UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

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

For the transition period from to

Commission File Number 001-32288

NEPHROS, INC.

(Exact name of registrant specified in its charter)

Delaware	**13-3971809**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

380 Lackawanna Place
South Orange, NJ 07079
(Address of Principal Executive Offices)

(201) 343-5202
(Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of exchange on which registered
Common stock, par value $0.001 per share	NEPH	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange 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 ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See 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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2023, was $10,420,918. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Stock Market on June 30, 2023. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and stockholders holding greater than 10% of the voting stock of the registrant as of June 30, 2023.

As of March 6, 2024, there were 10,543,675 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2024 Proxy Statement will be filed within 120 days of December 31, 2023.

NEPHROS, INC. AND SUBSIDIARIES

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FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain statements in this Annual Report on Form 10-K constitute "forward-looking statements." Such statements include statements regarding our ability to increase our revenue, limit our expenses and other expected operating results, including our ability and the timing of our business generating positive cash flows from operations, the adequacy of our existing capital resources to fund our operations, our belief that we will maintain good relationships with our suppliers, distributors and customers, and other statements that are not historical facts, including statements that may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include, but are not limited to, the risks that:

- we face significant challenges in obtaining market acceptance of our products, which, if not obtained, could adversely affect our potential sales and revenues;
- product-related deaths or serious injuries or product malfunctions 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 face potential liability associated with the production, marketing and sale of our products, and the expense of defending against claims of product liability could materially deplete our assets and generate negative publicity, which could impair our reputation;
- to the extent our products or marketing materials are found to violate any provisions of the U.S. Food, Drug and Cosmetic Act (the "FDC Act") or any other statutes or regulations, we could be subject to enforcement actions by the U.S. Food and Drug Administration (the "FDA") or other governmental agencies;
- we may not be able to obtain funding when needed or on terms favorable to us in order to continue operations;
- we may not have sufficient capital to successfully implement our business plan;
- we may not be able to effectively market and sell our products;
- we may not be able to sell our water filtration products at competitive prices or profitably;
- we may encounter problems with our suppliers, manufacturers, and distributors;
- we may encounter unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures;
- we may not be able to obtain appropriate or necessary regulatory approvals to achieve our business plan;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products;
- we may not be able to achieve sales growth in key geographic markets.

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this Annual Report on Form 10-K, is set forth in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including our other periodic reports filed with the SEC. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements because of new information, future events or otherwise, except as required by law.

PART I

Item 1. Business

Overview

We are a commercial-stage company that develops and sells high performance water solutions to the medical and commercial markets.

In medical markets, we sell water filtration products. Our medical water filters, mostly classified as ultrafilters, are used primarily by hospitals for the prevention of infection from waterborne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

In commercial markets, we manufacture and sell water filters that improve the taste and odor of water and reduce biofilm, bacteria, and scale build-up in downstream equipment. Our products are marketed primarily to the food service, hospitality, convenience store, and health care markets. These commercial products are also marketed into medical markets, as supplemental filtration to our medical filters.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize an alternative method to hemodialysis. We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular, water purification.

Our Products

Water Filtration Products

We develop and sell water filtration products used in both medical and commercial applications. Our water filtration products employ multiple filtration technologies, as described below.

In medical markets, our primary filtration mechanism is to pass liquids through the pores of polysulfone hollow fiber. Our filters' pores are significantly smaller than those of competing products, resulting in highly effective elimination of waterborne pathogens, including legionella bacteria (the cause of Legionnaires disease) and viruses, which are not eliminated by most other microbiological filters on the market. Additionally, the fiber structure and pore density in our hollow fiber enables significantly higher flow rates than in other polysulfone hollow fiber.

Our primary sales strategy in medical markets is to sell through value-added resellers ("VARs"). Leveraging VARs has enabled us to rapidly expand our access to target customers with limited sales staff expansion. In addition, while we are currently focused on medical markets, the VARs that support these customers also support a wide variety of commercial and industrial customers. We believe that our VAR relationships have and will continue to facilitate growth in filter sales outside of the medical industry.

In commercial markets, we develop and sell our filters, for which carbon-based absorption is the primary filtration mechanism. These products allow us to improve water's odor and taste, to reduce scale and heavy metals, and to reduce other water contaminants for customers who are primarily in the food service, convenience store, and hospitality industries. These commercial products are also sold into medical markets, as supplemental filtration to our medical filters.

In commercial markets, our model combines both direct and indirect sales. Through our employee sales staff, we have sold products directly to a number of convenience stores, hotels, casinos, and restaurants. We have also signed an agreement with a partner to be the exclusive distributor to resell select water filters and related products to customers in the commercial food and beverage markets subject to meeting certain minimum thresholds.

Target Markets

Our ultrafiltration products currently target the following markets:

- Hospitals and Other Healthcare Facilities: Filtration of water for washing and drinking as an aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures, and washing of surgeons' hands.
- Dialysis Centers and Home/Portable Dialysis Machines: Filtration of water or bicarbonate concentrate used in hemodialysis.
- Commercial Facilities: Filtration and purification of water for consumption, including for use in ice machines and soft drink dispensers.
- Military and Outdoor Recreation: Individual water purification devices used by soldiers and backpackers to produce drinking water in the field, as well as filters customized to remote water processing systems.

Hospitals and Other Healthcare Facilities. Nephros filters are a leading tool used to provide proactive protection to patients in high-risk areas (e.g., ice machines, surgical rooms, NICUs) and reactive protection to patients in broader areas during periods of water pathogen outbreaks. Our products are used in hundreds of medical facilities to aid in infection control, both proactively and reactively.

As of 2023, according to the American Hospital Association, there are approximately 6,129 hospitals in the U.S., with approximately 920,000 beds. Over 34 million patients were admitted to these hospitals. The U.S. Department of Health and Human Services estimates that healthcare associated infections ("HAI") occur in approximately 1 out of every 31 hospital patients, which calculates to over one million patients in 2023. HAIs affect patients in hospitals or other healthcare facilities and are not present or incubating at the time of admission. They also include infections acquired by patients in the hospital or facility, but appearing after discharge, and occupational infections among staff. Many HAIs are caused by waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities.

In January 2022, the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services ("CMS") expanded its requirements – originally implemented in 2017 – for facilities to develop policies and procedures that inhibit the growth and spread of legionella and other opportunistic pathogens in building water systems. In this 2022 update, CMS requires teams to be assigned to the development of formal water management plans ("WMPs"), as well as detailed documentation regarding the development of the WMPs and their execution. CMS surveyors regularly review policies, procedures, and reports documenting water management implementation results to verify that facilities are compliant with these requirements. We believe that these CMS regulations may have a positive impact on the sale of our HAI-inhibiting ultrafilters.

We currently have FDA 510(k) clearance on the following portfolio of medical device products for use in the hospital setting to aid in infection control:

- The DSU-H and SSU-H are in-line, 0.005-micron ultrafilters that provide dual- and single-stage protection, respectively, from waterborne pathogens. They are primarily used to filter potable water feeding ice machines, sinks, and medical equipment, such as endoscope washers and surgical room humidifiers. The DSU-H has an up to 6-month product life in a typical hospital setting, while the SSU-H has an up to 3-month product life.

- The S100 is a point-of-use, 0.01-micron microfilter that provides protection from waterborne pathogens. The S100 is primarily used to filter potable water feeding sinks and showers. The S100 has an up to 3-month product life when used in a hospital setting.

- The HydraGuard™ and HydraGuard™ - Flush are 0.005-micron cartridge ultrafilters that provide single-stage protection from waterborne pathogens. The HydraGuard ultrafilters are primarily used to filter potable water feeding ice machines and medical equipment, such as endoscope washers and surgical room humidifiers. The HydraGuard has an up to 6-month product life and the HydraGuard - Flush has an up to 12-month product life when used in a hospital setting.

Our complete hospital infection control product line, including in-line, and point-of-use can be viewed on our website at https://www.nephros.com/infection-control/. We are not including the information on our website as a part of, nor incorporating it by reference into, this Annual Report on Form 10-K.

Dialysis Centers - Water/Bicarbonate. In the dialysis water market, Nephros ultrafiltration products are among the highest performing products on the market. The DSU-D, SSU-D and the SSUmini have become the standard endotoxin filter in many portable reverse osmosis systems. The EndoPur®, our large-format ultrafilter targeted at dialysis clinic water systems, provides the smallest pore size available.

To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate, two essential ingredients for making dialysate, the liquid that removes waste material from the blood. According to the National Institute of Health, there are approximately 7,100 dialysis clinics in the United States servicing approximately 500,000 patients annually. We estimate that there are over 100,000 hemodialysis machines in operation in the United States.

We currently have FDA 510(k) clearance on the following portfolio of medical device products for use in the dialysis setting to aid in bacteria, virus, and endotoxin retention:

- The DSU-D, SSU-D and SSUmini are in-line, 0.005-micron ultrafilters that provide protection from bacteria, viruses, and endotoxins. All of these products have an up to 12-month product life in the dialysis setting and are used to filter water following treatment with a reverse osmosis ("RO") system, and to filter bicarbonate concentrate. These ultrafilters are primarily used in the water lines and bicarbonate concentrate lines leading into dialysis machines, and as a polish filter for portable RO machines.

- The EndoPur is a 0.005-micron cartridge ultrafilter that provides single-stage protection from bacteria, viruses, and endotoxins. The EndoPur has an up to 12-month product life in the dialysis setting and is used to filter water following treatment with an RO system. More specifically, the EndoPur is used primarily to filter water in large RO systems designed to provide ultrapure water to an entire dialysis clinic. The EndoPur is a cartridge-based, "plug and play" market entry that requires no plumbing at installation or replacement. The EndoPur is available in 10", 20", and 30" configuration.

Commercial and Industrial Facilities. Our commercial NanoGuard® product line accomplishes ultrafiltration via small pore size (0.005 micron) technology, filtering bacteria and viruses from water. In addition, our commercial filtration offerings include technologies that are primarily focused on improving odor and taste and on reducing scale and heavy metals from filtered water.

Our commercial market focus is on the hotel, restaurant, and convenience store markets. In March 2022, we entered into an agreement to provide water filtration systems to an organization that services approximately 3,000 Quick Service Restaurants ("QSR"). Effective January 1, 2023, we entered into a new supply agreement with this commercial partner, which superseded the March 2022 agreement. Under the January 2023 agreement, we engaged this commercial partner to be our exclusive distributor to the food, beverage and hospitality industries. We continue to pursue other national accounts, which, over time, may result in step-change increases in commercial market revenue.

Over time, we believe that the same water safety management programs currently underway at medical facilities may migrate to commercial markets. As the epidemiology of waterborne pathogens expands, links to contamination sources will become more efficient and the data more readily available. In cases where those sources are linked to restaurants, hotels, office buildings and residential complexes, the corporate owners of those facilities will likely face increasing liability exposure. We expect that building owners will come to understand ASHRAE-188, which outlines risk factors for buildings and their occupants, and provides water safety management guidelines. We believe, in time, most commercial buildings will need to follow the basic requirements of ASHRAE-188: create a water management plan, perform routine testing, and establish a plan to treat the building in the event of a positive test.

As demand for water testing and microbiological filtration grows, we will be ready to deploy our expertise and solutions based on years of experience servicing the medical market. We believe that we have an opportunity to offer unique expertise and products to the commercial market, and that our future revenue from the commercial market could even surpass our infection control revenue.

We currently market the following portfolio of proprietary products for use in the commercial, industrial, and food service settings:

- The NanoGuard set of products are in-line, 0.005-micron ultrafilter that provides dual-stage retention of any organic or inorganic particle larger than 15,000 Daltons. NanoGuard products are designed to fit a variety of existing plumbing configurations, including 10" and 20" standard housings, and Nephros and Everpure® manifolds. Included in the NanoGuard product line are both conventional and flushable filters.

- The Nephros line of commercial filters provides a variety of technology solutions that improve water quality in food service, convenience store, hospitality, and industrial applications. Nephros filters improve water taste and odor, and reduce sediment, dirt, rust particles and other solids, chlorine and heavy minerals, lime scale build-up, and both particulate lead and soluble lead.

Nephros commercial products combine effectively with NanoGuard ultrafiltration technologies to offer full-featured solutions to the commercial water market, including to existing users of Everpure filter manifolds.

Hemodiafiltration (HDF) Systems and Specialty Renal Products, Inc.

The current standard of care in the United States for patients with chronic renal failure is hemodialysis ("HD"), a process in which toxins are cleared via diffusion. Patients typically receive HD treatments at least 3 times weekly for 3-4 hours per treatment. HD is most effective in removing smaller, easily diffusible toxins. For patients with acute renal failure, the current standard of care in the United States is hemofiltration ("HF"), a process where toxins are cleared via convection. HF offers a much better removal of larger sized toxins when compared to HD; however, HF treatment is more challenging for patients, as it is performed daily, and typically takes 12-24 hours per treatment.

Our company was originally founded to develop and commercialize a hemodiafiltration ("HDF") medical device. HDF is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the United States, HDF is prevalent in Europe and is performed for a growing number of patients. Clinical experience and literature demonstrate that HDF's benefits, among other factors, include enhanced clearance of middle and large molecular weight toxins, improved patient survival, reduced incidence of dialysis-related amyloidosis, improved patient quality of life and reduced hospitalizations and overall length of stays.

Our original HDF device ("HDF1") was cleared by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with chronic renal failure in 2012, but did not gain market acceptance due to, among other reasons, the feeling that it was too difficult to use.

We previously held a majority stake in Specialty Renal Products, Inc. ("SRP"), a development-stage medical device company that was focused primarily on the development of the second-generation HDF device ("HDF2"). SRP undertook efforts to redesign and dramatically simplify our HDF device. We believe those updates made the system significantly easier to use. On May 13, 2022, the FDA gave 510(k) clearance to SRP's second-generation model of the OLpūrH2H Hemodiafiltration System, which enables nephrologists to provide HDF treatment to patients with end stage renal disease. In January 2023, SRP management began exploring strategic partnerships to support a commercial launch of the HDF product but was unsuccessful in identifying a partner. By late February 2023, SRP had nearly exhausted its capital resources and, due to its limited capital and lack of prospects for securing a strategic partnership or additional financing, the board of directors of SRP adopted a plan on March 6, 2023 to wind down SRP operations, liquidate its remaining assets and dissolve the company. That plan was approved by SRP's stockholders on March 9, 2023, and on April 13, 2023, SRP filed a certificate of dissolution with the State of Delaware. SRP's cash resources were sufficient to satisfy all of its outstanding liabilities other than its obligations to us under a loan with an outstanding balance of approximately $1.5 million. Accordingly, SRP assigned to us all of its remaining assets, including its intellectual property rights in the HDF2 device, in satisfaction of its outstanding loan balance. Although we have no current plans to do so, we may re-evaluate opportunities for HDF in the future.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 1997. Our principal executive offices are located at 380 Lackawanna Place, South Orange, New Jersey 07079, and our telephone number is (201) 343-5202. We also have an office in Whippany, New Jersey. For more information about Nephros, please visit our website at *www.nephros.com*. We are not including the information on our website as a part of, nor incorporating it by reference into, this Annual Report on Form 10-K.

Manufacturing and Suppliers

We do not, and do not intend to in the near future, manufacture any of our medical device filtration products. We do manufacture some of our commercial filtration products in our facility in South Orange, New Jersey.

On April 23, 2012, we entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement, as amended, Medica granted us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, with certain limitations on territory, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the filtration products during the term of the License and Supply Agreement. The filtration covered under the License and Supply Agreement include both certain products based on Medica's proprietary Versatile microfiber technology and certain filtration products based on Medica's proprietary Medisulfone ultrafiltration technology. The term of the License and Supply Agreement with Medica expires on December 31, 2028, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement. We currently have an understanding with Medica whereby we have agreed to pay interest per month at the EURIBOR 360-day rate plus 500 basis points calculated on the principal amount of any outstanding invoices that are overdue by more than 15 days beyond the original payment terms.

In exchange for the rights granted, we agreed to make minimum annual aggregate purchases from Medica throughout the term of the License and Supply Agreement.

Sales and Marketing

Our New Jersey headquarters oversees global sales and marketing activity of our ultrafilter products. We work with multiple distributors for our ultrafilter products in the hospital and dialysis water markets. For the food service and hospitality markets, we have contracted with Donastar LLC as our master distributor. For other prospective markets for our ultrafilter products, we are pursuing alliance opportunities for joint product development and/or distribution. Our ultrafilter manufacturer in Europe shares certain intellectual property rights with us for one of our dual stage ultrafilter designs.

Research and Development

Our research and development efforts continue on several fronts directly related to our current product lines. For the ultrafiltration systems business, we are continually working with existing and potential distributors of ultrafilter products to develop solutions to meet customer needs.

Major Customers

For the years ended December 31, 2023 and 2022, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2023	2022
A	23%	26%
B	11%	10%
Total	34%	36%

As of December 31, 2023 and 2022, the following customers accounted for the following percentages of our accounts receivable, respectively:

Customer	2023	2022
A	12%	21%
B	6%	10%
C	3%	10%
Total	21%	41%

Competition

With respect to the water filtration market, we compete with companies that are well-entrenched in the water filtration domain. These companies include Pall Corporation (wholly owned by Danaher Corporation), which manufactures point-of-use microfiltration products, as well as 3M and Pentair, who manufacture the Cuno® and Everpure® brands of water filtration and purification products, respectively. 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 and/or acquisition 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 also apply 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. patent for the "Method and Apparatus for a Hemodiafiltration Module for use with a Dialysis Machine," has claims that cover the OLpūr MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have issued patents on our water filtration products and applications in process to cover various applications in residential, commercial, and remote environments.

As of December 31, 2023, we had four U.S. patents and one Canadian patent. In addition, we have one pending patent application in the United States. Our pending US patent application relates to filter technologies, including liquid purification filter systems that are particularly suited for use in harsh environments.

Trademarks

As of December 31, 2023, in the United States, we secured registrations of the trademarks ENDOPUR, HYDRAGUARD, NANOGUARD, and NEPHROS. In the US, we filed two trademark applications for BECAUSE WATER MATTERS. In the UK, we secured registrations for the trademarks NANOGUARD, NEPHROS HYDRAGUARD, and PATHOGUARD.

Governmental Regulation

The research and development, manufacturing, promotion, marketing, and distribution of our ESRD therapy products in the United States, Europe 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 Food, Drug, and Cosmetics (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 into 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 ("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, Section 510(k), and Section 515 of the FDC Act require a manufacturer who intends to market a medical device to submit a premarket notification (Section 510(k)) or a request for premarket approval (Section 515), to the FDA.

A 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 premarket approval under Section 515. The 510(k) clearance process is generally faster and simpler than the premarket approval process.

Premarket approval (PMA) is the FDA's process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury, or are new and present unknown safety or effectiveness issues or risks. PMA is the most stringent type of device marketing application required by the FDA. To gain approval, the manufacturer must present adequate scientific evidence to assure that the device is safe and effective for its intended use(s).

For any devices cleared through the 510(k) clearance 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 510(k) clearance submission. Accordingly, if we do obtain Section 510(k) clearance for any of our ESRD therapy and/or filtration products, we will need to submit another Section 510(k) notification if we significantly affect that product's safety or effectiveness through subsequent modifications or enhancements.

All of our products have been cleared by the FDA as Class II devices, such as.

- *DSU Dual Stage UltraFilter:* In June 2009, we received FDA 510(k) clearance of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

- *SSU-D/DSU-D Dual Stage UltraFilter:* In July 2011, we received FDA 510(k) clearance of the SSU/DSU to be used to filter water or bicarbonate concentrate used in hemodialysis procedures.

- *OLpūr H2H Module and OLpūr MD 220 Hemodiafilter:* In April 2012, we received FDA 510(k) clearance of the OLpūr H2H Module and OLpūr MD 220 Hemodiafilter for use with a UF controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of patients with chronic renal failure in the United States.

- *DSU-H/SSU-H:* In October 2014, we received FDA 510(k) clearance of the DSU-H and SSU-H ultrafilters to be used to filter EPA quality drinking water. The filters retain bacteria, viruses, and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control.

- *S100 Point of Use Filter:* In April 2016, we received FDA 510(k) clearance of the S100 point-of-use filter to be used to filter EPA quality drinking water. The filters retain bacteria. By retaining bacteria in water for washing and drinking, the filter may aid in infection control.

- *HydraGuard:* In December 2016, we received FDA 510(k) clearance of the HydraGuard 10" ultrafilter intended to be used to filter EPA quality drinking water. The filter retains bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filter aids in infection control.

- *EndoPur:* In March 2017, we received FDA 510(k) clearance of the EndoPur ultrafilter intended to be used to filter water used in hemodialysis devices. It assists in providing hemodialysis quality water. The device is not a complete water treatment system but serves to remove biological contaminants. Therefore, it must be used in conjunction with other water treatment equipment (Reverse Osmosis, Deionization, etc.).

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.

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.

We and our contract manufacturers are required to manufacture our products in compliance with current Good Manufacturing Practice (GMP) requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that we or any of our contract manufacturers, or regulated suppliers, are not in compliance with these requirements, there may be a material adverse effect on our manufacturing operations, effecting our ability to sell.

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.

In 2017, the European Union (EU) adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements.

As defined in EU Medical Device Regulation (Council Regulations 2017/745), 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.

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 13485/2016 and other statutory requirements, and the manufacturer's products conform to 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 Européene, 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.

Medical Devices sold in Europe/ anticipated to be sold in Europe, shall be examined, and classified as:

- Class I: Provided non-sterile or do not have a measuring function; Low Risk
- Class I: Provided sterile and/or have a measuring function; Low/medium risk
- Class IIa: Medium risk
- Class IIb: Medium/high risk
- Class III: High risk

Currently we are in the process to seek approval for CE certification under EU Medical Device Regulation (Council Regulations 2017/745). Once approved, the following products will have certification from BSI America for CE marking and adherence to ISO13485 standards as Class IIa (Rule 3) medical devices:

- *SSU-D/DSU-D/SSUmini Ultrafilters:* Intended to be used to filter water or bicarbonate concentrate used in hemodialysis procedures.

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

In November 2007 and May 2011, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpūr MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the Canadian approval of our OLpūr MD220 Hemodiafilter and DSU products, we have not obtained any regulatory approvals to sell any of our products outside of the United States and the European Union and there is no assurance that any such clearance or certification will be issued.

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. Our manufacturing facilities are subject to audits and have been certified to be ISO 13485:2016, which allows us to sell our products in the United States and Canada.

In November 2020, we received MDSAP certification to continue sales and compliance in the United States and Health Canada. The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations authorized by the participating Regulatory Authorities to audit under MDSAP requirements. The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan, and the United States.

In November 2023, we received approval for expansion of our MDSAP certification to include Brazil. This expansion provides Nephros the approval to sell the following medical devices in Brazil:

- *SSSUmini Ultrafilters:* Intended to be used to filter water or bicarbonate concentrate used in hemodialysis procedures.

- *EndoPur Filters:* The device is not a complete water treatment system but serves to remove biological contaminants. Therefore, it must be used in conjunction with other water treatment equipment (Reverse Osmosis, Deionization, etc.).

Product Liability and Insurance

The production, marketing and sale of our 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 $3 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, 2023, we employed a total of 31 full-time employees, including 11 employed in sales/marketing/customer support, 15 in logistics, general, and administrative, and 4 in research and development and 1 in manufacturing. None of our employees are currently represented by a labor union or covered by a collective bargaining agreement and we believe that our relations with our employees are good. During 2023, we had limited voluntary turnover. Going forward, we intend to focus on maintaining our current good relations with our employees and continuing to develop and explore ways to collaborate with our employees and create a well-regarded workplace.

Available Information

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Exchange Act requires us to file periodic reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. These materials may be obtained electronically by accessing the SEC's website at http://www.sec.gov.

Item 1A. Risk Factors

Risks Related to Our Overall Business and Operations

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

As of December 31, 2023, we had an accumulated deficit of $144.4 million as a result of historical operating losses. While we believe that revenues will increase following our planned sales team expansion, there can be no guarantee of this. We may continue to incur additional losses in the future depending on the timing and marketplace acceptance of our products and as a result of operating expenses being higher than our gross margin from product sales. 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 market acceptance 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 that exceed our per unit costs; and
- our ability to continue to develop products and maintain a competitive advantage in our industry.

If we are unable to achieve profitability, we will need additional capital to fund our operating activities. Such capital is likely to be from the sale of shares of our common stock or other equity securities or from loans or other debt securities. However, there is no assurance that such capital will be available on favorable terms or at all.

We may be unable to achieve or sustain revenue growth.

Our business and future prospects are substantially dependent upon our ability to significantly grow our product revenue. Although our sales were approximately 43% higher in 2023 compared to 2022, there is no assurance that we will be able to continue our sales growth in future periods. Our ability to increase our revenues in future periods will depend on our ability to significantly grow our customer base and then consistently obtaining product reorders from those customers. If we cannot sustain significant revenue growth for an extended period, our financial results will be adversely affected, and our stock price may decline.

We face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues.

Our success depends on our ability to both maintain our existing customers and to continue growing our customer base. If we are unable to maintain and further grow our customer base, our ability to grow revenue will be limited and we will have difficulty achieving profitability. Our ability to grow our customer base also depends on our ability to continue increasing achieve market acceptance of our water filter products, including among healthcare facility customers, or may not be deemed suitable for other commercial, military, industrial or retail applications. Factors that may affect our ability to achieve acceptance of our water filtration products and technologies in the marketplace include whether such products will be safe for use, whether they will be effective and whether they will be cost-effective.

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

In order to successfully 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. The extent to which we fail to successfully commercialize our products will limit our ability to be profitable.

We rely on, and for the foreseeable future expect to continue to rely on, a limited number of independent manufacturers to produce our products. 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. If we are successful in continuing to increase our product revenue, we will need to also increase our supply requirements. However, our contracted manufacturers could experience manufacturing and control problems in connection with their manufacture of our products, which could disrupt their ability to timely and adequately supply us with product. If we experience any of these problems with respect to our manufacturers' 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.

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. 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. In particular, our ability to grow sales in our commercial business depends largely on the efforts of a distribution partner with respect to which we have given exclusive distribution rights to our products in the food, beverage and hospitality markets. We cannot assure that 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 have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.

Our business strategy depends in part on our ability to sell our products to hospitals and other healthcare facilities, including dialysis clinics. We have limited experience with respect to sales and marketing. If we are unsuccessful at manufacturing, marketing, and selling our products, our operations and potential revenues will be materially adversely affected.

We are dependent on third parties to supply us with our products to us, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers to provide us with certain components of our products. With respect to our proprietary filter material used in our DSU-H, SSU-H, S100 and HydraGuard™ and HydraGuard™ – Flush filters, we rely on a single source supplier. Our agreement with that supplier will expire in 2028 and although our relationship with this supplier is good, there can be no assurance that our current agreement will guarantee uninterrupted supply or that we will be able to renew the agreement on favorable terms, or at all. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand and our customers' demands.

Companies in the United States and around the world have experienced a disruption in the supply of certain components and raw materials, such as resins and polymers, which may adversely affect us and our ability to obtain these components in a timely manner, in the volumes we require, or at all. In addition, the prices of these components and other supplies we rely upon in the manufacture of our products may rise. For example, we and our suppliers have recently experienced, and may continue to experience, rising costs due to inflation, such as costs of materials, labor and freight. If inflation continues to rise, the prices of our components may rise, resulting in increased expenses to us that we may not be able to offset by raising the prices of our products.

Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products, or price increases of these supplies, could have a material adverse effect on our business, financial condition and results of operations.

We operate with a limited senior management team and are highly dependent on our sales and marketing personnel. Our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We operate our business with a two-person senior management team. We have a Chief Executive Officer and a Chief Financial Officer, who together directly oversee operations, sales and finances. Our dependence on two officers to perform multiple functions exposes us to various risks, including the risk that two officers may be unable to devote sufficient or timely attention to all aspects of operating our business and that in the event of a sudden departure of one officer, we may not be able to promptly identify a successor. We do not carry key person life insurance on any of our employees. If we are unable to recruit and retain qualified personnel to our senior management teams, we will be unlikely to achieve our objectives of continuing to grow our company and our business may otherwise be harmed.

In addition, our need to significantly increase our revenue is also dependent on the personnel in our sales and marketing organization. Although we have recently added a number of new sales and marketing professionals, our success will depend on their ability to quickly integrate into our business and our ability to develop and retain them as employees. Our ability to increase our sales revenue may be materially impaired if we experience attrition in our sales and marketing organization.

We rely on information technology systems and network infrastructure to operate and manage our business. If we experience a breach, cyber attack or other disruption to these systems or data, our business, results of operations and financial condition could be adversely affected.

We are increasingly dependent on sophisticated information technology systems to operate our business, including to process, transmit and store sensitive data. Specifically, we rely on our information technology systems to effectively manage sales and marketing, accounting and financial functions, inventory management, and our research and development data. Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure.

Although we believe our computer and communications hardware is protected by reasonable physical, technical, and administrative safeguards, it is still vulnerable to system malfunction, computer viruses, and cybersecurity breaches – including ransomware, phishing, malware, brute force, insider threats, and other cyber attacks and security incidents. These events could lead to the unauthorized access to information systems maintained by us or our service providers or customers and result in the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, customers, distributors or our suppliers. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world, including countries that engage in state-sponsored cyber attacks. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. Additionally, the regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. If our information technology systems are compromised, we could be subject to fines, damages, litigation and enforcement actions and we could lose trade secrets or other confidential information, the occurrence of which could harm our reputation, business, results of operations and financial condition.

Our information systems, and those of third parties with whom we contract, also require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology. The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our operations and could result in decreased sales, increased overhead costs, excess inventory and product shortages, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

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 water-filtration products, particularly to healthcare facility customers, have inherent risks of liability in the event of product failure or claim of harm caused by product operation. Voluntary recalls could subject us to claims or proceedings by consumers, the FDA or other regulatory authorities which may adversely impact our sales and revenues. Furthermore, even meritless claims of product liability may be costly to defend against. Although we have acquired product liability insurance 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 contract manufacturer ("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.

We cannot assure you that our products will be safe or that there will not be product-related deaths, serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances 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 products will prove to be safe or that there will not be product-related deaths or serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm. Under the FDC Act, we are required to submit medical device reports ("MDRs") to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products 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. Additionally, any of the following could occur:

- 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 market and sell our 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 products.

Risks Related to Government Regulation

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 medically approved products. If we violate the FDC Act or other regulatory requirements (either with respect to our ultrafilters or otherwise) 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 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.

If we develop new water filter products in the future, we may be required to obtain regulatory approvals and clearances in the countries in which we intend to sell such products. 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 new products to market and enhance our revenues.

Our current water filter products that we market and sell to healthcare facilities and dialysis centers have 510(k) clearance from the FDA. However, we will need to continue developing new products in the future to continue to compete in our industry, and such new products may require obtaining regulatory approvals in the U.S. and other jurisdictions in which we intend to market them.

We cannot ensure that any new products developed by us in the future, will be approved for marketing. The clearance and/or approval processes 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 regulatory approval for any of our existing or new 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 would prevent us from selling our affected products in the applicable regions. If we cannot sell some of our products in such regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

Over time, we intend to market our products globally. Requirements pertaining to the sale of our products vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our products in many 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 products in a particular region, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

Significant additional governmental regulation could subject us to unanticipated delays that 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 enforcement actions by the FDA and/or other agencies, all of which could impair our ability to have manufactured and to sell the affected products.

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

Approval or clearance of our products could be withdrawn, delayed, or denied 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 products in the European Community. The FDA also imposes requirements through quality system requirements regulations, which include requirements for good manufacturing practices. Failure by our manufacturers to comply with these requirements could prevent us from obtaining FDA pre-clearance or approval of our products and from marketing such products in the United States. Although the manufacturing facilities and processes that we use to manufacture our OLpūr MD HDF 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. 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.

To market our products in the European Community, the United States, and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our 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 products manufactured in such facilities and our revenues may be materially adversely affected.

Risks Related to our Intellectual Property

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 4 granted U.S. patents will expire at various times from 2029 to 2039, 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 for or obtain additional 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 and, in the event we further expand our operations, the laws of other countries may not adequately protect our trade secrets.

Risks Related to Owning Our Common Stock

The prices at which shares of the common stock trade have been and will likely continue to be volatile.

During the two years ended December 31, 2023, our common stock has traded at prices ranging from a high of $6.19 to a low of $0.91 per share. Due to the lack of an active trading market for our common stock, we expect the prices at which our common stock might trade to continue to be highly volatile. The expected volatile price of our stock will make it difficult for investors to predict the value of an investment in our common stock, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our common stock. These include, but are not limited to:

- period-to-period fluctuations in our results of operations;
- sales of our common stock or other financing transactions;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- achievement or rejection of regulatory approvals by our competitors or us;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- threatened or actual litigation; and
- changes in financial estimates by securities analysts.

We are not able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

Our common stock could be further diluted as a result of the issuance of additional shares of common stock, warrants or options.

In the past we have issued common stock and warrants in order to raise capital to help fund our business. We have also issued stock options and restricted stock as compensation for services and incentive compensation for our employees, directors, and consultants. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock, or could obligate us to issue additional shares of common stock.

Market sales of large amounts of our common stock, or the potential for those sales even if they do not actually occur, may have the effect of depressing the market price of our common stock, the supply of common stock available for resale could be increased, which could stimulate trading activity and cause the market price of our common stock to drop, even if our business is doing well. Furthermore, the issuance of any additional shares of our common stock or securities convertible into our common stock could be substantially dilutive to holders of our common stock if they do not invest in future offerings.

We have never paid dividends and do not intend to pay cash dividends.

We have never paid dividends on our common stock and currently do not anticipate paying cash dividends on our common stock for the foreseeable future. Consequently, any returns on an investment in our common stock in the foreseeable future will have to come from an increase in the value of the stock itself. As noted above, the lack of an active trading market for our common stock will make it difficult to value and sell our common stock. While our dividend policy will be based on the operating results and capital needs of our business, we anticipate that all earnings, if any, will be retained to finance our future operations.

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 smaller reporting 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 "Risk Factors" 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. 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.

Our directors, executive officers, and Wexford Capital LP ("Wexford") 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 March 1, 2024, Wexford, our largest stockholder, beneficially owned approximately 35% of our outstanding common stock. Collectively, Wexford, our directors and our executive officers beneficially owned approximately 37.5% of our outstanding common stock. As a result of this ownership, Wexford has the ability to exert significant influence over our policies and affairs, including the election of directors. Wexford, whether acting alone or acting with other stockholders, could 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 Wexford, whether acting alone or acting with other 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. The interests of Wexford in any matter put before the stockholders may differ from those of any other stockholder.

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 Wexford or any other large stockholder, 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. Future sales of our common stock by stockholders could depress the market price of our common stock.

Item 1B. Unresolved Staff Comments

Not required.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented cybersecurity processes, technologies, and controls to aid in our efforts to assess, identify, and manage cybersecurity risks. Our enterprise risk management framework considers cybersecurity risk alongside other company risks as part of our overall risk assessment process.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program and shares common methodologies, reporting channels, and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology ("IT") environment;
- an outsourced security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test, or otherwise assist with aspects of our security controls;
- cybersecurity awareness training for our employees, incident response personnel, and senior management. This includes mandatory computer-based training, internal communications, and regular phishing awareness campaigns that are designed to emulate real-world contemporary threats and provide immediate feedback (and, if necessary, additional training or remedial action) to employees.

In addition to the processes, technologies, and controls that we have in place to reduce the likelihood of a material cybersecurity incident (or series of related cybersecurity incidents), our outsourced security team has a written incident response plan outlining how to address cybersecurity events that occur. We have assigned a team comprised of finance and technology personnel to review the plan annually to serve as a framework for the execution of responsibilities across businesses and operational roles. The incident response plan is designed to help us coordinate actions to prepare for, detect, respond to and recover from cybersecurity incidents, and includes processes to triage, assess severity, escalate, contain, investigate, and remediate the incident, as well as to assess the need for disclosure, comply with applicable legal obligations and mitigate the impact to our brand and reputation and on impacted parties.

In addition to the cybersecurity incident response plan, our outsourced team conducts tabletop exercises to enhance our incident response preparedness. They also have processes to oversee and identify material risks from cybersecurity threats associated with our use of third-party service providers. Such processes include conducting due diligence and risk assessment of our current and potential vendors that examine such vendor's cybersecurity protocols and adherence to applicable regulations.

We also maintain business continuity and disaster recovery plans to prepare for and respond to the potential for any disruption in the technology we rely on. Additionally, we maintain insurance coverage that, subject to its terms and conditions, is intended to help us cover certain costs associated with cybersecurity incidents and information system failures.

We (or the third parties we rely on) may not be able to fully, continuously, or effectively implement security controls as intended. As described above, we utilize a risk-based approach and judgment to determine whether and how to implement certain security controls and it is possible that we may not implement the necessary controls if we are unable to recognize or underestimate a particular risk. In addition, security controls, no matter how well designed or implemented, may only mitigate and not fully eliminate cybersecurity risks. Cybersecurity events, when detected by security tools or third parties, may not always be identified immediately or addressed in the manner intended by our cybersecurity incident response plan.

Governance

Based on the information available as of the date of this Annual Report, we have no reason to believe any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For additional information, see "Risks Related to Cybersecurity, Data Privacy and IT Systems," in Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Given that cybersecurity risks can impact various areas of responsibility of the Committees of the Board, as well as the overall size of the Board, the Board believes it is useful and effective for the entire Board to maintain direct oversight over cybersecurity matters. We have implemented processes that will include regular updates to the Board from our Chief Executive Officer and Chief Financial Officer for its review and feedback regarding cybersecurity governance processes, the status of projects to strengthen internal cybersecurity, results from third-party assessments, and also discusses any significant cyber incidents, including recent incidents at other companies and the emerging threat landscape.

Our cybersecurity risk management strategy processes, discussed in greater detailed above, are led by our Chief Financial Officer, in conjunction with our outsourced security team, under the supervision of our Chief Executive Officer. Our Chief Financial Officer has over 5 years of prior work experience in various roles involving supervising the implementation of various information technology systems. These individuals are informed about and monitor the prevention, mitigation, detection and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including their roles in our overall enterprise risk management. As discussed above, our Chief Executive Officer and Chief Financial Officer regularly report to the Board about cybersecurity threat risks, among other cybersecurity related matters.

Item 2. Properties

Our U.S. facilities are located at 380 Lackawanna Place, South Orange, New Jersey 07079 and 30 Leslie Court, Whippany, NJ 07981. We use these facilities to house our corporate headquarters, research, manufacturing, and distribution facilities.

We believe our current facilities are adequate to meet our needs, although we may consolidate facilities in the future. We do not own any real property for use in our operation or otherwise.

Item 3. Legal Proceedings

There are currently no material pending legal proceedings and, as far as we are aware, no governmental authority is contemplating any material proceeding to which we are a party or to which any of our properties is subject.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Common Stock Information

Our common stock is quoted on the Nasdaq Capital Market under the symbol "NEPH". Our common stock commenced trading on August 14, 2019.

As of December 31, 2023, there were approximately 44 holders of record and approximately 1,300 beneficial holders of our common stock.

Recent Sales of Unregistered Securities

Except as previously reported in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, we have not sold any equity securities during the year ended December 31, 2023, that were not registered under the Securities Act of 1933, as amended.

Issuer Repurchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of 2023.

Equity Compensation Plan Information

See Part III, Item 12, under the heading "Equity Compensation Plan Information," which is incorporated by reference herein.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion includes forward-looking statements about our business, financial condition and results of operations including discussions about management's expectations for our business. These statements represent projections, beliefs and expectations based on current circumstances and conditions and in light of recent events and trends, and these statements should not be construed either as assurances of performances or as promises of a given course of action. Instead, various known and unknown factors are likely to cause our actual performance and management's actions to vary, and the results of these variances may be both material and adverse. A list of the known material factors that may cause our results to vary, or may cause management to deviate from its current plans and expectations, is included in Item 1A, "Risk Factors," of this Annual Report on Form 10-K. The following discussion should also be read in conjunction with the consolidated financial statements and notes included in Item 8, "Financial Statements and Supplemental Data," of this Annual Report on Form 10-K.

Business Overview

We are a commercial-stage company that develops and sells high performance water solutions to the medical and commercial markets.

Our medical water filters, mostly classified as ultrafilters, are used primarily by hospitals for the prevention of infection from waterborne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. Because our ultrafilters capture contaminants as small as 0.005 microns in size, they minimize exposure to a wide variety of bacteria, viruses, fungi, parasites, and endotoxins.

Our commercial water filters improve the taste and odor of water and reduce biofilm, cysts, particulates, and scale build-up in downstream equipment. Our products are marketed primarily to the food service, hospitality, convenience store, and health care markets, and are also sold into medical institutions to supplement our medical filters.

We previously held a majority stake in Specialty Renal Products, Inc. ("SRP"), a development-stage medical device company that was focused primarily on developing hemodiafiltration ("HDF") technology. On May 13, 2022, the FDA gave 510(k) clearance to SRP's second-generation model of the OLpūrH2H Hemodiafiltration System, which enables nephrologists to provide HDF treatment to patients with end stage renal disease. In January 2023, SRP management began exploring strategic partnerships to support a commercial launch of the HDF product but was unsuccessful in identifying a partner. By late February 2023, SRP had nearly exhausted its capital resources and, due to its limited capital and lack of prospects for securing a strategic partnership or additional financing, the board of directors of SRP adopted a plan on March 6, 2023 to wind down SRP operations, liquidate its remaining assets and dissolve the company. That plan was approved by SRP's stockholders on March 9, 2023, and on April 13, 2023, SRP filed a certificate of dissolution with the State of Delaware. SRP's cash resources were sufficient to satisfy all of its outstanding liabilities other than its obligations to us under a loan with an outstanding balance of approximately $1.5 million. Accordingly, SRP assigned to Nephros all of its remaining assets, including its intellectual property rights in the HDF2 device, in satisfaction of its outstanding loan balance. Although we have no current plans to do so, we may re-evaluate opportunities for HDF in the future.

Recent Accounting Pronouncements

We are subject to recently issued accounting standards, accounting guidance and disclosure requirements. For a description of these new accounting standards, see "Note 2 – Summary of Significant Accounting Policies," to our consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of financial statements in accordance with GAAP requires application of management's subjective judgments, often requiring 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 "Note 2 – Summary of Significant Accounting Policies," to our consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K, we believe that the following accounting policies require the application of significant judgments and estimates.

Inventories

Our inventory reserve requirements are based on various factors including product expiration date and estimates for the future sales of the product. Reserve assessments include inventory obsolescence based upon expiration date, damaged, or rejected product, slow-moving products, and other considerations. We continue to monitor our inventory reserves amounts and policies, and to update both as required by relevant circumstances.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past, including recently, 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 market acceptance of our products, expense management, and progress in continuing to achieve positive operating cash flow. 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.

Fiscal Year Ended December 31, 2023, Compared to the Fiscal Year Ended December 31, 2022

The following table sets forth our summarized, consolidated results of operations for the years ended December 31, 2023 and 2022 (in thousands except percentages):

	Years Ended December 31,		**$ Increase**	**% Increase**
	2023	**2022**	**(Decrease)**	**(Decrease)**
Total net revenues	$ 14,238	$ 9,975	$ 4,263	43%
Cost of goods sold	5,833	5,244	589	11%
Gross margin	8,405	4,731	3,674	78%
Gross margin %	59%	47%	-	
Research and development expenses	873	1,255	(382)	(30)%
Depreciation and amortization expenses	214	218	(4)	(2)%
Selling, general and administrative expenses	8,911	7,593	1,318	17%
Operating loss from continuing operations	(1,593)	(4,335)	2,742	(63)%
Interest expense	(2)	(20)	18	(90)%
Interest income	64	14	50	357%
Other (expense) income, net	(44)	64	(108)	(169)%
Net loss from continuing operations	(1,575)	(4,277)	2,702	(63)%
Net loss from discontinued operations	-	(2,829)	2,829	100%
Net Loss	(1,575)	(7,106)	5,531	(78)%
Less: undeclared deemed dividend attributable to continuing noncontrolling interest	-	(276)	276	(100)%
Net loss attributable to Nephros, Inc. shareholders	$ (1,575)	$ (7,382)	5,807	(79)%

Net Revenues.

Total net revenues increased 43% in the year ended December 31, 2023, driven by investments in our executive and sales organizations, as well as partnering with a master distributor for much of our commercial business.

Gross Profit Margin

Gross profit margin was approximately 59% for the year ended December 31, 2023, compared to approximately 47% for the year ended December 31, 2022. The increase of approximately 12 percentage points reflects a return to target gross margins of 55%-60%. Lower gross margins in 2022 were primarily driven by large inventory write-downs due to expired product, and higher shipping expense from supply chain disruptions.

Research and Development Expenses

Research and development expenses decreased 30% primarily due to the wind down of SRP in 2023 and consequently a reduction in SRP-related research and development expense of $0 in 2023 versus $376,000 in 2022, and slightly decreased investment in 2023 in water filter research and development.

Depreciation and Amortization Expense

Depreciation and amortization expenses were $0.2 million for each of the years ended December 31, 2023 and 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $1.3 million or 17%, primarily due to increased bonus and sales commission expense associated with higher sales, the hiring of a new CEO and CFO to replace one person acting in both positions, and increased hires to support the sales organization.

Interest Expense

Interest expense was approximately $2,000 for the year ended December 31, 2023 compared to $20,000 for the year ended December 31, 2022. This reduction is primarily related to a lower principal balance of the company's secured note payable.

Interest Income

Interest income was approximately $64,000 for the year ended December 31, 2023 compared to approximately $14,000 for the ended December 31, 2022. The increase in interest income is due to higher interest rates earned on invested cash balances.

Other Income (Expense), net

Other expense was approximately $44,000 for the year ended December 31, 2023, compared to other income of $64,000 for the year ended December 31, 2022. This decrease is primarily a result of losses on foreign currency transactions in 2023. For the year ended December 31, 2022, other income related to the release of the cumulative translation adjustment from accumulated other comprehensive income (loss) on the liquidation of a foreign entity, related to the closure in the second quarter of 2022 of Nephros International, our wholly-owned subsidiary.

Loss from discontinued operations

Loss from discontinued operations was approximately $2.8 million for the year ended December 31, 2022. The discontinued operations are related to the company's former PDS operating segment.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2023 and 2022 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	As of December 31,	
Liquidity and Capital Resources	**2023**	**2022**
Cash and cash equivalents	$ 4,307	$ 3,634
Other current assets	4,098	4,627
Working capital	6,292	6,849
Stockholders' equity	8,358	8,881

We operate under an Investment, Risk Management and Accounting Policy adopted by our Board of Directors. Such policy limits the types of instruments or securities in which we may invest our excess funds: 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 are 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.

At December 31, 2023, we had an accumulated deficit of $144.4 million and we expect to incur additional operating losses from operations until such time, if ever, that we are able to increase product sales and/or licensing revenue to achieve profitability.

Based on cash that is available for our operations and projections of our future operations, as well as the fact that we generated $0.7 million in cash flow in 2023, we believe that our existing cash resources together with our anticipated revenue, will be sufficient to fund our current operating plan through at least the next 12 months from the date of issuance of the consolidated financial statements in this Annual Report on Form 10-K. Additionally, our operating plans are designed to help control operating costs, to increase revenue and to raise additional capital until such time as we generate sufficient cash flows to fund operations. If there were a decrease in the demand for our products due to either economic or competitive conditions, or if we are otherwise unable to achieve our plan or achieve our anticipated operating results, there could be a significant reduction in liquidity due to our possible inability to cut costs sufficiently. In such event, the Company may need to take further actions to reduce its discretionary expenditures, including further reducing headcount, reducing spending on R&D projects and reducing other variable costs.

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

- the market acceptance of our products, and our ability to effectively and efficiently produce, market and sell our products;
- 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 toward the development, marketing, and sales of our water filtration products and working capital purposes.

Net cash provided by operating activities was $0.8 million for the year ended December 31, 2023 compared to net cash used in operating activities of approximately $3.2 million for the year ended December 31, 2022, an increase of $4.1 million. This increase of $4.1 million is due primarily to a decrease in the net loss incurred of $5.5 million, in addition there was approximately $1.4 million in non-cash charges for impairment of assets held for sale in 2022.

Net cash used in investing activities was $0.1 million for the years ended December 31, 2023 and 2022

Net cash used in financing activities was approximately $79,000 for the year ended December 31, 2023. This was primarily from payments of $71,000 on our secured note, principal payments of approximately $7,000 on our finance lease obligation and principal payments of approximately $1,000 on our equipment financing debt.

Net cash provided by financing activities was $34,000 for the year ended December 31, 2022. This was primarily from proceeds from the exercise of warrants of $0.2 million and from the sale to Nephros of SRP preferred shares of $0.2 million, offset partially by payments of $0.3 million on our secured note, payments of employee taxes on restricted stock of approximately $31,000, principal payments of approximately $12,000 on our finance lease obligation and principal payments of approximately $3,000 on our equipment financing debt.

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 9 – License and Supply Agreement, net), the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2023, the Company had agreed to make minimum annual aggregate purchases from Medica of €3.8 million (approximately $4.1 million). For the year ended December 31, 2023, aggregate purchase commitments totaled €4.9 million (approximately $5.3 million). All purchase agreements were met.

Future purchase commitments under the License and Supply Agreement with Medica are as follows:

- 2024: €4,208,000
- 2025: €4,629,000
- 2026: €4,976,000

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Nephros, Inc. (the "Company") as of December 31, 2023 and 2022, and the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory Valuation

Critical Audit Matter Description

As described in Note 2 to the financial statements, inventory consists of finished goods and raw materials and is valued at the lower of cost or net realizable value using the first-in, first-out method. The Company's inventory reserve requirements are based on various factors including product expiration date and estimates for the future sales of the product. Reserve assessments include inventory obsolescence based upon expiration date, damaged or rejected product, slow-moving products, and other considerations.

We identified the assessment of the excess and obsolete inventory reserve as a critical audit matter. The principal consideration for our determination that this is a critical audit matter is the significant judgment by management to estimate the excess and obsolete inventory reserve, which led to a high degree of auditor judgment, subjectivity and effort in performing procedures to evaluate management's significant assumptions.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. The primary procedures we performed to address this critical audit matter included:

- testing management's process for estimating the excess and obsolete inventory reserve, including evaluating the appropriateness of the approach utilized and underlying assumptions
- testing the mathematical accuracy of the excess and obsolete inventory reserve calculation
- testing the completeness and accuracy of underlying data used in the analysis, including historical usage and inventory age

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2015.

Tewksbury, Massachusetts
March 15, 2024

NEPHROS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,307	$ 3,634
Accounts receivable, net	1,496	1,286
Inventory	2,470	3,153
Prepaid expenses and other current assets	132	188
Total current assets	8,405	8,261
Property and equipment, net	152	116
Lease right-of-use assets	1,807	984
Intangible assets, net	381	423
Goodwill	759	759
License and supply agreement, net	271	402
Other assets	86	54
TOTAL ASSETS	$ 11,861	$ 10,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of secured note payable	$ -	$ 71
Accounts payable	873	740
Accrued expenses	794	285
Current portion of lease liabilities	446	316
Total current liabilities	2,113	1,412
Equipment financing, net of current portion	-	1
Lease liabilities, net of current portion	1,390	705
TOTAL LIABILITIES	3,503	2,118
COMMITMENTS AND CONTINGENCIES (Note 17)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	-	-
Common stock, $.001 par value; 40,000,000 shares authorized at December 31, 2023 and 2022; 10,543,675 and 10,297,429 shares issued and outstanding at December 31, 2023 and 2022, respectively	10	10
Additional paid-in capital	152,754	148,413
Accumulated deficit	(144,406)	(142,831)
Subtotal	8,358	5,592
Noncontrolling interest	-	3,289
TOTAL STOCKHOLDERS' EQUITY	8,358	8,881
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,861	$ 10,999

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

NEPHROS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	2022
Net revenue:		
Product revenues	$ 14,110	$ 9,929
Royalty and other revenues	128	46
Total net revenues	14,238	9,975
Cost of goods sold	5,833	5,244
Gross Margin	8,405	4,731
Operating expenses:		
Research and development	873	1,255
Depreciation and amortization	214	218
Selling, general and administrative	8,911	7,593
Total operating expenses	9,998	9,066
Operating loss from continuing operations	(1,593)	(4,335)
Other (expense) income:		
Interest expense	(2)	(20)
Interest income	64	14
Other (expense) income, net	(44)	64
Total other income:	18	58
Loss from continuing operations	(1,575)	(4,277)
Net loss from discontinued operations	-	(2,829)
Net loss	(1,575)	(7,106)
Less: undeclared deemed dividend attributable to noncontrolling interest	-	(276)
Net loss attributable to Nephros, Inc. shareholders	(1,575)	(7,382)
Net loss per common share, basic and diluted from continuing operations	$ (0.15)	$ (0.42)
Net loss per common share, basic and diluted from discontinued operations	-	(0.28)
Net loss per common share, basic and diluted	$ (0.15)	$ (0.70)
Net loss per common share, basic and diluted, attributable to continuing noncontrolling interest	-	(0.03)
Net loss per common share, basic and diluted, attributable to Nephros, Inc, shareholders	$ (0.15)	$ (0.73)
Weighted average common shares outstanding, basic and diluted	10,386,018	10,297,134
Comprehensive loss:		
Net loss	$ (1,575)	$ (7,106)
Other comprehensive loss, foreign currency translation adjustments, net of tax	-	(14)
Comprehensive loss	(1,575)	(7,120)
Comprehensive loss attributable to continuing noncontrolling interest	-	(276)
Comprehensive loss attributable to Nephros, Inc. shareholders	$ (1,575)	$ (7,396)

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

NEPHROS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated		Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Subtotal	Interest	Equity
Balance, December 31, 2021	10,198,712	$ 10	$ 147,346	$ 64	$ (135,725)	$ 11,695	$ 3,054	$ 14,749
Net loss	-	-	-	-	(7,106)	(7,106)		(7,106)
Change in non-controlling interest							188	188
Restricted stock vesting	44,732	-	-		-	-	-	-
Elimination of cumulative translation adjustment, upon closing of wholly owned foreign subsidiary		-	-	(64)	-	(64)	-	(64)
Exercise of warrants	60,374	-	163	-	-	163	-	163
Restricted shares withheld for employee taxes	(6,389)	-	(31)	-	-	(31)	-	(31)
Stock-based compensation	-	-	935	-	-	935	47	982
Balance, December 31, 2022	10,297,429	$ 10	$ 148,413	$ -	$ (142,831)	$ 5,592	$ 3,289	$ 8,881
Net loss	-	-	-	-	(1,575)	(1,575)	-	(1,575)
Change in non-controlling interest	-	-	3,262	-	-	3,262	(3,262)	-
Cashless exercise of stock options	16,576	-				-		-
Restricted stock vesting	187,503	-	-	-	-	-	-	-
Stock-based compensation	-	-	1,079	-	-	1,079	(27)	1,052
Balance, December 31, 2023	10,501,508	$ 10	$ 152,754	$ -	$ (144,406)	$ 8,358	$ -	$ 8,358

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

NEPHROS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2023	2022
OPERATING ACTIVITIES:		
Net loss	$ (1,575)	$ (7,106)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	39	93
Amortization of intangible assets, license and supply agreement and finance lease right-of-use asset	175	258
Stock-based compensation	1,052	982
Inventory impairments and writeoffs	295	773
Increase (Decrease) in provision for bad debt	11	(1)
Impairment of assets held for sale	-	1,395
Gain (Loss) on foreign currency transactions	-	(60)
Decrease (Increase) in operating assets:		
Accounts receivable	(221)	357
Inventory	387	765
Prepaid expenses and other current assets	56	26
Change in right-of-use asset	(342)	353
Other assets	(31)	29
(Decrease) Increase in operating liabilities:		
Accounts payable	133	(593)
Accrued expenses	506	(150)
Lease liabilities	342	(355)
Net cash provided by (used in) operating activities	827	(3,234)
INVESTING ACTIVITIES:		
Purchase of property and equipment	(75)	(137)
Net cash used in investing activities	(75)	(137)
FINANCING ACTIVITIES:		
Proceeds from sale of subsidiary preferred shares to noncontrolling interest	-	188
Payments on secured note payable	(71)	(271)
Principal payments on finance lease liability	(7)	(12)
Principal payments on equipment financing	(1)	(3)
Payments to employee taxes on restricted stock	-	(31)
Proceeds from exercise of warrants	-	163
Net cash provided by (used in) financing activities	(79)	34
Effect of exchange rates on	-	(2)
Net increase (decrease) in cash and cash equivalents	673	(3,339)
Cash and cash equivalents, beginning of year	3,634	6,973
Cash and cash equivalents, end of year	$ 4,307	$ 3,634
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 2	$ 19
Cash paid for income taxes	$ -	$ -
Supplemental disclosure of noncash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease liability	$ 1,164	$ 743

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

NEPHROS, INC. AND SUBSIDIARIES

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. The Company was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced end stage renal disease ("ESRD") therapy technology and products.

Beginning in 2009, Nephros introduced high performance liquid purification filters to meet the demand for water purification in certain medical markets. The Company's filters, generally classified as ultrafilters, are primarily used in hospitals for the prevention of infection from waterborne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. The Company also develops and sells water filtration products for commercial applications, focusing on the hospitality and food service markets. The water filtration business is a reportable segment, referred to as the Water Filtration segment.

On October 4, 2022, the Company entered into a definitive asset purchase agreement with a third party for the sale of substantially all of the Company's Pathogen Detection Systems ("PDS") business, which had been previously reported as a separate reportable operating segment. As a result of the sale of the PDS business, we completely exited the PDS business. As a result, we determined that our PDS business had met the criteria for discontinued operations as of September 30, 2022. We no longer separately report the PDS business as a separate reportable segment in our financial statements including in this Annual Report for any of the periods presented.

In July 2018, the Company formed a subsidiary, Specialty Renal Products, Inc. ("SRP"), to drive the development of its second-generation hemodiafiltration system and other products focused on improving therapies for patients with renal disease. After SRP's formation, the Company assigned to SRP all of the Company's rights to three patents relating to the Company's hemodiafiltration technology, which were carried at zero book value. On March 9, 2023, the SRP Stockholders approved a plan of dissolution to wind down SRP's operations, liquidate SRP's remaining assets and dissolve SRP. Pursuant to such plan, SRP filed a certificate of dissolution with the State of Delaware on April 13, 2023. As a result of the SRP Stockholders' approval of the plan of dissolution and provisions therein and after satisfying all of SRP's liabilities, there are no assets available for distribution to the holders of any of SRP's capital stock, including its Series A Preferred Stock. As such, the value recorded to non-controlling interest was written to zero and the impact reclassified to the Company's additional paid-in capital as the Company retained control of SRP.

The Company's primary U.S. facility is located at 380 Lackawanna Place, South Orange, New Jersey 07079. This location along with our Whippany, NJ facility, houses the Company's corporate headquarters, research, manufacturing, and distribution facilities.

Note 2 - Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nephros, Inc. and its subsidiaries, including the Company's wholly owned subsidiary Nephros International, which was dissolved during the quarter ended June 30, 2022, and SRP, which was dissolved pursuant to a plan of dissolution adopted by its stockholders on March 9, 2023 and the subsequent filing of a certificate of dissolution with the State of Delaware on April 13, 2023. All intercompany accounts and transactions were eliminated in the preparation of the accompanying consolidated financial statements.

Discontinued Operations

See Note 3, Discontinued Operations, for a discussion of the Company's significant accounting policy surrounding the sale of substantially all of the Company's PDS business.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") 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 amount of revenues and expenses, during the reporting period. Actual results could differ materially from those estimates. Included in these estimates are assumptions about the collection of accounts receivable, value of inventories, useful life of fixed assets and intangible assets, the assessment of expected cash flows used in evaluating goodwill and other long-lived assets, the assessment of the ability to continue as a going concern and assumptions used in determining stock compensation such as expected volatility and risk-free interest rate.

Reclassifications

Certain reclassifications were made to the prior year's amounts to conform to the 2023 presentation. On the Consolidated Statements of Cash Flows, Inventory impairments and writeoffs reported as $623,000 for the year ended December 31, 2022, was increased to $773,000, and Inventory reported as $915,000 for the year ended December 31, 2022 was decreased to $765,000, to accurately reflect the non-cash portion of the change in inventories for the year ended December 31, 2022.

Liquidity

In February 2022, pursuant to a First Amendment to Series A Preferred Stock Purchase Agreement (the "Amendment") among SRP and the holders of SRP's outstanding shares of Series A Preferred Stock, SRP issued and sold an additional 100,003 shares of its Series A Preferred Stock at a price of $5.00 per share, resulting in total gross proceeds of $500,015. See "Note 15 – Stockholders' Equity – Noncontrolling Interest," below. In addition to the funds provided by the sale of these additional shares of Series A Preferred Stock, the Company and SRP also maintained a loan agreement under which the Company loaned $1.3 million to SRP, of which $1.0 million had been loaned during the year ended December 31, 2020. These loaned funds were used to fund SRP's operating activities through the FDA 510(k) clearance process of SRP's second-generation hemodiafiltration system, which was initially submitted to the FDA on February 24, 2021, and which received 510(k) clearance on May 13, 2022. In connection with SRP's plan of dissolution and pursuant to an agreement between the Company and SRP entered into on May 24, 2023, SRP assigned substantially all of its remaining assets to the Company in satisfaction of the entire loan balance. Accordingly, as of December 31, 2023, there was no outstanding balance of this loan.

The Company has sustained operating losses every quarter through December 31, 2023, generating an accumulated deficit of $144.4 million as of December 31, 2023. Throughout 2023, however, the Company's operating cash flows have been positive due to increased sales, improved gross margins, careful expense management, and the dispositions of the PDS and SRP businesses. These actions resulted in the Company generating cash from operations of approximately $0.8 million through the twelve months ended December 31, 2023. Based on these positive cash flows, the Company believes that its cash balances are sufficient to fund its current operating plan through at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. However, in the event that the Company's operating results do not meet its expectations, the Company may need to further reduce discretionary expenditures such as headcount, R&D projects, and other variable costs.

Concentration 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. The Company also limits its credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary.

Major Customers

For the years ended December 31, 2023 and 2022, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2023	2022
A	23%	26%
B	11%	10%
Total	34%	36%

As of December 31, 2023 and 2022, the following customers accounted for the following percentages of our accounts receivable, respectively:

Customer	2023	2022
A	12%	21%
B	6%	10%
C	3%	10%
Total	21%	41%

Cash and Cash Equivalents

The Company considers all highly liquid money market instruments with an original maturity of three months or less when purchased to be cash equivalents. The company also classifies, as cash equivalents, certificates of deposit with an original maturity of greater than three months for which there is no cost to withdrawal funds prior to maturity date. At December 31, 2023 and 2022, cash and cash equivalents were deposited in financial institutions and consisted entirely of immediately available fund balances. The Company maintains its cash deposits and cash equivalents with financial institutions it believes to be well-known and stable.

Accounts Receivable

The Company recognizes an allowance that reflects a current estimate of credit losses expected to be incurred over the life of a financial asset, including trade receivables. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses. The Company determines its allowance for credit losses by considering a number of factors, including the length of time balances are past due, the Company's previous loss history, the customer's current ability to pay its obligations to the Company and the expected condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they are determined to be uncollectible. The allowance for doubtful accounts was approximately $11,000 and $0 as of December 31, 2023 and 2022, respectively.

Inventory

For all medical device products and some commercial products, the Company engages third parties to manufacture and package its finished goods, which are shipped to the Company for warehousing, until sold to distributors or end customers. Some commercial products are manufactured at Company facilities. Inventory consists of finished goods and raw materials and is valued at the lower of cost or net realizable value using the first-in, first-out method.

Our inventory reserve requirements are based on various factors including product expiration date and estimates for the future sales of the product. Reserve assessments include inventory obsolescence based upon expiration date, damaged, or rejected product, slow-moving products, and other considerations.

License and Supply Rights

The Company's rights under the License and Supply Agreement with Medica are capitalized and stated at cost, less accumulated amortization, and are amortized using the straight-line method over the term of the License and Supply Agreement, which is from April 23, 2012 through December 31, 2028. The Company determines amortization periods for licenses based on its assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental, and regulatory issues, and contractual terms. See Note 9 – License and Supply Agreement, net for further discussion.

Leases

The Company determines if an arrangement contains a lease at inception. Leases are included in lease right-of-use ("ROU") assets and lease liabilities on the consolidated balance sheet.

Lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset includes any lease payments made and initial direct costs incurred and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company has elected as an accounting policy not to apply the recognition requirements in ASC 842 to short-term leases. Short-term leases are leases that have a term of 12 months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes the lease payments for short-term leases on a straight-line basis over the lease term.

The Company has also elected, as a practical expedient, by underlying class of asset, not to separate lease components from non-lease components and, instead, account for them as a single component.

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 three to seven years using the straight-line method.

The Company adheres to ASC 360 and periodically evaluates whether current facts or circumstances indicate that the carrying value of its depreciable assets to be held and used may not 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 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. For long-lived assets, 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 fair value less costs to sell. For the year ended December 31, 2022, See Note 3 Discontinued Operations, for a discussion of the Company's significant accounting policy surrounding the sale of substantially all of the Company's PDS business and related impairment charge. There were no impairment losses for long-lived assets recorded for the year ended December 31, 2023.

Intangible Assets

The Company's intangible assets include finite lived assets. Finite lived intangible assets, consisting of customer relationships, tradenames, service marks and domain names are amortized on a straight-line basis over the estimated useful lives of the assets.

Finite lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Impairment testing requires management to estimate the future undiscounted cash flows of an intangible asset using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in the impairment testing.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired. In accordance with ASC 350, "Goodwill and Other Intangibles," rather than recording periodic amortization, goodwill is subject to an annual assessment for impairment by applying a fair value-based test. If the fair value of the reporting unit exceeds the reporting unit's carrying value, including goodwill, then goodwill is considered not impaired, making further analysis not required. The Company reviews goodwill for possible impairment annually during the fourth quarter, or whenever events or circumstances indicate that the carrying amount may not be recoverable.

Fair Value Measurements

The Company measures certain financial instruments and other items at fair value.

To determine the fair value, the Company uses the fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use to value an asset or liability and are developed based on market data obtained from independent sources. Unobservable inputs are inputs based on assumptions about the factors market participants would use to value an asset or liability.

To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable:

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

Level 2 - Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.

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. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and also includes instruments for which the determination of fair value requires significant judgment or estimation.

Revenue Recognition

The Company recognizes revenue under ASC 606, "Revenue from Contracts with Customers." ASC 606 prescribes a five-step model for recognizing revenue, which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price; and (v) recognizing revenue. See Note 4 – Revenue Recognition for further discussion.

Shipping and Handling Costs

Shipping and handling costs charged to customers are recorded as revenue and as cost of goods sold and were approximately $107,000 and $98,000 for the years ended December 31, 2023 and 2022, respectively.

Research and Development Costs

Research and development costs represent a significant part of our business. Costs included in research and development are expensed as incurred and relate to the processes of discovering, testing and developing new products, improving existing products and regulatory compliance prior to FDA approval. Research and development costs include, but are not limited to, personnel expenses, consulting costs and equipment depreciation.

Stock-Based Compensation

The fair value of stock options is recognized as stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. The Company calculates stock-based compensation expense in accordance with ASC 718. The fair value of the Company's stock option awards is 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. 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.

Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement.

Other Income and Expense, net

Other expense of approximately $44,000 for the year ended December 31, 2023, is primarily a result of losses on foreign currency transactions. Other income of approximately $64,000 for the year ended December 31, 2022, is primarily related to the release of the cumulative translation adjustment from accumulated other comprehensive income (loss) on the liquidation of a foreign entity and of gains on foreign currency transactions related to the closure in the second quarter of 2022 of Nephros International, a wholly owned subsidiary of Nephros, Inc.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, 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, 2023 and 2022.

ASC 740 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. ASC 740 utilizes a two-step approach for evaluating uncertain tax positions. 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 that is more likely than not to be realized on settlement with the taxing authority. The Company is subject to income tax examinations by major taxing authorities for all tax years subsequent to 2016. During the years ended December 31, 2023 and 2022, the Company recognized no adjustments for uncertain tax positions. However, management's conclusions regarding this policy may be subject to review and adjustment at a later date based on factors including, but not limited to, on-going analyses of and changes to tax laws, regulation and interpretations, thereof.

See Note 13 – Income Taxes for further discussion.

Net Loss per Common Share

Basic loss per common share is calculated by dividing net loss available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted loss per common share is calculated by dividing net loss available to common shareholders by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants and unvested restricted stock, as applicable. The Company calculates dilutive potential common shares using the treasury stock method, which assumes the Company will use the proceeds from the exercise of stock options and warrants to repurchase shares of common stock to hold in its treasury stock reserves.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be antidilutive:

	December 31,	
	2023	2022
Shares underlying options outstanding	1,789,206	1,365,365
Unvested restricted stock	42,167	-

Foreign Currency Translation

Foreign currency translation is recognized in accordance with ASC 830. The functional currency of Nephros International Limited, the Company's Irish subsidiary 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 consolidated statements of operations and comprehensive loss are translated at the weighted average rate for the year.

Transactions denominated in a currency other than an entity's functional currency may give rise to transaction gains and losses. The Company recognizes transaction gains and losses within other (expense) income, net, within the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss, as defined in ASC 220, is the total of net loss and all other non-owner changes in equity (or other comprehensive loss). The Company's other comprehensive loss consists only of foreign currency translation adjustments.

Segment Reporting

The Company operates in only one business segment from which the Company's chief operating decision maker evaluates the financial performance of the Company.

Recent Accounting Pronouncements, Not Yet Effective

In December 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures," which enhances the transparency and decision usefulness of income tax disclosures. The guidance is effective for the Company's annual reporting period ending December 31, 2025. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, "Improvements to Reportable Segment Disclosures," which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance is effective for the Company beginning in the annual reporting period ending December 31, 2024 and interim periods beginning in fiscal year 2025. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

Note 3 – Discontinued Operations

In accordance with ASC 205-20, Presentation of Financial Statements: Discontinued Operations, a disposal of a component of an entity or a group of components of an entity (disposal group) is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results when the disposal group meets the criteria to be classified as held-for-sale. The consolidated statements of operations reported for current and prior periods report the results of operations of the discontinued operations, including the impairment loss recognized as a component of net income (loss) separate from the net income (loss) from continuing operations.

All discontinued operations relate to the Company's previously reported PDS segment, for the year ended December 31, 2022.

(In thousands)	Year Ended December 31, 2022
Total net revenues	$ 110
Gross margin	(259)
Research and development expenses	637
Depreciation and amortization expense	-
Selling, general and administrative expenses	535
Total operating expenses	1,175
Operating loss from discontinued operations	(1,434)
Impairment of assets held for sale	(1,395)
Loss from discontinued operations	$ (2,829)

On October 4, 2022, the Company entered into a definitive asset purchase agreement with a third party pursuant to which the Company agreed to sell substantially all of the assets used in the Company's PDS business. In consideration for the sale of these assets, the Company received $1,000 in cash at the closing, and will receive potential royalties payable to Nephros for a seven-year period commencing on January 1, 2023 subject to a minimum gross margin threshold. As such, the potential royalties payable to the Company are a gain contingency as they pertain to an uncertain event that will be resolved in future reporting periods. As a result, the Company will recognize the gain contingency when it is probable the contingency will be resolved, which is ultimately when settled. The Company determined all of the required criteria for held-for-sale and discontinued operations classification were met as of September 30, 2022. Additionally, the Company evaluated the disposal group including the relevant intangible assets and recorded an impairment loss of $1,395,000. Based upon the selling price less the costs of sale, the Company determined the net carrying value of the assets held for sale were impaired, and the value of the asset group to be sold was $0.

The following items related to discontinued operations were included in the consolidated statement of cash flows:

(in thousands)	For the Year ended December 31, 2022
Depreciation	$ 42
Amortization	82
Stock compensation	38
Impairment of assets held-for-sale	1,395
Operating lease right-of-use assets	33
Purchases of property and equipment	(34)

During year ended December 31, 2022, $49,000 of right-of-use assets related to discontinuing operations were obtained in exchange for operating lease liabilities.

Note 4 – Revenue Recognition

The Company recognizes revenue related to product sales when product is shipped via external logistics providers and the other criteria of ASC 606 are met. Product revenue is recorded net of returns and allowances. There was no allowance for sales returns at December 31, 2023 or 2022. In addition to product revenue, the Company recognizes revenue related to royalty and other agreements in accordance with the five-step model in ASC 606. Royalty and other revenues recognized for the years ended December 31, 2023 and 2022 (in thousands) is comprised of:

	Years Ended December 31,	
	2023	2022
Other revenue	$ 97	$ 46
Royalty revenue under the Sublicense Agreement with CamelBak [(1)]	31	-
Total royalty and other revenues	$ 128	$ 46

(1) In May 2015, the Company entered into a Sublicense Agreement (the "Sublicense Agreement") with CamelBak Products, LLC ("CamelBak"). Under this Sublicense Agreement, the Company granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the IWTD. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay the Company a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay a fixed per-unit fee for any other sales made. CamelBak was also required to meet or exceed certain minimum annual fees payable to the Company, and, if such fees are not met or exceeded, the Company was able to convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. In the first quarter of 2019, the Sublicense Agreement was amended to eliminate the minimum fee obligations starting May 6, 2018 and, as such, CamelBak has no further minimum fee obligations. The Sublicense Agreement expired on December 31, 2022, though we and CamelBak thereafter orally agreed to continue operating under the terms of the Sublicense agreement. In March 2024, we entered into a further written amendment to the Sublicense Agreement, which was made effective December 31, 2022, that extended the term of the Sublicense Agreement through December 31, 2025.

Other Revenue – Other revenues are derived from sales of services to customers, which primarily include installation, training and testing on product and equipment sold to certain customers.

Note 5 – Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level of classification for each reporting period.

At December 31, 2023 and December 31, 2022, the Company's cash equivalents consisted of money market funds. The Company values its cash equivalents using observable inputs that reflect quoted prices for securities with identical characteristics and classify the valuation techniques that use these inputs as Level 1.

At December 31, 2023 and December 31, 2022, the fair value measurements of the Company's assets and liabilities measured on a recurring basis were as follows:

	Fair Value Measurements at Reporting Date Using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)	
December 31, 2023			
Cash	$ 274	$ -	$ -
Money market funds	2,515	-	-
Certificate of deposit	1,518		
Cash and cash equivalents	$ 4,307	$ -	$ -
December 31, 2022			
Cash	$ 1,598	-	-
Money market funds	2,036	-	-
Cash and cash equivalents	$ 3,634	$ -	$ -

Assets and Liabilities Not Measured at Fair Value on a Recurring Basis

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value as of December 31, 2023 and 2022 due to the short-term maturity of these instruments.

The carrying amounts of the secured long-term note payable, lease liabilities and equipment financing approximate fair value as of December 31, 2023 and 2022 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

Note 6 - Inventory

Inventory is stated at the lower of cost or net realizable value using the first-in, first-out method and consists of raw materials and finished goods. The Company's inventory components as of December 31, 2023 and December 31, 2022, were as follows:

(In thousands)	December 31,	
	2023	2022
Finished goods	$ 2,144	$ 2,709
Raw material	326	422
Work in process	-	22
Total inventory	$ 2,470	$ 3,153

Note 7 - Property and Equipment, Net

Property and equipment as of December 31, 2023 and 2022 was as follows (in thousands):

	Estimated Useful Life	December 31,	
		2023	2022
Manufacturing and research equipment	3-7 years	$ 843	$ 843
Capitalized internal use software and website development	5 years	103	103
Computer equipment	3-4 years	43	43
Furniture and fixtures	7 years	37	37
Leasehold improvements	Life of lease	88	13
Property and equipment, gross		1,114	1,039
Less: accumulated depreciation		(962)	(923)
Property and equipment, net		$ 152	$ 116

Depreciation related to equipment utilized in the manufacturing process is recognized in cost of goods sold on the consolidated statements of operations and comprehensive loss. Depreciation expense for the years ended December 31, 2023 and 2022 was approximately $39,000 and $93,000, respectively. Approximately $3,000 of depreciation expense has been recognized in cost of goods sold for the year ended December 31, 2023. Approximately $22,000 of depreciation expense has been recognized in cost of goods sold for the year ended December 31, 2022.

Note 8 – Intangible Assets and Goodwill

Intangible Assets

Intangible assets at December 31, 2023 and December 31, 2022 are set forth in the table below. Gross carrying values and accumulated amortization of the Company's intangible assets by type are as follows:

	December 31, 2023			December 31, 2022		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
			(in thousands)			
Tradenames, service marks and domain names	$ 50	$ (50)	$ -	$ 50	$ (40)	$ 10
Customer relationships	540	(159)	381	540	(127)	413
Total intangible assets	$ 590	$ (209)	$ 381	$ 590	$ (167)	$ 423

The Company recognized amortization expense of approximately $42,000 for the years ended December 31, 2023 and December 31, 2022 in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

As of December 31, 2023, future amortization expense for each of the next five years is (in thousands):

Fiscal Years	
2024	$ 32
2025	32
2026	32
2027	32
2028	32

The Company recognized approximately $1.0 million in intangible asset impairment charges during the year ended December 31, 2022, related to the fair value of assets held for sale. (See Note 3–Discontinued Operations).

Goodwill

Goodwill had a carrying value on the Company's consolidated balance sheets of $0.8 million at December 31, 2023 and 2022, respectively. The Company concluded the carrying value of goodwill was not impaired as of December 31, 2023, or 2022 as the Company determined that it was not more likely than not that the fair value of goodwill was less than its carrying value.

Note 9 – License and Supply Agreement, net

On April 23, 2012, the Company entered into a License and Supply Agreement (as thereafter amended, the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement, Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, with certain limitations on territory, during the term of the License and Supply Agreement. In addition, the Company granted Medica an exclusive license under the Company's intellectual property to make the filtration products during the term of the License and Supply Agreement. The filtration products covered under the License and Supply Agreement include both certain products based on Medica's proprietary Versatile microfiber technology and certain filtration products based on Medica's proprietary Medisulfone ultrafiltration technology. In December 2023, the Company signed a new agreement with Medica which extends the term until December 31, 2028, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

In exchange for the license, the gross value of the intangible asset capitalized was $2.3 million. License and supply agreement, net, on the consolidated balance sheet is $0.3 million and $0.4 million as of December 31, 2023 and 2022, respectively. Accumulated amortization is $2.0 million and $1.9 million as of December 31, 2023 and 2022, respectively. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Amortization expense of $0.1 million was recognized in each of the years ended December 31, 2023 and 2022 on the consolidated statement of operations and comprehensive loss.

As of December 11, 2023, the Company contractually has agreed to pay interest per month at the EURIBOR 360-day rate plus 500 basis points calculated on the principal amount of any outstanding invoices that are overdue by more than 15 days beyond the original payment terms. There was no interest recognized for the years ended December 31, 2023 or 2022.

In addition, for the period beginning April 23, 2014 through December 31, 2023, the Company paid Medica a royalty rate of 3% of net sales of the filtration products sold, subject to reduction as a result of a supply interruption pursuant to the terms of the License and Supply Agreement. Royalty expense of $0.4 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively, was recognized and is included in cost of goods sold on the consolidated statement of operations and comprehensive loss. Approximately $90,000 and $71,000 of this royalty expense was included in accounts payable as of December 31, 2023 and 2022, respectively.

Note 10 – Secured Note Payable

On March 27, 2018, the Company entered into a Secured Promissory Note Agreement (the "Secured Note") with Tech Capital for a principal amount of $1.2 million. During the year ended December 31, 2023, the principal balance of the Secured Note was paid off. As of December 31, 2022, the principal balance of the Secured Note was $0.1 million.

The Secured Note has a maturity date of April 1, 2023. The unpaid principal balance accrues interest at a rate of 8% per annum. Principal and interest payments are due on the first day of each month commencing on May 1, 2018. The Secured Note is subject to terms and conditions of and is secured by security interests granted by the Company in favor of Tech Capital under the Loan and Security Agreement entered into on August 17, 2017 and subsequently amended on December 20, 2019 (the "Loan Agreement"). An event of default under such Loan Agreement is an event of default under the Secured Note and vice versa.

During each of the years ended December 31, 2023 and 2022, the Company made payments under the Secured Note of approximately $71,000 and $289,000 respectively. Included in the total payments made, approximately $1,000 and $18,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023 and 2022, respectively.

Note 11 – Leases

The Company has operating leases for corporate offices, warehouse space, an automobile and office equipment. The leases have remaining lease terms of 1 year to 5 years.

Lease cost, as presented below, includes costs associated with leases for which right-of-use ("ROU") assets have been recognized as well as short-term leases.

The components of total lease costs were as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Operating lease cost	$ 334	$ 351
Finance lease cost:		
Amortization of right-of-use assets	7	12
Interest on lease liabilities	2	2
Total finance lease cost	9	14
Variable lease cost	44	53
Total lease cost	$ 387	$ 418

Supplemental cash flow information related to leases was as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 408	$ 365
Financing cash flows from finance leases	$ 7	$ 12

Supplemental balance sheet information related to leases was as follows (in thousands except years):

	December 31, 2023	December 31, 2022
Operating lease right-of-use assets	$ 1,803	$ 972
Finance lease right-of-use assets	$ 4	$ 12
Current portion of operating lease liabilities	$ 442	$ 309
Operating lease liabilities, net of current portion	1,390	700
Total operating lease liabilities	$ 1,832	$ 1,009
Current portion of finance lease liabilities	$ 4	$ 8
Finance lease liabilities, net of current portion	-	4
Total finance lease liabilities	$ 4	$ 12
Weighted average remaining lease term		
Operating leases	4.3 years	3.9 years
Finance leases	0.6 years	1.5 years
Weighted average discount rate		
Operating leases	8.0%	8.0%
Finance leases	8.0%	8.0%

As of December 31, 2023, maturities of lease liabilities were as follows (in thousands):

	Operating Leases	Finance Leases
2024	$ 562	$ 4
2025	435	-
2026	450	-
2027	450	-
2028	251	-
Total future minimum lease payments	2,148	4
Less imputed interest	(316)	-
Total	$ 1,832	$ 4

Note 12 - Accrued Expenses

Accrued expenses as of December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
Accrued bonus	$ 537	$ 76
Accrued directors' fees	-	126
Accrued legal	10	4
Accrued sales commission	117	36
Accrued sales tax payable	22	7
Accrued franchise tax	14	10
Accrued other	94	26
	$ 794	$ 285

Note 13 - Income Taxes

There was no income tax current or deferred tax benefit or expense recognized during the years ended December 31, 2023 and 2022.

A reconciliation of the income tax benefit computed at the statutory tax rate to the Company's effective tax rate for the years ended December 31, 2023, and 2022 is as follows:

	Years Ended December 31,	
	2023	2022
U.S. federal statutory rate	21.00%	21.00%
State taxes	12.22%	4.79%
Expired NOLs and credits	(115.56)%	(12.78)%
Stock-based compensation	(4.54)%	(2.43)%
Federal research and development credits	-%	0.62%
Foreign Rate Differential	-%	9.15%
Other	0.12%	3.44%
Non-taxable Cancelation of Indebtedness	19.14%	-%
Valuation allowance	67.62%	(23.78)%
Effective tax rate	-%	-%

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2023 and 2022 are as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carry forwards	$ 16,700	$ 17,672
Research and development credits	1,087	1,401
Nonqualified stock option compensation expense	613	543
Lease liabilities	449	243
Capital loss carryforwards	2,072	1,946
Fixed and intangible basis difference	-	328
Other temporary book - tax differences	713	243
Total deferred tax assets	21,634	22,376
Deferred tax liabilities:		
Lease right-of-use assets	(442)	(234)
Fixed and intangible asset basis difference	(116)	-
Total deferred tax liabilities	(558)	(234)
Deferred tax assets, net	21,076	22,142
Valuation allowance for deferred tax assets	(21,076)	(22,142)
Net deferred tax assets after valuation allowance	$ -	$ -

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. The Company's valuation allowance decreased approximately $1.1 million from December 31, 2022 to December 31, 2023.

At December 31, 2023, the Company had Federal income tax net operating loss carryforwards of $77.3 million and State income tax net operating loss carryforwards of $6.8 million. The Company had Federal research and development tax credit carryforwards of $1.1 million at December 31, 2023. The Company's net operating losses and research and development tax credits may ultimately be limited by Section 382 of the Internal Revenue Code and, as a result, the Company may be unable to offset future taxable income (if any) with losses, or its tax liability with credits, before such losses and credits expire. Included in the Federal net operating loss carryforwards are $14 million of losses generated from 2018 onward that have an indefinite carryover period. The remaining Federal and New Jersey net operating loss carryforwards and Federal and New Jersey tax credit carryforwards will expire at various times between 2024 and 2041 unless utilized.

The Company has analyzed the tax positions taken or expected to be taken in its tax returns and concluded it has no liability related to uncertain tax positions. The Company is subject to income tax examinations by major taxing authorities for all tax years subsequent to 2018 and does not anticipate a change in its uncertain tax positions within the next twelve months. The Company's policy is to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Note 14 - Stock Plans and Share-Based Payments

The fair value of stock options and restricted stock is recognized as stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. The Company calculates stock-based compensation expense in accordance with ASC 718. The fair value of stock-based awards is amortized over the vesting period of the award.

Stock Plans

In 2015, the Board of Directors adopted the Nephros, Inc. 2015 Equity Incentive Plan ("2015 Plan"). As of December 31, 2023, including amendments approved by the Board of Directors, 2,547,400 shares of common stock were approved for issuance pursuant to stock options, restricted stock and other equity incentive awards to the Company's employees, directors and consultants. The maximum contractual term for stock options granted under the 2015 Plan is 10 years.

As of December 31, 2023, options to purchase 1,774,819 shares of common stock had been issued to employees under the 2015 Plan and were outstanding. The options issued to employees expire on various dates between April 15, 2025 and December 27, 2033. Taking into account all options and restricted stock granted under the 2015 Plan, there are 65,580 shares available for future grant under the 2015 Plan. Generally, grants vest based on a service condition only and vest between two to four years.

The Company's previously adopted and approved plan, the 2004 Stock Incentive Plan ("2004 Plan"), expired in the year ended December 31, 2014. As of December 31, 2023, options to purchase 14,387 shares of common stock had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between February 5, 2024 and March 26, 2024. No shares are available for future grants under the 2004 Plan. Options currently outstanding are fully vested.

On November 1, 2023, the Company issued 122,524 stock options outside of the 2015 Plan to the Company's new Chief Financial Officer. The terms for these options are identical to those issued to employees under the 2015 Plan.

Stock Options

The Company has elected to recognize forfeitures as they occur. Stock-based compensation expense recognized for the years ended December 31, 2023 and 2022 was $1.0 million and $0.9 million, respectively.

For the year ended December 31, 2023, $1.0 million and approximately $39,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss. For the year ended December 31, 2022, $0.8 million and approximately $63,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss.

The following table issued summarizes the option activity for the years ended December 31, 2023 and 2022:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2021	1,426,510	$ 6.29
Options granted	279,115	1.91
Options forfeited or expired	(340,260)	6.88
Options exercised	-	-
Outstanding at December 31, 2022	1,365,365	$ 5.25
Options granted	583,089	1.47
Options forfeited or expired	(102,722)	5.87
Options exercised (1)	(56,526)	2.47
Outstanding at December 31, 2023	1,789,206	$ 4.07

(1) 56,526 options were exercised via cashless exercise which resulted in 16,576 shares issued.

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2023 and 2022.

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2022	968,441	$ 5.55
Vested and expected to vest at December 31, 2022	1,342,342	$ 5.26
Exercisable at December 31, 2023	1,171,824	$ 5.25
Vested and expected to vest at December 31, 2023	1,753,398	$ 4.12

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The below assumptions for the risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility were utilized for the stock options granted during the year ended December 31, 2023.

Assumption for Option Grants	2023	2022
Stock Price Volatility	72.40%	75.44%
Risk-Free Interest Rates	3.71%	2.74%
Expected Life (in years)	6.22	5.64
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 weighted-average fair value of options granted in 2023 and 2022 is $0.99 and $1.25, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2023 was approximately $1.4 million and $0 respectively. 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 as of December 31, 2023 was approximately 6.4 years.

The intrinsic values of stock options exercised was approximately $58,000 for the year ended December 31, 2023. No stock options were exercised for the year ended December 31, 2022.

As of December 31, 2023, there was $0.6 million of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans which will be amortized over the weighted average remaining requisite service period of 2.97 years.

There was no tax benefit related to expense recognized in the twelve months ended December 31, 2023 and 2022, as the Company is in a net operating loss position.

Restricted Stock

The Company has issued restricted stock as compensation for the services of certain employees and non-employee directors. The grant date fair value of restricted stock is based on the fair value of the common stock on the date of grant, and compensation expense is recognized based on the period in which the restrictions lapse.

The following table summarizes restricted stock activity for the years ended December 31, 2023 and 2022:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2021	59,732	$ 8.07
Granted	-	-
Vested	(44,732)	7.87
Forfeited	(15,000)	8.66
Nonvested at December 31, 2022	-	-
Granted	299,670	1.47
Vested	(187,503)	1.08
Nonvested at December 31, 2023	42,167	$ 3.18

The total fair value of restricted stock that vested during the years ended December 31, 2023 and 2022 was approximately $0.2 million and $0.4 million, respectively.

Total stock-based compensation expense for restricted stock was approximately $322,000 and $42,000 for the year ended December 31, 2023 and 2022, respectively and is recognized in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

Approximately $154,000 of stock compensation expense was recognized in the year ended December 31, 2022 related to restricted stock granted to board members and employees for the year ended December 31, 2023 to settle liabilities for services incurred in the respective prior fiscal year.

As of December 31, 2023, there was approximately $15,000 of unrecognized compensation expense related to restricted stock-based awards granted under the equity compensation plans, which will be amortized over the weighted average remaining requisite service period of 0.4 years. As of December 31, 2022, there was no unrecognized compensation expense related to the restricted stock awards.

The aggregate shares of common stock legally issued and outstanding as of December 31, 2023 is greater than the aggregate shares of common stock outstanding for accounting purposes by the amount of unvested restricted shares.

SRP Equity Incentive Plan

SRP's 2019 Equity Incentive Plan was approved on May 7, 2019 under which 150,000 shares of SRP's common stock are reserved for the issuance of options and other awards. This plan is no longer operational, due to the wind down of SRP's operations and its April 2023 dissolution.

Due to the Company's deemed acquisition of the non-controlling interest in SRP during the year ended December 31, 2023, all remaining equity-based awards have been forfeited and no further expense will be incurred related to these awards. There were no SRP stock options or other equity awards granted during the year ended December 31, 2023. For the year ended December 31, 2023, a credit of approximately ($27,000) was recognized for expense related to the SRP equity-based awards. Stock-based compensation expense related to the SRP stock grants was approximately $47,000 during the year ended December 31, 2022. Stock-based compensation expense related to the SRP equity-based awards is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. Stock-based compensation expense related to the SRP stock options is presented by the Company as noncontrolling interest on the consolidated balance sheet as of December 31, 2022.

Note 15 - Stockholders' Equity

Noncontrolling Interest

Pursuant to the terms and conditions of a Series A Preferred Stock Purchase Agreement, dated September 9, 2018, among SRP and the purchasers identified therein (the "SRP Purchase Agreement"), SRP sold to such purchasers an aggregate of 600,000 shares of its Series A Preferred Stock (the "Series A Preferred") at a price of $5.00 per share resulting in total gross proceeds of $3.0 million. On February 1, 2022, SRP and such purchasers amended the SRP Purchase Agreement to allow for the sale of an additional 100,003 shares of Series A Preferred, all of which were sold on February 4, 2022, for aggregate gross proceeds of $500,015 and otherwise on the same terms and conditions as set forth in the SRP Purchase Agreement. Approximately $188,000 of the proceeds from the February 2022 sales were recorded as an increase to the equity of the non-controlling interests. The Company purchased 62,500 shares of SRP's Series A Preferred at such closing and, as a result, maintained its 62.5% stock ownership position in SRP. The other purchasers at the February 2022 closing included the Company's Chief Executive Officer, who purchased 313 shares, and Lambda Investors LLC ("Lambda"), an affiliate of Wexford Capital, which together with its affiliates owns approximately 36% of the Company's common stock, which purchased 25,938 shares of the Series A Preferred in February 2022. Such purchases were made on the same terms as all other purchasers. In addition to the funds provided by the SRP Purchase Agreement, the Company loaned to SRP to the principal amount of $1.3 million, $1.0 million of which was advanced during the year ended December 31, 2020.

As of December 31, 2022, the non-controlling interest in SRP held by holders of the Series A Preferred was classified as equity on the accompanying consolidated balance sheet, as the non-controlling interest is redeemable only upon the occurrence of events that are within the control of the Company. As a result of the adoption of the plan of liquidation and dissolution by SRP's stockholders and the subsequent filing of a certificate of dissolution of SRP with the State of Delaware, the redemption feature related to the Series A Preferred Stock effectively terminated. As such, the value of the Series A Preferred Stock previously presented in non-controlling interest was reclassified to additional paid in capital as the Company retained control of SRP.

In March 2023, the board of directors of SRP adopted, and the stockholders of SRP approved, a plan to wind down SRP's operations and dissolve, and in April 2023, SRP filed a certificate of dissolution with the State of Delaware. In accordance with its plan of dissolution, after SRP satisfied its other outstanding liabilities, SRP assigned to the Company all of its remaining assets, including its intellectual property rights, in satisfaction of outstanding indebtedness owed to the Company in the approximate amount of $1.5 million. No other assets are available for distribution to any of SRP's stockholders, including the Company, in respect of their shares of SRP capital stock, including the Series A Preferred. As a result of the dissolution described above, it was determined approximately $24,000 of inventory likely had no value, and was written off in the period ended March 31, 2023.

Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. The company had no outstanding warrants at December 31, 2023 and December 31, 2022.

Warrants Exercised During 2022

During the year ended December 31, 2022, warrants to purchase 60,374 shares of the Company's common stock were exercised, resulting in proceeds of $0.2 million and the issuance of 60,374 shares of the Company's common stock. Of the warrants exercised during the year ended December 31, 2022, warrants to purchase 14,815 shares of the Company's common stock were exercised by members of management, resulting in proceeds of approximately $40,000. Warrants to purchase 63,102 shares of the Company's common stock expired unexercised during the year ended December 31, 2022.

Note 16 – Savings Incentive Match Plan

On January 1, 2017, the Company established a Savings Incentive Match Plan for Employees Individual Retirement Account (SIMPLE IRA), which covers all employees. The SIMPLE IRA Plan provides for voluntary employee contributions up to statutory IRA limitations. The Company matches 100% of employee contributions to the SIMPLE IRA Plan, up to 3% of each employee's salary. The Company contributed and expensed approximately $91,000 and $104,000 to the SIMPLE IRA in 2023 and 2022, respectively.

Note 17 - Commitments and Contingencies

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 9 – License and Supply Agreement, net), the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2023, the Company agreed to make minimum annual aggregate purchases from Medica of €3.8 million (approximately $4.1 million). For the year ended December 31, 2023, aggregate purchase commitments totaled €4.9 million (approximately $5.3 million). All minimum purchase requirements were met.

Future purchase commitments under the License and Supply Agreement with Medica are as follows:

- 2024: €4,208,000
- 2025: €4,629,000
- 2026: €4,976,000
- 2027: €5,349,000
- 2028: €5,750,000

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, the Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of the disclosure controls and procedures as of December 31, 2023. Based upon this evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures were effective as of December 31, 2023. Accordingly, management believes that the financial statements included in this Annual Report on Form 10-K present fairly in all material respects the financial position, results of operations and cash flows for the period presented.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision of the Chief Executive Officer and Chief Financial Officer, management conducted an evaluation of the effectiveness of the internal control over financial reporting as of December 31, 2023 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework". Based on the assessment, management concluded that the internal control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

There were no changes in the internal control over financial reporting that occurred during the most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

Item 9B. Other Information

We are reporting the following information in lieu of reporting on a Current Report on Form 8-K:

Item 1.01 Entry into a Material Definitive Agreement.

On December 11, 2023, Nephros, Inc. (the "Company") entered into a license and supply agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products (collectively, the "Products"), and to engage in an exclusive supply arrangement for the Products. The License and Supply Agreement supersedes and replaces that certain License and Supply Agreement, dated April 23, 2012, as amended (the "Prior Agreement") between the Company and Medica, which Prior Agreement was terminated by the parties upon entry into the License and Supply Agreement.

Under the License and Supply Agreement, Medica granted the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the Products in the Territory (as defined in the License and Supply Agreement). In addition, the Company granted to Medica an exclusive license under the Company's intellectual property to make the Products during the term of the License and Supply Agreement. In exchange for the rights granted, the Company has agreed to make minimum annual aggregate purchases from Medica of €3,825,000, €4,208,000, €4,629,000, €4,976,000, €5,349,000 and €5,750,000 for the years 2023, 2024, 2025, 2026, 2027 and 2028, respectively. The License and Supply Agreement contains standard representations and warranties and indemnification obligations of the parties.

The term of the License and Supply Agreement commenced on December 11, 2023 and continues in effect through December 31, 2028, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

The foregoing description of the License and Supply Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the License and Supply Agreement, a copy of which is filed as Exhibit 10.36 to this Annual Report on Form 10-K and is incorporated herein by reference.

Item 1.02 Termination of a Material Definitive Agreement.

The information related to the termination of the Prior Agreement contained in Item 1.01 of this Item 9B of this Annual Report on Form 10-K is incorporated herein by reference.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information set forth under the captions "Proposal No. 1 – Election of Directors," "Corporate Governance" and "Delinquent Section 16(a) Reports" in the 2024 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption "Compensation Matters" in the 2024 Proxy Statement is incorporated herein by reference.

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

The information set forth under the captions "Stock Ownership of Management and Principal Stockholders" and "Compensation Matters" in the 2024 Proxy Statement is incorporated herein by reference.

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

The information set forth under the captions "Corporate Governance" and "Certain Relationships and Related Transactions" in the 2024 Proxy Statement is incorporated herein by reference**.**

Item 14. Principal Accounting Fees and Services

The information set forth under the caption "Proposal No. 2 – Ratification of Selection of Independent Registered Public Accounting Firm" in the 2024 Proxy Statement is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report:

(1) Consolidated Financial Statements of Nephros, Inc.

Report of independent registered public accounting firm, Baker Tilly US, LLP. 1 Highwood Drive, Tewksbury, MA 01876, Firm ID - 23
Consolidated balance sheets as of December 31, 2023 and 2022.
Consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022.
Consolidated statements of changes in stockholders' equity for the years ended December 31, 2023 and 2022.
Consolidated statements of cash flows for the years ended December 31, 2023 and 2022.
Notes to consolidated financial statements.

(2) Exhibits:

Exhibit No.	Description
2.1	Agreement for Purchase and Sale of Assets, dated October 4, 2022, by and between Nephros, Inc. and BWSI, LLC, incorporated by reference to Exhibit 2.1 to Nephros Inc.'s Current Report on Form 8-K, filed with the SEC on November 21, 2022 (pursuant to Item 601(b)(2)(ii) of Regulation S-K, certain information contained in this Exhibit 2.1 has been redacted as indicated therein).
3.1	Conformed Copy of the Fourth Amended and Restated Certificate of Incorporation, incorporating those Certificates of Amendment dated June 4, 2007; June 29, 2007; November 13, 2007; October 23, 2009; March 10, 2011; March 11, 2011 and July 8, 2019, incorporated by reference to Exhibit 3.1 to Nephros, Inc.'s Quarterly Report on Form 10-K for the quarter ended June 30, 2019, filed with the SEC on August 7, 2019.
3.2	Second Amended and Restated By-Laws of the Registrant, incorporated by reference to Exhibit 3.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on December 3, 2007.
4.1	Specimen of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the SEC on July 20, 2004.
4.2	Description of Capital Stock, incorporated by reference to Exhibit 4.5 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 27, 2020.
10.1	Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the SEC on July 20, 2004. †
10.2	Amendment No. 1 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 4.3 to Nephros, Inc.'s Registration Statement on Form S-8 (Reg. No. 333-127264), filed with the SEC on August 5, 2005. †
10.3	Amendment No. 2 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.7 to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the SEC on November 13, 2007. †
10.4	Amendment No. 3 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.51 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 31, 2009 †
10.5	Amendment No. 4 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit A to Nephros, Inc.'s Definitive Proxy Statement, filed with the SEC on December 2, 2010. †

Exhibit No.	Description
10.6	Amendment No. 5 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Appendix A to Nephros, Inc.'s Definitive Proxy Statement, filed with the SEC on April 11, 2013. †
10.7	Amendment No. 6 to Nephros, Inc. 2004 Stock Incentive Plan, dated June 14, 2013, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed with the SEC on August 13, 2013. †
10.8	Nephros, Inc. 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.9	Form of Incentive Stock Option Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.10	Form of Non-Qualified Stock Option Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.11	Form of Restricted Stock Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.5 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.12	Form of Restricted Stock Unit Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.6 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.13	Nephros, Inc. Director Compensation Policy, incorporated by reference to Exhibit 10.15 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 26, 2018.
10.14	License and Supply Agreement, dated April 23, 2012, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 26, 2012.
10.15	Second Amendment to License and Supply Agreement, dated May 4, 2015, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 10, 2015.
10.16	Third Amendment to License and Supply Agreement, dated May 5, 2017, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on May 9, 2017.
10.17	Fourth Amendment to License and Supply Agreement, dated September 26, 2017, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on September 27, 2017.
10.18	Registration Rights Agreement, dated September 19, 2007, among the Registrant and the Holders, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on September 25, 2007.
10.19	Form of Registration Rights Agreement, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.57 to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-169728), filed with the SEC on October 1, 2010.
10.20	Registration Rights Agreement, dated February 4, 2013, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.68 to Nephros, Inc.'s Registration Statement on Form S-1 (Reg. No. 333-187036), filed with the SEC on March 4, 2013.

Exhibit No.	Description
10.21	First Amendment to Registration Rights Agreement, dated May 23, 2013, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed with the SEC on August 13, 2013.
10.22	Registration Rights Agreement, dated November 12, 2013, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on November 14, 2013.
10.23	First Amendment to Registration Rights Agreement, dated April 14, 2014, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, filed with the Securities and Exchange Commission on May 14, 2014.
10.24	Registration Rights Agreement, dated August 29, 2014, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on September 3, 2014.
10.25	First Amendment to Registration Rights Agreement, dated September 23, 2014, between the Registrant and Wexford Capital LP, incorporated by reference to Exhibit 10.5 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 13, 2014.
10.26	Registration Rights Agreement dated March 17, 2017, among the Registrant and the Purchasers identified therein, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on March 23, 2017.
10.27	Amended and Restated Loan and Security Agreement, dated May 26, 2020, by and between Tech Capital, LLC and the Registrant, incorporated by reference to Exhibit 10.2 to Nephros Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 5, 2020.
10.28	Amended and Restated Secured Promissory Note (Single Advance – Non-Revolving), dated May 26, 2020, issued by the Registrant, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 5, 2020.
10.29	Employment Agreement between the Registrant and Andrew Astor, dated August 23, 2020, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020. †
10.30	Employment Agreement dated May 5, 2023, between Nephros, Inc. and Robert Banks (incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2023). †
10.31	Letter Agreement, dated July 28, 2023, between the Nephros, Inc. and Judy Krandel. * †
10.32	Inducement Stock Option Agreement, dated November 1, 2023, between Nephros, Inc. and Judy Krandel. * †
10.33	Amendment to Employment Agreement, dated August 9, 2023, between Nephros, Inc. and Andrew Astor (incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023). †
10.34	License and Supply Agreement, dated December 11, 2023, between the Registrant and Medica S.p.A. (pursuant to Item 601(b)(2)(ii) of Regulation S-K, certain information contained in this Exhibit 10.34 has been redacted as indicated therein).*
21.1	List of Subsidiaries of Nephros, Inc. *
23.1	Consent of Baker Tilly US, LLP Independent Registered Public Accounting Firm. *
24.1	Power of Attorney (included on the signature page). *

Exhibit No.	Description
31.1	Certification by the Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification by the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
97.1	Nephros, Inc. Policy for Recoupment of Erroneously Awarded Compensation. *
101	Interactive Data File. *

* Filed herewith.
† Management contract or compensatory plan arrangement.
\+ Confidential treatment has been granted for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEPHROS, INC.

Date: March 15, 2024

By: */s/ Robert Banks*
Name: Robert Banks
Title: President, Chief Executive Officer (Principal Executive Officer)

Date: March 15, 2024

By: */s/ Judy Krandel*
Name: Judy Krandel
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

We, the undersigned directors and officers of Nephros, Inc., hereby severally constitute and lawfully appoint Robert Banks, our true and lawful attorney-in-fact with full power to him to sign for us, in our names in the capacities indicated below, the Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Nephros, Inc. and any and all amendments thereto, and to file the same with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Robert Banks Robert Banks	President, Chief Executive Officer (Principal Executive Officer)	March 15, 2024
/s/ Judy Krandel Judy Krandel	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2024
/s/ Arthur H. Amron Arthur H. Amron	Director	March 15, 2024
/s/ Oliver Spandow Oliver Spandow	Director	March 15, 2024
/s/ Alisa Lask Alisa Lask	Director	March 15, 2024
/s/Joe Harris Joe Harris	Director	March 15, 2024

Exhibit 10.31

July 28, 2023
Judith Krandel

Dear Judy,

I am very pleased to offer you the position of Chief Financial Officer (CFO) at Nephros ("the Company"). Initially, the position is targeted at an expected time commitment of 50% and the compensation is structured at the same level. This percentage – of both time and pay – may be increased or decreased from time to time by mutual agreement, in writing. Your employment is expected to begin on or about November 1, 2023.

As CFO, your primary responsibilities will be to manage the financial, risk management, and administrative operations of Nephros, including accounting, financial reporting, financial strategies, and control systems. You will also work closely with me in representing the Company to the public markets, and also partner with me in developing and executing strategies for increasing the market value of Nephros.

Your initial annual base salary will be $140,000, which is based on the aforementioned 50% time commitment. Your salary will be reviewed annually, beginning January 1, 2025.

In addition, you will be eligible to receive an annual bonus targeted at 25% of your base salary, based on the Company's achievements of its goals. If your bonus is payable for 2023 company performance, it will be prorated to your start date. Bonuses may be paid in cash, restricted stock, or a combination of the two, at the Company's discretion and in accordance with similar payments to other senior executives.

Subject to approval of the Company's board of directors, you will be granted an option to purchase 122,524 shares of the Company's stock (1.0% of current fully diluted shares) pursuant to the Company's 2015 Equity Incentive Plan (the "2015 Plan"). Your right to exercise the stock options will vest over four years, in accordance with standard practices of the Company. In the event of a Change of Control (as such term is defined in the 2015 Plan), notwithstanding anything to the contrary contained herein, all shares subject to the option that have not then vested shall vest and become exercisable immediately and, unless all such options are cashed- out in the Change of Control transaction, shall remain exercisable for a period of not less than 360 days (or the expiration of the Option term, if sooner), regardless of whether your employment is terminated in connection with such Change of Control transaction.

Notwithstanding the foregoing, unless otherwise determined by the board of directors, no change in ownership of the Company's outstanding securities shall be deemed a Change of Control if such change in ownership is caused by or relates solely to any disposition or acquisition of any Company securities by Wexford Capital, LP and/or its affiliates. This stock option will be subject to the terms and conditions of the 2015 Plan and a separate stock option agreement in the standard form approved for use under the 2015 Plan by the board of directors.

Nephros currently provides its employees with a benefits package, including:

- Health plan – Approximately 90% company-paid
- Health Reimbursement Plan – 100% company-paid
- Dental and Vision Plan – 100% company-paid
- Life Insurance – 100% company-paid
- Flexible Spending Account – employee-paid
- Long- and Short-Term Disability Plan – employee-paid
- SIMPLE IRA Savings Plan – employee-paid with up to 3% company match
- 15 PTO days annually. "Use it or lose it" policy, where lawful

Please note that, as set forth in the Company's employee handbook, the employee benefits provided to you by the Company are subject to change by the Company, in its sole discretion, at any time and from time to time.

Even though some provisions of this letter refer to future dates, they are merely reference points for certain events that are scheduled for as long as you are employed by the Company. Your employment with the Company is for an indefinite term and nothing in this letter modifies your at-will employment relationship with the Company. Further, your employment will also be subject to (a) the Company's personnel policies and procedures as set forth in the Company's Employee Handbook and other documents, (b) your entry into a Confidentiality, Invention Assignment and Non-Competition Agreement in the form separately provided to you, and (c) Nephros' general satisfaction with your work performance. Either you or Nephros may terminate your employment with the Company for any reason.

If you have any questions regarding the details of this offer, please feel free to contact me. We are very excited about having you on our team. If you agree to the conditions that have been outlined, please sign, date, and return by e-mail at your earliest convenience.

Respectfully,

Robert Banks, President & Chief Executive Officer

Accepted:

/s/ Judith Krandel

Judith Krandel

Exhibit 10.32

NEPHROS, INC.

INDUCEMENT STOCK OPTION AGREEMENT

THIS INDUCEMENT STOCK OPTION AGREEMENT (this "Agreement"), made effective as of this 1st day of November, 2023, by and between Nephros, Inc., a Delaware corporation (the "Company"), and Judy Krandel ("Participant").

W I T N E S S E T H:

WHEREAS, the Company maintains the Nephros, Inc. 2015 Equity Incentive Plan (as it may be amended and/or restated from time to time, the "Plan");

WHEREAS, as an inducement material to Participant's acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, the Company desires to grant this Option (as defined below) to Participant outside of the Plan pursuant to the terms of this Agreement;

WHEREAS, notwithstanding the foregoing, the Company and Participant intend for this Agreement and the Option to be subject to all of the terms and conditions of the Plan, as if the Option had been granted under the Plan;

WHEREAS, the Administrator of the Plan has determined that, as of the effective date of this Agreement, the fair market value of the Company's Common Stock is $1.71 per share; and

WHEREAS, all of the capitalized terms used in this Agreement and not otherwise defined in this Agreement have the same respective meanings as defined in the Plan.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants herein contained, the parties hereto agree as follows:

1. **Grant of Option**. The Company hereby grants to Participant on the date set forth above (the "Date of Grant"), the right and option (the "Option") to purchase all or portions of an aggregate of one hundred twenty-two thousand five hundred twenty-four (122,524) shares of Common Stock at a per share price of $1.71, on the terms and conditions set forth herein, and subject to adjustment pursuant to Section 16 of the Plan. This Option is a nonqualified stock option and will not be treated as an incentive stock option, as defined under Section 422, or any successor provision, of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder.

2. **Duration and Exercisability**.

a. **General**. The term during which this Option may be exercised shall terminate at the close of business on November 1, 2033, except as otherwise provided in Paragraphs 2(b) through 2(e) below. This Option shall become exercisable according to the following schedule:

Twenty-five percent (25%) of the shares subject to the Option will vest and become exercisable on the first anniversary of the Date of Grant, and the remaining seventy-five (75%) of the shares subject to the Option will thereafter vest and become exercisable in twelve approximately equal quarterly installments.

Once the Option becomes exercisable to the extent of one hundred percent (100%) of the aggregate number of shares specified in Paragraph 1, Participant may continue to exercise this Option under the terms and conditions of this Agreement until the termination of the Option as provided herein. If, upon an exercise of this Option, Participant does not purchase the full number of shares which Participant is then entitled to purchase, Participant may purchase upon any subsequent exercise prior to this Option's termination such previously unpurchased shares in addition to those Participant is otherwise entitled to purchase.

b. **Termination of Employment or Service Relationship for Cause**. If Participant ceases to be a Director of the Company or any Subsidiary for Cause, as defined below, the unexercised portion of this Option shall immediately expire, and all rights of Participant under this Option shall be forfeited.

For purposes of this Section 2, "Cause" shall mean (i) the conviction of Participant for the commission of any felony, (ii) the commission by Participant of any crime involving moral turpitude (*e.g.*, larceny, embezzlement) which results in harm to the business, reputation, prospects or financial condition of the Company or any Affiliate, or (iii) a disciplinary discharge pursuant to the terms of the Company's management handbooks or policies as in effect at the time.

c. **Termination of Employment or Service Relationship (other than for Cause, Disability or Death)**. If Participant ceases to be an Employee of the Company or any Subsidiary for any reason other than for Cause, disability or death, this Option shall completely terminate on the earlier of: (i) the close of business on the three-month anniversary date of Participant's termination; and (ii) the expiration date of this Option stated in Paragraph 2(a) above. In such period following Participant's termination, this Option shall be exercisable only to the extent the Option was exercisable on the vesting date immediately preceding such termination but had not previously been exercised. To the extent this Option was not exercisable upon such termination, or if Participant does not exercise the Option within the time specified in this Paragraph 2(c), all rights of Participant under this Option shall be forfeited.

d. **Disability**. If Participant ceases to be an Employee of the Company or any Subsidiary because of disability (as defined in Code Section 22(e), or any successor provision), this Option shall terminate on the earlier of: (i) the close of business on the twelve-month anniversary date of Participant's termination; and (ii) the expiration date of this Option stated in Paragraph 2(a) above. In such period following Participant's termination, this Option shall be exercisable only to the extent the Option was exercisable on the vesting date immediately preceding such termination but had not previously been exercised. To the extent this Option was not exercisable upon such termination, or if Participant does not exercise the Option within the time specified in this Paragraph 2(d), all rights of Participant under this Option shall be forfeited.

e. **Death**. In the event of Participant's death, this Option shall terminate on the earlier of: (i) the close of business on the twelve-month anniversary of the date of Participant's death; and (ii) the expiration date of this Option stated in Paragraph 2(a) above. In such period following Participant's death, this Option may be exercised by the person or persons to whom Participant's rights under this Option shall have passed by Participant's will or by the laws of descent and distribution only to the extent the Option was exercisable on the vesting date immediately preceding the date of Participant's death, but had not previously been exercised. To the extent this Option was not exercisable upon the date of Participant's death, or if such person or persons fail to exercise this Option within the time specified in this Paragraph 2(e), all rights under this Option shall be forfeited.

3. **Manner of Exercise**.

a. **General**. The Option may be exercised only by Participant (or other proper party in the event of death or incapacity), subject to the conditions of the Plan and subject to such other administrative rules as the Administrator may deem advisable, by delivering within the option period written notice of exercise to the Company at its principal office. The notice shall state the number of shares as to which the Option is being exercised and shall be accompanied by payment in full of the option price for all shares designated in the notice. The exercise of the Option shall be deemed effective upon receipt of such notice by the Company and upon payment that complies with the terms of the Plan and this Agreement. The Option may be exercised with respect to any number or all of the shares as to which it can then be exercised and, if partially exercised, may be so exercised as to the unexercised shares any number of times during the option period as provided herein.

b. **Form of Payment**. Subject to the approval of the Administrator, payment of the exercise price by Participant may be (i) in cash, or with a personal check or certified check, (ii) by the transfer from Participant to the Company of previously acquired unencumbered shares of Common Stock, (iii) through the withholding of shares of Common Stock from the number of shares otherwise issuable upon the exercise of the Option (*e.g.*, a net share settlement), (iv) through broker-assisted cashless exercise if such exercise complies with applicable securities laws and any insider trading policy of the Company, (v) such other form of payment as may be authorized by the Administrator, or (vi) by a combination thereof. In the event Participant elects to pay the exercise price in whole or in part with previously acquired shares of Common Stock or through a net share settlement, the then-current Fair Market Value of the Common Stock delivered or withheld shall equal the total exercise price for the shares being purchased in such manner. For purposes of this Agreement, "previously acquired shares of Common Stock" means shares of Common Stock which Participant has owned for at least six (6) months prior to the exercise of the option (or for such period of time, if any, required by applicable accounting principles).

c. **Stock Transfer Records**. As soon as practicable after the effective exercise of all or any part of the Option, Participant shall be recorded on the stock transfer books of the Company as the owner of the shares purchased, and the Company shall deliver to Participant one or more duly issued stock certificates evidencing such ownership, or, if requested by Participant and permitted by the Company's governing documents, its designated agent, and applicable law, shall cause the purchased shares to be issued in book-entry form. All requisite original issue or transfer documentary stamp taxes shall be paid by the Company.

4. **General Provisions**.

a. **Employment or Other Relationship; Rights as Stockholder**. This Agreement shall not confer on Participant any right with respect to the continuance of employment or any other relationship with the Company or any of its Subsidiaries, nor will it interfere in any way with the right of the Company to terminate such employment or relationship. Nothing in this Agreement shall be construed as creating an employment or service contract for any specified term between Participant and the Company or any Affiliate. Participant shall have no rights as a stockholder with respect to shares subject to this Option until such shares have been issued to Participant (or, if permitted, a book entry made) upon exercise of this Option. No adjustment shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property), distributions or other rights for which the record date is prior to the date such shares are issued, except as provided in Section 15 of the Plan.

b. **280G Limitations**. Notwithstanding anything in the Plan, this Agreement or in any other agreement, plan, contract or understanding entered into from time to time between Participant and the Company or any of its Subsidiaries to the contrary (except an agreement that expressly modifies or excludes the application of this Paragraph 4(b)), the exercisability of this Option shall not be accelerated in connection with a Change of Control to the extent that such acceleration, taking into account all other rights, payments and benefits to which Participant is entitled under any other plan or agreement, would constitute a "parachute payment" or an "excess parachute payment" for purposes of Code Sections 280G and 4999, or any successor provisions, and the regulations issued thereunder; provided, however, that the Administrator, in its sole discretion and in accordance with applicable law, may modify or exclude the application of this Paragraph 4(b).

c. **Securities Law Compliance**. The exercise of all or any parts of this Option shall only be effective at such time the Company and its counsel shall have determined that the issuance and delivery of Common Stock pursuant to such exercise will not violate any state or federal securities or other laws. If the issuance of such shares upon exercise is not registered under a then-currently effective registration statement under the Securities Act of 1933, as amended, Participant may be required by the Company, as a condition of the effectiveness of any exercise of this Option, to give any written assurances that are necessary or desirable in the opinion of the Company and its counsel to ensure the issuance complies with applicable securities laws, including that all Common Stock to be acquired pursuant to such exercise shall be held, until such time that such Common Stock is registered and freely tradable under applicable state and federal securities laws, for Participant's own account without a view to any further distribution thereof; that the certificates (or, if permitted, book entries) for such shares shall bear an appropriate legend or notation to that effect; and that such shares will be not transferred or disposed of except in compliance with applicable state and federal securities laws.

d. **Extension of Expiration Date**. In the event that the exercise of this Option would be prohibited solely because the issuance of shares of Common Stock pursuant to the Option would violate applicable securities laws, the Administrator may, in its sole discretion and in accordance with Code Section 409A and the regulations, notices and other guidance of general applicability thereunder, permit the expiration of the Option to be tolled during such time as its exercise is so prohibited; provided, however, that the expiration date may not thereby be extended more than 30 days after the date the exercise first would no longer violate applicable securities laws.

e. **Mergers, Recapitalizations, Stock Splits, Etc.** Except as otherwise specifically provided in any employment, change of control, severance or similar agreement executed by Participant and the Company, pursuant and subject to Section 15 of the Plan, certain changes in the number or character of the Common Stock of the Company (through sale, merger, consolidation, exchange, reorganization, divestiture (including a spin-off), liquidation, recapitalization, stock split, stock dividend or otherwise) shall result in an adjustment, reduction or enlargement, as appropriate, in Participant's rights with respect to any unexercised portion of the Option (*i.e.*, Participant shall have such "anti-dilution" rights under the Option with respect to such events, but, subject to the Administrator's discretion, shall not have "preemptive" rights).

f. **Shares Reserved**. The Company shall at all times during the term of this Agreement reserve and keep available such number of shares as will be sufficient to satisfy the requirements of this Agreement.

g. **Withholding Taxes**. To permit the Company to comply with all applicable federal and state income tax laws or regulations, the Company may take such action as it deems appropriate to ensure that, if necessary, all applicable federal and state payroll, income, or other taxes are withheld from any amounts payable by the Company to Participant. If the Company is unable to withhold such federal and state taxes, for whatever reason, Participant hereby agrees to pay to the Company an amount equal to the amount the Company would otherwise be required to withhold under federal or state law. Subject to such rules as the Administrator may adopt, the Administrator may, in its sole discretion, permit Participant to satisfy such withholding tax obligations, in whole or in part by: (i) delivering shares of Common Stock, or (ii) electing to have the Company withhold shares of Common Stock otherwise issuable to Participant as a result of the exercise of the Option. In either case, such shares shall have a Fair Market Value, as of the date the amount of tax to be withheld is determined under applicable tax law, equal to the statutory minimum amount required to be withheld for tax purposes. Participant's request to deliver shares or to have shares withheld for purposes of such withholding tax obligations shall be made on or before the date that triggers such obligations, or, if later, the date that the amount of tax to be withheld is determined under applicable tax law, and shall be irrevocable on such date if approved by the Administrator. Participant's request shall comply with such rules as the Administrator may adopt to assure compliance with Rule 16b-3, if applicable.

h. **Nontransferability**. Unless otherwise permitted by the Administrator in its sole discretion, during the lifetime of Participant, the Option shall be exercisable only by Participant or by Participant's guardian or other legal representative, and shall not be assignable or transferable by Participant, in whole or in part, other than by will or by the laws of descent and distribution.

i. **2015 Equity Incentive Plan**. The Company and Participant acknowledge and agree that the Option is granted outside of the Plan. Notwithstanding the foregoing, the Option evidenced by this Agreement is subject to and in all respects limited and conditioned as provided in the Plan, a copy of which Plan has been made available to Participant and is hereby incorporated into this Agreement. All capitalized terms in this Agreement not defined herein shall have the meanings ascribed to them in the Plan. The Plan governs this Option and, in the event of any questions as to the construction of this Agreement or in the event of a conflict between the Plan and this Agreement, the Plan shall govern, except as the Plan otherwise provides.

j. **Lockup Period Limitation**. Participant agrees that in the event the Company advises Participant that it plans an underwritten public offering of its Common Stock in compliance with the Securities Act of 1933, as amended, Participant will execute any lock-up agreement the Company and the underwriter(s) deem necessary or appropriate, in their sole discretion, in connection with such public offering.

k. **Blue Sky Limitation.** Notwithstanding anything in this Agreement to the contrary, in the event the Company makes any public offering of its securities and it is determined that it is necessary to reduce the number of issued but unexercised stock purchase rights so as to comply with any state securities or Blue Sky law limitations with respect thereto, and such determination is affirmed by the Board of Directors, unless the Board of Directors determines otherwise, (i) the exercisability of this Option and the date on which this Option must be exercised shall be accelerated, provided that the Company agrees to give Participant 15 days' prior written notice of such acceleration, and (ii) any portion of this Option or any other option granted to Participant pursuant to the Plan which is not exercised prior to or contemporaneously with such public offering shall be canceled. Notice shall be deemed given when delivered personally or when deposited in the United States mail, first class postage prepaid and addressed to Participant at the address of Participant on file with the Company.

l. **Affiliates**. Participant agrees that, if Participant is an "affiliate" of the Company or any Affiliate (as defined in applicable legal and accounting principles) at the time of a Change of Control (as defined in Section 1(f) of the Plan), Participant will comply with all requirements of Rule 145 of the Securities Act of 1933, as amended, and the requirements of such other applicable legal or accounting principles, and will execute any documents necessary to ensure such compliance.

m. **Stock Legend**. The Administrator may require that the certificates (or, if permitted, book entries) for any shares of Common Stock purchased by Participant (or, in the case of death, Participant's successors) shall bear an appropriate legend or notation to reflect the restrictions of Paragraph 4(c) and Paragraphs 4(j) through 4(l) of this Agreement; provided, however, that failure to so endorse any of such certificates shall not render invalid or inapplicable Paragraph 4(c) or Paragraphs 4(j) through 4(l).

n. **Scope of Agreement**. This Agreement shall bind and inure to the benefit of the Company and its successors and assigns and Participant and any successor or successors of Participant permitted by Paragraph 2 or Paragraph 4(h) above. This Award is expressly subject to all terms and conditions contained in the Plan and in this Agreement, and Participant's failure to execute this Agreement shall not relieve Participant from complying with such terms and conditions.

o. **Choice of Law**. The law of the state of Delaware shall govern all questions concerning the construction, validity, and interpretation of this Plan, without regard to that state's conflict of laws rules.

p. **Severability**. In the event that any provision of this Plan shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining provisions of this Plan, and the Plan shall be construed and enforced as if the illegal or invalid provision had not been included.

q. **Arbitration**. Any dispute arising out of or relating to this Agreement or the alleged breach of it, or the making of this Agreement, including claims of fraud in the inducement, shall be discussed between the disputing parties in a good faith effort to arrive at a mutual settlement of any such controversy. If, notwithstanding, such dispute cannot be resolved, such dispute shall be settled by binding arbitration. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The arbitrator shall be a retired state or federal judge or an attorney who has practiced securities or business litigation for at least 10 years. If the parties cannot agree on an arbitrator within 20 days, any party may request that the chief judge of the District Court of Essex County, select an arbitrator. Arbitration will be conducted pursuant to the provisions of this Agreement, and the commercial arbitration rules of the American Arbitration Association, unless such rules are inconsistent with the provisions of this Agreement. Limited civil discovery shall be permitted for the production of documents and taking of depositions. Unresolved discovery disputes may be brought to the attention of the arbitrator who may dispose of such dispute. The arbitrator shall have the authority to award any remedy or relief that a court of this state could order or grant; provided, however, that punitive or exemplary damages shall not be awarded. The arbitrator may award to the prevailing party, if any, as determined by the arbitrator, all of its costs and fees, including the arbitrator's fees, administrative fees, travel expenses, out-of-pocket expenses and reasonable attorneys' fees. Unless otherwise agreed by the parties, the place of any arbitration proceedings shall be Essex County, New Jersey.

******Signature Page Follows******

ACCORDINGLY, the parties hereto have caused this Agreement to be executed on the day and year first above written.

NEPHROS, INC.

By: */s/ Robert Banks*
Name: Robert Banks
Its: Chief Executive Officer

/s/ Judy Krandel
Judy Krandel

[Inducement Stock Option Agreement Signature Page]

Exhibit 10.34

Pursuant to Item 601 of Regulation S-K, certain information in this Exhibit 10.34 has been redacted. Information that was redacted has been noted in this document with a placeholder identified by the mark "[*****]." The registrant believes the redacted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential. If requested by the Commission or its staff, the Registrant will promptly provide on a supplemental basis an unredacted copy of this exhibit and its materiality and privacy or confidentiality analyses.

LICENSE AND SUPPLY AGREEMENT

This LICENSE and SUPPLY AGREEMENT (this "Agreement") is entered into as of December 11, 2023 (the "Effective Date") by and between Nephros, Inc., a Delaware corporation with its principal office at 380 Lackawanna Place, South Orange, New Jersey 07079, U.S.A. ("Nephros"), and Medica S.p.A., with registered office in Medolla (MO), Via Degli Artigiani, 7 – 41036, Italy ("Medica"), and sometimes herein referred to individually as a "Party" and collectively, as the "Parties".

RECITALS

1. Medica develops, manufactures, markets, and sells ultrafiltration products based in part upon a proprietary ultrafiltration technology.

2. Nephros currently markets and sells filtration products based upon its own proprietary filtration technology and products based in part upon Medica's proprietary filtration technology.

3. The Parties are currently parties to that certain License and Supply Agreement, dated April 23, 2012, as amended from time to time (collectively, the "Prior Agreement") pursuant to which Medica exclusively supplies Nephros, and Nephros exclusively markets and sells, the Medica Products (defined below) within the Territory (defined below) in conjunction with the Nephros Products (defined below).

5. Nephros and Medica desire to terminate the Prior Agreement and to enter into this new License and Supply Agreement setting forth the Parties' understanding with respect to the supply of Medica Products and Nephros Products and related marketing rights within the Territory, and the ownership and licensing of Intellectual Property, among other things.

NOW, THEREFORE, in consideration of the foregoing and of the mutual representations, warranties and covenants contained herein, the Parties agree as follows:

1. Definitions

1.1 "Affiliate" of a Party hereto means any entity which controls, is controlled by or is under common control with, such Party, For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest for an entity other than a corporation) or if it has management control of the other entity. Any reference in this Agreement to a Party shall include the Affiliates of that Party (unless the context requires otherwise).

1.2 "Agents" shall mean any officer, director, employee, agent, subcontractor, or other authorized representative of a Party or Person.

1.3 "Applicable Law" shall mean: (a) all laws, statutes, constitutions, treaties, rules, regulations, ordinances, codes, guidance, and common law, and (b) all judicial, executive, legislative, administrative or military orders, directives, decrees, injunctions, judgments, Permits, agreements, and other legal requirements, in each case, of, with, or adopted or imposed by any Governmental Authority, now or hereafter in effect and, in each case, as amended from time to time, including, without limitation, any of the foregoing that relate to or govern (i) the manufacture, quality, marketing, sale, promotion, storage handling, distribution or disposal of the Product and (ii) health, safety, industrial hygiene, or sanitation.

1.4 "cGMP'" means the current applicable regulatory requirements for current good manufacturing practices promulgated by the FDA applicable to the Products as well as those required by other Regulatory Authorities in the Territory, as the same may be amended from time to time.

1.5 "Change of Control" shall mean, with respect to a Party, any event in which: (a) any Person or group (as such term is defined in the U.S. Securities Exchange Act of 1934, as amended) acquires beneficial ownership of securities of such Party representing more than fifty percent (50%) of the voting power of the then outstanding securities of such Party with respect to the election of directors of such Party; (b) a Party enters into a merger, consolidation, or similar transaction with any Person in which such Party is not the surviving entity in such transaction; or (c) a Party enters into a transaction to sell to any Person, in one or more related transactions, assets (i) representing all or substantially all of such Party's assets, (ii) representing all or substantially all of such Party's assets, or (iii) solely with respect to Medica, all or substantially all of its assets relating to the Products, including without limitation, the Medica IP; provided, however, that with respect to Nephros, no transaction with Wexford Capital LC or any Affiliate thereof shall constitute a Change of Control.

1.6 "Claim" shall mean any claim, suit, action, cause of action, proceeding, investigation, dispute, demand, order, directive, obligation, loss, injury, liability, damage, deficiency, assessment, fine, penalty, forfeiture, judgment, lien, diminution of value, notice of violation or non-compliance, cost, and expense, including, without limitation, attorneys' fees and expenses incurred to enforce this Agreement, cost of defense, and cost of settlement.

1.7 "Commercialization" means any and all activities directed to marketing, promoting, distributing, offering for sale and selling the Products. When used as a verb "Commercialize" means to engage in Commercialization.

1.8 "Confidential Information" shall have the meaning ascribed to such term in Section 8.1.

1.9 "Direct Claim" shall have the meaning ascribed to such term in Section 9.5.

1.10 "Disclosing Party" shall have the meaning ascribed to such term in Section 8.1.

1.11 "FDA" shall mean the U.S. Food and Drug Administration.

1.12 "Governmental Authority" shall mean any national, state, commonwealth, provincial, local or foreign governmental authority, entity, body, branch, agency, department, bureau, board, commission, officer, official, court, adjudicator, tribunal, or other entity, including any Agent, division or subdivision thereof in the Territory exercising executive, legislative, judicial, regulatory or administrative authority over the manufacture, quality, marketing, sale, promotion, storage, handling, testing, labeling, packaging, distribution, supply or disposal of medical device products, including, without limitation, any and all state, commonwealth, provincial, local and foreign equivalents.

1.13 "Indemnitee" shall have the meaning ascribed to such term in Section 9.3.1.

1.14 "Indemnitor" shall have the meaning ascribed to such term in Section 9.3.1.

1.15 "Installment Payments" shall have the meaning ascribed to such term in Section 4.1.

1.16 "Intellectual Property" means all worldwide patents, copyrights, trademarks, service marks, logos, package designs, trade names, trade secrets, rights in data and all other intellectual property rights (in each case whether registered or unregistered), and including all applications and registrations with respect thereto.

1.17 "Invalidity Claim" shall have the meaning ascribed to such term in Section 7.3.1.

1.18 "Joint Invention" means, whether or not protected or protectable, and whether or not Confidential Information, all enhancements, technical modifications, inventions, improvements, technology, data, works, designs, discoveries, tool drawings, manufacturing processes and revisions to the Products that are conceived, reduced to practice, created, written, designed, developed, authored, or made by a Party, its Affiliates or Agents, or any Person on behalf of a Party alone or in combination with others, directly relating to the Products, or derived from a Party's practice of the Joint Patents.

1.19 "Joint Patents" means: (a) the Patents Rights recited in Schedule 1; (b) the Patent Rights covered by the Joint Inventions; and (c) any and all divisions, continuations, continuations- in-part, patents of addition, reissues, renewals, extensions, registrations, confirmations, re- examinations, supplementary protection certificates or the like of any such Patent Rights and any patents issuing thereon, and foreign equivalents of any of the foregoing in the Territory to the extent such Patent Rights relate to (a) or (b) of this Section 1.19.

1.20 "Minimum Purchase Requirement" shall have the meaning ascribed to such term in Section 3.2.

1.21 "Medica IP'' means Intellectual Property owned or controlled by Medica and which is used in or to develop or manufacture the Products, including without limitation, Medica's right, title and interest in and to the Joint Patents and the Joint Inventions.

1.22 "Medica Products" shall mean any Medica water filtration products based in whole or in part upon Medica's proprietary Medisulfone® fiber technology and/or other polysulfone based hollow fiber, and Versatile-PES® fiber technology or other polyethersulfone based hollow fiber, or upon technology in existence as of the Effective Date or developed at any time during the Term, including without limitation, those covered under Schedule 2 (the "Product Schedule"), but subject to the exclusions set forth in the Product Schedule.

1.23 "Nephros IP" means Intellectual Property owned or controlled by Nephros and which is used in or to develop or manufacture the Products, including without limitation, Nephros' right, title and interest in and to the Joint Patents and the Joint Inventions.

1.24 "Nephros Products" shall mean any Nephros filtration products based in whole or in part upon Nephros' proprietary filtration technology in existence as of the Effective Date or developed at any time during the Term, including, without limitation, those covered under the Product Schedule.

1.25 "Net Sales" means, for any period of determination, the aggregate amount invoiced by Nephros for any Affiliate, permitted successor, permitted assignee, or agent of Nephros) to a third puny distributor, agent, contractor or end user for the sale of a Products during such period less the following amounts that are actually incurred, allowed and taken or specifically allocated and not already reflected in the amount invoiced: (a) reasonable credits, refunds and allowances for spoiled, damaged, outdated and returned Products, (b) trade volume and cash discounts and rebates (including coupons and government charge-backs) in amounts that are usual and customary to the trade, and (c) sales, use, and other like taxes, excluding income tax. The amounts of any deductions accrued pursuant to clauses (a) — (c) shall be determined from books and records maintained in accordance with U.S. GAAP, consistently applied, and shall only be deducted once and only to the extent not otherwise deducted from the aggregate amount invoiced, "Net Sales" shall not include revenue received by Nephros (or any of its Affiliates) from transactions with an Affiliate, where the Product in question will be resold to an independent third party distributor, agent or end user by the Affiliate where such revenue received by the Affiliate from such resale is included in Net Sales.

1.26 "Patent Rights" means all existing patents and patent applications and all patent applications hereafter filed, including any continuations, continuations-in-part, divisions, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing, or as applicable portions thereof or individual claims therein.

1.27 "Permit" shall main any application permit, authorization, license, approval, registration, franchise, certificate, permission, exemption, consent, variance, or equivalent decision or document of, from, or required or issued by any Governmental Authority or under any Applicable Law, as amended or supplemented from time to time.

1.28 "Person" shall mean and include, without limitation: (a) any corporation, partnership, Limited liability company, joint venture, joint stock company, association, trust, business trust, estate, unincorporated organization, or other business entity recognized under Applicable Law, other than the Nephros or Medica; (b) any Governmental Authority; or (c) any individual.

1.29 "Pricing Schedule" means the prices for the Products as set forth in Schedule 3 attached hereto.

1.30 "Prior Agreement" shall have the meaning ascribed to such term in the Recitals.

1.31 "Products" shall mean collectively, the Medica Products and the Nephros Products.

1.32 "Raw Materials" shall have the meaning ascribed to such term in Section 5.2.

1.33 "Receiving Party" shall have the meaning ascribed to such term in Section 8.1.

1.34 "Regulatory Authority" means any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental authority in the Territory involved in the granting of approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations for the marketing, sale, manufacturing, testing, labeling, packaging, shipping or supply of medical devices.

1.35 "Specifications" means the written specifications for a Product mutually agreed upon by the Parties including us are mutually agreed in writing by the Parties from time to time after the Effective Date and during the Term, which shall become a part of and incorporated by reference in this Agreement.

1.36 "Supply" means the manufacture, processing, testing, storing, labeling and packaging for and sale and delivery of the Products by Medial for Nephros and its Affiliates and Nephros' designated sublicensees and distributors.

1.37 "Supply Interruption" shall have the meaning ascribed to such term in Section 5.5.

1.38 "Term" shall have the meaning ascribed to such term in Section 10.1.

1.39 "Territory" means North America, Central America, Brazil, Columbia, Venezuela, Chile, Ecuador, Peru, United Kingdom (only for Quanta Dialysis Systems), Australia and New Zealand. By the end of 2025 the Parties will meet in good faith in order to evaluate if there are no commercial activities in one or some countries of the Territory. The Territory could be reduced on mutual agreement.

1.40 "Third Party" means any Person other than Nephros and Medica and their respective Affiliates.

1.41 "Third Party Claim" shall have the meaning ascribed to such term in Section 9.3.1.

2. Licenses and Grants.

2.1 Commercialization License. Subject to the terms and conditions of this Agreement, Medica hereby grants to Nephros, and Nephros accepts, an exclusive,, with right of sublicense, under Medica's IP to Commercialize the Products in the Territory. Medica covenants and agrees with Nephros that during the Term Medica will not grant any license or similar right with respect to the Products to Commercialize, or to make or have made the Products for sale in the Territory.

2.2 Manufacturing License. Subject to the terms and conditions of this Agreement, Nephros hereby grants to Medica, and Medica accepts an exclusive, worldwide license under the Nephros IP to make and have made the Products during the Term under the terms and conditions set forth in this Agreement. Nephros covenants and agrees with Medica that during the Term Nephros will not grant any license or similar right to make or have made the Products for sale in the Territory.

2.3 Joint Inventions. Each Party hereby grants to the other Party an exclusive (as to Third Parties), royalty-free, license under the Joint Inventions solely in furtherance of the license grants set forth in Section 2.1 and Section 2.2.

2.4 Trademarks. Subject to the terms and conditions of this Agreement, Medica hereby grants to Nephros, and Nephros accepts, an exclusive, license to use Medica's Versatile-PES®" and "Medisulfone®" marks and variations of same in the Territory solely in conjunction with the sale and distribution of the Products.

2.5 Reservation of Rights. Each Party retains all rights in and to its Intellectual Property not specifically granted to the other Party in Section 2.1 through Section 2.4.

3. Other Risks and Obligations of the Parties.

3.1 Diligent Efforts. Nephros shall: (a) exercise diligent efforts to promote, market and establish and/or increase the sales of the Medica Products in the Territory to customers in both the private and institutional sectors; (b) schedule periodic discussions, or as Medica may request, between Medica's representatives and Nephros' personnel in order to facilitate the dissemination of information about the Medica Products and any promotional and marketing programs related to the Medica Products; (c) inform each of its customers in a timely manner of such programs; and (d) prominently display and actively promote the Medica Products at any tradeshows and other trade meetings which Nephros attends when consistent with the application of the Medica Products. Nephros shall further, employ and maintain at all times, at its cost and expense, professional service representatives in sufficient number for the full promotion, marketing and sale of the Medica Products in the Territory. Any and all such professional service representatives shall be deemed Agents of Nephros and not those of Medica, and Nephros shall train such professional service representatives and direct their activities.

3.2 Minimum Purchase Requirement. During each calendar year during the Term, Nephros shall make minimum annual aggregate purchases ("Minimum Purchase Requirement") from Medica as follows:

Year	Minimum Purchase Requirement	
2023	€	3,825,000
2024	€	4,208,000
2025	€	4,629,000
2026	€	4,976,000
2027	€	5,349,000
2028	€	5,750,000

The Minimum Purchase Requirement will be measured by purchase orders submitted by Nephros in each calendar year. For 2023, purchase orders submitted in 2023 under the Prior Agreement will be counted toward the Minimum Purchase Requirement. In the event that Medica is unable to deliver Products that are included Nephros' forecast, as described in Section 5.4.1., and that have binding purchase orders, the Minimum Purchase Requirement set forth for a given year above will be divided by twelve (12) and for every month when there are Products delivered by Medica more than ten (10) weeks later than the forecasted Products requirement, the Minimum Purchase Requirement in that month will be reduced by 8%.

3.3 Information Sharing. Each Party shall provide the other Party with marketing materials, clinical trial data, other information relating to clinical use of the Products, quality control, approvals, recalls, adverse events and any other information developed or received by the other Party concerning the Products promptly upon such information being developed or becoming available to the other Party and in any event upon the request of Nephros or Medica, as applicable.

3.4 Right to Audit. Each Party shall ensure that the other Party's authorized representatives and, to the extent permitted by Applicable Law, each Governmental Authority, having jurisdiction, may examine and inspect, during regular business hours, its facilities or, subject to any reasonable confidentiality restrictions or obligations relating thereto, such Party's facilities and the facilities of any subcontractor used by it in the performance of this Agreement. This right to inspect may be exercised upon reasonable written notice but no earlier than five (5) business days, at any time during the Term of this Agreement, or such longer period as shall be required by Applicable Law.

4. Payments and Reports.

4.1 Manner of Payment. All sums ("Installment Payments") due under this Agreement shall be payable in Euros by bank wire in immediately available funds to such bank account(s) as Medica shall designate. All amounts overdue to Medica hereunder by more than 15 days shall bear interest per month at the EURIBOR 360 Day rate + 500 basis points (calculated as a monthly equivalent rate) as published in the *Financial Times* as of the first business day of the month in which the overdue payment is due.

4.2 Terms and Withholding. Except as set forth in this Section 4.2, all payments under this Agreement will be made without any deduction or withholding for or on account of any tax, duties, levies, or other charges unless such deduction or withholding is required by Applicable Law or regulations to be assessed against Medica. If Nephros is so required to deduct or withhold, Nephros will: (a) notify Medica of such requirement in writing; (b) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against Medica; and (c) forward to Medial an official receipt (or certified copy) or other documentation reasonably acceptable to Medica evidencing such payment to such authorities.

4.3 Financial Record Keeping; Audits. Nephros shall keep books and accounts of record in connection with sales of the Products in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder, Nephros shall maintain such records for a period of at least five (5) years atter the end of the calendar quarter in which they were generated; provided, however, that if any records are in dispute and Nephros has received written notice from Medica of the records which are in dispute, Nephros shall keep such records until the later of one (1) year or until such dispute is resolved.

5. Manufacturing and Supply.

5.1 Supply. Subject to the terms and conditions hereof and in the Schedules, during the Term, Medica shall exclusively Supply Nephros and Nephros Affiliates and their respective sublicensees and distributors with, and Nephros shall exclusively purchase from Medica, all of Nephros' and its Affiliates' or their respective sublicensees and distributors' requirements for the Products in the Territory during the Term, pursuant to purchase orders delivered by Nephros or its Affiliates or Nephros' Third Party distributor to Medica in accordance with Section 5.4.

5.2 Raw Materials. Medica shall have responsibility for the procurement, manufacture, quality control, processing, testing, storage, treatment and handling of all packaging, raw materials, work-in-process and other materials used for Supply (collectively, "Raw Materials"). Medica shall Supply the Products in accordance with the terms and conditions of this Agreement and the applicable Product Schedule, Specifications, and cGMP. Medica shall be solely responsible for disposing of all Raw Materials and wastes arising from its performance hereunder and for performance of its obligations hereunder in accordance with Applicable Law in effect at the time and place of manufacture of the Products.

5.3 Quality Control. All quality control processes and procedures relating to the Products shall be the sole cost and responsibility of Medica. Medica shall conduct quality control testing of Products prior to shipment in accordance with the applicable Specifications and Applicable Law. Medica shall prepare and retain records pertaining to such testing as required by Applicable Law and Medical's standard operating procedures. With every finished lot Medica will provide Nephros with a certificate of conformity and applicable device history records (i.e Product Record, Bioburden, Sterilization, etc.) showing that the Products have been manufactured to Specifications and pass all quality control testing.

5.4 Forecasts, Order and Delivery of Products.

5.4.1 Nephros shall deliver to Medica monthly rolling forecasts of the quantities of the Products required by Nephros (and/or its Affiliates or their respective sublicensees and distributors) for the following four months. The quantities of Product set forth in the first 12 weeks contained in any such forecast and issued via a purchase order shall be firm and binding on Nephros during the Term. The forecast quantities of Products set forth in the remaining months of the forecast period shall be non-binding good faith estimates of Nephros' Product requirements for such months and shall be used by Medica for production planning. Medica shall, no later than ten (10) days after receipt of each such forecast notify Nephros in writing of any objections or prospective problems in meeting Nephros' forecasted requirements.

5.4.2 Nephros shall furnish to Medica binding purchase orders for the quantities of Products which Nephros shall purchase and Medica shall deliver. Such purchase orders shall be delivered by Nephros at least twelve (12) weeks in advance of the delivery date specified therein. Medica shall not maintain a quantity of safety stock of the Products. Each such purchase order shall designate the quantity of Product ordered and the date by which Medica must deliver the Product to Nephros or to any Nephros Affiliate or any Third Party designated by Nephros. No provision of any purchase order submitted by Nephros or its Affiliate or any Third Party designated by Nephros, or of any confirmation or acknowledgement submitted by Medica, shall be controlling to the extent it sets forth any terms or conditions that are additional to, or in conflict or inconsistent with, the terms or conditions of this Agreement or the Supply Schedule.

5.4.3 Medica shall deliver the quantities of Product set forth in each purchase order Ex Works Incoterms 2020, published by the International Chamber of Commerce at Medica's facility to Nephros' designated carrier as specified by Nephros in the applicable purchase order. Nephros reserves the right to designate the carrier for shipment from Medica's facility, provided that Medica has approved such carrier for the facility, such approval not to be unreasonably withheld, conditioned, or delayed. Risk of loss and damage and title to Product shall pass to Nephros when the Product is delivered to Nephros' designated carrier.

5.5 Supply Interruption. A "Supply Interruption" will be deemed to have occurred and continuing if Nephros has ordered Product from Medica, and Nephros documents that during a period of at least two (2) consecutive months Nephros has not received at least ninety percent (90%) of those quantities of Product so ordered. In the event of a Supply Interruption (other than as a result of an act or omission by Nephros or any of its Affiliates or sublicensees or distributors), which Medica has not cured within thirty (30) days after receipt of written notice from Nephros detailing the Supply Interruption, including a listing of all outstanding purchase orders, not in limitation of any other rights or remedies available to Nephros under this Agreement or otherwise, Nephros shall be entitled to a reduction of 1% of the purchase price on the affected Products during the duration of the Supply Interruption and, once cured, for an additional period equivalent to the duration of the Supply Interruption. Notwithstanding the foregoing, no Supply Interruption will be deemed to have occurred if the applicable outstanding purchase orders referenced above exceed one hundred twenty percent (120%) of the applicable quantities of Product set forth in the forecast delivered by Nephros for the calendar quarter immediately preceding such purchase order. Medica shall be deemed to have cured such Supply Interruption upon delivery to Nephros of quantities of Product covered under such outstanding orders but only for that amount which does not exceed one hundred twenty percent (120%) of the applicable quantities of Product set forth in the forecast delivered by Nephros for the calendar quarter immediately preceding such purchase order.

5.6 Invoice. Medica shall invoice Nephros for all quantities of Product delivered in accordance herewith. Each invoice shall be delivered concurrently with each shipment of Product. In accordance with Section 4.5, payment shall be due within forty five (45) days after delivery of the invoice to Nephros; provided, however, that if Nephros rejects such shipment pursuant to Section 5.8, then payment shall be due within forty five (45) days after receipt by Nephros of replacement Product.

5.7 Price; Price Escalation. The price for Product delivered hereunder, including any applicable discounts relating to samples, shall be as set forth in the Pricing Schedule. Prices shall be subject to increase no more than once per annum, based upon documented increases in direct labor and material costs. Any price increase hereunder shall be implemented in the calendar year following the year in which the increase occurred and shall be subject to a three percent (3%) annual increase limit.

5.8 Product Not in Compliance with Purchase Order. Within thirty (30) days after receipt of any Product, Nephros or its agent shall perform an examination of the documentation, if any, provided with each shipment of Product, and shall determine whether such Product meets the requirements of the applicable purchase order. In the event that Nephros determines, within such thirty (30) day period, that any Product supplied by Medica does not conform to the applicable purchase order, Nephros shall give Medica written notice thereof and the reason(s) therefor within thirty (30) days after receipt thereof. If Nephros does not submit written notice of rejection within such thirty day period, such Product shall be deemed accepted by Nephros. If a shipment is rejected, Medica shall have the right, and if such right is exercised shall not be deemed in default hereunder to: (a) correct such shipment to conform to the applicable purchase order; or (b) grant Nephros a credit on that portion of the shipment that is nonconforming.

5.9 Inspections by Regulatory Authorities. Medica shall allow representatives of any Regulatory Authority to inspect the relevant parts of the facility where the Supply of Product is carried out and to inspect the lot, batch and other manufacturing records to verify compliance with cGMP and ISO 13485 and other Applicable Law and practices and shall promptly notify Medica of the scheduling of any such inspection relating to Supply, Medica shall promptly send to Nephros a copy of any reports, citations, or warning letters received by Medica in connection with an inspection by a Regulatory Authority to the extent such documents relate to or affect Supply.

6. Representations and Warranties.

6.1 Representations of Medica. Medica hereby represents and warrants to Nephros that the following statements are and shall be true and correct in all material respects.

6.1.1 Organization and Good Standing. Medica: (a) is an entity duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation; (b) has the entity power and authority to conduct the business in which it presently is engaged, to enter into this Agreement, and to perform its obligations hereunder; (c) is qualified to do business in, and is in good standing in, each jurisdiction where the nature of its business in such jurisdiction requires it to be so qualified; and (d) is in good standing with regard to manufacturing quality control with aspect to the requirements of the FDA and ISO or other jurisdictions in the Territory which Nephros intends to sell the Products.

6.1.2 Authorization and Binding Effect. All corporate action on the part of Medica and its officers and directors necessary for the authorization, execution, and delivery of this Agreement and for the performance of all of Medica's obligations hereunder has been taken, and this Agreement, when executed and delivered, shall constitute a valid and legally binding obligation of Medica enforceable against Medica in accordance with the terms of this Agreement, except as enforceability may be limited by bankruptcy, insolvency, and other laws affecting creditors' rights generally or by general equitable principles.

6.1.3 Execution, Delivery and Performance. The execution, delivery, and performance by Medica of this Agreement do not: (a) violate or breach the certificate of incorporation, articles of association, bylaws, or other constituent documents of Medica; (b) violate or conflict with any Applicable Law; (c) violate, breach, cause a default under, or otherwise give rise to a right of termination, cancellation, or acceleration with respect to (presently, with the giving of notice or the passage of time), any agreement, contract, or instrument to which Medica is a party or by which any of its assets are bound; or (d) result in creation or imposition of any lien, pledge, mortgage, claim, charge, or encumbrance upon any assets of Medica.

6.1.4 Governmental and Other Consents. No consent, authorization, license, Permit, registration or approval of, or exemption or other action by, any Person is required in connection with Medica's execution and delivery of this Agreement or with the performance by Medica of its obligations hereunder that has not been obtained.

6.1.5 Litigation. To Medica's knowledge, no Third Party has filed, or threatened in writing to file any claim, lawsuit, charge, complaint or other action alleging infringement of any Medica IP in the Territory.

6.1.6 Existence and Validity of Medica IP. Any registered Medica IP is valid and subsisting in the Territory.

6.1.7 Inconsistent Obligations. Medica has, as of the Effective Date, no obligation or commitment, and will not, during the Term, assume or undertake any obligation or commitment, that is inconsistent with its obligations under, or the terms and conditions of, this Agreement.

6.1.8 Supply of Product. Medica shall ensure its ability to supply Product in accordance with the terms of this Agreement.

6.1.9 Specifications and Regulatory Compliance. When supplied, the Products shall be manufactured in accordance with the applicable Specifications, and all other requirements of the FDA and other Applicable Laws and in accordance with cGMP and current E.U. Good Manufacturing Practices.

6.1.10 Approval. Medica has, and during the Term Medica shall maintain, all necessary and appropriate approvals with the FDA and each other applicable Governmental Authority to qualify Medica as a supplier of the Products, and Medica shall: (a) respond fully and accurately to all inquiries directed to it by any Governmental Authority (and Medici shall promptly notify Nephros of same and provide copies of all such written inquiries and Medica's written responses and submissions relating thereto); (b) assist Nephros in responding to inquiries directed to any of them by any Governmental Authority and relating to the Products; and (c) provide a Governmental Authority with such information and data as is requested by such Governmental Authority with respect to the manufacture of the Products (and Medial shall promptly provide copies thereof to Nephros).

6.2 Representations of Nephros. Nephros hereby represents and warrants to Medica that the following statements are and shall be true and correct in all material respects:

6.2.1 Organization and Good Standing. Nephros: (a) is a corporation duly organized, validly existing, and in good standing under the laws of Delaware; (b) has the corporate power and authority to conduct the business in which it presently is engaged, to enter into this Agreement, and to perform its obligations hereunder; and (c) is qualified to do business in, and is in good standing in, each jurisdiction where the nature of its business in such jurisdiction requires it to be so qualified.

6.2.2 Authorization and Binding Effect. All corporate action on the part of Nephros and its officers and directors necessary for the authorization, execution, and delivery of this Agreement and for the performance of all of Nephros' obligations hereunder has been taken, and this Agreement, when executed and delivered, shall constitute a valid and legally binding obligation of Nephros enforceable against Nephros in accordance with the terms of this Agreement, except as enforceability may be limited by bankruptcy, insolvency, and other laws affecting creditors' rights generally or by general equitable principles.

6.2.3 Execution, Delivery and Performance. The execution, delivery, and performance by Nephros of this Agreement do not: (a) violate or breach the certificate of incorporation, articles of association, bylaws, or other constituent documents of Nephros; (b) to the best of Nephros' knowledge, violate or conflict with any Applicable Law; (c) violate, breach, cause a default under, or otherwise give rise to a right of termination, cancellation, or acceleration with respect to (presently, with the giving of notice or the passage of time), any agreement, contract, or instrument to which Nephros is a party or by which any of its assets are bound; or (d) result in creation or imposition of any lien, pledge, mortgage, claim, charge, or encumbrance upon any assets of Nephros.

6.2.4 Governmental and Other Consents. No consent, authorization, license, Permit, registration or approval of, or exemption or other action by, any Person is required in connection with Nephros' execution and delivery of this Agreement or with the performance by Nephros of its obligations hereunder that has not been obtained.

6.2.5 Inconsistent Obligations. Nephros has, as of the Effective Date, no obligation or commitment, and will not, during the Term, assume or undertake any obligation or commitment, that is inconsistent with its obligations under, or the terms and conditions of, this Agreement.

7. Patents and Infringement Matters.

7.1 Prosecution and Maintenance of Patents.

7.1.1 Nephros shall have the right to prepare, file, prosecute, maintain, and extend all Patent Rights covering the Joint Patents and related applications. Nephros shall use commercially reasonable efforts to prepare, file, prosecute and maintain, and shall consult with Medica prior to abandoning any Joint Patents or related applications that are material to and relevant to the matters contemplated in this Agreement. If Nephros fails to undertake (or, after commencement of such filing, prosecution and/or maintenance, ceases) the prosecution or the maintenance of any such Patent Rights, then Medica shall have the right, at its election but not obligation, and Medica shall be entitled, at its sole cost and expense, to file, prosecute and/or maintain such Joint Patent in the Territory in the name of Nephros and shall be entitled to reimbursement for its expenses upon an agreed upon recovery schedule.

7.1.2 Each of the Parties shall execute or have executed by its appropriate agents such documents as may be necessary to obtain, perfect or maintain any Patent Rights covering the Joint Patents filed or to be filed pursuant to this Agreement, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such patent rights.

7.1.3 Nephros shall determine, in consultation with Medica, if a Joint Invention warrants patent protection, or whether it should be kept as a trade secret or know-how. If Nephros decides that a patent application should be prepared, filed and prosecuted as a Joint Invention, then the claims, strategy, timing and location of first filing said patent shall be mutually agreed upon by the Parties and costs shared equally or as otherwise agreed by the Parties. If Nephros decides not to go forward with a patent application the Joint Invention will remain know-how available to both Parties subject to Section 9 and neither Party shall publish on or license the know-how without the prior written agreement of the other Party.

7.2 Protection of the Joint Patents and Joint Inventions.

7.2.1 In case of an infringement of the Joint Patents or Intellectual Property rights covering the Joint Inventions in the Territory by a Third Party, Nephros shall decide whether to act or not in order to protect the Joint Patents or Joint Inventions in its sole discretion, Nephros shall have the sole and exclusive right to select counsel for any suit initiated pursuant to this Section 7.

7.2.2 In the event that Nephros determines not to act to protect the Joint Patents or ceases an enforcement action after commencement, Medica may, with prior written authorization by Nephros, act in order to protect the Joint Patents at its sole expense and retain any recovery in connection therewith, subject to reimbursement of any expenses incurred by Nephros in connection with an enforcement action commenced under Section 7.3.1.

7.2.3 If a Party is rewarded financially as a result of successfully enforcing the Joint Patents or Joint Inventions against an infringement, the Parties shall share in any such financial rewards in the amount determined in good faith by the Parties. If required under Applicable Law in order for the Party to initiate and/or maintain such suit, the other Party shall join as a party to the suit. The other Party shall, in any se, whether required by Applicable Law or not, offer reasonable assistance to the initiating Party in connection therewith.

7.3 Patent Invalidity Claims; Claimed Infringement.

7.3.1 If a Third Party at any time asserts a claim that any Joint Patents are invalid or otherwise unenforceable (an "Invalidity Claim") control of the response to such claim in the Territory shall, as between the Parties, be determined in the same manner as enforcement rights with lispct.t to such Joint Patents is determined pursuant to Section 7.2, and the non-controlling Party shall cooperate with the controlling Party in the preparation and formulation of such response, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. If an Invalidity Claim is asserted with respect to the Joint Patents or any Patent Rights covered by the Joint Inventions, the Parties shall cooperate and shall mutually agree upon an appropriate course of action and shall share equally in the cost and expense of such action.

7.3.2 In the event that a Party becomes aware of any claim that the practice by either Party of the Joint Patents, Intellectual Property rights covering Joint Inventions, the Medica IP, or the Nephros IP infringes the Intellectual Property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, the Parties shall cooperate and shall mutually agree upon an appropriate course of action Each Party shall provide to the other Part) copies of any notices it receives from third parties regarding any patent nullity actions, any declaratory judgment actions and any alleged infringement or misappropriation of Third Party Intellectual Property relating to the Commercialization, manufacture or supply of the Products. Such notices shall be provided promptly, but in no event after more than fifteen (15) days following receipt thereof.

8. Confidentiality.

8.1 General. Pursuant to the terms of this Agreement, each of Nephros and Medica (in such capacity, the "Disclosing Party") has disclosed and will be disclosing to the other Party, and to the officers, directors, employees, agents and/or representatives of each (in such capacity, the "Receiving Party") certain secret, confidential or proprietary data, trade secrets, know-how, intellectual property and related information, including, without limitation, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information ("Confidential Information"). The Receiving Party shall make no use of any Confidential Information of the Disclosing Party except in the exercise of its rights and the performance of its obligations set forth in this Agreement. The Receiving Party: (a) shall keep and hold as confidential, and shall cause its officers, directors, employees, agents and representatives to keep and hold as confidential, all Confidential Information of the Disclosing Party; and (b) shall not disclose, and shall cause its officers, directors, employees, agents and representatives not to disclose, arty Confidential Information of the Disclosing Party. A Disclosing Party's Confidential Information shall, at all times be and remain the property of the Disclosing Party, its Affiliates and/or licensors, which shall retain the sole and exclusive right, title and/or interest thereto. A Receiving Party shall have no right to use a Disclosing Party's Confidential Information except as expressly set forth in this Agreement.

8.2 Exceptions. The above restrictions on the use and disclosure of Confidential Information shall not apply to any information which: (a) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality); (b) is or becomes generally available to the public other than through any act or omission of the Receiving Party in breach of this Agreement; (c) is acquired by the Receiving Party from a Third Party who is not directly or indirectly under an obligation of confidentiality to the Disclosing Party with respect to same; or (d) is developed independently by the Receiving Party without use, direct or indirect, of Confidential Information. In addition, nothing in this Section 8 shall be interpreted to limit the ability of either Party to disclose its own Confidential Information to any other Person on such terms and subject to such conditions as it deems advisable or appropriate. Notwithstanding anything in this Agreement to the contrary, during the Term Medica shall keep and hold as confidential the trade secrets and know-how relating to the manufacturing of fiber for the Products without regard to Section 8.1.

8.3 Permitted Disclosure. It shall not be a breach of Section 8.1 if a Receiving Party discloses Confidential Information of a Disclosing Party: (a) pursuant to Applicable Law, including securities laws applicable to a public company, to any Governmental Authority; or (b) in a judicial, administrative or arbitration proceeding to enforce such Party's rights under this Agreement; provided, that, the Receiving Party (i) provides the Disclosing Party with as much advance written notice as possible of the required disclosure, (ii) reasonably cooperates with the Disclosing Party in any attempt to prevent, limit or seek confidential treatment for the disclosure, and (iii) discloses only the minimum amount of Confidential Information necessary for compliance.

8.4 Confidential Terms. Each Party acknowledges and agrees that the terms and conditions of this Agreement shall be considered Confidential Information of each Party and shall be treated accordingly. Notwithstanding the foregoing, each Party acknowledges and agrees that the other may be required to disclose some or all of the information included in this Agreement in order to comply with its obligations under securities laws, and hereby consents to such disclosure to the extent deemed advisable or appropriate by its respective counsel (but only after consulting with the other to the extent practicable). The Parties may also disclose the existence of this Agreement and terms thereof to their directors, investors, officers, employees, attorneys, accountants and other advisers on a need to know basis provided such Persons are under obligations of confidentiality substantially similar to this Section 8.

8.5 Equitable Remedies. Each Party specifically recognizes that any breach by it of this Section 8 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available.

8.6 Return. Upon the expiration or termination of this Agreement, or at any time at Disclosing Party's request: (a) Receiving Party shall promptly return to Disclosing Party or destroy all materials (in written, electronic or other form) containing or constituting Proprietary Information of Disclosing Party, including any copies and extracts thereof; and (b) Receiving Party shall not use such Confidential Information in any way for any purpose.

8.7 Electronic Copy. As an exception to Section 8.6, the Receiving Party will be able to make an electronic copy of the materials returned to the Disclosing Party for legal compliance obligations, and the Receiving Party shall not be required to destroy any computer files stored securely by the Receiving Party that are created during automatic system back-up, provided, however, that the same confidentiality and non-use obligations as agreed in the Agreement shall remain valid for so long as such back-up exists.

9. Indemnification; Limitation of Liability.

9.1 Indemnification by Medica. Medica shall, at its cost and expense, indemnify on demand, defend, and forever hold harmless Nephros and its Affiliates from and against any Claim arising out of or resulting from: (a) any breach by Medica or any of its Agents or Affiliates of an) obligation, representation, or warranty of Medica under this Agreement; (b) any negligence, error, or omission by Medica or any of its Agents of Affiliates with respect to its or their obligations under or by reason of this Agreement; (c) any violation of Applicable Law that materially adversely impacts Nephros; (d) any fine, penalty, litigation cost, or other assessment of any kind, including, without limitation, those levied by any Governmental Authority; or (e) infringement by the Product resulting from the Improvements of a patent or trademark of any Person, except to the extent that any such Claim shall be within the indemnification obligations of Nephros under Section 9.2.

9.2 Indemnification by Nephros. Nephros shall, at its cost and expense, indemnify on demand, defend, and forever hold harmless Medica and its Affiliates from and against any Claim arising out of or resulting from: (a) any breach by Nephros or any of its Agents of any obligation, representation, or warranty of Nephros under this Agreement; (b) any negligence, ann., or omission by Nephros or any of its Agents with respect to its or their obligations under this Agreement; or (c) any violation of Applicable Law that materially adversely impacts Medica, except to the extent that any such Claim shall be within the indemnification obligations of Medica under Section 9.1.

9.3 Procedure for Indemnification.

9.3.1 Notice. In the case of a Claim made by Third Party (a "Third Party Claim") as to which a Party (the "Indemnitor") may be obligated to provide indemnification pursuant to this Agreement, such Party seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually materially prejudiced as a result of such failure.

9.3.2 Defense of Claim. If a Third Party Claim is made against an Indemnitee, the Indemnitor will be entitled, within thirty (30) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof by providing written notice to Indemnitee of its intention to assume the defense of such Third Party Claims within mid thirty (30) day period (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of a Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnitor and the Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided, further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one separate counsel for such Indemnitee. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all correspondence and documents relating to or In connection with such Third Party Claim and keep the Indemnitee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnitee (including, without limitation, providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control by written acknowledgement of the defense of any Third Party Claim within the thirty day period set forth above, or if such good faith and diligent defense Is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, after three (3) business days' notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

9.3.3 Settlement of Claims. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee will agree to a reasonable settlement, compromise or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Liabilities (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and Irrevocably releases the Indemnitee completely from all Liabilities in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise or discharge (including, without limitation, the consent to entry of any judgment), and the Indemnitee may refuse to agree to any such settlement, compromise or discharge, that provides for injunctive or other nonmonetary relief affecting the Indemnitee. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee shall not (unless required by Law) admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnitor's prior written consent (which consent shall not be unreasonably withheld, delayed or conditioned).

9.4 Assumption of Defense. Notwithstanding anything to the contrary contained herein, an Indemnitee shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnitee upon written notice to the Indemnitor pursuant to this Section 9.4. In which case, the Indemnitor shall be relieved of liability under Section 9.1 or 9.2, as applicable, solely for such Third Party Claim.

9.5 Direct Claims. Any Claim which does not involve a Third Party Claim (a "Direct Claim") shall be asserted by reasonably prompt written notice (stating in reasonable detail, the basis of such claim and a reasonable estimate of the amount thereof) given by the Indemnitee to the Indemnitor. For a period of sixty (60) days from and after the receipt of the written notice the Parties shall attempt in good faith to resolve such Direct Claim. If the parties are unable to resolve such Direct Claim, the party seeking recourse may thereafter institute proceedings under Section 11.13 to enforce said Direct Claim.

9.6 Limitation of Liability. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT APPLY IN CASES OF FRAUD OR BREACHES OF THIS AGREEMENT MADE INTENTIONALLY IN BAD FAITH OR IN RECKLESS DISREGARD FOR THE PROVISIONS OF THIS AGREEMENT AND SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FOR THIRD PARTY CLAIMS UNDER THIS SECTION 9.

10. Term and Termination.

10.1 This Agreement shall commence on the Effective Date and shall continue in effect through December 31, 2028 ("Term"), or until terminated by either Party in accordance with this Agreement.

10.2 Either Party shall have the right to terminate this Agreement at any time for a material breach of this Agreement by the other Party, provided that the non-breaching Party shall have first given thirty (30) days prior written notice to the breaching Party describing such material breach and stating the non-breaching Party's intention to terminate this Agreement if such material breach remains uncured, and the breathing Party thereafter fails to cure such material breach within thirty (30) days thereafter.

10.3 This Agreement may be terminated by Medica upon written notice upon Nephros' failure to cure a monetary default under this Agreement within thirty (30) days after written notice thereof is provided to Nephros.

10.4 This Agreement may be terminated by Nephros upon ninety (90) days' written notice to Medica for convenience.

10.5 If either Party becomes insolvent, makes an assignment for the benefit of its creditors, is placed in the hands of a receiver or liquidates its business, and such action is not cured within thirty (30) days, then, in any such case, the other Party shall have the immediate right, in its sole discretion, to terminate this Agreement by giving written notice to that Party.

10.6 No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have for any acts or omissions or breach hereunder by the other Party prior to the termination date.

10.7 The following provisions shall survive the expiration or termination of this Agreement: Section 1, Section 3.4, Section 5, Section 7, Section 8, Section 9, , this Section 10.7, Section 11 and provisions relating to accrued payment obligations.

11. Miscellaneous.

11.1 Compliance with Laws. At all times during the Term, each Party shall comply in all material respects with Applicable Law in effect in the Territory that is applicable to the Products or the conduct of business under this Agreement.

11.2 Independent Contractor. Neither Nephros nor Medica, together in each case with their respective employees or representatives, are under any circumstances to be considered as employees, partners, joint venturers, agents or representatives of the other by virtue of this Agreement, and neither shall have the authority or power to bind the other or contract in the other's name.

11.3 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given when so delivered in person, by overnight courier, or by facsimile transmission (with receipt confirmed by automatic transmission report), as follows:

If to Nephros:	Nephros, Inc. 380 Lackawanna Place South Orange, New Jersey 07079 USA Attn: Mr. Robert Banks, President & CEO robert.banks@nephros.com and info@nephros.com Facsimile: +1.201.343.5207
If to Medica:	Medica S.p.A. Via Degli Artigiani, 7 41036 Medolla (MO) - ITALY Attn: Marco Fecondini, CEO marco.fecondini@medica-spa.com Facsimile: (+39) 0535 52605

Either Party may by notice given in accordance with this Section 11.3 to the other Party designate another address or person for receipt of notices hereunder.

11.4 Binding Effect; No Assignment; No Third Party Beneficiaries. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Neither Nephros nor Medial may assign any of its rights or delegate any of its liabilities or obligations hereunder without the prior written consent of the other whether in connection with a Change of Control or otherwise. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than Medica and Nephros and their respective successors and permitted assigns any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement, except for Affiliates entitled to indemnification pursuant to Section 9.

11.5 No Implied Waivers; Rights Cumulative. No failure on the part of Nephros or Medica to exercise and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, including the right or power to terminate this Agreement, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

11.6 Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

11.7 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance (except for any obligation for the payment of money), in whole or in part, nor shall the other Party have the right to terminate this Agreement except us otherwise specifically provided in this Section 11.7, where delivery or performance has been affected by a condition beyond a Party's reasonable control, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority; provided that the Party affected by such a condition shall, within ten (10) days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its best efforts to remedy us inability to perform; provided, however, that in the event the suspension of performance continues for ninety (90) days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the other Party.

11.8 Section Headings; Construction. The headings of Sections in this Agreement are provided for convenience only and shall not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement. All words used in this Agreement shall be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms and shall be deemed to be following by the words "without limitation."

11.9 Amendment; Waiver. This Agreement may not be amended except by an instrument signed by each of the Parties hereto. Any Party hereto may: (a) extend the time for the performance of any of the obligations or other acts of another Party hereto; or (b) waive compliance with any of the agreements of another Party or any conditions to its own obligations, in each case only to the extent such obligations, agreements, or conditions are intended for its benefit; provided, however, that any such extension or waiver shall be binding upon a Party only if such extension or waiver is set forth in a writing executed by such Party.

11.10 Rules of Construction. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or ruling of construction providing that ambiguities in an agreement or other document shall be construed against the Party drafting such agreement or document.

11.11 Publication. Nephros and Medical agree not to issue any press relate or other public statement disclosing the existence of or relating to this Agreement or the Ancillary Agreements without the express written consent of the other Party; provided, however, that neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law, including securities laws applicable to a public company, subject to notifying the other Party in writing and giving such other Party reasonable time to comment on the same prior to disclosure.

11.12 Expenses. Except as expressly set forth herein, each Party hereto shall bear all fees and expenses incurred by such Party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, including attorneys', accountants' and other professional fees and expenses.

11.13 Governing Law/Disputes. This Agreement shall be construed and governed in all respects, and the respective rights of the Parties determined, according to the substantive laws of the State of New York, U.S., without regard to its conflict of laws principles. The application of the United Nations Convention on Contracts for the International Sales of Goods is hereby expressly excluded. Any controversy or claim arising out of or relating to this Agreement or the applicability of this Section 11.13 that is not resolved amicably will be determined by binding arbitration under the Rules of Arbitration of the International Chamber of Commerce. Such arbitration shall be conducted by a sole arbitrator mutually selected by written agreement of the Parties. In the event that the Parties are not able to mutually select the sole arbitrator, the arbitration shall be conducted by a panel of three (3) arbitrators, consisting of one neutral arbitrator to be selected by each of the Parties and a third neutral arbitrator to be selected jointly by the two (2) arbitrators selected by the Parties. Each arbitrator shall be an attorney actively engaged in the practice of law for at least ten (10) years and shall have experience with and knowledge of the medical device industry. The place of the arbitration will be New York, New York. The language of the arbitration shall be English. Prior to commencement of hearings, each of the arbitrators appointed must provide an oath of impartiality. Judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The cost of any such arbitration shall be divided equally by Nephros and Medica, with each Party bearing its own attorneys' fees and costs. Notwithstanding anything to the contrary contained in this Agreement, either Party shall has the right to bring an action or Claim for interim measures, including specific performance or injunctive relief in order to preserve its rights or enforce the obligations of the other Party under this Agreement, in any court of competent jurisdiction or having jurisdiction over any of the Parties or their respective assets, without the need to submit such matter to arbitration under this Section 11.13.

11.14 Entire Agreement. The Parties expressly agree that the Prior Agreement is hereby terminated. This Agreement together with its Schedules, contains the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements, written or oral, among the Parties thereto.

11.15 Counterparts; Electronic Transmissions. This Agreement may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Electronic transmissions of this Agreement (e.g., fax, .pdf, etc.), and reproductions thereof, signed by the Parties shall in all respects be deemed to be originals.

[*Signatures on follow page*]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

NEPHROS, INC.

By: */s/ Robert Banks*
Robert Banks
President & Chief Executive Officer

MEDICA, S.p.A.

By: */s/ Marco Fecondini*
Marco Fecondini
Chief Executive Officer

Schedule 1

JOINT PATENTS

Device Name: **Dual-Stage Ultrafilter (DSU)**
REDUNDANT ULTRAFILTRATION

Official Patent Title DEVICES

ISSUED PATENTS

Country	Grant Date	Expiration Date	Grant No.
United States	17-Aug-10	June 15, 2026	7,775,375

Schedule 2

Products

Any water and dialysate solution filtration products of Nephros or Medica based in whole or in part upon Medica's proprietary Medisulfone fiber technology and/or other polysulfone based hollow fiber or technology having a nominal pore size of less than 0.2 micron in existence as of the Effective Date or developed at any time during the Term.

The following Medica products are excluded from this License and Supply Agreement:

- Blood, plasma and haemoderivates filtration products (not including MD220 for HDF)
- Filtration products manufactured by Medica or Medica USA and sold by Evoqua as of the date of the Asset deal signed in April 2023 between Medica and Evoqua. Medica will not provide, sell, or distribute products to Evoqua consisting of membranes included in the products licensed to Nephros under this agreement.
- Fluid concentration/clarification/purification products related to the life science/bioprocessing field (perfusion and harvesting).
- Filters based on Graphene technology. Medica will allow Nephros the right of first refusal to distribute Graphene technology products.
- Ultrafilter for Mozarc Medtronic machine

Schedule 3
Pricing

[*****]

Exhibit 21.1

Subsidiaries of Nephros, Inc.

Name	Jurisdiction	Percentage Equity
Biocon 1, LLC	Nevada	100%
Aether Water Systems, LLC	Nevada	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements of Nephros, Inc. on Form S-8 (Nos 333-127264; 333-148236; 333-188592; 333-205167; 333-223849; 333-232707, 333-238563 and 333-256712) and on Form S-3 (Nos 333-225109, 333-232708, 333-234528 and 333-259370), of our report dated March 15, 2024, relating to the consolidated financial statements of Nephros, Inc. as of and for the years ended December 31, 2023 and 2022, which appears in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Baker Tilly US, LLP

Tewksbury, Massachusetts
March 15, 2024

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Banks, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Nephros, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 15, 2024

/s/ Robert Banks

Robert Banks
President, Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Judy Krandel, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Nephros, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15€ and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 15, 2024

/s/ Judy Krandel

Judy Krandel
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF 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

In connection with the Annual Report on Form 10-K of Nephros, Inc. (the "Company") for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Banks, President, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 15, 2024

/s/ Robert Banks

Robert Banks
President, Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF 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

In connection with the Annual Report on Form 10-K of Nephros, Inc. (the "Company") for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Judy Krandel, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 15, 2024

/s/ Judy Krandel

Judy Krandel
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

NEPHROS, INC.

Policy for the Recoupment of Erroneously Awarded Compensation

Description

Nephros, Inc., a Delaware corporation (the "***Company***"), has adopted this Policy for the Recoupment of Erroneously Awarded Compensation (the "***Policy***"), pursuant to the requirements of Nasdaq Listing Rule 5608 and Securities Exchange Act Rule 10D-1. The Policy sets forth the circumstances under which the Company will recoup certain incentive compensation paid to the Executive Officers of the Company in connection with certain financial restatements.

Each Executive Officer is required to sign and return to the Company the Acknowledgement Form attached hereto as Exhibit A, pursuant to which such Executive Officer will agree to be bound by the terms and comply with this Policy in exchange for adequate and reasonable consideration; *provided, however*, that any failure by an Executive Officer to return a signed Acknowledgement Form does not affect the validity or enforceability of this Policy.

Definitions

(A) "***Clawback Period***" means the three completed fiscal years immediately preceding the earlier of (i) the date the Company's board of directors concludes, or reasonably should have concluded, that a Covered Accounting Restatement is required to be prepared or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Covered Accounting Restatement, in either case regardless of if or when such Covered Accounting Restatement is filed (such date, the "***Clawback Trigger Date***"), and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(B) "***Committee***" means the Compensation Committee of the Board of Directors of the Company.

(C) "***Covered Accounting Restatement***" means an accounting restatement prepared due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial restatements (i.e., a "Big R" restatement), or that would result in a material misstatement if the error were corrected only in the current period or left uncorrected in the current period (i.e., a "little r" restatement). For the avoidance of doubt, a Covered Accounting Restatement will not include changes to the Company's financial statements that do not represent error corrections under accounting standards applicable to the Company at the time of the accounting restatement, including as a result of a (i) retrospective application of a change in accounting principle, (ii) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization, (iii) retrospective reclassification due to a discontinued operation, (iv) retrospective application of a change in reporting entity, and (v) retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(D) "***Covered Incentive-Based Compensation***" means any Incentive-Based Compensation (i) received by a current or former Executive Officer after beginning service as an Executive Officer, provided that the current or former Executive Officer served as an Executive Officer at any time during the performance period applicable to such Incentive-Based Compensation, (ii) received on or after **[**December 1**]**, 2023 (the "***Effective Date***"), and (iii) received while the Company had a listed class of securities on a national securities exchange. For purposes of this Policy, Incentive-Based Compensation is deemed to be "received" in the fiscal year in which the financial reporting measure included in the Incentive-Based Compensation award is attained or satisfied, regardless of whether the payment or grant occurs before or after such fiscal year, and regardless of whether the Incentive-Based Compensation continues to be subject to a service-based vesting condition.

(E) "***Executive Officer***" has the meaning assigned to it in Nasdaq Listing Rule 5608(d).

(F) "***Financial Reporting Measure***" means (i) any measure determined in accordance with accounting principles used in the Company's financial statements, whether presented in or outside of the Company's financial statements and whether or not included in a filing with the Securities and Exchange Commission, (ii) any measures derived wholly or in part from such measures (including non-GAAP measures), and (iii) other performance measures affected by accounting-related information, including stock price, total shareholder return and relative total shareholder return.

(G) "***Incentive-Based Compensation***" means any compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure, which may include awards granted under the Company's annual incentive plan as well as performance-based restricted stock units, and which may include Incentive-Based Compensation contributed to a plan, other than a tax-qualified retirement plan. For the avoidance of doubt, Incentive-Based Compensation shall not include equity awards that vest solely based on continued service and were not granted based on the attainment of any Financial Reporting Measure or any bonus compensation based on discretionary or subjective goals or goals that are not based on any Financial Reporting Measure.

(H) "***Sarbanes-Oxley Act Section 304***" means Section 304 of the Sarbanes-Oxley Act of 2002.

General Rules

In the event the Company determines it is required to prepare a Covered Accounting Restatement, the Committee shall review any Covered Incentive-Based Compensation received by a current or former Executive Officer of the Company during the Clawback Period. In the event the Committee determines that the amount of any such Covered Incentive-Based Compensation that was received during the Clawback Period exceeds the amount that otherwise would have been received had it been determined based on the restated results (the "***Erroneously Awarded Compensation***"), the amount of such Erroneously Awarded Compensation shall be recouped on a pre-tax basis.

Recoupment under this Policy with respect to an Executive Officer shall not require the finding of any misconduct by such Executive Officer or such Executive Officer being found responsible for the accounting error leading to the Covered Accounting Restatement.

For purposes of this section, Incentive-Based Compensation is deemed to be "received" in the fiscal year in which the financial reporting measure included in the Incentive-Based Compensation award is attained or satisfied, regardless of whether the payment or grant occurs before or after such fiscal year.

Calculation of Erroneously Awarded Compensation

In the event any applicable Covered Incentive-Based Compensation has been granted in the form of equity or equity-based awards, and such awards remain outstanding as of the Clawback Trigger Date, the Erroneously Awarded Compensation shall be calculated as the number of shares received in excess of the number that should have been received (or the corresponding value of such shares). In the event that any applicable Covered Incentive-Based Compensation is in a nonqualified deferred compensation plan, the Company shall calculate the amount contributed to the notional account based on the Erroneously Awarded Compensation and any earnings accrued to-date on that notional amount, and that sum shall be considered "Erroneously Awarded Compensation" with respect to that plan.

For the avoidance of doubt, in the event Covered Incentive-Based Compensation is attained only partially based on the achievement of financial reporting measures, only the portion of such compensation based on or derived from the financial reporting measures shall be subject to recoupment.

In the event the Erroneously Awarded Compensation is not able to be calculated directly from information in an accounting restatement (e.g., equity awards subject to total shareholder return ("***TSR***") or stock price measures), in order to determine the amount of such Erroneously Awarded Compensation that shall be subject to recoupment, the Committee shall use a reasonable estimate of the effect of the Covered Accounting Restatement on the TSR or stock price upon which the Covered Incentive-Based Compensation was received (in which case the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to The Nasdaq Stock Market).

Method for Recoupment

The Committee shall, in its discretion, determine the appropriate means for recoupment of any Erroneously Awarded Compensation, including but not limited to the cancellation of outstanding and future annual or long-term incentive compensation or requiring repayment by the applicable Executive Officer, provided that the recoupment occurs reasonably promptly. For the avoidance of doubt, the Committee may, subject to compliance with applicable law, affect recoupment under this Policy from any amount otherwise payable to the applicable Executive Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by such Executive Officer. The Committee may consider all applicable facts and circumstances in determining the appropriate means for recoupment, including pursuing an appropriate balance of cost and speed.

Recoupment shall be required in all circumstances unless the Committee determines that it would be impracticable and that one of the conditions set forth in in accordance with Nasdaq Listing Rule 5608(b)(1)(iv).

Non-Exclusive; Conflicts

This Policy is in addition to any and all other rights the Company may have to pursue remedies against an employee or former employee in connection with an accounting restatement or for misconduct or similar behavior in the course of employment by the Company, all of which are expressly retained by the Company. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies, including termination of employment and institution of legal proceedings, as well as rights of repayment, forfeiture, offset or recoupment that may be available to the Company pursuant to any other forfeiture policy or similar provisions in any employment agreement, equity award agreement or similar agreement, or any other legal remedies available to the Company. Nothing in this Policy restricts the Company from seeking recoupment under any other compensation recoupment Policy or any applicable provisions in plans, agreements, awards or other arrangements that contemplate the recoupment of compensation from an Executive.

The Company's rights under this Policy are in addition to the reimbursement provisions of Sarbanes-Oxley Act Section 304; *provided*, that any amounts paid pursuant to Sarbanes-Oxley Act Section 304 will be considered in determining any amounts recovered under this Policy.

The Company will not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recoupment of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

The provisions of this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision shall be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

Indemnification Prohibition

The Company is not permitted to indemnify any Executive Officer against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned, recovered or recouped pursuant to the terms of this Policy, or (ii) any claims relating to the Company's enforcement of its rights under this Policy. The Company is also prohibited from paying or reimbursing an Executive Officer for purchasing insurance to cover any such loss. To the extent of a conflict with any agreement with an Executive Officer that purports to provide indemnification rights to the Executive Officer that conflict with the foregoing, this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

Reporting and Disclosure

The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by applicable Securities and Exchange Commission filings.

Amendment or Termination

The Committee may amend or terminate this Policy from time to time in its discretion, including as required to comply with any applicable law or regulation. Any such amendment will be binding on employees who continue in the employment after the effective date of such amendment.

Administration

The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Committee has full and final authority to make all determinations under this Policy, in each case to the extent permitted under applicable rules and regulations and in compliance with (or pursuant to an exemption from the application of) Section 409A of the Internal Revenue Code. All determinations and decisions made by the Committee hereunder shall be final, conclusive and binding on all persons.

Any action or inaction by the Committee with respect to an Executive Officer under this Policy in no way limits the Committee's actions or decisions not to act with respect to any other Executive Officer under this Policy or under any similar policy, agreement or arrangement, nor shall any such action or inaction serve as a waiver of any rights the Company may have against any Executive Officer other than as set forth in this Policy.

This Policy is intended to comply with the requirements set forth in Nasdaq Listing Rule 5608 (as such rule may be amended from time to time) and shall be construed and interpreted in accordance with such intent.

Successors

This Policy shall be binding and enforceable against all Executive Officers and, to the extent required by applicable law or guidance from the Securities and Exchange Commission or Nasdaq, their beneficiaries, heirs, executors, administrators, and other legal representatives.

Governing Law; Venue

The validity, enforceability, construction and interpretation of this Policy shall be governed by and construed exclusively in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles of any jurisdictions.

Exhibit A

Acknowledgement Form

NEPHROS, INC.

Policy for the Recoupment of Erroneously Awarded Compensation

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Nephros, Inc. Policy for the Recoupment of Erroneously Awarded Compensation (the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees, in exchange for receipt of adequate and reasonable consideration, that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation to the Company to the extent required by, and in a manner consistent with, the Policy and the Committee's determinations thereunder.

_____

Signature

_____

Printed Name

_____

Date