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, 2024

☐ **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, 2024, was $14,091,124. 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, 2024. 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, 2024.

As of March 17, 2025, there were 10,600,350 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 2025 Annual Meeting of Stockholders (the "2025 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2025 Proxy Statement will be filed within 120 days of December 31, 2024.

NEPHROS, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

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 the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the timeline for regulatory approval of our products, the availability of funding sources for continued development of such products, 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; and
- 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, heavy metals, chemical compounds, scale build-up in downstream equipment, and other various contaminants. 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 addition to VARs, we also utilize a direct salesforce that targets key geographic regions throughout the country, as well as focuses on the hospital and dialysis markets.

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. Centers for Disease Control and Prevention ("CDC") 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. These policies must be in accordance with The American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 188-2015 and the CDC toolkit. Facilities must regularly monitor water systems and take corrective actions when needed to ensure safe water for patients, residents and visitors. 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 American Journal of Kidney Diseases, 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 with Donastar LLC 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 Donastar, which superseded the March 2022 agreement. Under the January 2023 agreement, we engaged Donastar to be our exclusive distributor to the food, beverage and hospitality industries. Effective September 2024, we ended our exclusive relationship with Donastar. Although Donastar continues to distribute our products on a non-exclusive basis, we are expanding our distribution in the commercial market in order 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 provide 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.

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, 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, 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, the Company granted to 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. As of December 11, 2023, the Company has agreed with Medica 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, as discussed above, we had contracted with Donastar LLC as our exclusive distributor. Effective September 2024, we ended our exclusive relationship with Donastar. Although Donastar continues to distribute our products on a non-exclusive basis, we are broadening our market reach through new distributor relationships. 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, 2024 and 2023, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2024	2023
A	25%	23%
B	8%	11%
Total	33%	34%

As of December 31, 2024 and 2023, the following customer accounted for the following percentage of our accounts receivable:

Customer	2024	2023
A	13%	12%

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 Company and Pentair, which 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 end stage renal disease ("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, 2024, we had five U.S. patents and one Canadian patent. Notably, the fifth U.S. patent, granted in 2024, pertains to filter technologies, including liquid purification filter systems that are particularly suited for use in harsh environments.

Trademarks

As of December 31, 2024, in the United States, we secured registrations of the trademarks ENDOPUR, HYDRAGUARD, NANOGUARD, and NEPHROS. In the US, we filed one trademark application 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 endotoxins. 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.

Regulatory Authorities in Regions Outside of the United States

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 devices. It assists in providing hemodialysis quality water or bicarbonate concentrate. 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 (RO, DI, etc.).
- *EndoPur Filters:* Is intended to be used to filter water used with 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.).

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, 2024, we employed a total of 31 full-time employees, including 12 employed in sales/marketing/customer support, 13 in logistics, general, and administrative, and 5 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 2024, 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 be able to maintain or improve our profitability in the future.

As of December 31, 2024, we had an accumulated deficit of $144.3 million as a result of prior historical operating losses. While we believe that revenues will increase following our expansion of the sales team in 2024, 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 sold our first commercial product in March 2004, and the year ended December 31, 2024 was only our first profitable year in our history with net income of $0.1 million. 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 maintain 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, our revenues declined slightly in 2024 compared to 2023. There is no assurance that we will be able to resume 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 maintaining profitability. Our ability to grow our customer base also depends on our ability to achieve further 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 maintain commercialization of 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 maintain commercial success of our products, could 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.

The revenue from our emergency response business is unpredictable and is subject to factors outside our control. As a result, our revenue and operating results may vary significantly from period to period.

A portion of our revenue is derived from the sale of our filtration products to address outbreaks of waterborne pathogens in hospitals and other buildings and facilities, which we sometimes refer to as our emergency response (ER) business. In these situations, building operators often look to us to install our filtration systems in order to immediately remediate an active outbreak. However, the frequency, timing and severity of such outbreaks are unpredictable. During periods in which several outbreaks occur across the territories we serve we may see a significant increase in the demand for our filtration products, leading to increased sales. On the other hand, during periods when only a small number of outbreaks occur, we see reduced demand for our products. Given the difficulty in predicting the timing and magnitude of sales based on our ER business, we may experience quarter-to-quarter fluctuations in revenue resulting in the potential for a sequential decline in quarterly revenue.

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, if needed, provide 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, following the termination of our exclusive distribution relationship with Donastar in the food, beverage and hospitality markets, our ability to grow sales in our commercial business will depend largely on the efforts of new distribution partners in these 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 are dependent on third parties to supply us with our products, 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, Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company. Our agreement with Medica will expire in 2028 and although we believe 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 Medica and our other 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 may experience a disruption in the supply of certain components and raw materials, as happened during the worldwide pandemic starting in 2020. A disruption in such items as resins and polymers, could 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. In addition, with the change in U.S. presidential administration in January 2025, there is increased risk of new tariffs which could also affect the prices we pay for critical supplies and materials.

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 are subject to minimum purchase obligations under our License and Supply Agreement with Medica and failure to meet these minimum purchase requirements may result in termination of the agreement, which could materially impact our ability to obtain our filtration products.

On December 11, 2023, we entered into a license and supply agreement (the "License and Supply Agreement") with Medica for the marketing and sale of certain filtration products based upon Medica's proprietary ultrafiltration technology in

conjunction with our filtration products (collectively, the "Products"), and to engage in an exclusive supply arrangement for the Products, meaning Medica is our sole supplier for the filter material used in certain of our products. Under the License and Supply Agreement, Medica granted to us 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, we granted to Medica an exclusive license under our intellectual property to make the Products during the term of the License and Supply Agreement.

In exchange for the rights granted, we have agreed to make minimum annual aggregate purchases from Medica of €4,208,000, €4,629,000, €4,976,000, €5,349,000 and €5,750,000 for the years 2024, 2025, 2026, 2027 and 2028, respectively. We satisfied our minimum purchase obligations for 2024, but if we are unable to satisfy the minimum purchase commitments in future years, we may be in breach of the License and Supply Agreement, giving Medica a right of termination. If the License and Supply Agreement is terminated, we may be unable to obtain our filtration products from an alternative supplier on commercially favorable terms, if at all. If we are unable to obtain our filtration products from an alternative supplier, we may be unable to supply our products to our customers, which could have a material adverse effect on our results of operations and damage our reputation.

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. We have limited resources to add sales and marketing professionals at this time. Accordingly, our success will depend on our ability to continue developing and retaining our personnel. Our ability to increase our sales revenue may be materially impaired if we experience attrition in our sales and marketing organization or if we are unsuccessful in developing our sales personnel.

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. 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 any of our future products by 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 FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The FDA 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 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 United States.

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 5 granted U.S. patents will expire at various times from 2029 to 2044, assuming they are properly maintained.

The protection provided by our patents 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, 2024, our common stock has traded at prices ranging from a high of $4.04 to a low of $0.95 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, 2025, Wexford, our largest stockholder, beneficially owned approximately 34% 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 Our Overall Business and Operations – We rely on information technology systems and network infrastructure…" 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. 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, 2024, there were approximately 41 holders of record of our common stock. The actual number of holders of common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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, 2024, 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 2024.

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. In May 2022, SRP received 510(k) clearance from the FDA for 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.

Inventory Reserves

We value our inventories at the lower of cost or net realizable value using the first-in, first-out method, whereby we make estimates regarding the value of our inventories, including an assessment of excess and obsolete inventories. We utilize both specific product identification and historical product demand as the basis for estimating our excess or obsolete inventory reserve. A portion of our inventories are subject to expiration dating, which can be extended in certain circumstances. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, and apply a consistent policy to estimate the reserve, unless circumstances change that would require us to reassess our policy such as a sudden and significant decline in demand for our products, new technology, or macroeconomic conditions. If inventory is written down, a new cost basis is established that cannot be increased in future periods.

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, 2024, compared to the Fiscal Year Ended December 31, 2023

The following table sets forth our summarized, consolidated results of operations for the years ended December 31, 2024 and 2023 (in thousands except percentages):

	Years Ended December 31,		$ Increase (Decrease)	% Increase (Decrease)
	2024	2023		
Total net revenues	$ 14,162	$ 14,238	$ (76)	(1)%
Cost of goods sold	5,439	5,833	(394)	(7)%
Gross margin	8,723	8,405	318	4%
Gross margin %	62%	59%	-	3%
Research and development expenses	906	873	33	4%
Depreciation and amortization expenses	135	214	(79)	(37)%
Selling, general and administrative expenses	7,676	8,911	(1,235)	(14)%
Operating Income (loss)	6	(1,593)	1,599	(100)%
Interest expense	(1)	(2)	1	(50)%
Interest income	94	64	30	47%
Other (expense) income, net	(10)	(44)	34	(77)%
Income (loss) before income taxes	89	(1,575)	1,664	(106)%
Income tax expense	(15)	-	(15)	-
Net Income (loss)	$ 74	$ (1,575)	1,649	(105)%

Net Revenues.

Total net revenues decreased 1% in the year ended December 31, 2024. This decrease was primarily driven by decreased revenue from emergency response orders, which were unusually large in 2023 but not repeated to the same degree in 2024. We believe that one contributor to this decline is the reduced stringency of waterborne risk response in territories previously committed to both proactive filtration measures and robust corrective actions. Consequently, we experienced the effects of a relaxation of requirements for emergency relief and remediation. However, the decrease in emergency response orders was partially offset by increased revenue from programmatic or recurring sales, which were 9% more than the same period in 2023. This increase in programmatic sales was due to the development of our newer sales personnel hired in 2023 and a number of new customer accounts.

Gross Profit Margin

Gross profit margin was approximately 62% for the year ended December 31, 2024, compared to approximately 59% for the year ended December 31, 2023. The increase of approximately 3 percentage points reflects more favorable terms with our largest supplier.

Research and Development Expenses

Research and development expenses increased 4% primarily due to an increase in headcount.

Depreciation and Amortization Expense

Depreciation and amortization expenses were $0.1 million for the year ended December 31, 2024, and $0.2 million for the year ended December 31, 2023.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $1.2 million or 14%, primarily due to a decrease in stock compensation, bonus, and commission expense

Interest Expense

Interest expense was approximately $1,000 for the year ended December 31, 2024, compared to $2,000 for the year ended December 31, 2023.

Interest Income

Interest income was approximately $94,000 for the year ended December 31, 2024, compared to approximately $64,000 for the ended December 31, 2023. The increase in interest income is due to higher interest rates earned on invested cash balances.

Other (Expense), net

Other expense was approximately $10,000 for the year ended December 31, 2024, compared to $44,000 for the year ended December 31, 2023. This decrease is primarily a result of losses on foreign currency transactions in 2023.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2024 and 2023 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	**2024**	**2023**
Cash and cash equivalents	$ 3,760	$ 4,307
Other current assets	4,538	4,098
Working capital	6,736	6,292
Stockholders' equity	8,585	8,358

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, 2024, we had an accumulated deficit of $144.3 million. We may continue to incur additional operating losses until such time, if ever, that we are able to consistently increase product sales to achieve profitability. Based on cash that is available for our operations and projections of our future operations, we believe that our cash balances will be sufficient to fund our current operating plan through at least the next 12 months from the date of issuance of the condensed 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 so we can continue to 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 used in operating activities was $0.5 million for the year ended December 31, 2024 compared to net cash provided by operating activities of approximately $0.8 million for the year ended December 31, 2023. Net cash used in operating activities in 2024 was primarily due to an increase in inventory of approximately $0.4 million, an increase in accounts receivable of approximately $0.3 million, a decrease in accounts payable and accrued expenses of approximately $0.2 million each, offset by an increase in inventory impairments and write-offs of approximately $0.3 million. Net cash provided by operating activities in 2023 was primarily due to a decline in inventory of approximately $0.4 million, an increase in accrued expenses of approximately $0.5 million, partially offset by an increase in accounts receivable of approximately $0.2 million.

Net cash used in investing activities was approximately $50,000 and $75,000 for the years ended December 31, 2024 and 2023 respectively,

Net cash used in financing activities was approximately $5,000 for the year ended December 31, 2024. This was primarily from principal payments on our finance lease obligation.

Net cash used in financing activities was $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.

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 Shareholders of Nephros, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nephros, Inc. (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 consolidated 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 consolidated 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 Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

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

Tewksbury, Massachusetts
March 24, 2025

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,760	$ 4,307
Accounts receivable, net	1,781	1,496
Inventory	2,615	2,470
Prepaid expenses and other current assets	142	132
Total current assets	8,298	8,405
Property and equipment, net	161	152
Lease right-of-use assets	1,377	1,807
Intangible assets, net	349	381
Goodwill	759	759
License and supply agreement, net	216	271
Other assets	50	86
TOTAL ASSETS	$ 11,210	$ 11,861
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	649	873
Accrued expenses	565	794
Current portion of lease liabilities	348	446
Total current liabilities	1,562	2,113
Lease liabilities, net of current portion	1,063	1,390
TOTAL LIABILITIES	2,625	3,503
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	-	-
Common stock, $.001 par value; 40,000,000 shares authorized at December 31, 2024 and 2023; 10,544,691 and 10,543,675 shares issued and outstanding at December 31, 2024 and 2023, respectively	11	10
Additional paid-in capital	152,906	152,754
Accumulated deficit	(144,332)	(144,406)
TOTAL STOCKHOLDERS' EQUITY	8,585	8,358
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,210	$ 11,861

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

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

	Years Ended December 31,	
	2024	2023
Net revenue:		
Product revenues	$ 14,035	$ 14,110
Royalty and other revenues	127	128
Total net revenues	14,162	14,238
Cost of goods sold	5,439	5,833
Gross Margin	8,723	8,405
Operating expenses:		
Research and development	906	873
Depreciation and amortization	135	214
Selling, general and administrative	7,676	8,911
Total operating expenses	8,717	9,998
Operating income (loss)	6	(1,593)
Other (expense) income:		
Interest expense	(1)	(2)
Interest income	94	64
Other expense net	(10)	(44)
Total other income	83	18
Income (loss) before income taxes	89	(1,575)
Income tax expense	(15)	-
Net income (loss)	74	(1,575)
Net income (loss) per common share, basic	$ 0.01	$ (0.15)
Net income (loss) per common share, diluted	$ 0.01	$ (0.15)
Weighted average common shares outstanding, basic	10,525,197	10,386,018
Weighted average common shares outstanding, diluted	10,602,004	10,386,018

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		Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Subtotal	Interest	Equity
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
Net income	-	-	-	74	74	-	74
Cashless exercise of stock options	1,016	-	-	-	-	-	-
Restricted stock vesting	42,167	1	(1)	-	-	-	-
Stock-based compensation	-	-	153	-	153	-	153
Balance, December 31, 2024	10,544,691	$ 11	$ 152,906	$ (144,332)	$ 8,585	$ -	$ 8,585

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,	
	2024	2023
OPERATING ACTIVITIES:		
Net income (loss)	$ 74	$ (1,575)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	46	39
Amortization of intangible assets, license and supply agreement and finance lease right-of-use asset	91	175
Stock-based compensation	153	1,052
Inventory impairments and writeoffs	262	295
Change in right-of-use asset	447	342
Increase (Decrease) in provision for bad debt	-	11
Gain on asset disposal	(5)	-
Gain on foreign currency transactions	(6)	-
Decrease (Increase) in operating assets:		
Accounts receivable	(285)	(221)
Inventory	(407)	387
Prepaid expenses and other current assets	(10)	56
Other assets	36	(31)
(Decrease) Increase in operating liabilities:		
Accounts payable	(220)	133
Accrued expenses	(226)	506
Lease liabilities	(442)	(342)
Net cash provided by (used in) operating activities	(492)	827
INVESTING ACTIVITIES:		
Sale of property and equipment	5	-
Purchase of property and equipment	(55)	(75)
Net cash used in investing activities	(50)	(75)
FINANCING ACTIVITIES:		
Payments on secured note payable	-	(71)
Principal payments on finance lease liability	(5)	(7)
Principal payments on equipment financing	-	(1)
Net cash used in financing activities	(5)	(79)
Net increase (decrease) in cash and cash equivalents	(547)	673
Cash and cash equivalents, beginning of year	4,307	3,634
Cash and cash equivalents, end of year	$ 3,760	$ 4,307
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 2	$ 2
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
Right-of-use asset obtained in exchange for finance lease liability	$ 22	$ -

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.

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, and 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 subsidiary, SRP, which was dissolved pursuant to a plan of dissolution adopted by its stockholders in March 2023 and the subsequent filing of a certificate of dissolution with the State of Delaware in April 2023. All intercompany accounts and transactions were eliminated in the preparation of the accompanying condensed consolidated financial statements.

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.

Liquidity

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. See "Note 14 – Stockholders' Equity – Noncontrolling Interest". Accordingly, as of December 31, 2024, there was no outstanding balance of this loan.

Although we generated net income for the year ended December 31, 2024, we had negative cash flow from operations of approximately $500,000 for the same period. Our operations have consumed substantial amounts of cash since inception, generating an accumulated deficit of $144.3 million as of December 31, 2024. Additionally, we cannot be certain that we will be able to generate a sufficient amount of product revenue to maintain profitability on an ongoing basis.

The Company continues to focus on growth in sales and managing tight expenses with the goal of returning to cash flow positive from operations. The Company believes that the tight focus on expenses and its current 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 condensed consolidated financial statements. However, if 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, 2024 and 2023, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2024	2023
A	25%	23%
B	8%	11%
Total	33%	34%

As of December 31, 2024 and 2023, the following customer accounted for the following percentage of our accounts receivable:

Customer	2024	2023
A	13%	12%

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, 2024 and 2023, 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 as of December 31, 2024, and 2023, 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.

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. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. See Note 8 – 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. There were no impairment losses for long-lived assets recorded for the year ended December 31, 2024 and 2023.

Direct internal and external costs to implement internal-use software are capitalized. Capitalized costs are depreciated over the estimated useful life of the software, generally five years, beginning when software is ready for its intended use.

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 3 – 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 $126,000 and $107,000 for the years ended December 31, 2024 and 2023, respectively. The company has elected the practical expedient and treats shipping and handling as a fulfillment cost.

Warranty Costs

The Company's customers may return products due to defects, malfunctions, or if no longer needed (credit) within 30 days from the date of the original purchase, subject to inspection and approval by the Company. However, return quantities have historically been minimal/insignificant due to the Company's rigorous pre-shipment inspection processes and ongoing customer support. The Company does not therefore accrue for warranty expense.

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. 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.

Other Income and Expense, net

Other expense of approximately $10,000 and $44,000 for the years ended December 31, 2024 and 2023, respectively, primarily resulted from losses on foreign currency transactions.

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 until 2024 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, 2024 and 2023.

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, 2024 and 2023, 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 12 – Income Taxes for further discussion.

Net Income (Loss) per Common Share

Basic income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted income (loss) per common share is calculated by dividing net income (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.

A reconciliation of the Company's basic and diluted income (loss) per common share is as follows:

(In thousands, except share and per share data)	Year Ended December 31, 2024	2023
Numerator:		
Net income (loss)	$ 74	$ (1,575)
Denominator:		
Basic weighted average common shares outstanding	10,525,197	10,386,018
Effect of potentially dilutive options	76,807	—
Diluted weighted average common shares outstanding	10,602,004	10,386,018
Income (loss) per common share:		
Basic	$ 0.01	$ (0.15)
Diluted	$ 0.01	$ (0.15)

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

	December 31, 2024	2023
Shares underlying options outstanding	1,161,986	1,789,206
Unvested restricted stock	-	42,167

Foreign Exchange Transaction Gains/Losses

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.

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.

Recently Adopted Accounting Pronouncements

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 Company adopted this guidance as of December 31, 2024. See Note 2 for additional disclosures.,

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 2024, the FASB issued ASU 2024-03, "ASC 220- Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures," which requires entities, in the notes to financial statements, to disclose specified information about certain costs and expenses. The guidance is effective for the Company's annual periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

Note 3 – Revenue Recognition

The Company recognizes revenue related to product sales at a point-in-time when product is shipped via external logistics providers and the other criteria of ASC 606 are met. Product revenue is recorded net of variable consideration which includes prompt pay discounts, other discounts, and returns and allowances. The allowance for sales returns was approximately $5,000 as of December 31, 2024. There was no allowance for sales returns as of December 31, 2023. 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.

Sales-based royalties, for which the license is the predominant item to which the royalties relate, are recognized (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) Royalty and other revenues recognized for the years ended December 31, 2024 and 2023 (in thousands) is comprised of:

	Years Ended December 31,	
	2024	2023
Other revenue	$ 121	$ 97
Royalty revenue under the Sublicense Agreement with CamelBak [(1)]	6	31
Total royalty and other revenues	$ 127	$ 128

[(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 4 – 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, 2024 and December 31, 2023, 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, 2024 and December 31, 2023, 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, 2024			
Money market funds	$ 1,866		
Cash equivalents	$ 1,866	$ -	$ -
December 31, 2023			
Money market funds	$ 2,515		
Certificate of deposit	1,518	-	-
Cash equivalents	$ 4,033	$ -	$ -

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

The carrying amounts of cash, accounts receivable, accounts payable and accrued expenses approximate fair value as of December 31, 2024 and 2023 due to the short-term maturity of these instruments.

The carrying amounts of the lease liabilities and equipment financing approximate fair value as of December 31, 2024 and 2023 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

Note 5 - 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, 2024 and December 31, 2023, were as follows:

(In thousands)	December 31,	
	2024	2023
Finished goods	$ 2,261	$ 2,144
Raw material	354	326
Total inventory	$ 2,615	$ 2,470

Note 6 - Property and Equipment, Net

Property and equipment as of December 31, 2024, and 2023 was as follows (in thousands):

	Estimated Useful Life	December 31,	
		2024	2023
Manufacturing and research equipment	3-7 years	$ 899	$ 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	88
Property and equipment, gross		1,170	1,114
Less: accumulated depreciation		(1,009)	(962)
Property and equipment, net		$ 161	$ 152

Depreciation expense for the years ended December 31, 2024 and 2023 was approximately $46,000 and $39,000, respectively.

Note 7 – Intangible Assets and Goodwill

Intangible Assets

Intangible assets at December 31, 2024 and December 31, 2023 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, 2024			December 31, 2023		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
	(in thousands)					
Customer relationships	540	(191)	349	540	(159)	381
Total intangible assets	$ 540	$ (191)	$ 349	$ 540	$ (159)	$ 381

The Company recognized amortization expense of approximately $32,000 and $42,000 for the years ended December 31, 2024 and 2023, respectively, which is included in selling, general, and administrative expenses on the accompanying consolidated statement of operations.

As of December 31, 2024, future amortization expense for each of the next five years is (in thousands):

Fiscal Years	
2025	$ 32
2026	32
2027	32
2028	32
2029	32

Goodwill

Goodwill had a carrying value on the Company's consolidated balance sheets of $0.8 million at December 31, 2024 and 2023, respectively. The Company concluded the carrying value of goodwill was not impaired as of December 31, 2024, or 2023 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 8 – 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. Medica is currently the Company's sole supplier of the filter material used in certain of the Company's 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 rights granted, the Company agreed to make minimum annual aggregate purchases from Medica of €4,208,000, €4,629,000, €4,976,000, €5,349,000 and €5,750,000 for the years 2024, 2025, 2026, 2027 and 2028, respectively. The Company satisfied its minimum purchase requirement for 2024, but if the Company is unable to satisfy its remaining minimum purchase commitment for 2025 and beyond, it will be in breach of the License and Supply Agreement, giving Medica a right of termination.

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 $0.2 million and $0.3 million as of December 31, 2024 and 2023, respectively. Accumulated amortization is $2.1 million as of December 31, 2024 and $2.0 million as of December 31, 2023. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Amortization expense of $54,000 and $131,000 was recognized for the years ended December 31, 2024 and 2023, respectively, in the consolidated statement of operations.

As of December 11, 2023, the Company has contractually 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, 2024 or 2023.

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 for the year ended December 31, 2023 was recognized and is included in cost of goods sold on the consolidated statement of operations. Approximately $90,000 of this royalty expense was included in accounts payable as of December 31, 2023.

Note 9 – 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 remaining balance of principal and accrued interest under the Secured Note was paid in full.

The Secured Note had a maturity date of April 1, 2023. The unpaid principal balance accrued interest at a rate of 8% per annum. Principal and interest payments were due on the first day of each month commencing on May 1, 2018. The Secured Note was 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 the year ended December 31, 2023, the Company made payments under the Secured Note of approximately $71,000. Included in the total payments made, approximately $1,000 was recognized as interest expense on the consolidated statement of operations for the year ended December 31, 2023.

Note 10 – Leases

The Company has operating leases for corporate offices, and office equipment. The leases have remaining lease terms of 2 to 4 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, 2024	Year ended December 31, 2023
Operating lease cost	$ 447	$ 334
Finance lease cost:		
Amortization of right-of-use assets	5	7
Interest on lease liabilities	2	2
Total finance lease cost	7	9
Variable lease cost	108	44
Total lease cost	$ 562	$ 387

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

	Year ended December 31, 2024	Year ended December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 562	$ 408
Financing cash flows from finance leases	$ 5	$ 7

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

	December 31, 2024	December 31, 2023
Operating lease right-of-use assets	$ 1,355	$ 1,803
Finance lease right-of-use assets	$ 22	$ 4
Current portion of operating lease liabilities	$ 343	$ 442
Operating lease liabilities, net of current portion	1,046	1,390
Total operating lease liabilities	$ 1,389	$ 1,832
Current portion of finance lease liabilities	$ 5	$ 4
Finance lease liabilities, net of current portion	17	-
Total finance lease liabilities	$ 22	$ 4
Weighted average remaining lease term		
Operating leases	3.6 years	4.3 years
Finance leases	3.8 years	0.6 years
Weighted average discount rate		
Operating leases	8.0%	8.0%
Finance leases	8.0%	8.0%

As of December 31, 2024, maturities of lease liabilities were as follows (in thousands):

	Operating Leases	Finance Leases
2025	$ 435	$ 7
2026	450	7
2027	450	7
2028	251	5
Total future minimum lease payments	1,586	26
Less imputed interest	(197)	(4)
Total	$ 1,389	$ 22

Note 11 - Accrued Expenses

Accrued expenses as of December 31, 2024 and 2023 were as follows (in thousands):

	December 31,	
	2024	2023
Accrued bonus	$ 209	$ 537
Accrued directors' fees	129	-
Accrued legal	7	10
Accrued sales commission	123	117
Accrued sales tax payable	35	22
Accrued taxes	9	14
Accrued other	53	94
	$ 565	$ 794

Note 12 - Income Taxes

The components of the provision (benefit) for income taxes for the years ended December 31, 2024 and 2023 consisted of the following:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Current		
Federal	-	-
State and local	$ 15	-
Total Current	$ 15	-
Deferred:		
Federal	-	-
State and local	-	-
Total Deferred	-	-
Total provision (benefit) for income taxes	$ 15	-

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, 2024, and 2023 is as follows:

	Years Ended December 31,	
	2024	2023
U.S. federal statutory rate	21.00%	21.00%
State taxes	55.78%	12.22%
Expired NOLs and credits	1,062.20%	(115.56)%
Stock-based compensation	63.65%	(4.54)%
Federal research and development credits	-%	-%
Foreign Rate Differential	-%	-%
Other	0.09%	0.12%
Non-taxable Cancelation of Indebtedness	-%	19.14%
Valuation allowance	(1,186.05)%	67.62%
Effective tax rate	16.67%	-%

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2024 and 2023 are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carry forwards	$ 15,628	$ 16,700
Research and development credits	980	1,087
Nonqualified stock option compensation expense	601	613
Lease liabilities	348	449
Capital loss carryforwards	2,090	2,072
Fixed and intangible basis difference	-	-
Other temporary book - tax differences	857	713
Total deferred tax assets	20,504	21,634
Deferred tax liabilities:		
Lease right-of-use assets	(339)	(442)
Fixed and intangible asset basis difference	(134)	(116)
Total deferred tax liabilities	(473)	(558)
Deferred tax assets, net	20,031	21,076
Valuation allowance for deferred tax assets	(20,031)	(21,076)
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 million from December 31, 2023 to December 31, 2024.

At December 31, 2024, the Company had Federal income tax net operating loss carryforwards of $72.6 million and State income tax net operating loss carryforwards of $5.9 million. The Company had Federal research and development tax credit carryforwards of $1 million at December 31, 2024. 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 State net operating loss carryforwards and Federal and State tax credit carryforwards will expire at various times between 2025 and 2043 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 2020 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 13 - 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. 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

On April 12, 2024, the Board of Directors adopted, and on May 23, 2024, the Company's stockholders approved, the Nephros, Inc. 2024 Equity Incentive Plan ("2024 Plan"). As of December 31, 2024, there were a total of 1,503,054 shares of common stock reserved for issuance under the 2024 Plan, which includes as of such date options to purchase 2,000 shares of common stock that have been issued to employees and remain outstanding. The options issued to employees expire on various dates between November 6, 2034 and November 18, 2034. Generally, grants vest based on a service condition only and vest between two to four years. The share reserve under the 2024 Plan is be automatically increased from time to time for shares subject to outstanding stock awards under the 2015 Plan (as defined below) and that following the effective date of the 2024 Plan: (i) are not issued because such stock award or any portion thereof expires or otherwise terminates without all of the shares covered by such stock award having been issued; (ii) are not issued because such stock award or any portion thereof is settled in cash; (iii) are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for

the vesting of such shares; (iv) are withheld or reacquired to satisfy the exercise, strike or purchase price; or (v) are withheld or reacquired to satisfy a tax withholding obligation. However, the maximum number of shares that may be available for issuance under the 2024 Plan cannot exceed 2,615,875. The maximum contractual term for stock options granted under the 2024 Plan is 10 years.

The Company had previously adopted the Nephros, Inc. 2015 Equity Incentive Plan ("2015 Plan"), pursuant to which the Company granted equity awards to its officers, directors, employees and other service providers. Following the adoption of the 2024 Plan, the Company ceased using the 2015 Plan for granting equity awards.

As of December 31, 2024, options to purchase 1,236,793 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 May 14, 2034. No shares are available for future grants under the 2015 Plan.

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 related to stock options was approximately $0.1 million and $0.8 million for the years ended December 31, 2024, and 2023, respectively.

For the year ended December 31, 2024, approximately $131,000 and $6,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations. For the year ended December 31, 2023, $718,000 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.

The following table issued summarizes the option activity for the years ended December 31, 2024:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2023	1,374,742	$ 3.69
Options granted	87,198	2.12
Options forfeited	(206,510)	4.04
Options expired	(11,886)	4.09
Options exercised [(1)]	(4,751)	2.13
Outstanding at December 31, 2024	1,238,793	$ 3.20

(1) 4,751 options were exercised via cashless exercise which resulted in 1,016 shares issued.

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2024.

	Shares	Weighted Average Exercise Price
Vested at December 31, 2024	789,730	$ 4.01
Vested and expected to vest at December 31, 2024	1,212,747	$ 3.23

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following weighted-average assumptions:

Assumption for Option Grants	2024	2023
Stock Price Volatility	69.54%	72.40%
Risk-Free Interest Rates	4.45%	3.71%
Expected Life (in years)	6.08	6.22
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 2024 and 2023 is $1.40 and $0.99, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2024 was approximately $42,000 and $41,000 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, 2024 was approximately 6.5 years.

The intrinsic values of stock options exercised was approximately $2,000 and $58,000 for the years ended December 31, 2024, and 2023 respectively.

As of December 31, 2024, there was $0.5 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 2.28 years.

There was no tax benefit related to expense recognized in the twelve months ended December 31, 2024 and 2023, 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, 2024 and 2023:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2022	-	$ -
Granted	299,670	1.47
Vested	(187,503)	1.08
Nonvested at December 31, 2023	42,167	$ 3.18
Granted	-	-
Vested	(42,167)	3.18
Nonvested at December 31, 2024	-	$ -

The total fair value of restricted stock that vested during the years ended December 31, 2024 and 2023 was approximately $0.1 million and $0.2 million, respectively.

Total stock-based compensation expense for restricted stock was approximately $15,000 and $322,000 for the year ended December 31, 2024 and 2023, respectively and is recognized in selling, general and administrative expenses on the accompanying consolidated statement of operations.

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, 2024, there was no unrecognized compensation expense related to restricted stock-based awards granted under the equity compensation plans. 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

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 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 equity-based awards is included in selling, general and administrative expenses on the accompanying consolidated statement of operations.

Note 14 - Stockholders' Equity

Noncontrolling Interest

In separate transactions in September 2018 and February 2022, SRP issued and sold an aggregate of 700,003 shares of its Series A Preferred Stock for aggregate gross proceeds of approximately $3.5 million. Of such shares, the Company purchased 62,500 shares in the February 2022 transaction, maintaining a 62.5% ownership stake in SRP. Approximately $188,000 of the proceeds from the February 2022 sales were recorded as an increase to the equity of the non-controlling interests. In addition to the Company's purchase of Series A Preferred Stock from SRP, the Company also loaned to SRP the principal amount of $1.3 million, $1.0 million of which was advanced during the year ended December 31, 2020.

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.

Note 15 – 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 $105,000 and $91,000 to the SIMPLE IRA in 2024 and 2023, respectively.

Note 16 – Segment Information

The Company operates in one operating segment, and therefore one reportable segment, focused on the development and sale of high-performance water solutions to the medical and commercial markets. The Company manages business activities on a consolidated basis primarily through the development and commercialization of water filtration products, which are sold to U.S. and international customers.

The accounting policies for the Company's single operating segment are the same as those described in the summary of significant accounting policies. The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM manages the Company's business activities as a single operating and reportable segment at the consolidated level. Accordingly, our CODM uses consolidated net income (loss) to measure segment profit or loss, allocate resources, and assess performance. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The following is a summary of the significant revenue and expense categories, and consolidated net income (loss) provided to the CODM (in thousands):

	Years Ended December 31,	
	2024	2023
Net revenue:		
Product revenues	$ 14,035	$ 14,110
Royalty and other revenues	127	128
Total net revenues	14,162	14,238
Cost of goods sold	5,439	5,833
Gross Margin	8,723	8,405
Operating expenses:		
Research and development	906	873
Selling, general and administrative	7,676	8,911
Other operating expenses [(1)]	135	214
Total operating expenses	8,717	9,998
Operating income (loss)	6	(1,593)
Other income	83	18
Income tax expense	(15)	-
Net income (loss)	74	(1,575)

[(1)] Other operating expenses is comprised of depreciation and amortization.

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, 2024. 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, 2024. 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, 2024 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, 2024.

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

During the three months ended December 31, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

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 2025 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption "Compensation Matters" in the 2025 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 2025 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 2025 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 2025 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, 2024 and 2023.

Consolidated statements of operations for the years ended December 31, 2024 and 2023.

Consolidated statements of changes in stockholders' equity for the years ended December 31, 2024 and 2023.

Consolidated statements of cash flows for the years ended December 31, 2024 and 2023.

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. 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. †
10.2	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. †
10.3	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. †
10.4	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. †

Exhibit No.	Description
10.5	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. †
10.6	Nephros, Inc. 2024 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on May 24, 2024. †
10.7	Form of Stock Option Agreement under 2024 Equity Incentive Plan. *†
10.8	Form of Restricted Stock Grant Notice under 2024 Equity Incentive Plan. *†
10.9	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.
10.10	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.
10.11	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.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17	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.
10.18	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.
10.19	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). †
10.20	Letter Agreement, dated July 28, 2023, between the Nephros, Inc. and Judy Krandel (incorporated by reference to Exhibit 10.31 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023). †

Exhibit No.	Description
10.21	Inducement Stock Option Agreement, dated November 1, 2023, between Nephros, Inc. and Judy Krandel (incorporated by reference to Exhibit 10.32 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023). †
10.22	License and Supply Agreement, dated December 11, 2023, between the Registrant and Medica S.p.A. (incorporated by reference to Exhibit 10.34 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023) (pursuant to Item 601(b)(2)(ii) of Regulation S-K, certain information contained in this Exhibit 10.22 has been redacted as indicated therein).
19.1	Nephros, Inc. Insider Trading Policy. *
23.1	Consent of Baker Tilly US, LLP Independent Registered Public Accounting Firm. *
24.1	Power of Attorney (included on the signature page). *
31.1	Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
97.1	Nephros, Inc. Policy for Recoupment of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97.1 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023).
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 24, 2025

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

Date: March 24, 2025

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, 2024 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 24, 2025
/s/ Judy Krandel Judy Krandel	Chief Financial Officer (Principal Financial and Accounting Officer)	March 24, 2025
/s/ Arthur H. Amron Arthur H. Amron	Director	March 24, 2025
/s/ Oliver Spandow Oliver Spandow	Director	March 24, 2025
/s/ Alisa Lask Alisa Lask	Director	March 24, 2025
/s/Joe Harris Joe Harris	Director	March 24, 2025