prevent us from marketing our ESRD therapy products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA approval of our ESRD therapy products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpur MDHDF filter series have been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to European Union requirements for medical devices, they have not been inspected by the FDA. Similarly, although some of the facilities and processes that we expect to use to manufacture our OLpur H 2 H and OLpur NS2000 have been inspected by the FDA, they have not been inspected by any notified body. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that any of the facilities or processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent our obtaining the approvals we need to market our products in the European Community and the United States.

Even with approval to market our ESRD therapy products in the European Community, the United States and other countries, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our ESRD therapy products, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers, then we may not be able to continue to market the ESRD therapy products manufactured in such facilities and our revenues may be materially adversely affected.

If our products are commercialized, we may face significant challenges in obtaining market acceptance of such products, which could adversely affect our potential sales and revenues.

Our products are new to the market, and we do not yet have an established market or customer base for our products. Acceptance of our ESRD therapy products in the marketplace by both potential users, including ESRD patients, and potential purchasers, including nephrologists, dialysis clinics and other health care providers, is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform dialysis patients and nephrologists, dialysis clinics and other health care providers of the benefits of using our ESRD therapy products. We may encounter significant clinical and market resistance to our products and our products may never achieve market acceptance. We may not be able to build key relationships with physicians, clinical groups and government agencies, pursue or increase sales opportunities in Europe or elsewhere, or be the first to introduce hemodiafiltration therapy in the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace include whether:

- such products will be safe for use;
- such products will be effective;
- such products will be cost-effective;
- we will be able to demonstrate product safety, efficacy and cost-effectiveness;
- there are unexpected side effects, complications or other safety issues associated with such products; and
- government or third party reimbursement for the cost of such products is available at reasonable rates, if at all.

Acceptance of our water filtration products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance and endurance standards. Our water filtration products and technology may not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial, military, industrial or retail applications.

Many of the same factors that may affect our ability to achieve acceptance of our ESRD therapy products in the marketplace will also apply to our water filtration products, except for those related to side effects, clinical trials and third party reimbursement.

If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute our products effectively and/or customers may decide not to order our products, and, in either case, our sales and revenues will suffer.

Our strategy requires us to distribute our products and provide a significant amount of customer service and maintenance and other technical service. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure you we will be able to organize and manage this network on a cost-effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products and our sales and revenues will suffer.

We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.

We expect to manufacture and to market our products in our Target European Market and elsewhere outside of the United States. We expect that our revenues from our Target European Market will initially account for a significant portion of our revenues. Our international operations are subject to a number of risks, including the following:

- fluctuations in exchange rates of the United States dollar could adversely affect our results of operations;
- we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems;
- local regulations may restrict our ability to sell our products, have our products manufactured or conduct other operations;
- political instability could disrupt our operations;
- some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow; and
- some countries could impose additional taxes or restrict the import of our products.

Any one or more of these factors could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to keep our key management and scientific personnel, then we are likely to face significant delays at a critical time in our corporate development and our business is likely to be damaged.

Our success depends upon the skills, experience and efforts of our management and other key personnel, including our chief executive officer, certain members of our scientific and engineering staff and our marketing executives. As a relatively new company, much of our corporate, scientific and technical knowledge is concentrated in the hands of these few individuals. We do not maintain key-man life insurance on any of our management or other key personnel. The loss of the services of one or more of our present management or other key personnel could significantly delay the development and/or launch of our products as there could be a learning curve of several months or more for any replacement personnel. Furthermore, competition for the type of highly skilled individuals we require is intense and we may not be able to attract and retain new employees of the caliber needed to achieve our objectives. Failure to replace key personnel could have a material adverse effect on our business, financial condition and operations.

Our fourth amended and restated certificate of incorporation, as amended, limits liability of our directors and officers, which could discourage you or other stockholders from bringing suits against our directors or officers in circumstances where you think they might otherwise be warranted.

Our fourth amended and restated certificate of incorporation, as amended, provides, with specific exceptions required by Delaware law, that our directors are not personally liable to us or our stockholders for monetary damages for any action or failure to take any action. In addition, we have agreed to, and our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws provide for, mandatory indemnification of directors and officers to the fullest extent permitted by Delaware law. These provisions may discourage stockholders from bringing suit against a director or officer for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against any of our directors or officers.

If and to the extent we are found liable in certain proceedings or our expenses related to those or other legal proceedings become significant, then our liquidity could be materially adversely affected and the value of our stockholders' interests in us could be impaired.

In April 2002, we 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, we 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 we agreed to issue Hermitage or its designees, upon the closing of certain transactions contemplated by a separate settlement agreement between us and Lancer Offshore, Inc., 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 our common stock for $8.80 per share, if adjusted for the reverse stock split pursuant to the antidilution provisions of such warrant, as amended). Because Lancer Offshore, Inc. never satisfied the closing conditions and, consequently, a closing has not been held, we have not issued any warrants to Hermitage in connection with our settlement with them. In June 2004, Hermitage threatened to sue us for warrants it claims are due to it under its settlement agreement with us as well as a placement fee and additional warrants it claims are, or will be, owed in connection with our initial public offering completed on September 24, 2004, as compensation for allegedly introducing us to one of the underwriters. We had some discussions with Hermitage in the hopes of reaching an amicable resolution of any potential claims, most recently in January 2005. We have not heard from Hermitage since then.

If and to the extent we are found to have significant liability to Hermitage in any lawsuit Hermitage may bring against us, then our liquidity could be materially adversely affected and/or our stockholders could experience dilution in their investment in us and the value of our stockholders' interests in us could be impaired.

We may use our financial resources in ways with which you do not agree and in ways that may not yield a favorable return.

Our management has broad discretion over the use of our financial resources, including the net proceeds from our initial public offering and our subsequent financings. Stockholders may not deem such uses desirable. Our use of our financial resources may vary substantially from our currently planned uses. We cannot assure you that we will apply such proceeds effectively or that we will invest such proceeds in a manner that will yield a favorable return or any return at all.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our common stock.

Several provisions of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation, as amended, and our second amended and restated bylaws could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our common stock could be reduced as a result. These provisions include:

- authorizing our board of directors to issue "blank check" preferred stock without stockholder approval;
- providing for a classified board of directors with staggered, three-year terms;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

As a relatively new company with little or no name recognition and with several risks and uncertainties that could impair our business operations, we are not likely to generate widespread interest in our common stock. Without widespread interest in our common stock, our common stock price may be highly volatile and an investment in our common stock could decline in value.

Unlike many companies with publicly traded securities, we have little or no name recognition in the investment community. We are a relatively new company and very few investors are familiar with either our company or our products. We do not have an active trading market in our common stock, and one might never develop, or if it does develop, might not continue.

Additionally, the market price of our common stock may fluctuate significantly in response to many factors, many of which are beyond our control. Risks and uncertainties, including those described elsewhere in this "Certain Risks and Uncertainties" section could impair our business operations or otherwise cause our operating results or prospects to be below expectations of investors and market analysts, which could adversely affect the market price of our common stock. As a result, investors in our common stock may not be able to resell their shares at or above their purchase price and could lose all of their investment.

Securities class action litigation is often brought against public companies following periods of volatility in the market price of such company's securities. As a result, we may become subject to this type of litigation in the future. Litigation of this type could be extremely expensive and divert management's attention and resources from running our company.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results, which could have a material adverse effect on our business, financial condition and the market value of our securities.
Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our reputation and operating results may be harmed.

As of December 31, 2007, management reported a material weakness in the company's internal control over financial reporting due to an insufficient number of resources in the accounting and finance department that does not allow for a thorough review process. Throughout fiscal year 2008, we implemented the following measures which resulted in the remediation of this material weakness as of December 31, 2008:

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

Our directors, executive officers and principal stockholders control a significant portion of our stock and, if they choose to vote together, could have sufficient voting power to control the vote on substantially all corporate matters.

As of December 31, 2008, our directors, executive officers and principal stockholders beneficially owned approximately 62.3% of our outstanding common stock. As of December 31, 2008, Lambda Investors LLC beneficially owned 37.7% of our outstanding common stock. As of December 31, 2008, Ronald O. Perelman beneficially owned 8.3% of our outstanding common stock. As of December 31, 2008, Enso Global Equities Master Partnership LP beneficially owned 5.7% of our outstanding common stock. As of December 31, 2008, Southpaw Credit Opportunity Master Fund LP beneficially owned 3.1% of our outstanding common stock. As of December 31, 2008, WPPN LP, Wasserstein SBIC Ventures II L.P., WV II Employee Partners, LLC and BW Employee Holdings, LLC, entities that may be deemed to be controlled by Bruce Wasserstein, beneficially owned an aggregate of 5.5% of our outstanding common stock.

Our principal stockholders may have significant influence over our policies and affairs, including the election of directors. Should they act as a group, they will have the power to elect all of our directors and to control the vote on substantially all other corporate matters without the approval of other stockholders. Furthermore, such concentration of voting power could enable those stockholders to delay or prevent another party from taking control of our company even where such change of control transaction might be desirable to other stockholders.

Future sales of our common stock could cause the market price of our common stock to decline.

The market price of our common stock could decline due to sales of a large number of shares in the market, including sales of shares by our large stockholders, or the perception that such sales could occur. These sales could also make it more difficult or impossible for us to sell equity securities in the future at a time and price that we deem appropriate to raise funds through future offerings of common stock.

Prior to our initial public offering we entered into registration rights agreements with many of our existing security holders that entitled them to have an aggregate of 10,020,248 shares registered for sale in the public market. Moreover, many of those shares, as well as the 184,250 shares we sold to Asahi, could be sold in the public market without registration once they have been held for one year, subject to the limitations of Rule 144 under the Securities Act. In addition, we entered into a registration rights agreement with the holders of our New Notes pursuant to which we granted the holders certain registration rights with respect to the shares of common stock issuable upon conversion of the New Notes and upon exercise of the Class D Warrants.

Risks Related to the ESRD Therapy Industry

We expect to face significant competition from existing suppliers of renal replacement therapy devices, supplies and services. If we are not able to compete with them effectively, then we may not be profitable.

We expect to compete in the ESRD therapy market with existing suppliers of hemodialysis and peritoneal dialysis devices, supplies and services. Our competitors include Fresenius Medical Care AG and Gambro AB, currently two of the primary machine manufacturers in hemodialysis, as well as B. Braun Biotech International GmbH, and Nikkiso Corporation and other smaller machine manufacturers in hemodialysis. B. Braun Biotech International GmbH, Fresenius Medical Care AG, Gambro AB and Nikkiso Corporation also manufacture HDF machines. These companies and most of our other competitors have longer operating histories and substantially greater financial, marketing, technical, manufacturing and research and development resources and experience than we have. Our competitors could use these resources and experiences to develop products that are more effective or less costly than any or all of our products or that could render any or all of our products obsolete. Our competitors could also use their economic strength to influence the market to continue to buy their existing products.

We do not have a significant established customer base and may encounter a high degree of competition in further developing one. Our potential customers are a limited number of nephrologists, national, regional and local dialysis clinics and other healthcare providers. The number of our potential customers may be further limited to the extent any exclusive relationships exist or are entered into between our potential customers and our competitors. We cannot assure you that we will be successful in marketing our products to these potential customers. If we are not able to develop competitive products and take and hold sufficient market share from our competitors, we will not be profitable.

Some of our competitors own or could acquire dialysis clinics throughout the United States, our Target European Market and other regions of the world. We may not be able to successfully market our products to the dialysis clinics under their ownership. If our potential market is materially reduced in this manner, then our potential sales and revenues could be materially reduced.

Some of our competitors, including Fresenius Medical Care AG and Gambro AB, manufacture their own products and own dialysis clinics in the United States, our Target European Market and/or other regions of the world. In 2005, Gambro AB divested its U.S. dialysis clinics to DaVita, Inc. and entered a preferred, but not exclusive, ten-year supplier arrangement with DaVita, Inc., whereby DaVita, Inc. will purchase a significant amount of renal products and supplies from Gambro AB Renal Products. Because these competitors have historically tended to use their own products in their clinics, we may not be able to successfully market our products to the dialysis clinics under their ownership. According to the Fresenius Medical Care AG 2007 Form 20-F annual report, Fresenius Medical Care AG provides treatment in its own dialysis clinics to approximately 173,863 patients in approximately 2,238 facilities around the world of which approximately 1,602 facilities are located in the North America. According to DaVita, Inc.'s 2007 Annual Report, DaVita, Inc. provides treatment in 1,359 outpatient dialysis centers serving approximately 107,000 patients in the United States.

We believe that there is currently a trend among ESRD therapy providers towards greater consolidation. If such consolidation takes the form of our competitors acquiring independent dialysis clinics, rather than such dialysis clinics banding together in independent chains, then more of our potential customers would also be our competitors. If our competitors continue to grow their networks of dialysis clinics, whether organically or through consolidation, and if we cannot successfully market our products to dialysis clinics owned by these competitors or any other competitors and do not acquire clinics ourselves, then our revenues could be adversely affected.

If the size of the potential market for our products is significantly reduced due to pharmacological or technological advances in preventative and alternative treatments for ESRD, then our potential sales and revenues will suffer.

Pharmacological or technological advances in preventative or alternative treatments for ESRD could significantly reduce the number of ESRD patients needing our products. These pharmacological or technological advances may include:

- the development of new medications, or improvements to existing medications, which help to delay the onset or prevent the progression of ESRD in high-risk patients (such as those with diabetes and hypertension);
- the development of new medications, or improvements in existing medications, which reduce the incidence of kidney transplant rejection; and
- developments in the use of kidneys harvested from genetically-engineered animals as a source of transplants.

If these or any other pharmacological or technological advances reduce the number of patients needing treatment for ESRD, then the size of the market for our products may be reduced and our potential sales and revenues will suffer.

If government and other third party reimbursement programs discontinue their coverage of ESRD treatment or reduce reimbursement rates for ESRD products, then we may not be able to sell as many units of our ESRD therapy products as otherwise expected, or we may need to reduce the anticipated prices of such products and, in either case, our potential revenues may be reduced.

Providers of renal replacement therapy are often reimbursed by government programs, such as Medicare or Medicaid in the United States, or other third-party reimbursement programs, such as private medical care plans and insurers. We believe that the amount of reimbursement for renal replacement therapy under these programs has a significant impact on the decisions of nephrologists, dialysis clinics and other health care providers regarding treatment methods and products. Accordingly, changes in the extent of coverage for renal replacement therapy or a reduction in the reimbursement rates under any or all of these programs may cause a decline in recommendations or purchases of our products, which would materially adversely affect the market for our products and reduce our potential sales. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could also reduce our potential revenues.

As the number of managed health care plans increases in the United States, amounts paid for our ESRD therapy products by non-governmental programs may decrease and we may not generate sufficient revenues to be profitable.

We expect to obtain a portion of our revenues from reimbursement provided by non-governmental programs in the United States. Although non-governmental programs generally pay higher reimbursement rates than governmental programs, of the non-governmental programs, managed care plans generally pay lower reimbursement rates than insurance plans. Reliance on managed care plans for dialysis treatment may increase if future changes to the Medicare program require non-governmental programs to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of these patients. If the reliance on managed care plans for dialysis treatment increases, more patients join managed care plans or managed care plans reduce reimbursement rates, we may need to reduce anticipated prices of our ESRD therapy products or sell fewer units, and, in either case, our potential revenues would suffer.

If HDF does not become a preferred therapy for ESRD, then the market for our ESRD therapy products may be limited and we may not be profitable.

A significant portion of our success is dependent on the acceptance and implementation of HDF as a preferred therapy for ESRD. There are several treatment options currently available and others may be developed. HDF may not increase in acceptance as a preferred therapy for ESRD. If it does not, then the market for our ESRD therapy products may be limited and we may not be able to sell a sufficient quantity of our products to be profitable.

If the per-treatment costs for dialysis clinics using our ESRD therapy products are higher than the costs of clinics providing hemodialysis treatment, then we may not achieve market acceptance of our ESRD therapy products in the United States and our potential sales and revenues will suffer.

If the cost of our ESRD therapy products results in an increased cost to the dialysis clinic over hemodialysis therapies and such cost is not separately reimbursable by governmental programs or private medical care plans and insurers outside of the per-treatment fee, then we may not gain market acceptance for such products in the United States unless HDF therapy becomes the standard treatment method for ESRD. If we do not gain market acceptance for our ESRD therapy products in the United States, then the size of our market and our anticipated sales and revenues will be reduced.

Proposals to modify the health care system in the United States or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, then our margins and our profitability will be adversely affected.

A substantial portion of the cost of treatment for ESRD in the United States is currently reimbursed by the Medicare program at prescribed rates. Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reform proposals. We cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in the Medicare program could affect the pricing of our ESRD therapy products. As we are not yet established in our business and it will take some time for us to begin to recoup our research and development costs, our profit margins are likely initially to be lower than those of our competitors and we may be more vulnerable to small decreases in price than many of our competitors.

Health administration authorities in countries other than the United States may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the United States, these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates for dialysis products.

Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our ESRD therapy products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

If patients in our Target European Market were to reuse dialyzers, then our potential product sales could be materially adversely affected.

In the United States, a majority of dialysis clinics reuse dialyzers — that is, a single dialyzer is disinfected and reused by the same patient. However, the trend in our Target European Market is towards not reusing dialyzers, and some countries (such as France, Germany, Italy and the Netherlands) actually forbid the reuse of dialyzers. As a result, each patient in our Target European Market can generally be expected to purchase more dialyzers than each United States patient. The laws forbidding reuse could be repealed and it may become generally accepted to reuse dialyzers in our Target European Market, just as it currently is in the United States. If reuse of dialyzers were to become more common among patients in our Target European Market, then there would be demand for fewer dialyzer units and our potential product sales could be materially adversely affected.

Item 8. Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Nephros, Inc.

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and Subsidiary (collectively, "the Company") as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nephros, Inc. and Subsidiary as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred negative cash flow from operations and net losses since inception. These conditions, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ ROTHSTEIN, KASS & COMPANY, P.C.

Roseland, New Jersey
March 27, 2009

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share Amounts)

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,306	$ 3,449
Short-term investments	7	4,700
Accounts receivable, less allowances of $4 and $7, respectively	404	419
Inventory, less allowances of $0 and $30, respectively	724	336
Prepaid expenses and other current assets	162	392
Total current assets	3,603	9,296
Property and equipment, net	412	762
Other assets	21	27
Total assets	$ 4,036	$ 10,085
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 986	$ 488
Accrued expenses	411	781
Accrued severance expense	105	60
Total current liabilities	1,502	1,329
Total liabilities	1,502	1,329
Commitments and Contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2008 and 2007; no shares issued and outstanding at December 31, 2008 and 2007	—	—
Common stock, $.001 par value; 60,000,000 authorized at December 31, 2008 and 2007, respectively; 38,165,380 shares issued and outstanding at December 31, 2008 and 2007	38	38
Additional paid-in capital	90,375	90,220
Accumulated other comprehensive income	70	110
Accumulated deficit	(87,949)	(81,612)
Total stockholders' equity	2,534	8,756
Total liabilities and stockholders' equity	$ 4,036	$ 10,085

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

(In Thousands, Except Share and Per Share Amounts)

	Years Ended December 31 2008	2007
Product revenue	$ 1,473	$ 1,196
Cost of goods sold	1,064	876
Gross margin	409	320
Operating expenses:		
Research and development	1,977	1,920
Depreciation and amortization	447	352
Selling, general and administrative	4,702	5,527
Total operating expenses	7,126	7,799
Loss from operations	(6,717)	(7,479)
Interest income	199	138
Interest expense	—	(535)
Amortization of beneficial conversion feature	—	(13,429)
Amortization of debt discount	—	(4,556)
Amortization of deferred financing costs	—	(992)
Impairment of auction rate securities	(114)	—
Gain on sale of investments	114	—
Gain on exchange of debt	—	330
Other income	181	167
Net loss	$ (6,337)	$ (26,356)
Net loss per common share, basic and diluted	$ (0.17)	$ (1.68)
Weighted average common shares outstanding, basic and diluted	38,165,380	15,646,286

The accompanying notes are an integral part of these consolidated financial statements.

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NEPHROS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Capital	(Loss)	Deficit	Total
Balance, January 1, 2007	12,317,992	$ 12	$ 53,135	$ 12	$ (55,256)	$ (2,097)
Comprehensive income:						
Net loss					(26,356)	(26,356)
Net unrealized gains on foreign currency translation				98		98
Comprehensive loss						(26,258)
Debt discount on issuance of convertible note			785			785
Beneficial conversion feature and warrant valuation			17,192			17,192
Conversion of notes and related accrued interest	25,847,388	26	18,223			18,249
Noncash stock-based compensation			885			885
Balance, December 31, 2007	38,165,380	$ 38	$ 90,220	$ 110	$ (81,612)	$ 8,756
Comprehensive income:						
Net loss					(6,337)	(6,337)
Net unrealized losses on foreign currency translation				(40)		(40)
Comprehensive loss						(6,377)
Noncash stock-based compensation			155			155
Balance, December 31, 2008	38,165,380	$ 38	$ 90,375	$ 70	$ (87,949)	$ 2,534

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Years Ended December 31, 2008	Years Ended December 31, 2007
Operating activities:		
Net loss	$ (6,337)	$ (26,356)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	447	352
Impairment of auction rate securities	114	—
Loss on disposal of equipment	—	4
Beneficial conversion features	—	13,429
Amortization of debt discount	—	4,556
Amortization of deferred financing costs	—	992
Change in valuation of derivative liability	—	7
Noncash stock-based compensation	155	885
Gain on sale of investments	(114)	—
Gain on exchange of debt	—	(330)
(Increase) decrease in operating assets:		
Accounts receivable	1	(154)
Inventory	(409)	217
Prepaid expenses and other current assets	227	63
Deferred costs	—	(2)
Other assets	8	(3)
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	138	2
Accrued severance expense	45	(38)
Accrued interest-convertible notes	—	498
Other liabilities	—	(564)
Net cash used in operating activities	(5,725)	(6,442)
Investing activities		
Purchase of property and equipment	(97)	(145)
Purchase of short-term investments	—	(4,700)
Proceeds from sales of property and equipment	3	—
Maturities of short-term investments	4,693	2,800
Net cash provided by (used in) investing activities	4,599	(2,045)
Financing activities		
Proceeds from private placement of convertible notes	—	12,677
Payment of deferred financing costs	—	(992)
Net cash provided by financing activities	—	11,685
Effect of exchange rates on cash	(17)	(2)
Net increase (decrease) in cash and cash equivalents	(1,143)	3,196

Cash and cash equivalents, beginning of year		3,449		253
Cash and cash equivalents, end of year	$	2,306	$	3,449
Supplemental disclosure of cash flow information				
Cash paid for interest	$	—	$	36
Cash paid for taxes	$	1	$	3
Supplemental disclosure of non-cash investing and financing activities				
Convertible note issued on debt exchange	$	—	$	5,300
Stock issued upon conversion of convertible notes	$	—	$	17,977
Stock issued upon conversion of accrued interest of convertible notes	$	—	$	272

The accompanying notes are an integral part of these consolidated financial statements.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Nature of Operations

Nephros, Inc. ("Nephros" or the "Company") was incorporated under the laws of the State of Delaware on April 3, 1997. Nephros was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced End Stage Renal Disease ("ESRD") therapy technology and products. The Company has three products in various stages of development in the hemodiafiltration, or HDF, modality to deliver improved therapy for ESRD patients. These are the OLpur TM MDHDF filter series or "dialyzers," designed expressly for HDF therapy, the OLpur TM H 2 H TM , an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy, and the OLpur TM NS2000 system, a stand-alone hemodiafiltration machine and associated filter technology. In 2006, the Company introduced its Dual Stage Ultrafilter ("DSU") water filter system, which represents a new and complementary product line to the Company's existing ESRD therapy business. The DSU incorporates the Company's unique and proprietary dual stage filter architecture.

On June 4, 2003, Nephros International Limited was incorporated under the laws of Ireland as a wholly-owned subsidiary of the Company. In August 2003, the Company established a European Customer Service and financial operations center in Dublin, Ireland.

Note 2 — Basis of Presentation and Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Nephros International Limited. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, at the date of the financial statements and the reported amounts of revenues and expenses, during the reporting period. Actual results could differ from those estimates.

Going Concern and Management's Response

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses and difficulty in generating sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on the Company's current cash flow projections, it will need to raise additional funds through either the licensing or sale of its technologies or additional public or private offerings of its securities. The Company continues to investigate strategic funding opportunities as they are identified. However, there is no guarantee that the Company will be able to obtain further financing. If it is unable to raise additional funds on a timely basis or at all, the Company would not be able to continue its operations.

The Company has incurred significant losses in its operations in each quarter since inception. For the years ended December 31, 2008 and 2007, the Company has incurred net losses of $6,337,000 and $26,356,000, respectively. In addition, the Company has not generated positive cash flow from operations for the years ended December 31, 2008 and 2007. To become profitable, the Company must increase revenue substantially and achieve and maintain positive gross and operating margins. If the Company is not able to increase revenue and gross and operating margins sufficiently to achieve profitability, the Company’s results of operations and financial condition will be materially and adversely affected.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

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

The Company's independent registered public accounting firm has included a paragraph in its audit report regarding the Company's ability to continue as a going concern.

There can be no assurance that the Company's future cash flow will be sufficient to meet its obligations and commitments. If the Company is unable to generate sufficient cash flow from operations in the future to service its commitments the Company will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing its planned activities or ceasing its operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable the Company to continue to satisfy its capital requirements

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

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

On September 27, 2007, the Company received a warning letter from the AMEX stating that the staff of the AMEX Listing Qualifications Department had determined that the Company was not in compliance with Section 121B(2)(c) of the AMEX Company Guide requiring that at least 50% of the directors of the Company's board of directors are independent directors. This non-compliance was due to the fact that William J. Fox, Judy Slotkin, W. Townsend Ziebold and Howard Davis resigned from the Company's board of directors on September 19, 2007, concurrently with the appointment of Paul Mieyal and Arthur Amron to the board of directors, in accordance with the Company's September 2007 financing. Consequently, the Company's board of directors consisted of five directors, two of whom were independent. The AMEX had given the Company until December 26, 2007 to regain compliance with the independence requirements. On November 16, 2007, James S. Scibetta was appointed to serve as an independent director on the Company's board of directors. On December 5, 2007 the Company received a letter from the AMEX acknowledging that the Company had resolved the continued listing deficiency identified in their September 27, 2007 letter.

On September 12, 2008, the Company received a letter from the AMEX notifying the Company of its noncompliance with certain continued listing standards. The following are the listing standards that the Company was in noncompliance of:

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

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

In response to that letter, the Company submitted a plan of compliance to the AMEX on October 13, 2008 advising the AMEX of the actions the Company has taken, or will take, that would bring it into compliance with the continued listing standards by April 30, 2009.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

Subsequent to December 31, 2008, on January 8, 2009, the Company received a letter from the AMEX notifying the Company that it was rejecting the plan. The AMEX further notified the Company that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, the Company decided not to seek an appeal of the AMEX's intention to delist the Company's common stock.

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

Effective February 4, 2009, the Company's common stock is now quoted on the Over the Counter Bulletin Board under the symbol "NEPH.OB".

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits and money market accounts. The Company considers all highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximate cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

Short-Term Investments

The Company had $7,000 of short-term investments consisting of a certificate of deposit at December 31, 2008.

At December 31, 2007, the Company held short-term investments, carried at fair market value, primarily representing auction rate debt securities ("ARS"). These securities were classified as "available-for-sale." Management determines the appropriate classification of its short-term investments at the time of purchase and evaluates such designation as of each balance sheet date. Interest earned on short-term investments is included in interest income.

ARS are long-term debt instruments with interest rates reset through periodic short-term auctions.

See Note 3 for a further discussion of short-term investments as of December 31, 2008 and December 31, 2007.

Accounts Receivable

The Company provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts at December 31, 2008 and 2007 was $4,000 and $7,000, respectively. There was no allowance for sales returns at December 31, 2008 or 2007.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

Inventory

The Company engages third parties to manufacture and package inventory held for sale, takes title to certain inventory once manufactured, and warehouses such goods until packaged for final distribution and sale. Inventory consists of finished goods and raw materials (fiber) held at the manufacturers' facilities, and are valued at the lower of cost or market using the first-in, first-out method.

Patents

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. All costs and direct expenses incurred in connection with patent applications have been expensed as incurred.

Property and Equipment, net

Property and equipment, net is stated at cost less accumulated depreciation. These assets are depreciated over their estimated useful lives of four to seven years using the straight line method.

Impairment for Long-Lived Assets

The Company adheres to SFAS No. 144, "Accounting for the Impairment on Disposal of Long-Lived Assets" and periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived assets, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including a discounted value of estimated future cash flows. The Company reports an asset to be disposed of at the lower of its carrying value or its estimated net realizable market value. There were no impairment losses for long-lived assets recorded for the years ended December 31, 2008 and December 31, 2007.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturity of these instruments.

Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104 "Revenue Recognition" ("SAB No. 104"). SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectibility is reasonably assured.

The Company recognizes revenue related to product sales when delivery is confirmed by its external logistics provider and the other criterion of SAB No. 104 are met. Product revenue is recorded net of returns and allowances. All costs and duties relating to delivery are absorbed by Nephros. All shipments are currently received directly by the Company's customers.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

Shipping and Handling Costs

Shipping and handling costs are recorded as cost of goods sold and are $31,000 and $35,000 for the years ended December 31, 2008 and 2007, respectively.

Research and Development Costs

Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004) "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. The fair value of the Company's stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of compensation costs requires that the Company estimate the number of awards that will be forfeited during the vesting period. The fair value of stock-based awards is amortized over the vesting period of the award. For stock-based awards that vest based on performance conditions (e.g. achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109 "Accounting for Income Taxes," which requires accounting for deferred income taxes under the asset and liability method. Deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable in future years to differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities.

For financial reporting purposes, the Company has incurred a loss in each period since its inception. Based on available objective evidence, including the Company's history of losses, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2008 and December 31, 2007.

Effective January 1, 2007, the Company adopted the Financial Accounting Standards Board ("FASB") Interpretation No. 48, Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 ("FIN 48"). FIN 48 prescribes, among other things, a recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return. FIN 48 utilizes a two-step approach for evaluating uncertain tax positions accounted for in accordance with SFAS 109. Step one or recognition, requires a company to determine if the weight of available evidence indicates a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two or measurement, is based on the largest amount of benefit, which is more likely than not to be realized on settlement with the taxing authority. The adoption of the provisions of FIN 48 did not have a material impact on the Company's consolidated financial statements. During the year ended December 31, 2008, the Company recognized no adjustments for uncertain tax positions.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

Loss per Common Share

In accordance with SFAS No. 128 "Earnings per Share," net loss per common share amounts ("basic EPS") was 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. The following securities have been excluded from the dilutive per share computation as they are antidilutive.

	2008	2007
Stock options	2,696,225	2,256,580
Warrants	11,090,248	11,090,248

Foreign Currency Translation

Foreign currency translation is recognized in accordance with SFAS No. 52 "Foreign Currency Translation." The functional currency of Nephros International Limited is the Euro and its translation gains and losses are included in accumulated other comprehensive income. The balance sheet is translated at the year-end rate. The statement of operations is translated at the weighted average rate for the year.

Comprehensive Income (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 years ended December 31, 2008 and 2007, the comprehensive loss was approximately $6,377,000 and $26,258,000, respectively.

Reclassification

Certain 2007 amounts were reclassified to conform to the 2008 presentation.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). This Standard defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. It applies to other accounting pronouncements where the FASB requires or permits fair value measurements but does not require any new fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, "Effective Date of FASB Statement No.157" ("FSP 157-2"), which delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The Company adopted SFAS

157 for financial assets and liabilities on January 1, 2008. The disclosures required under SFAS 157 are set forth in this note under fair value of financial instruments. The Company is currently in the process of evaluating the effect, if any, that the adoption of FSP 157-2 will have on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 155" ("SFAS 159"). This statement permits entities to choose to measure selected assets and liabilities at fair value. The Company adopted SFAS 159 on January 1, 2008 resulting in no material impact to the Company's consolidated financial statements.

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

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Basis of Presentation and Significant Accounting Policies – (continued)

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “Business Combinations” (“SFAS 141R”). SFAS 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. SFAS 141R determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is not permitted. The effect of SFAS 141R on the Company’s consolidated financial statements will be dependent on the nature and terms of any business combinations that occur after its effective date.

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

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

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

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

Note 3 — Short-Term Investments

SFAS No. 157 provides a framework for measuring fair value under generally accepted accounting principles in the United States and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. SFAS No. 157 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs, other than Level 1 prices, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 3 — Short-Term Investments – (continued)

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

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

The following table reflects the activity for the Company's ARS measured at fair value using Level 3 inputs for the year ended December 31, 2008:

	Auction Rate Securities
Balance as of December 31, 2007	$ 4,700,000
Sale of Securities	(4,700,000)
Gain on sale of investments	114,000
Impairment of auction rate securities	(114,000)
Balance as of December 31, 2008	$ —

As of December 31, 2008, the Company had grouped certificates of deposit using a Level 1 valuation because market prices are readily available in active markets.

The Company invested in auction rate securities ("ARS"), which are long-term debt instruments with interest rates reset through periodic short-term auctions. If there are insufficient buyers when such a periodic auction is held, then the auction "fails" and the holders of the ARS are unable to liquidate their investment through such auction. With the liquidity issues experienced in global credit and capital markets, the ARS held by the Company experienced multiple failed auctions in the first quarter of fiscal year 2008. As a result of the failed auctions, the Company did not consider the affected ARS liquid and accordingly, the Company classified its ARS as noncurrent assets as of March 31, 2008.

Based upon an analysis of other-than-temporary impairment factors, the Company wrote down ARS with an original par value of $4,400,000 to an estimated fair value of $4,286,000 as of March 31, 2008. The Company reviewed impairments associated with the above in accordance with Emerging Issues Task Force ("EITF") 03-1 and FASB Staff Position SFAS 115-1 and SFAS 124-1, "The Meaning of Other-Than-Temporary-Impairment and Its Application to Certain Investments," to determine the classification of the impairment as "temporary" or "other-than-temporary." The Company determined the ARS classification to be "other-than-temporary", and charged an impairment loss of $114,000 on the ARS to its results of operations during the three months ended March 31, 2008. Subsequently during the three months ended June 30, 2008, $300,000 of principal on the Company's ARS had been paid back from the debtor. As a result of the payment, the Company's investment decreased from a par value of $4,400,000 to approximately $4,100,000. The net book value of the Company's ARS at June 30, 2008 was $3,986,000. On July 22, 2008, the Company sold its ARS to a third party at 100% of par value, for proceeds of $4,100,000 and as a result, the Company reclassified the ARS from Available-for-Sale to Trading Securities.

In accordance with SFAS No. 115, “Accounting for Certain Investments in Debt and Equity Securities,” the ARS, classified as Trading Securities, were valued at their fair value of $4,100,000 at June 30, 2008. The adjustment of the ARS’ carrying value from $3,986,000 net book value to $4,100,000 fair value resulted in an Unrealized Holding Gain of $114,000 which was recorded in the Company’s Consolidated Statement of Operations for the three and six months ended June 30, 2008. As a result of the sale of investment on July 22, 2008, the Company reclassified the unrealized holding gain of $114,000 to a realized gain on sale of investments.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 4 — Inventory

The Company's inventory components as of December 31, 2008 and 2007, were as follows:

	December 31, 2008	December 31, 2007
Raw Materials	$ 382,000	$ 62,000
Finished Goods	342,000	304,000
Total Gross Inventory	724,000	366,000
Less: Inventory reserve	—	30,000
Total Inventory	$ 724,000	$ 336,000

During 2007, the design of the Dual Stage Ultra Filter product was changed. Accordingly, at December 31, 2007, this inventory has been written off as research and development and clinical trial expense in the amount of $82,000.

Note 5 — Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2008 and 2007, were as follows:

	December 31, 2008	December 31, 2007
Prepaid insurance premiums	$ 88,000	$ 211,000
Advances on product development services	—	96,000
Other	74,000	85,000
Prepaid expenses and other current assets	$ 162,000	$ 392,000

Note 6 — Property and Equipment, Net

Property and equipment as of December 31, 2008 and 2007, was as follows:

	Life	December 31, 2008	December 31, 2007
Manufacturing equipment	5 years	$ 2,057,000	$ 2,028,000
Research equipment	5 years	91,000	91,000
Computer equipment	4 years	61,000	70,000
Furniture and fixtures	7 years	39,000	39,000
Leasehold improvements	Term of lease	—	15,000
		2,248,000	2,243,000
Less: accumulated depreciation		1,836,000	1,481,000
Property and equipment, net		$ 412,000	$ 762,000

The Company contracts with a contract manufacturer ("CM") to manufacture the Company's ESRD therapy products. The Company owns certain manufacturing equipment located at CM's manufacturing plant.

Depreciation expense for the years ended December 31, 2008 and 2007 was $447,000 and $352,000, respectively, including amortization expense relating to research and development assets.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7 — Accrued Expenses

Accrued expenses as of December 31, 2008 and 2007 were as follows:

	December 31, 2008	December 31, 2007
Accrued Clinical Trial	$ 102,000	$ 223,000
Accrued Management Bonus and Directors' Compensation	119,000	—
Accrued Accounting	75,000	218,000
Accrued Legal	32,000	123,000
Accrued Other	83,000	217,000
	$ 411,000	$ 781,000

Note 8 — Convertible Notes

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 "Old Notes") issued by the Company for the face value thereof. The Company closed on the sale of the first tranche of Old 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 Old Notes, in an aggregate principal amount of $200,000, on June 30, 2006 (the "Second Tranche"). The Old Notes were secured by substantially all of the Company's assets.

The Old Notes contain a prepayment feature that requires the Company to issue common stock purchase warrants to the holders for partial consideration of certain prepayments that the holders may demand under certain circumstances. Pursuant to the Old Notes, the Company must offer the holders the option (the "Holder Prepayment Option") of prepayment (subject to applicable premiums) of their Old Notes, if the Company completes an asset sale in excess of $250,000 outside the ordinary course of business (a "Major Asset Sales"), 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 Old Notes and carried at fair value in the financial instruments. The Company recorded an embedded derivative liability of $71,000 in the 3rd quarter of 2006. The change in value of the derivative liability was recorded as other income (expense). The change in value amounted to $7,000 through September 19, 2007, the Exchange Date. Also, the debt discount, of $71,000, created by bifurcating the Holder Prepayment Option, was being amortized over the term of the debt. The amortization of the debt discount through September 19, 2007, the Exchange Date, was recorded as interest expense and amounted to $8,000.

On September 19, 2007, the Old Notes were exchanged for New Notes as described under the heading "Convertible Notes due 2008."

Convertible Notes Due 2008

The Company entered into a Subscription Agreement ("Subscription Agreement") with Lambda Investors LLC ("Lambda") on September 19, 2007 (the "First Closing Date"), GPC 76, LLC on September 20, 2007, Lewis P. Schneider on September 21, 2007 and Enso Global Equities Partnership LP ("Enso") on September 25, 2007 (collectively, the "New Investors") pursuant to which the New Investors purchased an aggregate of $12,677,000 principal amount of Series A 10% Secured Convertible Notes due 2008 (the "Purchased Notes") of the Company, for the face value thereof (the "Offering"). Concurrently with the Offering, the Company entered into an Exchange Agreement (the "Exchange Agreement") with each of Southpaw Credit Opportunities Master Fund LP, 3V Capital Master Fund Ltd., Distressed/High Yield Trading Opportunities, Ltd., Kudu Partners, L.P. and LJHS Company (collectively, the "Exchange Investors" and together with the New Investors, the "Investors"), pursuant to which the Exchange Investors agreed to exchange the principal and accrued but unpaid interest in an aggregate amount of $5,600,000 under the Old Notes, for new Series B 10% Secured Convertible Notes due 2008 in an aggregate principal amount of $5,300,000 (the "Exchange Notes", and together with the Purchased Notes, the "New Notes") (the "Exchange", and together with the Offering, the "Financing").

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Convertible Notes – (continued)

The Company has obtained the approval of its stockholders representing a majority of its outstanding shares to the issuance of shares of its common stock issuable upon conversion of the New Notes and exercise of the Class D Warrants (as defined below) issuable upon such conversion, as further described below. The stockholder approval was effective on November 13, 2007. Accordingly, the New Notes were converted into common stock of the Company on November 14, 2007.

Upon effectiveness of such approval, all principal and accrued but unpaid interest (the "Conversion Amount") under the New Notes automatically converted into (i) shares of the Company's common stock at a conversion price per share of the Company's common stock (the "Conversion Shares") equal to $0.706 and (ii) in the case of the Purchased Notes, but not the Exchange Notes, Class D Warrants (the "Class D Warrants") for purchase of shares of the Company's common stock (the "Warrant Shares") in an amount equal to 50% of the number of shares of the Company's common stock issued to the New Investors in accordance with clause (i) above with an exercise price per share of the Company's common stock equal to $0.90 (subject to anti-dilution adjustments).

National Securities Corporation ("NSC") and Dinosaur Securities, LLC ("Dinosaur" and together with NSC, the "Placement Agent") acted as co-placement agents in connection with the Financing pursuant to an Engagement Letter, dated June 6, 2007 and a Placement Agent Agreement dated September 18, 2007. The Placement Agent received (i) an aggregate cash fee equal to 8% of the face amount of the Lambda Purchased Note and the Enso Purchased Note allocated and paid 6.25% to NSC and 1.75% to Dinosaur, and (ii) warrants ("Placement Agent Warrant") with a term of five years from the date of issuance to purchase 10% of the aggregate number of shares of the Company's common stock issued upon conversion of the Lambda Purchased Note and the Enso Purchased Note with an exercise price per share of the Company's common stock equal to $0.90.

The Company recorded a debt discount related to the issuance of the Exchange Notes, of $785,000 and was amortizing the discount over the term of the Exchange Notes. The amortization of the debt discount through November 14, 2007, the Automatic Conversion Date, was recorded as interest expense and amounted to $120,000. The remaining balance of the debt discount of $665,000 was written off to interest expense when the Exchange Notes were converted into common stock.

On October 24, 2007, the SEC accepted the Schedule 14C filed by the Company thereby setting the "Automatic Conversion Date" of both the Series A and Series B Notes to be November 14, 2007. The acceptance date also became the measurement date to calculate the value of the embedded beneficial conversion feature in each note and the detachable warrants included in the Series A Notes.

The Company allocated the proceeds from the sale of the Purchased Notes between the Purchased Notes and the Class D Warrants based upon their relative fair values, resulting in the recognition of a discount of $3,763,000. The value of the Class D Warrants was computed using the Black-Scholes option pricing model. Second, in accordance with EITF No. 00-27, "Application of Issue 98 - 5 to Certain Convertible Instruments" after allocating a portion of the Purchased Notes proceeds to the Class D Warrants, the Company calculated the value of the embedded beneficial conversion feature in the Purchased Notes by comparing the carrying value of the proceeds, net of the warrant discount, to the fair value of the shares issuable upon conversion of the Purchased Notes. If there is a beneficial conversion, it is recognized, as an additional discount to the extent of the remaining proceeds. The Company recognized an additional discount of approximately $8,914,000 for the embedded beneficial conversion feature. The amortization of the discount and beneficial conversion feature through November 14, 2007, the Automatic Conversion Date, was recorded as interest expense and amounted to $239,000 and $566,000. The remaining balances of the discount of $3,524,000 and beneficial conversion feature of $8,348,000 were written off to interest expense when the Purchased Notes were converted into common stock. On November 14, 2007 the Purchased Notes, in aggregate principal amount of $12,677,000, and related accrued interest of $190,000, were converted into an aggregate of 18,225,128 shares of common stock.

In accordance with EITF No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios," the Company calculated the value of the embedded beneficial conversion feature in the Exchange Notes by comparing the carrying value of the proceeds to the fair value of the shares issuable upon conversion of the Exchange Notes. The Company recognized a discount of $4,515,000 for the embedded beneficial conversion feature. The amortization of the beneficial conversion feature through November 14, 2007, the Automatic Conversion Date, was recorded as interest expense and amounted to $286,000. The remaining balance of the beneficial conversion feature of $4,229,000 was written off to interest expense when the Exchange Notes were converted into common stock. On November 14, 2007 the Exchange Notes, in aggregate principal amount of $5,300,000, and related accrued interest of $81,000, were converted into an aggregate of 7,622,259 shares of common stock.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Convertible Notes – (continued)

As compensation for its services as co-placement agents, National Securities Corporation and Dinosaur Securities, LLC, received cash in the amount of $775,000 and $217,000 and five-year warrants to purchase an aggregate of 1,756,374 shares of the Company's common stock at an exercise price of $0.90 per share. These warrants contain a "cashless exercise" option. The total fee of $2,039,000, including the fair value of the warrants issued, was recorded as deferred financing costs. The deferred costs were written off and recorded as interest expense on November 14, 2007, the Automatic Conversion Date.

Acceleration of Non Cash Charges Upon Conversion of New Notes

The conversion of the New Notes to equity on November 14, 2007 resulted in an aggregate non-cash charge of $17,985,000, of which $13,429,000 relates to the amortization of the beneficial conversion features and $4,556,000 relates to the amortization of the debt discount.

Note 9 — Income Taxes

A reconciliation of the income tax provision computed at the statutory tax rate to the Company's effective tax rate is as follows:

	2008	2007
U.S. federal statutory rate	35.00%	35.00%
State & local taxes	10.79%	11.26%
Tax on foreign operations	(1.36)%	(0.51)%
Other	(3.03)%	(1.21)%
Valuation allowance	(44.11)%	(45.53)%
Effective tax rate	(2.71)%	(0.99)%

Significant components of the Company's deferred tax assets as of December 31, 2008 and 2007 are as follows:

	2008	2007
Deferred tax assets:		
Net operating loss carry forwards	$ 29,357,000	$ 26,734,000
Research and development credits	957,000	896,000
Nonqualified stock option compensation expense	1,751,000	1,703,000
Other temporary book – tax differences	(63,000)	2,000
Total deferred tax assets	32,002,000	29,335,000
Valuation allowance for deferred tax assets	(32,002,000)	(29,335,000)
Net deferred tax assets	$ —	$ —

A valuation allowance has been recognized to offset the Company's net deferred tax asset as it is more likely than not that such net asset will not be realized. The Company primarily considered its historical loss and potential Internal Revenue Code Section 382 limitations to arrive at its conclusion that a valuation allowance was required.

At December 31, 2008, the Company had Federal, New York State and New York City income tax net operating loss carryforwards of $60,584,000 each and foreign income tax net operating loss carryforwards of $8,997,000. The Company also had Federal research tax credit carryforwards of $957,000 at December 31, 2008 and $896,000 at December 31, 2007. The Federal net operating loss and tax credit carryforwards will expire at various times between 2012 and 2026 unless utilized. During 2008, the Company received $147,000 payroll based research and development credits from New York State.

On January 1, 2007, the Company adopted the provisions of FIN 48, “Accounting for Uncertainty in Income Taxes — An interpretation of FASB Statement No.109.” Implementation of FIN 48 did not result in a cumulative effect adjustment to the accumulated deficit.

It is the Company’s policy to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 — Stock Plans, Share-Based Payments and Warrants

Stock Plans

In 2000, the Company adopted the Nephros 2000 Equity Incentive Plan. In January 2003, the Board of Directors adopted an amendment and restatement of the plan and renamed it the Amended and Restated Nephros 2000 Equity Incentive Plan (the "2000 Plan"), under which 2,130,750 shares of common stock had been authorized for issuance upon exercise of options granted and which may have been granted by the Company.

As of December 31, 2007, 353,392 options had been issued to non-employees under the 2000 Plan and were outstanding. Such options expire at various dates between January 30, 2008 and March 15, 2014 all of which are fully vested. As of December 31, 2007, 1,082,137 options had been issued to employees under the 2000 Plan and were outstanding. Such options expire at various dates between December 31, 2009 and March 15, 2014 all of which are fully vested.

As of December 31, 2008, 220,888 options had been issued to non-employees under the 2000 Plan and were outstanding. Such options expire at various dates through March 15, 2014 all of which are fully vested. As of December 31, 2008, 916,506 options had been issued to employees under the 2000 Plan and were outstanding. Such options expire at various dates between December 31, 2009 and March 15, 2014 all of which are fully vested.

The Board retired the 2000 Plan in June 2004, and thereafter no additional awards may be granted under the 2000 Plan.

In 2004, the Board of Directors adopted and the Company's stockholders approved the Nephros, Inc. 2004 Stock Incentive Plan, and, in June 2005, the Company's stockholders approved an amendment to such plan (as amended, the "2004 Plan"), that increased to 800,000 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. In May 2007, the Company's stockholders approved an amendment to the 2004 Plan that increased to 1,300,000 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan. In addition, in June 2008, the Company's stockholders approved an amendment to the 2004 Plan that increased to 2,696,976 the number of shares of the Company's common stock that are authorized for issuance by the Company pursuant to grants of awards under the 2004 Plan.

As of December 31, 2007, 628,500 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between December 14, 2014 and September 15, 2018, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2007, there were 478,948 shares available for future grants under the 2004 Plan. As of December 31, 2007, 192,552 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 11, 2014 and November 30, 2017, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

As of December 31, 2008, 1,366,279 options had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between December 14, 2014 and November 8, 2017, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years. At December 31, 2008, there were 2,050,924 shares available for future grants under the 2004 Plan. As of December 31, 2008, 192,552 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between November 11, 2014 and November 30, 2017, and vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

Share-Based Payment

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. Unvested options as of December 31, 2008 currently vest upon a combination of the following: immediate vesting or straight line vesting of two or four years.

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 met. Stock based compensation expense recognized for the years ended December 31, 2008 and 2007 was approximately $155,000 or less than $0.01 per share and approximately $885,000 or $0.06 per share, respectively.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 — Stock Plans, Share-Based Payments and Warrants – (continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the below assumptions related to risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility.

	Option Pricing Assumptions	
Grant Year	2008	2007
Stock Price Volatility	89%-90%	84% – 86%
Risk-Free Interest Rates	3.45% to 3.47%	3.97% to 4.83%
Expected Life (in years)	6.25	5.8 to 6.0
Expected Dividend Yield	0%	0%

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 option’s life.

The total fair value of options vested during the fiscal year ended December 31, 2008 was approximately $102,000. The total fair value of options vested during the fiscal year ended December 31, 2007 was approximately $1,473,000.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2008:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding as of December 31, 2008	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable as of December 31, 2008	Weighted Average Exercise Price
$0.32 - $0.37	1,270,471	5.7	$ 0.35	520,471	$ 0.32
$0.75	375,000	9.3	$ 0.75	—	$ —
$0.80 – $1.49	306,279	1.9	$ 1.15	285,446	$ 1.17
$1.76	165,630	4.4	$ 1.76	165,630	$ 1.76
$2.32 – $2.64	335,703	4.8	$ 2.42	335,703	$ 2.42
$2.78 – $4.80	243,142	4.6	$ 3.23	243,142	$ 3.23
Total Outstanding	2,696,225		$ 1.10	1,550,392	$ 1.54

The number of new options granted in 2008 and 2007 is 1,125,000 and 610,000, respectively. The weighted-average fair value of options granted in 2008 and 2007 is $0.38 and $0.76, respectively.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 10 — Stock Plans, Share-Based Payments and Warrants – (continued)

The following table summarizes the option activity for the years ended December 31, 2008 and 2007:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2007	2,256,580	$ 1.53
Options granted	1,125,000	$ 0.50
Options canceled	(685,355)	$ 1.46
Outstanding at December 31, 2008	2,696,225	$ 1.10
Expected to vest at December 31, 2008	1,079,375	$ 0.50
Exercisable at December 31, 2008	1,550,392	$ 1.54

The aggregate intrinsic value of stock options outstanding at December 31, 2008 and the stock options vested or expected to vest is $0. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest is 6.4 years.

As of December 31, 2008, the total remaining unrecognized compensation cost related to non-vested stock options amounted to $355,000 and will be amortized over the weighted-average remaining requisite service period of 3.4 years.

Warrants

Class D Warrants — As disclosed above in Note 8, the Company issued Class D Warrants to purchase an aggregate of 9,112,566 shares of the Company's common stock to the Investors upon conversion of the Purchased Notes. The Company recorded the issuance of the Class D Warrants at their approximate fair market value of $3,763,000. The value of the Class D Warrants was computed using the Black-Scholes option pricing model.

Placement Agent Warrants — As disclosed above in Note 8, the Company issued Placement Agent Warrants to purchase an aggregate of 1,756,374 shares of the Company's common stock to the Company's placement agents in connection with their roles in the Offering. The Company recorded the issuance of the Placement Agent Warrants at their approximate fair market value of $1,047,000. The value of the Placement Agent Warrants was computed using the Black-Scholes option pricing model.

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2008.

Total Outstanding Warrants

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable
IPO Underwriter Warrants	3/24/2005	9/20/2009	$ 7.50	200,000
Lancer Warrants	1/18/2006	1/18/2009	$ 1.50	21,308

Class D Warrants	11/14/2007	11/14/2012	$ 0.90	9,112,566
Placement Agent Warrants	11/14/2007	11/14/2012	$ 0.90	1,756,374
Total all Outstanding Warrants			$ 1.02 (1)	11,090,248

(1) Weighted average.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 11 — 401(k) Plan

The Company has established a 401(k) deferred contribution retirement plan (the “401(k) Plan”) which covers all employees. The 401(k) Plan provides for voluntary employee contributions of up to 15% of annual earnings, as defined. As of January 1, 2004, the Company began matching 100% of the first 3% and 50% of the next 2% of employee earnings to the 401(k) Plan. The Company contributed and expensed $29,000 and $50,000 in 2008 and 2007, respectively.

Note 12 — Commitments and Contingencies

Settlement Agreements

Plexus Services Corp.

In June 2002, the Company entered into a settlement agreement with one of its suppliers, Plexus Services Corp. The Company had an outstanding liability to such supplier in the amount of $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 $10.56 per share which expired on 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 $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 final payment of $25,000 was paid on September 26, 2007.

Lancer Offshore, Inc.

In August 2002, the Company entered into a subscription agreement with Lancer Offshore, Inc. (“Lancer”), pursuant to which Lancer agreed to purchase, in several installments, (1) $3,000,000 principal amount of secured convertible notes due March 15, 2003 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 $8.80 per share. In accordance with the subscription agreement, the first installment of securities, consisting one-half of the total, 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, among other things, the $1,500,000 secured convertible note issued to Lancer in August 2002 was cancelled. However, Lancer never fulfilled the conditions to the subsequent closing under the settlement agreement and, accordingly, the Company never issued the $1,500,000 non-convertible 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 brought by the Receiver for Lancer Offshore, Inc. (the “Ancillary Proceeding”) that was commenced on March 8, 2004. On December 19, 2005, the Court 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 final payment of $400,000 was made on October 3, 2007.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12 — Commitments and Contingencies – (continued)

Manufacturing and Suppliers

The Company does not intend to manufacture any of its products or components. The Company has entered into an agreement dated May 12, 2003, and amended on March 22, 2005 with a contract manufacturer ("CM"), a developer and manufacturer of medical products, to assemble and produce the Company's OLpur MD190, MD220 or other filter products at the Company's option. The agreement requires the Company to purchase from CM the OLpur MD190s and MD220s or other filter products that the Company directly markets in Europe, or are marketed by our distributor. In addition, CM will be given first consideration in good faith for the manufacture of OLpur MD190s, MD220s or other filter products that the Company does not directly market. No less than semiannually, CM will provide a report to representatives of both parties to the agreement detailing any technical know-how that CM has developed that would permit them to manufacture the filter products less expensively and both parties will jointly determine the actions to be taken with respect to these findings. If the fiber wastage with respect to the filter products manufactured in any given year exceeds 5%, then CM will reimburse the Company up to half of the cost of the quantity of fiber represented by excess wastage. CM will manufacture the OLpur MD190 or other filter products in accordance with the quality standards outlined in the agreement. Upon recall of any OLpur MD190 or other filter product due to CM having manufactured one or more products that fail to conform to the required specifications or having failed to manufacture one or more products in accordance with any applicable laws, CM will be responsible for the cost of recall. The agreement also requires that the Company maintain certain minimum product-liability insurance coverage and that the Company indemnify CM against certain liabilities arising out of the Company's products that they manufacture, providing they do not arise out of CM's breach of the agreement, negligence or willful misconduct. The term of the agreement is through May 12, 2009, with successive automatic one-year renewal terms, until either party gives the other notice that it does not wish to renew at least 90 days prior to the end of the term. The agreement may be terminated prior to the end of the term by either party upon the occurrence of certain insolvency-related events or breaches by the other party. Although the Company has no separate agreement with respect to such activities, CM has also been manufacturing the Company's DSU in limited quantities.

The Company also entered into an agreement in December 2003, and amended in June 2005, with a fiber supplier ("FS"), a manufacturer of medical and technical membranes for applications like dialysis, to continue to produce the fiber for the OLpur MDHDF filter series. Pursuant to the agreement, FS is the Company's exclusive provider of the fiber for the OLpur MDHDF filter series in the European Union as well as certain other territories through September 2009. Notwithstanding the exclusivity provisions, the Company may purchase membranes from other providers if FS is unable to timely satisfy the Company's orders.

The Company is committed to use one supplier for its production of products for sale in Europe; however no minimum purchase requirements are in effect.

Contractual Obligations

At December 31, 2008, the Company had an operating lease that will expire on November 30, 2011 for the rental of its U.S. office and research and development facilities as well as an operating lease that will expire on August 31, 2008, unless renewed for a twelve month period or a rolling six month lease, for the rental of its office in Ireland. Rent expense for the years ended December 31, 2008 and 2007 totaled $222,000 and $191,000, respectively.

Contractual Obligations and Commercial Commitments

The following tables summarize our approximate minimum contractual obligations and commercial commitments as of December 31, 2008:

		Payments Due in Period			
Contractual Obligations	Total	Within 1 Year	Years 1 – 3	Years 3 – 5	More than 5 Years
Leases	$ 296,000	$ 115,000	$ 181,000	$ —	$ —
Employment Contracts	1,066,250	425,000	641,250		
Total	$ 1,362,250	$ 540,000	$ 822,250	$ —	$ —

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NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12 — Commitments and Contingencies – (continued)

Registration Payment Arrangement

In September 2007, the Company issued $12,677,000 and $5,300,000 in convertible notes and, as partial compensation to placement agents in connection therewith, issued warrants to purchase an aggregate of 1,756,374 shares of common stock. Upon conversion of such notes in November 2007, the Company issued an aggregate of 25,847,388 shares of common stock and warrants to purchase an aggregate of 9,112,566 shares of common stock to the former holders of such notes. As part of such offering, the Company has entered into an arrangement requiring the Company to use its best efforts to file a registration statement with the SEC covering resale of the shares of common stock and for such registration statement to be declared effective on or prior to June 20, 2008 (the Effectiveness Date). The Initial Resale Registration Statement was declared effective on May 5, 2008.

Employee Severance Agreement

On September 19, 2007, in connection with Mr. Fox's resignation as Executive Chairman, Nephros and Mr. Fox entered into a Separation Agreement and Release (the "Separation Agreement"), pursuant to which the parties mutually agreed to terminate Mr. Fox's employment with Nephros and the employment agreement between Nephros and Mr. Fox made as of July 1, 2006 (the "Employment Agreement"), effective immediately. Nephros will pay Mr. Fox an aggregate of $142,500 payable in equal installments for a period of six months after the Termination Date (as defined in the Separation Agreement). Nephros also paid to Mr. Fox any accrued but unpaid Base Salary (as defined in the Employment Agreement) for services rendered through the Termination Date. The final payment to Mr. Fox was made in the first quarter of 2008.

On May 7, 2008, the Company entered into a separation agreement and release with Mr. Lerner, Chief Financial Officer, pursuant to which, the employment agreement between the Company and Mr. Lerner, dated as of March 6, 2006, was terminated. Pursuant to the separation agreement, Mr. Lerner agreed to remain employed by the Company and to consult with the Company's officers, directors and agents and otherwise provide assistance in the Company's transition to a new chief financial officer until a separation date as late as May 15, 2008. The separation agreement provides that (i) Mr. Lerner will continue to receive his current base salary for a period of three months following the separation date, to be paid in accordance with the Company's normal payroll practices, and (ii) the Company will reimburse Mr. Lerner for up to $5,000 of reasonable expenses for professional outplacement assistance.
The separation agreement also contains mutual releases and other customary provisions.

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

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

The Separation Agreement also stated that, in accordance with their respective terms, the options granted to Mr. Barta on January 24, 2000, December 14, 2004 and November 8, 2007 - to the extent vested prior to the Separation Date - shall remain exercisable until three months after the Separation Date, and the options granted to Mr. Barta on January 30, 2003 shall remain exercisable until nine months after the Separation Date. A number of the options that were granted to Mr. Barta on November 8, 2007 remained unvested and were cancelled and forfeited by Mr. Barta as of the Separation Date. The separation agreement also contains mutual releases and other customary provisions. The balance due Mr. Barta as of December 31, 2008 was $105,000.

Former Employee Claim

A former Company employee in France filed a claim in October 2008 stating that he is due 30,000 Euro or approximately $42,000 in back wages. The individual left the Company four years ago and signed a Separation Agreement which stated the Company had no further liability to the individual. The Company's attorney has advised that the Separation Agreement is valid and should preclude any liability. The matter will be heard before a French court sometime in 2009. No date has been set at this time.

NEPHROS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12 — Commitments and Contingencies – (continued)

The Company evaluated this issue in light of FASB Statement No. 5, Accounting for Contingencies and determined that although the contingent loss is clearly able to be estimated, management's assessment is that the likelihood of the loss being incurred is remote due to the existence of an executed Separation Agreement which clearly states the Company has no further liability to the former employee. The prescribed treatment of this item as described, per FASB Statement No. 5, Accounting for Contingency, is to disclose the existence of the contingency and the amount of the potential loss but the loss is not to be recorded. No accrual has been made for this item in the 2008 financial statements.

Note 13 — Concentration of Credit Risk

Cash and cash equivalents are financial instruments which potentially subject the Company to concentrations of credit risk. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. To date, the Company has not experienced any impairment losses on its cash and cash equivalents.

Major Customers

For the year ended December 31, 2008 and 2007, one customer accounted for 78% and 91%, respectively, of the Company's sales. In addition, as of December 31, 2008 and 2007, that customer accounted for 66% and 98%, respectively, of the Company's accounts receivable.

Note 14 — Subsequent Event

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

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

- Section 1003(a)(iii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $6,000,000 if such issuer has sustained net losses in its five most recent fiscal years;
- Section 1003(a)(ii), which states AMEX will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders' equity of less than $4,000,000 if such issuer has sustained net losses in its three of its four most recent fiscal years; and
- Section 1003(f)(v), which states AMEX will normally consider suspending dealings in, or removing from the list, common stock that sells for a substantial period of time at a low price per share.

The AMEX further notified us that the AMEX intends to strike the common stock from the AMEX by filing a delisting application with the Securities and Exchange Commission pursuant to Rule 1009(d) of the AMEX Company Guide. Given the turmoil in the capital markets, we have decided not to seek an appeal of the AMEX's intention to delist our common stock.

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

Effective February 4, 2009, the Company’s common stock is now quoted on the Over the Counter Bulletin Board under the symbol “NEPH.OB”.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes in or disagreements with our accountants since our formation required to be disclosed pursuant to Item 304 of Regulation S-B, except that on July 16, 2007, we changed auditors as reported on our Form 8-K filed on July 16, 2007.

Item 9A(T). Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e),which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

Changes in Internal Control Over Financial Reporting

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

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

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

Other than the matters discussed above, there were no other significant changes in our internal control over financial reporting or in other factors that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Through the evaluation of the Sarbanes-Oxley internal control assessment, a more structured approach, including checklists, reconciliations and analytical reviews, has been implemented to reduce risk in the financial reporting process.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes all of our Company's consolidated subsidiaries.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework." Based on this assessment, management believes that, as of December 31, 2008, our internal control over financial reporting was operating effectively.

This annual report does not include an attestation report by our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only a management assessment in this annual report.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance

We have adopted a written code of ethics and business conduct that applies to our directors, executive officers and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the American Stock Exchange by filing such amendment or waiver with the Securities and Exchange Commission. This code of ethics and business conduct can be found in the corporate governance section of our website, www.nephros.com.

The other information called for by this item is incorporated by reference to our definitive proxy statement relating to our 2008 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2009, then the information called for by this item will be filed as part of an amendment to this Form 10-K on or before such date, in accordance with General Instruction E(3).

Item 11. Executive Compensation

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2008 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2009, the information called for by this item will be filed as part of an amendment to this Form 10-K on or before such date, in accordance with General Instruction E(3).

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plan Information

The following table provides information as of December 31, 2008 about compensation plans under which shares of our common stock may be issued to employees, consultants or members of our Board of Directors upon exercise of options, warrants or rights under all of our existing equity compensation plans. Our existing equity compensation plans consist of our Amended and Restated Nephros 2000 Equity Incentive Plan and our Nephros, Inc. 2004 Stock Incentive Plan (together, our "Stock Option Plans") in which all of our employees and directors are eligible to participate.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by stockholders	13,346,828	$ 1.11	478,948
Equity compensation plans not approved by stockholders	—	—	—
All plans	13,346,828	$ 1.11	478,948

The other information called for by this item is incorporated by reference to our definitive proxy statement relating to our 2008 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2009, the information called for by this item will be filed as part of an amendment to this Form 10-K on or before such date, in accordance with General Instruction E(3).

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2008 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2009, the information called for by this item will be filed as part of an amendment to this Form 10-K on or before such date, in accordance with General Instruction E(3).

Item 14. Principal Accounting Fees and Services

The information called for by this item is incorporated herein by reference to our definitive proxy statement relating to our 2008 Annual Meeting of Stockholders, which will be filed with the SEC. If such proxy statement is not filed on or before April 30, 2009, the information called for by this item will be filed as part of an amendment to this Form 10-K on or before such date, in accordance with General Instruction E(3).

Item 15. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(5)
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant. (13)
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on November 13, 2007. (14)
3.5	Second Amended and Restated By-Laws of the Registrant.(16)
4.1	Specimen of Common Stock Certificate of the Registrant.(1)
4.2	Form of Underwriter's Warrant.(1)
4.3	Warrant for the purchase of shares of common stock dated January 18, 2006, issued to Marty Steinberg, Esq., as Court-appointed Receiver for Lancer Offshore, Inc.(17)
4.4	Form of Series A 10% Secured Convertible Note due 2008 convertible into Common Stock and Warrants. (15)
4.5	Form of Series B 10% Secured Convertible Note due 2008 convertible into Common Stock.(15)
4.6	Form of Class D Warrant.(15)
4.7	Form of Placement Agent Warrant.(15)
10.1	Amended and Restated 2000 Nephros Equity Incentive Plan.(1)(2)
10.2	2004 Nephros Stock Incentive Plan.(1)(2)
10.3	Amendment No. 1 to 2004 Nephros Stock Incentive Plan.(2)(5)
10.4	Amendment No. 2 to the Nephros, Inc. 2004 Stock Incentive Plan.(14)
10.5	Form of Subscription Agreement dated as of June 1997 between the Registrant and each Purchaser of Series A Convertible Preferred Stock. (1)
10.6	Amendment and Restatement to Registration Rights Agreement, dated as of May 17, 2000 and amended and restated as of June 26, 2003, between the Registrant and the holders of a majority of Registrable Shares (as defined therein). (1)
10.7	Employment Agreement dated as of November 21, 2002 between Norman J. Barta and the Registrant. (1)(2)
10.8	Amendment to Employment Agreement dated as of March 17, 2003 between Norman J. Barta and the Registrant. (1)(2)
10.9	Amendment to Employment Agreement dated as of May 31, 2004 between Norman J. Barta and the Registrant. (1)(2)
10.10	Employment Agreement effective as of July 1, 2007 between Nephros, Inc. and Norman J. Barta. (14)
10.11	Form of Employee Patent and Confidential Information Agreement.(1)
10.12	Form of Employee Confidentiality Agreement.(1)
10.13	Settlement Agreement dated June 19, 2002 between Plexus Services Corp. and the Registrant.(1)
10.14	Settlement Agreement dated as of January 31, 2003 between Lancer Offshore, Inc. and the Registrant. (1)
10.15	Settlement Agreement dated as of February 13, 2003 between Hermitage Capital Corporation and the Registrant. (1)

Exhibit No.	Description
10.16	Supply Agreement between Nephros, Inc. and FS, dated as of December 17, 2003. (1)(3)
10.17	Amended Supply Agreement between Nephros, Inc. and FS dated as of June 16, 2005. (3)(7)
10.18	Manufacturing and Supply Agreement between Nephros, Inc. and CM, dated as of May 12, 2003. (1)(3)
10.19	Amended Manufacturing and Supply Agreement between Nephros, Inc. and CM, dated as of March 22, 2005. (3)(8)
10.20	HDF-Cartridge License Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.21	Subscription Agreement dated as of March 2, 2005 between Nephros, Inc. and Asahi Kasei Medical Co., Ltd. (4)
10.22	Non-employee Director Compensation Summary.(2)(6)
10.23	Named Executive Officer Summary of Changes to Compensation.(2)(6)
10.24	Stipulation of Settlement Agreement between Lancer Offshore, Inc. and Nephros, Inc. approved on December 19, 2005. (8)
10.25	Consulting Agreement, dated as of January 11, 2006, between the Company and Bruce Prashker. (2)(8)
10.26	Summary of Changes to Chief Executive Officer's Compensation.(2)(8)
10.27	Employment Agreement, dated as of February 28, 2006, between the Company and Mark W. Lerner. (2)(8)
10.28	Form of 6% Secured Convertible Note due 2012 for June 1, 2006 Investors.(9)
10.29	Form of Prepayment Warrant.(9)
10.30	Form of Subscription Agreement, dated as of June 1, 2006.(9)
10.31	Form of Registration Rights Agreement, dated as of June 1, 2006.(9)
10.32	Form of 6% Secured Convertible Note due 2012 for June 30, 2006 Investors.(10)
10.33	Form of Subscription Agreement, dated as of June 30, 2006.(10)
10.34	Employment Agreement between Nephros, Inc. and William J. Fox, entered into on August 2, 2006. (2)(11)
10.35	Addendum to Commercial Contract between Nephros, Inc. and Bellco S.p.A, effective as of January 1, 2007. (3)
10.36	Form of Subscription Agreement between Nephros and each New Investor.(15)
10.37	Exchange Agreement, dated as of September 19, 2007, between Nephros and the Exchange Investors. (15)
10.38	Registration Rights Agreement, dated as of September 19, 2007, among Nephros and the Investors. (15)
10.39	Investor Rights Agreement, dated as of September 19, 2007, among Nephros and the Investors. (15)
10.40	Placement Agent Agreement, dated as of September 18, 2007, among Nephros, NSC and Dinosaur. (15)
10.41	License Agreement, dated October 1, 2007, between the Trustees of Columbia University in the City of New York, and Nephros. (17)
10.42	Executive Employment Agreement, dated as of April 1, 2008, between Nephros, Inc. and Gerald J. Kochanski. (18)
10.43	Separation Agreement, dated as of April 28, 2008, between Nephros, Inc. and Mark W. Lerner. (18)
10.44	Separation Agreement and Release, dated as of September 15, 2008, between Nephros, Inc. and Norman J. Barta. (19)
10.45	

	Employment Agreement, dated as of September 15, 2008, between Nephros, Inc. and Ernest A. Elgin III. (19)
10.46	Lease Agreement between Nephros, Inc. and 41 Grand Avenue, LLC dated as of November 20, 2008. (20)
10.47	Distribution Agreement between Nephros, Inc. and OLS, dated as of November 26, 2008.

Exhibit No.	Description
10.48	Lease Agreement between Nephros International LTD and Coldwell Banker Penrose & O'Sullivan dated November 30, 2008.
10.49	Distribution Agreement between Nephros, Inc. and Aqua Services, Inc., dated as of December 3, 2008.
10.50	Sales Management Agreement between Nephros, Inc. and Steve Adler, dated as of December 16, 2008.
10.51	Amendment No. 3 to the Nephros, Inc. 2004 Stock Incentive Plan.
21.1	Subsidiaries of Registrant.(12)
23.1	Consent of Rothstein Kass, Certified Public Accountants, dated as of March 31, 2008.
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.

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

(2) Management contract or compensatory plan arrangement.

(3) Portions omitted pursuant to a request for confidential treatment.

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

(5) Incorporated by reference to Nephros, Inc.'s Registration Statement on Form S-8 (No. 333-127264), as filed with the Securities and Exchange Commission on August 5, 2005.

(6) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on May 16, 2005.

(7) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB, filed with the Securities and Exchange Commission on August 15, 2005.

(8) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB, filed with the Securities and Exchange Commission on April 20, 2006.

(9) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2006.

(10) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 7, 2006.

(11)

Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 4, 2006.

(12) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2006, filed with the Securities and Exchange Commission on April 10, 2007.

(13) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 13, 2007.

(14) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the Securities and Exchange Commission on November 13, 2007.

(15) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2007.

(16) Incorporated by reference to Nephros, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2007.

(17) Incorporated by reference to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008.

(18) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the Securities and Exchange Commission on May 15, 2008.

(19) Incorporated by reference to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008, filed with the Securities and Exchange Commission on November 14, 2008.

(20) Incorporated by reference to Nephros, Inc. 's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 20, 2008.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

	NEPHROS, INC.
Date: March 27, 2009	By: /s/ Ernest A. Elgin III
	Name: Ernest A. Elgin III
	Title: President and Chief Executive Officer

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and the dates indicated.

Signature	Title	Date
/s/ Ernest A. Elgin Ernest A. Elgin	President and Chief Executive Officer (Principal Executive Officer)	March 27, 2009
/s/ Gerald J. Kochanski Gerald J. Kochanski	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2009
/s/ Arthur H. Amron Arthur H. Amron	Director	March 27, 2009
/s/ Lawrence J. Centella Lawrence J. Centella	Director	March 27, 2009
/s/ Paul A. Mieyal Paul A. Mieyal	Director	March 27, 2009
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Director	March 27, 2009
/s/ James S. Scibetta James S. Scibetta	Director	March 27, 2009