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, 2021

☐ **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. ☐

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, 2021, was $60.9 million. 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, 2020. 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, 2020.

As of March 1, 2022, there were 10,258,444 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 2022 Annual Meeting of Stockholders (the "2022 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2022 Proxy Statement will be filed within 120 days of December 31, 2021.

NEPHROS, INC. AND SUBSIDIARIES

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FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain statements in this Annual Report on Form 10-K constitute "forward-looking statements." Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the timeline for regulatory review and 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 our products;
- we may not be able to sell our water filtration products, pathogen detection system products or chronic renal failure therapy 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;
- products that appeared promising to us in research or clinical trials may not demonstrate anticipated efficacy, safety or cost savings in subsequent pre-clinical or clinical trials;
- we may not be able to secure or enforce adequate legal protection, including patent protection, for our products;
- we may not be able to achieve sales growth in key geographic markets; and
- future waves of COVID-19 infections may cause disruptions to our business, including reduced product sales and supply chain disruptions.

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

In commercial markets, we manufacture and sell water filters that improve the taste and odor of water and reduce biofilm, bacteria, and scale build-up in downstream equipment. Marketed under both the Nephros and AETHER brands, our products are marketed primarily to the food service, hospitality, convenience store, and health care markets.

Our pathogen detection systems are portable, near real-time systems designed to provide actionable data for infection control teams, biomedical engineers in dialysis clinics, and water quality teams in building management organizations.

We also have a subsidiary, Specialty Renal Products, Inc. (“SRP”), a development-stage medical device company, focused primarily on developing hemodiafiltration (“HDF”) technology. SRP is developing a second-generation of the Nephros OLpūr H2H Hemodiafiltration System, the FDA 510(k)-cleared medical device that enables nephrologists to provide HDF treatment to patients with end stage renal disease (“ESRD”).

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.

COVID-19 Pandemic

Most customers and prospects – including healthcare, hospitality, and food and beverage – have re-opened to our sales activity as the country has progressed through the COVID-19 pandemic. In addition, our filter emergency response business has normalized. We expect the pandemic to continue its overall trend toward abatement in the coming months, but recent infection increases from new viral variants may interrupt that abatement for a period of time, as has occurred with the Delta and Omicron variants.

During the pandemic, we maintained full operations, supporting our customers and strategic partners, with no significant interruptions in supply chain or service capabilities.

We believe that, as the COVID-19 pandemic generally subsides, we may experience a net positive impact on demand for our products, due especially to increased global awareness of infectious pathogens and the serious problems they cause. Specifically, we expect that:

- Purchase decisions for infection control filtration that had been deferred, both in new and existing customer organizations, may be re-prioritized.
- Demand for our pathogen detection products may increase as unoccupied buildings, including office buildings and hotels, are readied for re-occupation. Extended periods of low, or no, water flow through building piping creates opportunities for biofilm propagation – a problem our strategic partners are trained to eradicate.
- Demand for our commercial filtration products may increase as business returns to hotels, casinos, and restaurants.

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 expand rapidly our access to target customers without significant 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 will facilitate growth in filter sales outside of the medical industry.

In commercial markets, we develop and sell our Nephros- and AETHER-branded filters, for which carbon-based absorption is the primary filtration mechanism. Aether 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.

Our Aether filter offerings have the potential to generate accretive revenue growth in at least three ways. First, we expect the business to continue its organic growth. Second, cross-selling opportunities are generated by offering taste/odor-focused products to the medical markets, as well as pathogen-focused filtration to the commercial markets. Finally, as part of the more substantial Nephros organization, Aether may be able to compete for larger filtration contracts than may have been available to it as a smaller, independent firm.

In commercial markets, our model combines both direct and indirect sales. Our sales staff have sold products directly to a number of convenience stores, hotels, casinos, and restaurants. We are also pursuing large corporate contracts through partnerships.

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: Filtration of water or bicarbonate concentrate used in hemodialysis.
- Commercial and Industrial 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 2019, according to the American Hospital Association, there are approximately 6,100 hospitals in the U.S., with approximately 921,000 beds. In 2019, over 36 million patients were admitted to these hospitals. The U.S. Centers for Disease Control and Prevention ("CDC") estimates that healthcare associated infections ("HAI") occurr in approximately 1 out of every 31 hospital patients, which calculates to over 1 million patients in 2019. 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 June 2017, the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services ("CMS") announced the addition of requirements for facilities to develop policies and procedures that inhibit the growth and spread of legionella and other opportunistic pathogens in building water systems. Going forward, CMS surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities are compliant with these requirements. We believe that these CMS regulations may have a positive impact on the sale of our HAI-inhibiting ultrafilters.

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

- The DSU-H and SSU-H are in-line, 0.005-micron ultrafilters that provide dual- and single-stage protection, respectively, from waterborne pathogens. They are primarily used to filter potable water feeding ice machines, sinks, and medical equipment, such as endoscope washers and surgical room humidifiers. The DSU-H has an up to 6-month product life in a typical hospital setting, while the SSU-H has an up to 3-month 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, point-of-use, and cartridge filters, can be viewed on our website at http://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. Following a long pilot project at a major dialysis provider, we are now seeing growth in the use of this product. In addition, we aim to expand EndoPur's usage into heat-disinfected water systems, which will further open the market for this product.

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 6,500 dialysis clinics in the United States servicing approximately 468,000 patients annually. We estimate that there are over 100,000 hemodialysis machines in operation in the United States.

Medicare is the main payer for dialysis treatment in the United States. To be eligible for Medicare reimbursement, dialysis centers must meet the minimum standards for water and bicarbonate concentrate quality set by the Association for the Advancement of Medical Instrumentation ("AAMI"), the American National Standards Institute ("ANSI") and the International Standards Organization ("ISO"). We anticipate that the stricter standards approved by these organizations in 2009 will be adopted by Medicare in the near future.

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" configurations.

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, the AETHER brand expanded our product line to include water filtration and purification technologies that are primarily focused on improving odor and taste and on reducing scale and heavy metals from filtered water.

We purchased the AETHER brand to expedite our access to commercial markets and to expand our filtration expertise and capabilities. Our commercial market focus is on the hotel, restaurant, and convenience store markets. In the first-year post-acquisition, we upgraded Aether facilities to increase production and logistics capacity, integrated Aether products into the Nephros infection control product portfolio, and initiated sales efforts with several large commercial customers. We have recently added to our commercial sales team and, going forward, expect to close on one or more large contracts that 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 AETHER and Everpure® manifolds. Included in the NanoGuard product line are both conventional and flushable filters.

- The AETHER line of commercial filters, which are also sold under the Nephros brand, provide a variety of technology solutions that improve water quality in food service, convenience store, hospitality, and industrial applications. AETHER 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.

AETHER 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.

Military and Outdoor Recreation. We developed our individual water treatment device ("IWTD") in both in-line and point-of-use configurations. Our IWTD allows a soldier in the field to derive drinking water from any freshwater source. This enables the soldier to remain hydrated, to help maintain mission effectiveness and unit readiness, and to extend mission reach. Our IWTD has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by the U.S. Army Public Health Command and the U.S. Army Test and Evaluation Command for deployment.

In May 2015, we entered into a Sublicense Agreement (the "Sublicense Agreement") with CamelBak Products, LLC ("CamelBak"). Under this Sublicense Agreement, we 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 us 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 us a fixed per-unit fee for any other sales made. CamelBak was also required to meet or exceed certain minimum annual fees payable to us, and, if such fees are not met or exceeded, we were 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. Related to this Sublicense Agreement, approximately $5,000 of revenue was recognized during the year ended December 31, 2021. There was no royalty revenue recognized during the year ended December 31, 2021.

Pathogen Detection Systems

Pathogen Detection in Infection Control. We recently expanded our portfolio of solutions with the introduction of our PluraPath™ pathogen detection system, which we believe represents a significant growth opportunity for Nephros.

We developed the PluraPath pathogen detection system to provide real-time data to infection control teams executing their water management plans. We integrated our ultrafilter technology with emerging, quantitative polymerase chain reaction (qPCR) technology and real-time analytics. We chose a portable, open-source qPCR platform that allows us to parallel-processes up to 15 different bacteria and virus assays. We worked with industry experts to select and develop DNA- and RNA-based assays that could meet our goals of providing quantitative precision within one hour. We also developed a mobile application to extract and process the data real-time. Furthermore, we designed the system so that anyone can perform qPCR testing, not just someone with training in microbiological laboratory techniques.

With the PluraPath system, it will be possible to map and track the changes to levels of multiple bacterial and viral pathogens in a building's water system on a real-time basis, at cost levels equivalent to assays that currently take 24-72 hours or more and typically provide data on only a single pathogen. Using PluraPath, we expect that infection control teams will be able to quickly assess approximate levels of a broad array of pathogens in their water systems, and optimally focus their secondary disinfection efforts and point-of-use filtration; services and products offered by our strategic partners.

The PluraPath system does not replace culture-based assays, which are the current regulatory requirements for confirmation in testing for waterborne pathogens. Rather, we believe PluraPath will become a valuable tool in the arsenal of defense, permitting faster decision making about a larger target population of pathogens. Our objective is to provide our customers and strategic partners with a user-friendly system that delivers dependable, actionable data to infection control teams in less than an hour.

Pathogen Detection in Dialysis Facilities. We have also been investigating pathogen detection efforts in the dialysis space. The LAL (limulus amebocyte lysate) test is a dialysis industry standard assay that identifies the presence of potential endotoxins, agnostic to the source species. The source of endotoxins are gram-negative bacteria. LAL testing routinely takes 48-72 hours to provide results from the time of shipping the sample to a central laboratory. When dialysis clinics have urgent contamination or severely elevated endotoxin issues, they may have to shut down for extended periods of time creating enormous logistical issues for patients and increasing the cost of care.

To provide a real-time solution for this testing paradigm, we announced the DialyPath™ pathogen detection and endotoxin estimation system in October 2020. The DialyPath system mirrors our PluraPath but includes a gram-negative DNA marker test and test for six different gram-negative bacteria. The DialyPath system is designed to provide data on two test samples in one run in less than one hour. The system will provide an estimate of the overall endotoxin in the sample, as well as estimated levels of six specific endotoxin-generating bacteria known to be frequent invaders of dialysis clinic water systems.

Facility-Wide Pathogen Detection. Bacterial contaminants in water systems can originate from thousands of different bacterial families. The technology now exists to map the water system biome in real-time, on-site, using an enhanced form of the portable PluraPath system and a bioinformatics database. The SequaPath system provides the capability to screen water for over 20,000 different bacterial genera (families), including genera of the 40+ pathogenic bacteria listed by the Centers for Disease Control & Prevention (CDC) in their "Opportunistic Pathogens of Premise Plumbing." The system incorporates our proprietary filtration technology and a DNA sequencing step that makes it possible to screen rapidly for genera of waterborne pathogens. Like PluraPath, the SequaPath platform is portable, allowing for same-day on-site analysis.

The SequaPath technology was used in 2020 to perform an academic study that found far more bacteria in buildings unoccupied during the COVID-19 pandemic than in occupied buildings. The potential for building biome mapping is enormous. We are developing the technology, processes, and procedures to perform as many as 96 tests in a single run. SequaPath is currently available as a service offering.

While this service could be of value to the management of any water system in any building in any part of the world, we will first focus on the hospital customers of our strategic partners. Once proven in the hospital space, we believe that SequaPath has the potential to shift the building water testing paradigm across multiple markets and geographies.

Our Pathogen Detection Systems laboratories facility in Reno, Nevada, has matured into a first-class, environmental test development and manufacturing organization. The lab was recently enrolled in the CDC's ELITE Program, which recognizes approximately 150 US laboratories capable of advanced isolation techniques with respect to Legionella identification. Our focus extends well beyond Legionella. Indeed, we believe our laboratories now offer the most extensive list of CDC-noted, opportunistic waterborne pathogens in a single test on the market today.

On July 9, 2021, we acquired 100% of GenArraytion, Inc. ("GenArraytion"). This acquisition gave us access to GenArraytion's many proprietary assays, multiplexing technology, and selection methods for detecting waterborne pathogens and other microorganisms using Polymerase Chain Reaction technology. GenArraytion's assets will be integrated into our Pathogen Detection Systems segment.

Additional Pathogen Detection Markets. Due primarily to the intellectual property acquired in the GenArraytion acquisition, including proprietary techniques of rapid assay development, we are exploring additional pathogen detection market opportunities, including additional waterborne pathogen detection markets as well as non-waterborne areas, such as mosquito- and tick-borne illness and women's health panels.

Specialty Renal Products: HDF System

Introduction to HDF

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

Hemodiafiltration ("HDF") is an alternative dialysis modality that combines the benefits of HD and HF into a single therapy by clearing toxins using both diffusion and convection. Though not widely used in the United States, HDF is prevalent in Europe and is performed for a growing number of patients. Clinical experience and literature show the following clinical and patient benefits of HDF:

- Enhanced clearance of middle and large molecular weight toxins
- Improved survival - up to a 35% reduction in mortality risk
- Reduction in the occurrence of dialysis-related amyloidosis
- Reduction in inflammation
- Reduction in medication such as EPO and phosphate binders
- Improved patient quality of life
- Reduction in number of hospitalizations and overall length of stay

However, like HD, HDF can be resource-intensive and can require a significant amount of time to deliver one course of treatment.

Nephros HDF Background

Over the course of our history, we originally developed a medical device that enabled a standard HD machine to perform HDF. We refer to our approach as an on-line mid-dilution hemodiafiltration ("mid-dilution HDF") system. Our original solution included an OLpūr H2H Hemodiafiltration Module ("H2H Module"), an OLpūr MD 220 Hemodiafilter ("HDF Filter") and an H2H Substitution Filter ("Dialysate Filter").

Our H2H Module attaches to a standard HD machine to perform on-line HDF therapy. The HD machine controls and monitors the basic treatment functions, as it would normally when providing HD therapy. The H2H Module is a free-standing, movable device that is placed next to either side of an HD machine. The H2H Module connects to the clinic's water supply, drain, and electricity.

The H2H Module utilizes the HDF Filter and is very similar to a typical hollow fiber dialyzer assembled with a single hollow fiber bundle made with a high-flux (or high-permeability) membrane. The fiber bundle is separated into two discrete, but serially connected, blood paths. Dialysate flows in one direction that is counter-current to blood flow in Stage 1 and co-current to blood flow in Stage 2.

In addition to the HDF Filter, the H2H Module also utilizes a Dialysate Filter during patient treatment. The Dialysate Filter is a hollow fiber, ultrafilter device that consists of two sequential (redundant) ultrafiltration stages in a single housing. During on-line HDF with the H2H Module, fresh dialysate is redirected by the H2H Module's hydraulic (substitution) pump and passed through this dual-stage ultrafilter before being infused as substitution fluid into the extracorporeal circuit. Providing ultrapure dialysate is crucial for the success of on-line HDF treatment.

Our original HDF system conformed with current ANSI/AAMI/ISO standards and was cleared by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with chronic renal failure in 2012. To date, our HDF System is the only HDF system cleared by the FDA.

Over the last four years, DaVita Healthcare Partners, the Renal Research Institute (a research division of Fresenius Medical Care), and Vanderbilt University conducted post-market evaluations of our hemodiafiltration system in their clinics. We gathered direct feedback from these evaluations to develop a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm. The ultimate goal of the evaluations was to better understand the potential for HDF in the U.S. clinical setting in order to (a) improve the quality of life for the patient, (b) reduce overall expenditure compared to other dialysis modalities, (c) minimize the impact on nurse workflow at the clinic, and (d) demonstrate the pharmacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. The last evaluation was concluded at Vanderbilt in the first quarter of 2018.

Specialty Renal Products, Inc.

Over the past two years, we have dramatically simplified and redesigned our HDF device. Our updates have made the system significantly easier to use. By shifting from a reusable substitution ultrafilter to a disposable substitution ultrafilter, we were able to simplify the set-up process and substantially reduce the time required between patient treatments – two of the key complaints from users of our first-generation system. We used real-time user feedback to aid in the fine-tuning of our changes to the system that impacted usability. We believe our second-generation HDF system will meet the needs of both clinicians and patients.

In 2018, we spun-off the development of the HDF device into SRP. We raised $3 million of outside capital directly into SRP to fund the second-generation development described above. Nephros maintains a 62.5% ownership stake in SRP.

We submitted the second-generation HDF system for FDA clearance in June 2021. In October 2021, after an elongated review process, the FDA accepted SRP's HDF Assist Device into its "substantive review" phase for 510(k) clearance. In late December 2021, FDA requested additional information from SRP about its submission. Specifically, the FDA requested additional support for the shelf-life and stability of SRP's disposables; changes to its labels, documentation, and user screens; additional electrical testing; additional user testing; and additional HD machine-specific system performance testing. We expect to complete the work to address the FDA's list in March or April of this year.

Once the HDF system is cleared by the FDA, we intend to launch it at 2-3 clinics having previous experience with our device. Thereafter, we plan to expand our efforts, on a measured basis, to clinics that wish to provide HDF therapy to their patients. We believe this measured launch approach is more likely to be successful than a broader push into the market. Nephrologists in the United States are not trained on HDF therapy; however, we believe many nephrologists are interested in exploring the option. We also believe that early adopters will want to perform studies to better understand the technology. We intend to support these investigator-initiated studies.

In anticipation of clearance, SRP has begun to manufacture supplies for its commercial launch, identify and hire key commercial launch staff, and select its initial commercial clinics. Prior to FDA approval, supplies manufactured in preparation for commercial launch are expensed. We anticipate that SRP will obtain 510(k) clearance in the first half of 2022 and will be in position to launch in the second half of the year.

While a number of studies have been performed in Europe, the body of evidence for optimal use of HDF needs to be built in the U.S. treatment setting. According to European data from Fresenius, over 15% of dialysis treatments are HDF. That could translate to over 10 million individual treatments if HDF achieved that level of penetration in the United States. We do not believe that the United States will instantaneously mirror Europe. However, we do believe that HDF therapy has a place in the treatment landscape for patients with ESRD in the United States, and we look forward to enabling this pathway.

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 offices in Las Vegas and Reno, Nevada and in Dublin, Ireland. 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 Aether facility in Las Vegas, Nevada. In addition, we plan to manufacture some pathogen detection products in our Reno, Nevada facility.

Regarding the OLpūr MD190 and MD220, on June 27, 2011, we entered into a License Agreement (the "License Agreement"), effective July 1, 2011, as amended by the first amendment dated February 19, 2014, with Bellco S.r.l. ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of our patented mid-dilution dialysis filters. Under the License Agreement, as amended, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label, and CE mark in certain countries on an exclusive basis, and to do the same on a non-exclusive basis in certain other countries. The License Agreement expired on December 31, 2021.

On April 23, 2012, we entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with our filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement, as amended, Medica granted to us an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, with certain limitations on territory, during the term of the License and Supply Agreement. In addition, we granted to Medica an exclusive license under our intellectual property to make the filtration products during the term of the License and Supply Agreement. The filtration covered under the License and Supply Agreement include both certain products based on Medica's proprietary Versatile microfiber technology and certain filtration products based on Medica's proprietary Medisulfone ultrafiltration technology. The term of the License and Supply Agreement with Medica expires on December 31, 2025, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

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. As part of the License and Supply Agreement, we granted to Medica 300,000 options to purchase our common stock, which vested over the first three years of the agreement. We currently have an understanding with Medica whereby we have agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms.

Sales and Marketing

Under the Bellco License Agreement, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label, and CE mark in the territory, as defined in the License Agreement. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated territory.

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, our Aether division leads global sales and marketing activity. 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. Our pathogen detection systems organization is driving the development of PluraPath and other related systems planned for the future. Our SRP subsidiary is driving the development of our second-generation HDF system.

Major Customers

For the years ended December 31, 2021 and 2020, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2021	2020
A	17%	16%
B	11%	14%
C	7%	11%
Total	35%	41%

As of December 31, 2021 and 2020, the following customers accounted for the following percentages of our accounts receivable, respectively:

Customer	2021	2020
B	19%	5%
D	11%	3%
A	8%	19%
E	6%	12%
Total	44%	39%

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 (now wholly owned by Danaher Corporation), which manufactures point-of-use microfiltration products, as well as 3M and Pentair, who manufacture the Cuno® and Everpure® brands of water filtration and purification products respectively. Our methods of competition in the water filtration domain include:

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

The PluraPath pathogen detection system will compete in the $8 billion global water testing market. Portable, real-time water testing, however, is a relatively new market, with few competitors, including Spartan Bioscience.

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

We also compete with other suppliers of ESRD therapies, supplies and services. These suppliers include Fresenius Medical Care AG and Baxter International, Inc., currently two of the primary machine manufacturers in hemodialysis. Fresenius Medical Care AG and Baxter International, Inc. also manufacture HDF machines that are not currently approved in the United States.

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis products include Baxter International Inc., Fresenius Medical Care AG, Asahi Kasei Medical Co. Ltd., B. Braun Melsungen AG, Nipro Medical Corporation Ltd., Nikkiso Co., Ltd., Terumo Medical Corporation and Toray Medical Co., Ltd.

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

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

- continuing our efforts to develop, manufacture, and sell products that, when compared to competitive products, perform more efficiently, and are available at prices that are acceptable to the market;
- displaying our products and providing associated literature at major industry trade shows in the United States;
- initiating discussions with dialysis clinic medical directors, as well as representatives of dialysis clinical chains, to develop interest in our products;
- pursuing alliance opportunities in certain territories for distribution of our products and possible alternative manufacturing facilities; and
- entering into license agreements similar to our License Agreement with Bellco to expand market share.

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. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge" have claims that cover the OLpūr MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have issued patents on our water filtration products and applications in process to cover various applications in residential, commercial, and remote environments.

As of December 31, 2021, we had five U.S. patents, one Chinese patent, one French patent, one German patent, one Italian patent, one United Kingdom patent, and one Canadian patent. In addition, we had two pending patent applications in the United States. Our pending patent applications relate to a range of filter technologies, including liquid purification filter systems and portable systems for detecting waterborne pathogens by rapid filtration, concentration, and detection of the waterborne pathogens.

Trademarks

As of December 31, 2021, in the United States, we secured registrations of the trademarks HYDRAGUARD, NANOGUARD, ENDOPUR, FILPATH, PLURAPATH, DIALYPATH MULTIFLEX, MULTIFLEX BIOASSAY, GenArraytion and SEQUAPATH. In Canada, we filed trademark applications for PLURAPATH and SEQUAPATH. In Europe and the UK, we secured registrations for the trademark MULTIFLEX.

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 in one of three classes, namely Class I, II or III, on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness.

- Class I devices are medical devices for which general controls are deemed sufficient to ensure their safety and effectiveness. General controls include provisions related to (1) labeling, (2) producer registration, (3) defect notification, (4) records and reports and (5) quality service requirements ("QSR").

- Class II devices are medical devices for which the general controls for the Class I devices are deemed not sufficient to ensure their safety and effectiveness and require special controls in addition to the general controls. Special controls include provisions related to (1) performance and design standards, (2) post-market surveillance, (3) patient registries and (4) the use of FDA guidelines.

- Class III devices are the most regulated medical devices and are generally limited to devices that support or sustain human life or are of substantial importance in preventing impairment of human health or present a potential, unreasonable risk of illness or injury. Pre-market approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before a new medical device can be introduced to the market, Section 510(k), and Section 515 of the FDC Act require a manufacturer who intends to market a medical device to submit a premarket notification (Section 510(k)) or a request for premarket approval (Section 515), to the FDA.

A 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for premarket approval under Section 515. The 510(k) clearance process is generally faster and simpler than the premarket approval process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member nations in 1993, when it adopted its Medical Devices Directive 93/42/EEC. The European Union directive applies to both the manufacturer's quality assurance system and the product's technical design and discusses the various ways to obtain approval of a device (dependent on device classification), how to properly CE mark a device, and how to place a device on the market.

In 2017, the European Union (EU) adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation has a three-year implementation period to May 2020 and will replace the existing directives on medical devices in the EU. After May 2020, medical devices marketed in the EU require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2020, may be placed on the market until 2024. Complying with this new regulation will require us to incur significant costs and failure to meet the requirements of the regulation could adversely impact our business in the European Union and other countries that utilize or rely on European Union requirements for medical device registrations.

As defined in Medical Devices Directive 93/42/EEC, the regulatory approach necessary to demonstrate to the European Union that the organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices requires the certification of a full quality management system by a notified body. Initially, we engaged TÜV Rheinland of North America, Inc. ("TÜV Rheinland") as the notified body to assist us in obtaining certification to ISO 13485/2003 standard, which demonstrates the presence of a quality management system that can be used by an organization for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

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

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

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

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

In July 2003, we received a certification from TÜV Rheinland that our quality management system conforms to the requirements of the European Community. At the same time, TÜV Rheinland approved our use of the CE marking with respect to the design and production of high permeability hemodialyzer products for ESRD therapy. In April 2010, we changed our notified body from TÜV Rheinland to BSI America, Inc. and expanded our scope to include design and development and production of water filters.

Under the License Agreement with Bellco, as discussed above, we granted Bellco a license to manufacture, market and sell the covered products under its own name, label and CE mark in the stated territory. In addition, if requested by us, Bellco will be required to sell the covered products to our distributors in the stated territory.

The following products have been certified by BSI America for CE marking and adherence to ISO13485 standards as Class IIa (Rule 3) medical devices:

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

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

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

Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. Our manufacturing facilities are subject to audits and have been certified to be ISO 13485:2016 and Medical Device Directive 93/42/EEC, which allows us to sell our products in the United States, Canada, and Europe.

Currently we are in the process to seek approval for MDSAP compliance. 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.

Following the completion of MDSAP, this certification will allow us to sell our products in the United States, Canada, Europe, and other territories around the world, while maintaining our current approvals. The time and cost of obtaining new, and maintaining existing, market authorizations from countries outside of North America, and the requirements for licensing products in these countries may differ significantly from FDA requirements.

Reimbursement

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

Product Liability and Insurance

The production, marketing and sale of 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 $2 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, 2021, we employed a total of 34 full-time employees, including 9 employed in sales/marketing/customer support, 14 in general and administrative, and 11 in research and development. 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 2021, we had limited voluntary turnover and focused on maintaining our workforce throughout the COVID-19 pandemic. Going forward, we intend to focus on maintaining our current good relations with our employees and continuing to develop and explore ways to collaborate with our employees and create a well-regarded workplace.

Available Information

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

Item 1A. Risk Factors

Risks Related to Our Overall Business and Operations

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

As of December 31, 2021, we had an accumulated deficit of $135.7 million as a result of historical operating losses. While we believe that the revenues following the launch of our new products will help us achieve profitability, there can be no guarantee of this. We may continue to incur additional losses in the future depending on the timing and marketplace acceptance of our products and as a result of operating expenses being higher than our gross margin from product sales. We began sales of our first product in March 2004, and we may never realize sufficient revenues from the sale of our products or be profitable. Each of the following factors, among others, may influence the timing and extent of our profitability, if any:

- the market acceptance of our technologies and products in each of our target markets;
- our ability to effectively and efficiently manufacture, market and distribute our products;
- our ability to sell our products at competitive prices that exceed our per unit costs; and
- our ability to continue to develop products and maintain a competitive advantage in our industry.

The COVID-19 pandemic may continue to adversely impact our sales and revenues.

There is uncertainty with respect to our projections regarding the availability of sufficient cash resources as a result of the COVID-19 pandemic and the economic conditions it has caused. During the pandemic, we have seen decreased demand for our hospital filtration products, particularly in emergency pathogen outbreak response. In addition, sales to new customers – including water filtration and pathogen detection products – have been hindered by pandemic-related travel restrictions. Also, our commercial filtration products, which are primarily targeted at the hospitality and food service markets, have seen a decrease in demand, due to the closure or reduced occupancy of many hotels and restaurants. If these decreases in demand continue and we are unable to achieve our revenue plan, we may cut budgeted expenditures as appropriate to preserve our available capital resources, which could slow our revenue growth plans.

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

We have only a limited established customer base for our products. Our failure to achieve sufficient market acceptance and sell our products at competitive prices will limit our ability to generate revenue and be profitable. Our water filtration products and technologies may not achieve expected reliability, performance, and endurance standards. Our water filtration products and technologies may not achieve market acceptance, including among hospitals, 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.

Further, acceptance of our chronic renal failure therapy products in the marketplace by both potential users, including chronic renal failure patients, and potential purchasers, including nephrologists, dialysis clinics and other health care providers, is uncertain. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform dialysis patients and nephrologists, dialysis clinics and other health care providers of the benefits of using our products. We may encounter significant clinical and market resistance to our products and our products may never achieve market acceptance. We may not be able to build key relationships with physicians, clinical groups and government agencies, pursue or increase sales opportunities in Europe or elsewhere, or be the first to introduce HDF therapy in the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. Additionally, acceptance in the marketplace will depend on whether we will be able to demonstrate product safety, efficacy and cost-effectiveness, whether there are unexpected side effects, complications or other safety issues associated with such products, and whether government or third-party reimbursement for the cost of such products is available at reasonable rates, if at all.

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

In order to successfully commercialize our products, we need to be able to produce them in a cost-effective way on a large scale to meet commercial demand, while maintaining extremely high standards for quality and reliability. The extent to which we fail to successfully commercialize our products will limit our ability to be profitable.

We rely on, and for the foreseeable future expect to continue to rely on, a limited number of independent manufacturers to produce our products. Our manufacturers' systems and procedures may not be adequate to support our operations and may not be able to achieve the rapid execution necessary to exploit the market for our products. As we expect to continue ramping up our supply requirements, our contracted manufacturers could experience manufacturing and control problems as they begin to scale-up their manufacturing operations to timely and adequately supply us with product. If we experience any of these problems with respect to our manufacturers' scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

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

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

We have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.

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

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

The production, marketing and sale of kidney dialysis and water-filtration products have inherent risks of liability in the event of product failure or claim of harm caused by product operation. 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.

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

We expect to manufacture and to market our products globally. Our international operations are subject to a number of risks, including the following:

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

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

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.

We cannot sell our products, including certain modifications thereto, until we obtain the requisite regulatory approvals and clearances in the countries in which we intend to sell our products. If we fail to receive, or experience a significant delay in receiving, such approvals and clearances, then we may not be able to get our products to market and enhance our revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. We have obtained a Conformité Européene (“CE”) mark, which demonstrates compliance with the relevant European Union requirements and is a regulatory prerequisite for selling our products in the European Union and certain other countries that recognize CE marking (collectively, “European Community”), for our OLpūr MD 220 Hemodiafilter and our DSU. We have not yet obtained a CE mark for any of our other products. We previously received clearance from the FDA to market our OLpūr MD220 Hemodiafilter and OLpūr H2H Module for use with a hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for the treatment of chronic renal failure patients. We have not begun to broadly market these products and are actively seeking a commercialization partner in the United States.

We cannot ensure that any existing products that have not yet been approved, or any new products developed by us in the future, will be approved for marketing. The clearance and/or approval processes can be lengthy and uncertain, and each requires substantial commitments of our financial resources and our management’s time and effort. We may not be able to obtain further CE marking or regulatory approval for any of our existing or new products in a timely manner or at all. Even if we do obtain regulatory approval, approval may be only for limited uses with specific classes of patients, processes, or other devices. Our failure to obtain, or delays in obtaining, the necessary regulatory clearance and/or approvals would prevent us from selling our affected products in the applicable regions. If we cannot sell some of our products in such regions, or if we are delayed in selling while waiting for the necessary clearance and/or approvals, our ability to generate revenues from these products will be limited.

Over time, we intend to market our products globally. Requirements pertaining to the sale of our products vary widely from country to country. It may be very expensive and difficult for us to meet the requirements for the sale of our products in many countries. As a result, we may not be able to obtain the required approvals in a timely manner, if at all. If we cannot sell our products in a particular region, then the size of our potential market could be reduced, which would limit our potential sales and revenues.

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

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

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

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

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

Clinical studies that may be required for our products are costly and time-consuming, and their outcome is uncertain.

Before obtaining regulatory approvals for the commercial sale of any of our products, other than those for which we have already received marketing approval in the United States and elsewhere, we must demonstrate through clinical studies that our products are safe and effective.

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

- slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for similar devices or other factors;
- lower than expected retention rates of subjects in a clinical trial;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site’s review board, or other required approvals;

- longer treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product;
- adverse medical events or side effects in treated subjects; and
- lack of effectiveness of the product being tested.

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

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

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 11 granted U.S. patents will expire at various times from 2022 to 2040, assuming they are properly maintained.

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

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

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

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

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

Risks Related to Owning Our Common Stock

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.

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, 2021, our common stock has traded at prices ranging from a high of $11.67 to a low of $4.42 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:

- achievement or rejection of regulatory approvals by our competitors or us;
- publicity regarding actual or potential clinical or regulatory results relating to products under development by our competitors or us;
- delays or failures in initiating, completing, or analyzing clinical trials or the unsatisfactory design or results of these trials;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our results of operations;
- threatened or actual litigation;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

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.

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 February 23, 2022, Wexford, our largest stockholder, beneficially owned approximately 36% of our outstanding common stock. Collectively, Wexford, our directors and our executive officers beneficially owned approximately 40% 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 2. Properties

Our U.S. facilities are located at 380 Lackawanna Place, South Orange, New Jersey 07079; 3221 Polaris Avenue, Las Vegas, Nevada 89102; and 1015 Telegraph Street, Unit B, Reno, Nevada 89502. We use these facilities to house our corporate headquarters, research, manufacturing, and distribution facilities. The operations of our Aether division are based in our Las Vegas facility, and our Reno facility includes laboratory facilities used in our Pathogen Detection Systems business.

Our office in Europe is currently located at Ulysses House, Foley Street, Dublin, Ireland.

We believe our current facilities will be adequate to meet our needs. We do not own any real property for use in our operation or otherwise.

Item 3. Legal Proceedings

There are no currently 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, 2021, there were approximately 46 holders of record and approximately 1,800 beneficial holders of our common stock.

Recent Sales of Unregistered Securities

Except as previously reported in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, we have not sold any equity securities during the year ended December 31, 2021 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 2021.

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.

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

In commercial markets, we manufacture and sell water filters that improve the taste and odor of water and reduce biofilm, bacteria, and scale build-up in downstream equipment. Marketed under both the Nephros and AETHER brands, our products are marketed primarily to the food service, hospitality, convenience store, and health care markets.

Our pathogen detection systems are portable, near real-time systems designed to provide actionable data for infection control teams, biomedical engineers in dialysis clinics, and water quality teams in building management organizations.

We also have a subsidiary, Specialty Renal Products, Inc. ("SRP"), a development-stage medical device company, focused primarily on developing hemodiafiltration ("HDF") technology. SRP is developing a second-generation of the Nephros OLpūr H2H Hemodiafiltration System, the FDA 510(k)-cleared medical device that enables nephrologists to provide HDF treatment to patients with end stage renal disease ("ESRD").

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.

Recent Accounting Pronouncements

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of financial statements in accordance with GAAP requires application of management's subjective judgments, often requiring estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in "Note 2 – Summary of Significant Accounting Policies," to our consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K, we believe that the following accounting policies require the application of significant judgments and estimates.

Inventories

Our inventory reserve requirements are based on various factors including product expiration date and estimates for the future sales of the product. Reserve assessments include inventory obsolescence based upon expiration date, damaged, or rejected product, slow-moving products, and other considerations. During the year ended December 31, 2021, inventory reserves increased $0.2 million to $0.3 million primarily due to expiration of products that were manufactured in advance of demand, and which expired before sales began to accelerate. We continue to monitor our inventory reserves amounts and policies, and to update both as required by relevant circumstances.

Results of Operations

Fluctuations in Operating Results

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

Fiscal Year Ended December 31, 2021 Compared to the Fiscal Year Ended December 31, 2020

The following table sets forth our summarized, consolidated results of operations for the years ended December 31, 2021 and 2020 (in thousands except percentages):

	Years Ended December 31,		$ Increase	% Increase
	2021	2020	(Decrease)	(Decrease)
Total net revenues	$ 10,404	$ 8,561	$ 1,843	22%
Cost of goods sold	4,661	3,648	1,013	28%
Gross margin	5,743	4,913	830	17%
Gross margin %	55%	57%	-	(2)%
Research and development expenses	2,166	2,759	(593)	(21)%
Depreciation and amortization expenses	202	192	10	5%
Selling, general and administrative expenses	7,710	6,466	1,244	19%
Change in fair value of contingent consideration	-	(229)	(229)	(100)%
Loss from operations	(4,335)	(4,275)	60	1%
Interest expense	(41)	(110)	(69)	63%
Interest income	10	11	(1)	(9)%
Forgiveness of PPP Loan	482	-	482	100%
Other expense, net	17	(152)	(169)	(111)%
Net loss	(3,867)	(4,526)	(659)	(15)%
Less: Undeclared deemed dividend attributable to noncontrolling interest	(240)	(240)	-	-%
Net loss attributable to Nephros, Inc. shareholders	$ (4,107)	$ (4,766)	(659)	(14)%

Net Revenues. Our business is reported in three reportable segments: Water Filtration, Pathogen Detection and Renal Products. Our net revenues in each of these segments for the year ended December 31, 2021 and 2020 (in thousands, except percentages) were as follows:

	2021	2020	$ Increase	% Increase
Water Filtration	$ 10,217	$ 8,532	$ 1,685	20%
Pathogen Detection	187	29	158	545%
Total	$ 10,404	$ 8,561	$ 1,843	22%

The increase of approximately $1.8 million or 22%, was driven by several factors. These factors include new customer site acquisition which averaged more than one per day in 2021 and a customer retention rate of 90%. In addition, revenues related to install in base hospital increased 29%.

Total net revenues in the Pathogen Detection segment increased 545% reflecting early receptivity of the market to our pathogen detection products.

Gross Profit Margin

	2021	2020	% Increase (Decrease)
Water Filtration	55%	57%	(2)%
Pathogen Detection	54%	45%	9%
Total	55%	57%	(2)%

Consolidated gross profit margin was approximately 55% for the year ended December 31, 2021 compared to approximately 57% for the year ended December 31, 2021. The decrease of approximately 2% was driven by the Water Filtration segment primarily as a result of an increase in inventory obsolescence.

Research and Development Expenses

Research and development expenses by segment for the year ended December 31, 2021 and 2020 (in thousands, except percentages) were as follows:

	2021	2020	$ Increase (Decrease)	% Increase (Decrease)
Water Filtration	$ 1,251	$ 1,240	$ 11	1%
Pathogen Detection	668	262	406	155%
Renal Products	247	1,257	(1,010)	(80)%
Total	$ 2,166	$ 2,759	$ (593)	(21)%

Consolidated research and development expenses decreased $0.6 million primarily due to decreasing investment in the second-generation HDF product in the Renal Products segment, partially offset by increased research and development investments in our Pathogen Detection products.

Depreciation and Amortization Expense

Depreciation and amortization expenses were $0.2 million for each of the years ended December 31, 2021 and 2020.

Selling, General and Administrative Expenses

Selling, general and administrative expenses by segment for the year ended December 31, 2021 and 2020 (in thousands, except percentages) were as follows:

	2021	2020	$ Increase (Decrease)	% Increase (Decrease)
Water Filtration	$ 7,124	$ 5,693	$ 1,431	25%
Pathogen Detection	515	468	47	10%
Renal Products	71	305	(234)	(77)%
Total	$ 7,710	$ 6,466	$ 1,244	19%

Consolidated selling, general and administrative expenses increased $1.2 million primarily due to increased headcount related expenditures of $1.2 million and increased travel and marketing expenses of $0.2 million in the Water Filtration segment. This increase was partially offset by a decrease in headcount related expenditures of $0.2 million in the Renal Products segment.

Interest Expense

Interest expense was approximately $41,000 for the year ended December 31, 2021 compared to $110,000 for the year ended December 31, 2020. Both expenses included our secured note payable. The $69,000 reduction is primarily due to elimination of both our secured revolving credit facility and contingent consideration accretion expense.

Extinguishment of PPP loan

Our outstanding PPP loan was forgiven in January 2021 resulting in an extinguishment of approximately $482,000.

Other Income (Expense), net

Other income was approximately $17,000 for the year ended December 31, 2021 as a result of gains on foreign currency transactions. Other expense was approximately $152,000 for the year ended December 31, 2020 as a result of losses on foreign currency transactions.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2021 and 2020 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,	
Liquidity and Capital Resources	**2021**	**2020**
Cash and cash equivalents	$ 6,973	$ 8,249
Other current assets	6,661	6,905
Working capital	11,244	13,829
Stockholders' equity	14,749	15,573

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, 2021, we had an accumulated deficit of $135.7 million, and we expect to incur additional operating losses from operations until such time, if ever, that we are able to increase product sales and/or licensing revenue to achieve profitability.

Based on cash that is available for our operations and projections of our future operations, we believe that our cash balances will be sufficient to fund our current operating plan through at least the next twelve months from the date of issuance of the consolidated financial statements in this Annual Report on Form 10-K. Additionally, our operating plans are designed to help control operating costs, to increase revenue and to raise additional capital until such time as we generate sufficient cash flows from operations. If there were a decrease in the demand for our products due to either economic or competitive conditions, or we are unable to achieve our plan, there could be a significant reduction in liquidity due to our possible inability to cut costs sufficiently.

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

- the market acceptance of our products, and our ability to effectively and efficiently produce and market our products;
- the continued progress in, and the costs of, clinical studies and other research and development programs;
- the costs involved in filing and enforcing patent claims and the status of competitive products; and
- the cost of litigation, including potential patent litigation and any other actual or threatened litigation.

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

- the development, marketing, and sales of our water-filtration and water diagnostics product;
- the development of our second-generation HDF product; and
- working capital purposes.

Net cash used in operating activities was $1.4 million for the year ended December 31, 2021 compared to $6.9 million for the year ended December 31, 2020, a decrease of $5.5 million. The decrease of $5.5 million is due primarily to decreased expenditures on inventory, which were incurred in the first half of fiscal year 2020 to reduce the risk of possible supply chain interruptions early in the COVID-19 pandemic, and an increase in revenue for the year ended December 31, 2021 compared to the year ended December 31, 2020.

Net cash used in investing activities was $0.1 million for the year ended December 31, 2021 compared to $0.2 million for the year ended December 31, 2021. The change is due primarily due to decreased purchases of property and equipment.

Net cash provided by financing activities of $0.2 million for the year ended December 31, 2021 resulted from proceeds from the exercise of warrants and stock options of $0.5 million partially offset by payments on our secured note payable of $0.3 million.

Net cash provided by financing activities of $11.2 million for the year ended December 31, 2020 resulted from net proceeds from the issuance of common stock of $11.5 million, proceeds from a PPP loan of $0.5 million and proceeds from the exercise of warrants and stock options of $0.2 million, partially offset by net payments on our secured revolving credit facility of $0.6 million, payments on our secured note payable of $0.2 million and payment of contingent consideration related to the Aether Acquisition of $0.1 million.

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica, we agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2021, the Company agreed to make minimum annual aggregate purchases from Medica of €3.3 million (approximately $3.9 million). For the year ended December 31, 2021, the aggregate purchase commitments totaled €3.5 million (approximately $4.2 million).

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Nephros, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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

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

Excess and Obsolete Inventory Reserve

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

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

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others:

- testing management's process for estimating the excess and obsolete inventory reserve, including evaluating the appropriateness of the approach utilized and underlying assumptions
- testing the mathematical accuracy of the excess and obsolete inventory reserve calculation
- testing the completeness and accuracy of underlying data used in the analysis, including historical usage and inventory age
- developing an independent expectation of management's estimate, by performing sensitivity analyses to evaluate changes in the estimate that result from changes in management's significant assumptions

/s/ Baker Tilly US, LLP

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

Tewksbury, Massachusetts
March 3, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,973	$ 8,249
Accounts receivable, net	1,641	1,364
Inventory	4,795	5,304
Prepaid expenses and other current assets	225	237
Total current assets	13,634	15,154
Property and equipment, net	366	295
Lease right-of-use assets	730	1,037
Intangible assets, net	1,536	506
Goodwill	759	759
License and supply agreement, net	536	670
Other assets	89	89
TOTAL ASSETS	$ 17,650	$ 18,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of secured note payable	$ 248	$ 229
Accounts payable	1,334	423
Accrued expenses	444	341
Current portion of lease liabilities	364	332
Total current liabilities	2,390	1,325
Secured note payable, net of current portion	95	364
PPP loan	-	482
Equipment financing, net of current portion	4	7
Lease liabilities, net of current portion	412	759
TOTAL LIABILITIES	2,901	2,937
COMMITMENTS AND CONTINGENCIES (Note 19)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	-	-
Common stock, $.001 par value; 40,000,000 shares authorized at December 31, 2021 and 2020; 10,258,444 and 9,873,006 shares issued and outstanding at December 31, 2021 and 2020, respectively	10	10
Additional paid-in capital	147,346	144,296
Accumulated other comprehensive income	64	74
Accumulated deficit	(135,725)	(131,858)
Subtotal	11,695	12,522
Noncontrolling interest	3,054	3,051
TOTAL STOCKHOLDERS' EQUITY	14,749	15,573
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,650	$ 18,510

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

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

	Years Ended December 31,	
	2021	2020
Net revenue:		
Product revenues	$ 10,204	$ 8,453
Royalty and other revenues	200	108
Total net revenues	10,404	8,561
Cost of goods sold	4,661	3,648
Gross margin	5,743	4,913
Operating expenses:		
Selling, general and administrative	7,710	6,466
Research and development	2,166	2,759
Depreciation and amortization	202	192
Change in fair value of contingent consideration	-	(229)
Total operating expenses	10,078	9,188
Loss from operations	(4,335)	(4,275)
Other income (expense):		
Interest expense	(41)	(110)
Interest income	10	11
Extinguishment of PPP loan	482	-
Other income (expense), net	17	(152)
Total other income (expense):	468	(251)
Net loss	(3,867)	(4,526)
Less: Undeclared deemed dividend attributable to noncontrolling interest	(240)	(240)
Net loss attributable to Nephros, Inc. shareholders	$ (4,107)	$ (4,766)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.52)
Weighted average common shares outstanding, basic and diluted	10,017,830	9,078,549
Comprehensive loss:		
Net loss	$ (3,867)	$ (4,526)
Other comprehensive (loss) gain, foreign currency translation adjustments	(10)	9
Comprehensive loss	(3,877)	(4,517)
Comprehensive loss attributable to noncontrolling interest	(240)	(240)
Comprehensive loss attributable to Nephros, Inc. shareholders	$ (4,117)	$ (4,757)

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

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated		Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Subtotal	Interest	Equity
Balance, December 31, 2019	8,003,739	$ 8	$ 131,934	$ 65	$ (127,332)	$ 4,675	$ 3,014	$ 7,689
Net loss					(4,526)	(4,526)		(4,526)
Net unrealized gains on foreign currency translation, net of tax		-	-	9	-	9	-	9
Issuance of common stock, net of equity issuance costs of $1,048	1,770,833	2	11,450	-	-	11,452	-	11,452
Issuance of vested restricted stock	55,111	-	-	-	-	-	-	-
Exercise of warrants	40,012	-	163	-	-	163	-	163
Exercise of stock options	2,556	-	7	-	-	7	-	7
Cashless exercise of options	755	-	-	-	-		-	-
Noncash stock-based compensation		-	742	-	-	742	37	779
Balance, December 31, 2020	9,873,006	$ 10	$ 144,296	$ 74	$ (131,858)	$ 12,522	$ 3,051	$ 15,573
Net loss					(3,867)	(3,867)		(3,867)
Net unrealized losses on foreign currency translation, net of tax		-	-	(10)	-	(10)	-	(10)
Issuance of common stock for asset acquisition (see Note 3)	123,981	-	1,124	-		1,124	-	1,124
Issuance of vested restricted stock	23,781	-	-	-	-		-	-
Exercise of warrants	110,003	-	297	-	-	297	-	297
Exercise of stock options	42,231	-	204	-	-	204	-	204
Cashless exercise of options	14,747	-	-	-	-	-	-	-
Cashless exercise of warrants	10,963	-	-	-	-	-	-	-
Noncash stock-based compensation		-	1,425	-	-	1,425	3	1,428
Balance, December 31, 2021	10,198,712	$ 10	$ 147,346	$ 64	$ (135,725)	$ 11,695	$ 3,054	$ 14,749

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,	
	2021	2020
OPERATING ACTIVITIES:		
Net loss	$ (3,867)	$ (4,526)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	38	25
Amortization of intangible assets, license and supply agreement and finance lease right-of-use asset	214	183
Stock-based compensation, including stock options and restricted stock	1,259	779
Inventory obsolescence charge	213	20
Provision for bad debt expense	1	11
Extinguishment of PPP loan	(482)	-
Change in fair value of contingent consideration	-	(229)
Change in right of use asset	321	312
Accretion of contingent consideration	-	14
Loss on foreign currency transactions	3	1
(Increase) decrease in operating assets:		
Accounts receivable	(278)	(333)
Inventory	296	(2,762)
Prepaid expenses and other current assets	12	289
Other assets	-	(57)
Increase (decrease) in operating liabilities:		
Accounts payable	908	(538)
Accrued expenses	274	207
Lease liabilities	(329)	(299)
Net cash used in operating activities	(1,417)	(6,903)
INVESTING ACTIVITIES:		
Purchase of property and equipment	(36)	(239)
Payment of direct transaction costs for asset acquisition	(49)	-
Net cash used in investing activities	(85)	(239)
FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	-	11,452
Proceeds from Paycheck Protection Program Loan	-	479
Net payments from secured revolving credit facility	-	(560)
Principal payments on finance lease liability	(11)	(6)
Principal payments on equipment financing	(3)	(3)
Payments on secured note payable	(250)	(231)
Payment of contingent consideration	-	(85)
Proceeds from exercise of warrants	297	163
Proceeds from exercise of stock options	204	7
Net cash provided by financing activities	237	11,216
Effect of exchange rates on cash and cash equivalents	(11)	9
Net (decrease) increase in cash and cash equivalents	(1,276)	4,083
Cash and cash equivalents, beginning of year	8,249	4,166
Cash and cash equivalents, end of year	$ 6,973	$ 8,249
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 41	$ 93
Cash paid for income taxes	$ 79	$ 22
Supplemental disclosure of noncash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease liability	$ 21	$ 201
Right-of-use asset obtained in exchange for finance lease liability	$ -	$ 17
Issuance of common shares for asset acquisition	$ 1,124	$ -

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

NEPHROS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Organization and Nature of Operations

Nephros, Inc. ("Nephros" or the "Company") was incorporated under the laws of the State of Delaware on April 3, 1997. The Company was founded by health professionals, scientists and engineers affiliated with Columbia University to develop advanced end stage renal disease ("ESRD") therapy technology and products.

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

The Company's pathogen detection systems are portable, near real-time systems designed to provide actionable data for infection control teams and other organizations. The pathogen detection systems business is a reportable segment, referred to as the Pathogen Detection segment.

In July 2018, the Company formed a new 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. The Company transferred three patents to SRP, which were carried at zero book value. SRP is a reportable segment, referred to as the Renal Products segment.

The Company's primary U.S. facilities are located at 380 Lackawanna Place, South Orange, New Jersey 07079, 3221 Polaris Avenue, Las Vegas, Nevada 89102 and 1015 Telegraph Street, Unit B, Reno, Nevada 89502. These locations house the Company's corporate headquarters, research, manufacturing, and distribution facilities. In addition, the Company maintains small administrative offices in various locations in the United States and Ireland.

Note 2 - Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nephros, Inc. and its subsidiaries, including SRP, in which a controlling interest is maintained by the Company. Outside stockholders' interest in SRP of 37.5% is shown on the consolidated balance sheet as noncontrolling interest. All intercompany accounts and transactions were eliminated in the preparation of the accompanying 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, value of contingent consideration, 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

The Company has sustained operating losses and expects such losses to continue over the next several quarters. In addition, net cash from operations has been negative since inception, generating an accumulated deficit of $135.7 million as of December 31, 2021.

On September 5, 2018, SRP completed a private placement transaction whereby SRP sold preferred shares equivalent to 37.5% of its outstanding equity interests for aggregate proceeds of $3.0 million. As of approximately July 1, 2020, SRP had fully spent the proceeds from this private placement. On October 9, 2020, Nephros and SRP entered into a loan agreement under which Nephros agreed to lend up to $1.3 million to SRP, including the $1.0 million borrowed during the year ended December 31, 2020. These funds are to be used to fund SRP's operating activities and are expected to be sufficient to fund SRP through the planned FDA 510(k) clearance process of SRP's second-generation hemodiafiltration system, which was initially submitted to the FDA for "Special 510(k)" clearance in February 2021 and resubmitted for "Traditional 510(k)" clearance in June 2021. As of December 31, 2021, the outstanding balance, including accrued interest, was $1.3 million.

Based on cash that is available for the Company's operations and projections of future Company operations, the Company believes that its cash balances will be sufficient to fund its current operating plan – including any remaining negative impact of the COVID-19 pandemic – through at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. Additionally, the Company's operating plans are designed to help control operating costs and to increase revenue until such time as the Company generates sufficient cash flows from operations.

While significant progress has been made against the COVID-19 pandemic, some uncertainty remains with respect to the Company's projections regarding the availability of sufficient cash resources, due to the possibility that COVID-19 infections could increase again and cause further disruption to economic conditions. During the pandemic, particularly during calendar year 2020, the Company saw decreased demand for its hospital filtration products, particularly in emergency pathogen outbreak response. In addition, sales to new customers – including water filtration and pathogen detection products – were hindered by pandemic-related travel restrictions. Also, the Company's commercial filtration products, which are primarily targeted at the hospitality and food service markets, saw a decrease in demand, due to the closure of many hotels and restaurants. The Company believes that broad vaccine distribution and increased population immunity has reduced the probability of further significant negative COVID-19 impacts, but if these decreases in demand return and the Company is unable to achieve its revenue plan, the Company may need to reduce budgeted expenditures as appropriate to preserve its available capital resources, which could slow its revenue growth plans.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update ("ASU") 2019-12, "Simplifying the Accounting for Income Taxes," which removes certain exceptions to the general principles of the accounting for income taxes and also improves consistent application of and simplification of other areas when accounting for income taxes. The Company adopted this guidance as of January 1, 2021 and the guidance did not have an impact on its consolidated financial statements.

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, 2021 and 2020, the following customers accounted for the following percentages of the Company's revenues, respectively:

Customer	2021	2020
A	17%	16%
B	11%	14%
C	7%	11%
Total	35%	41%

As of December 31, 2021 and 2020, the following customers accounted for the following percentages of the Company's accounts receivable, respectively:

Customer	2021	2020
B	19%	5%
D	11%	3%
A	8%	19%
E	6%	12%
Total	44%	39%

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. At December 31, 2021 and 2020, 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 provides credit terms to customers in connection with purchases of the Company's products. Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential collection issues and returns. Factors considered include economic conditions, each customer's payment and return history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. The allowance for doubtful accounts was approximately $1,000 and $11,000 as of December 31, 2021 and 2020, respectively.

Inventory

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

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

License and Supply Rights

The Company's rights under the License and Supply Agreement with Medica are capitalized and stated at cost, less accumulated amortization, and are amortized using the straight-line method over the term of the License and Supply Agreement, which is from April 23, 2012 through December 31, 2025. The Company determines amortization periods for licenses based on its assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental, and regulatory issues, and contractual terms. See Note 9 – License and Supply Agreement, net for further discussion.

Leases

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

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

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

The Company has also elected, as a practical expedient, by underlying class of asset, not to separate lease components from nonlease 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 years ended December 31, 2021 and 2020.

Intangible Assets

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

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

Goodwill

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

Fair Value Measurements

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

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

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

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

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

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and also includes instruments for which the determination of fair value requires significant judgment or estimation.

Revenue Recognition

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

Shipping and Handling Costs

Shipping and handling costs charged to customers are recorded as revenue and as cost of goods sold and were approximately $71,000 and $47,000 for the years ended December 31, 2021 and 2020, respectively.

Research and Development Costs

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

Stock-Based Compensation

The fair value of stock options is recognized as stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. The Company calculates stock-based compensation expense in accordance with ASC 718. The fair value of the Company's stock option awards is estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. The fair value of stock-based awards is amortized over the vesting period of the award. For stock awards that vest based on performance conditions (e.g., achievement of certain milestones), expense is recognized when it is probable that the condition will be met.

Warrants

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

Other Income and Expense, net

Other income, net, of $0.5 million for the year ended December 31, 2021 is primarily due to the extinguishment of the U.S. Small Business Administration's Paycheck Protection Plan ("PPP") loan. Other expense, net, of $0.2 million for the year ended December 31, 2020 is primarily due to interest expense of $0.1 million and $0.1 million of foreign currency transaction losses.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, which requires accounting for deferred income taxes under the asset and liability method. Deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable in future years to differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities.

For financial reporting purposes, the Company has incurred a loss in each period since its inception. Based on available objective evidence, including the Company's history of losses, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2021 and 2020.

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, 2021 and 2020, 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.

The Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) was enacted into law on March 27, 2020. The act contains several tax relief and economic stimulus provisions. The enactment of the CARES Act did not have a material impact on the Company's financial statements.

See Note 15 – Income Taxes for further discussion.

Net Loss per Common Share

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

The following securities have been excluded from the dilutive per share computation as they are antidilutive:

	December 31,	
	2021	2020
Shares underlying options outstanding	1,426,510	1,265,660
Shares underlying warrants outstanding	123,476	260,597
Unvested restricted stock	59,732	-

Foreign Currency Translation

Foreign currency translation is recognized in accordance with ASC 830. The functional currency of Nephros International Limited, the Company's Irish subsidiary is the Euro, and its translation gains and losses are included in accumulated other comprehensive income. The balance sheet is translated at the year-end rate. The consolidated statements of operations and comprehensive loss are translated at the weighted average rate for the year.

Comprehensive Loss

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

Recent Accounting Pronouncements, Not Yet Effective

In May 2021, the FASB issued ASU 2021-04, "Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options," which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The guidance is effective for the Company beginning in the first quarter of fiscal year 2022. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, "Accounting for Contract Assets and Contract Liabilities from Contracts with Customers," which requires that an entity recognize contract assets and contract liabilities acquired in a business combination in accordance with Accounting Standards Codification ("ASC") 606. The guidance is effective for the Company beginning in the first quarter of fiscal year 2023 and should be applied prospectively. Early adoption is permitted. The Company will assess the impact, if any, of adopting this guidance on its consolidated financial statements.

Note 3 – Asset Acquisition

On July 9, 2021, the Company acquired 100% of GenArraytion, Inc. (“GenArraytion”). The acquisition did not qualify as a business combination and, as a result, was accounted for as an asset acquisition as the fair value of the gross assets acquired was primarily related to a single asset. The Company issued 123,981 shares of the Company’s common stock to GenArraytion, reflecting an aggregate purchase price of $1.2 million. The purchase price, including direct acquisition costs of approximately $49,000, was allocated among the acquired assets which include intellectual property and equipment, based upon their relative fair values at the date of acquisition.

Fifty percent of the 123,981 common shares issued were subject to a risk of forfeiture which lapsed during the three months ended September 30, 2021. The Company will also make royalty payments to GenArraytion equal to 5% of net sales of certain products over the next five years. Net revenues related to GenArraytion customers were not significant during the year ended December 31, 2021.

The total consideration of $1.2 million was allocated as follows to the acquired assets:

	Total Consideration
	(in thousands)
Intellectual property	$ 1,098
Equipment	75
Total consideration	$ 1,173

The acquired intellectual property is being amortized over its estimated useful life of 10 years (see Note 8 – Intangible Assets and Goodwill).

Note 4 – Revenue Recognition

The Company recognizes revenue related to product sales when product is shipped via external logistics provider and the other criteria of ASC 606 are met. Product revenue is recorded net of returns and allowances. There was no allowance for sales returns at December 31, 2021 or 2020. In addition to product revenue, the Company recognizes revenue related to royalty and other agreements in accordance with the five-step model in ASC 606. Royalty and other revenues recognized for the years ended December 31, 2021 and 2020 (in thousands) is comprised of:

	Years Ended December 31,	
	2021	2020
	$	$
Other revenue	121	40
Royalty revenue under the License Agreement with Bellco	59	48
Royalty revenue under the Sublicense Agreement with CamelBak [(1)]	20	-
Total royalty and other revenues	$ 200	$ 108

(1) In May 2015, the Company entered into a Sublicense Agreement (the “Sublicense Agreement”) with CamelBak Products, LLC (“CamelBak”). Under the 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 Company’s individual water treatment device. 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 were 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 obligation.

Bellco License Agreement

With regard to the OLpūr MD190 and MD220, on June 27, 2011, the Company entered into a License Agreement (the "License Agreement"), effective July 1, 2011, with Bellco S.r.l. ("Bellco"), an Italy-based supplier of hemodialysis and intensive care products, for the manufacturing, marketing and sale of the Company's patented mid-dilution dialysis filters (the "Products"). Under the License Agreement, as amended, the Company granted Bellco a license to manufacture, market and sell the Products under its own name, label, and CE mark in certain countries on an exclusive basis, and to do the same on a non-exclusive basis in certain other countries. Under the License Agreement with Bellco, the Company received upfront payments which were previously deferred and subsequently recognized as license revenue over the term of the License Agreement.

The License Agreement, as amended, and which expired as of December 31, 2021 also provided minimum sales targets which, if not satisfied, will, at the discretion of the Company, result in conversion of the license to non-exclusive status. Beginning on January 1, 2015 through and including December 31, 2021, Bellco committed to pay the Company a royalty based on the number of units of Products sold per year in the covered territory as follows: for the first 125,000 units sold in total, €1.75 (approximately $2.10) per unit; thereafter, €1.25 (approximately $1.50) per unit. The License Agreement also provided for a fixed royalty payment payable to the Company for the period beginning on January 1, 2015 through and including December 31, 2021 if the minimum sales targets are not met.

Note 5 – Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

The following table sets forth the Company's financial assets and liabilities that were measured at fair value on a recurring basis as of December 31, 2021 (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Cash	$ 2,952	$ -	$ -	$ 2,952
Money market funds	4,021	-	-	4,021
Cash and cash equivalents	$ 6,973	$ -	$ -	$ 6,973

The following table sets forth the Company's financial assets and liabilities that were measured at fair value on a recurring basis as of December 31, 2020 (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Cash	$ 4,238	$ -	$ -	$ 4,238
Money market funds	4,011	-	-	4,011
Cash and cash equivalents	$ 8,249	$ -	$ -	$ 8,249

The following table summarizes the change in fair value, as determined by Level 3 inputs, for the contingent consideration liability using unobservable Level 3 inputs for the year ended December 31, 2020 (in thousands):

	Contingent Consideration
Balance as of December 31, 2019	$ 300
Payments against contingent consideration	(85)
Change in fair value of contingent consideration liability	(229)
Accretion of contingent consideration liability	14
Balance as of December 31, 2020	$ -

For the year ended December 31, 2020 the change in fair value of contingent consideration of $0.2 million was due to the settlement of the contingent consideration liability. In October 2020, the Company entered into a Second Amendment to the Membership Interest Purchase Agreement dated December 31, 2018 related to the acquisition of the Aether business, in which the Company agreed to pay a lump sum of $0.1 million in full consideration for the Company's obligation to make payments of contingent consideration under the Membership Interest Purchase Agreement. Approximately $94,000 of the remaining obligation as a result of the lump sum settlement was paid out of amounts remaining in escrow.

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain levels of earnings in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. Fair value as of the date of acquisition is estimated based on projections of expected future cash flows of the acquired business. The Company estimated the contingent consideration liability using the income approach (discounted cash flow method), which requires the Company to make estimates and assumptions regarding the future cash flows and profits. Changes in these estimates and assumptions could have a significant impact on the amounts recognized.

There were no transfers between levels in the fair value hierarchy during the year ended December 31, 2021.

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

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value as of December 31, 2021 and 2020 due to the short-term maturity of these instruments.

The carrying amounts of the secured long-term note payable, lease liabilities and equipment financing approximate fair value as of December 31, 2021 and 2020 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

The carrying amount of the U.S. Small Business Administration's Paycheck Protection Program ("PPP") loan outstanding at December 31, 2020 did not include interest imputed at a market rate as the PPP loan was a transaction whereby the interest rate was prescribed by a government agency**.**

Note 6 - Inventory

The Company's inventory components as of December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
Finished goods	$ 3,760	$ 4,340
Raw material	1,035	964
Total inventory	$ 4,795	$ 5,304

Note 7 - Property and Equipment, Net

Property and equipment as of December 31, 2021 and 2020 was as follows (in thousands):

	Estimated Useful Life	December 31, 2021	December 31, 2020
Manufacturing and research equipment	3-7 years	$ 1,144	$ 1,045
Computer equipment	3-4 years	43	43
Furniture and fixtures	7 years	37	37
Leasehold improvements	2-4 years	25	13
Property and equipment, gross		1,249	1,138
Less: accumulated depreciation		(883)	(843)
Property and equipment, net		$ 366	$ 295

Depreciation related to equipment utilized in the manufacturing process is recognized in cost of goods sold on the consolidated statements of operations and comprehensive loss. Depreciation related to equipment utilized in research and development is recognized in research and development on the consolidated statements of operations and comprehensive loss. Equipment is capitalized due to various uses inclusive of R&D. Depreciation expense for the years ended December 31, 2021 and 2020 was approximately $38,000 and $25,000, respectively. Approximately $17,000 of depreciation expense has been recognized in cost of goods sold for the year ended December 31, 2021. Approximately $7,000 of depreciation expense has been recognized in research and development expenses for the year ended December 31, 2021. Approximately $16,000 of depreciation expense has been recognized in cost of goods sold for the year ended December 31, 2020.

Note 8 – Intangible Assets and Goodwill

Intangible Assets

The following table shows the gross carrying values and accumulated amortization of the Company's intangible assets by type as of December 31, 2021 and 2020:

	December 31, 2021			December 31, 2020		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
	(in thousands)					
Tradenames, service marks and domain names	$ 50	$ (30)	$ 20	$ 50	$ (20)	$ 30
Intellectual property	1,098	(26)	1,072	-	-	-
Customer relationships	540	(96)	444	540	(64)	476
Total intangible assets	$ 1,688	$ (152)	$ 1,536	$ 590	$ (84)	$ 506

The Company recognized amortization expense of approximately $68,000 for the year ended December 31, 2021. Of the approximately $68,000, approximately $42,000 was recognized in selling, general and administrative expenses and approximately $26,000 was recognized in cost of goods sold on the accompanying consolidated statement of operations and comprehensive loss.

The Company recognized amortization expense of approximately $42,000 for the year ended December 31, 2020 in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

As of December 31, 2021, future amortization expense for the next five years is estimated to be:

2022	$ 152,000
2023	$ 152,000
2024	$ 142,000
2025	$ 142,000
2026	$ 142,000

The Company did not recognize any intangible asset impairment charges during the years ended December 31, 2021 or 2020.

Goodwill

Goodwill had a carrying value on the Company's consolidated balance sheets of $0.8 million at December 31, 2021 and 2020, respectively. Goodwill has been allocated to the Water Filtration segment. The Company concluded the carrying value of goodwill was not impaired as of December 31, 2021 or 2020 as the Company determined that it was not more likely than not that the fair value of goodwill was less than its carrying value.

Note 9 – License and Supply Agreement, net

On April 23, 2012, the Company entered into a License and Supply Agreement (as thereafter amended, the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement Medica granted to the Company an exclusive license, with right of sublicense, to market, promote, distribute, offer for sale and sell the filtration products worldwide, with certain limitations on territory, during the term of the License and Supply Agreement. In addition, the Company granted 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. The term of the License Agreement with Medica expires on December 31, 2025, unless earlier terminated by either party in accordance with the terms of the License and Supply Agreement.

In exchange for the license, the gross value of the intangible asset capitalized was $2.3 million. License and supply agreement, net, on the consolidated balance sheet is $0.5 million and $0.7 million as of December 31, 2021 and 2020, respectively. Accumulated amortization is $1.8 million and $1.6 million as of December 31, 2021 and 2020, respectively. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Amortization expense of $0.1 million was recognized in each of the years ended December 31, 2021 and 2020 on the consolidated statement of operations and comprehensive loss.

As of September 2013, the Company has an understanding with Medica whereby the Company has agreed to pay interest to Medica at a 12% annual rate calculated on the principal amount of any outstanding invoices that are not paid pursuant to the original payment terms. There was no interest recognized for the years ended December 31, 2021 or 2020.

In addition, for the period beginning April 23, 2014 through December 31, 2025, the Company will pay 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 $0.3 million and $0.2 million for the year ended December 31, 2021 and 2020, respectively, was recognized and is included in cost of goods sold on the consolidated statement of operations and comprehensive loss. Approximately $70,000 and $68,000 of this royalty expense was included in accounts payable as of December 31, 2021 and 2020, respectively.

Note 10 – Secured Revolving Credit Facility

On August 17, 2017, the Company entered into the Loan and Security Agreement, subsequently amended on December 20, 2019 (the "Loan Agreement") with Tech Capital, LLC ("Tech Capital"). The Loan Agreement provided for a secured asset-based revolving credit facility (the "Revolver") of up to $2.5 million, which the Company drew upon and repaid from time to time during the term of the Loan Agreement. The Company used these proceeds for working capital and general corporate purposes.

On May 26, 2020, the Company terminated the Revolver and, as a result, recognized fees of approximately $7,000, which are included in interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2020. Although the Revolver was terminated, the Loan Agreement, as amended on May 26, 2020 to reflect this termination, remains in place for purposes of specifying obligations related to the Secured Note (see Note 11 – Secured Note Payable).

For the year ended December 31, 2020, excluding approximately $7,000 related to the termination of the Revolver, approximately $25,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss.

Note 11 – 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. The Secured Note was amended and restated on May 26, 2020 to reflect the then-current balance on the Secured Note. There were no other changes to the terms and conditions of the Secured Note. As of December 31, 2021 and 2020, the principal balance of the Secured Note was $0.3 million and $0.6 million, respectively.

The Secured Note has a maturity date of April 1, 2023. The unpaid principal balance accrues interest at a rate of 8% per annum. Principal and interest payments are due on the first day of each month commencing on May 1, 2018. The Secured Note is subject to the terms and conditions of and is secured by security interests granted by the Company in favor of Tech Capital under the Loan Agreement (see Note 10 – Secured Revolving Credit Facility). An event of default under such Loan Agreement will be an event of default under the Secured Note and vice versa. In the event the principal balance under the Loan Agreement is due, all amounts due under the Secured Note will also be due.
In addition, Nephros International Limited, a wholly owned subsidiary of the Company, unconditionally guaranteed the Company's obligations under the Loan Agreement.

During each of the years ended December 31, 2021 and 2020, the Company made payments under the Secured Note of $0.3 million. Included in the total payments made, approximately $38,000 and $58,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, future principal maturities are as follows (in thousands):

2022	$	248
2023		95
Total	$	343

Note 12 – Paycheck Protection Program Loan

On April 24, 2020, the Company obtained a loan from the U.S. Small Business Administration's Paycheck Protection Program ("PPP") in the amount of $0.5 million ("PPP loan"). Under the terms of the PPP, certain amounts of the loan may be forgiven if they are used for qualifying expenses during the first 24 weeks of the loan. On January 14, 2021, the U.S Small Business Administration notified the Company that, in accordance with the PPP terms, the PPP loan was forgiven in full, including all principal and interest outstanding as of the date of forgiveness. As such, $0.5 million has been recognized as an extinguishment of debt on the Company's consolidated statement of operations and comprehensive loss. The SBA reserves the right to audit any PPP loan, regardless of size. These audits may occur after forgiveness has been granted. In accordance with the Cares Act. All borrowers are required to maintain the PPP loan documentation for six years after the PPP loan was forgiven or repaid in full and to provide that documentation to the SBA upon request.

Note 13 – Leases

The Company has operating leases for corporate offices, an automobile and office equipment. The leases have remaining lease terms of approximately 1 year to 4 years.

The Company entered into an operating lease that began in December 2017 for 380 Lackawanna Place, South Orange, New Jersey 07079, which consists of approximately 7,700 square feet of space. The rental agreement expires in November 2022 with a monthly cost of approximately $11,000. Approximately $11,000 related to a security deposit for this U.S. office facility is classified as prepaid expenses and other current assets and other assets, respectively, on the consolidated balance sheet as of December 31, 2021 and 2020. The Company uses this facility to house its corporate headquarters and research facilities.

The Company entered into an operating lease in March 2019 for approximately 16,000 total square feet of office space at 3221 Polaris Avenue, Las Vegas, Nevada 89118. The rental agreement commenced in June 2019 and expires in August 2024 with a monthly cost of approximately $15,000. Approximately $20,000 related to a security deposit for this office facility is classified as other assets on the consolidated balance sheet as of December 31, 2021 and 2020.

The Company entered into an operating lease in March 2020 for 1015 Telegraph Street, Unit B, Reno, Nevada 89502. The rental agreement commenced in March 2020 and expires in February 2022 with an option to extend for two additional years that the Company is reasonably certain to exercise. The monthly cost is approximately $5,000. Approximately $5,000 related to a security deposit for this office facility is classified as other assets on the consolidated balance sheet as of December 31, 2021 and 2020.

The Company also has lease agreements for an automobile and office equipment.

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

	Year ended December 31, 2021	Year ended December 31, 2020
Operating lease cost	$ 391	$ 402
Finance lease cost:		
Amortization of right-of-use assets	12	7
Interest on lease liabilities	2	2
Total finance lease cost	14	9
Variable lease cost	48	43
Total lease cost	$ 453	$ 454

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

	Year ended December 31, 2021	Year ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 429	$ 392
Financing cash flows from finance leases	$ 11	$ 6

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

	December 31, 2021	December 31, 2020
Operating lease right-of-use assets	$ 706	$ 1,002
Finance lease right-of-use assets	$ 24	$ 35
Current portion of operating lease liabilities	$ 352	$ 321
Operating lease liabilities, net of current portion	400	735
Total operating lease liabilities	$ 752	$ 1,056
Current portion of finance lease liabilities	$ 12	$ 11
Finance lease liabilities, net of current portion	12	24
Total finance lease liabilities	$ 24	$ 35
Weighted average remaining lease term		
Operating leases	2.2 years	3.1 years
Finance leases	2.2 years	3.3 years
Weighted average discount rate		
Operating leases	8.0%	8.0%
Finance leases	8.0%	8.0%

As of December 31, 2021, maturities of lease liabilities were as follows (in thousands):

	Operating Leases	Finance Leases
2022	$ 395	$ 14
2023	269	8
2024	156	4
Total future minimum lease payments	820	26
Less imputed interest	(68)	(2)
Total	$ 752	$ 24

Note 14 - Accrued Expenses

Accrued expenses as of December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
Accrued bonus	$ 232	$ 81
Accrued directors' fees	-	169
Accrued legal	37	-
Accrued sales commission	34	24
Accrued sales tax payable	26	-
Accrued franchise tax	21	-
Accrued other	94	67
	$ 444	$ 341

Note 15 - Income Taxes

There was no income tax current or deferred tax benefit or expense recognized during the years ended December 31, 2021 and 2020.

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, 2021 and 2020 is as follows:

	Years Ended December 31,	
	2021	2020
U.S. federal statutory rate	21.00%	21.00%
State taxes	1.82%	1.31%
Expired NOLs and credits	(6.60)%	(31.40)%
Stock-based compensation	(2.17)%	(2.40)%
Federal research and development credits	2.59%	3.38%
Other	(1.27)%	2.98%
Paycheck protection loan forgiveness	2.62%	-
Valuation allowance	(17.99)%	4.98%
Effective tax rate	-%	(0.15)%

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2021 and 2020 are as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carry forwards	$ 18,473	$ 17,922
Research and development credits	1,413	1,348
Nonqualified stock option compensation expense	601	487
Lease liabilities	179	256
Other temporary book - tax differences	75	69
Total deferred tax assets	20,741	20,082
Deferred tax liabilities:		
Lease right-of-use assets	(169)	(244)
Fixed and intangible asset basis difference	(119)	(76)
Total deferred tax liabilities	(288)	(320)
Deferred tax assets, net	20,453	19,762
Valuation allowance for deferred tax assets	(20,453)	(19,762)
Deferred tax assets, net 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 increased approximately $691,000 from December 31, 2020 to December 31, 2021.

At December 31, 2021, the Company had Federal income tax net operating loss carryforwards of $81.8 million and State income tax net operating loss carryforwards of $4.9 million. Foreign income tax net operating loss carryforwards were $7.6 million as of December 31, 2021. The Company had Federal research and development tax credit carryforwards of $1.4 million at December 31, 2021. State research and development tax credit carryforwards of approximately $7,000 at December 31, 2021. 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 $13.0 million of losses generated from 2018 onward that have an indefinite carryover period. The remaining Federal and New Jersey net operating loss carryforwards and Federal and New Jersey tax credit carryforwards will expire at various times between 2021 and 2038 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 2016 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 16 - Stock Plans and Share-Based Payments

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

Stock Plans

In 2015, the Board of Directors adopted the Nephros, Inc. 2015 Equity Incentive Plan ("2015 Plan"). As of December 31, 2021, including amendments approved by the Board of Directors, 2,547,400 shares of common stock were approved for issuance pursuant to stock options, restricted stock and other equity incentive awards to the Company's employees, directors and consultants. The maximum contractual term for stock options granted under the 2015 Plan is 10 years.

As of December 31, 2021, options to purchase 1,349,471 shares of common stock had been issued to employees under the 2015 Plan and were outstanding. The options issued to employees expire on various dates between April 15, 2025 and December 14, 2031. Taking into account all options and restricted stock granted under the 2015 Plan, there are 633,209 shares available for future grant under the 2015 Plan. Generally, grants vest based on a service condition only and vest between two to four years.

The Company's previously adopted and approved plan, the 2004 Stock Incentive Plan ("2004 Plan"), expired in the year ended December 31, 2014. As of December 31, 2021, options to purchase 43,705 shares of common stock had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between March 24, 2021 and March 26, 2024. As of December 31, 2021, 33,334 options had been issued to non-employees under the 2004 Plan and were outstanding with an expiration date of April 23, 2023. No shares are available for future grants under the 2004 Plan. Options currently outstanding are fully vested.

Stock Options

The Company has elected to recognize forfeitures as they occur. Stock-based compensation expense recognized for the years ended December 31, 2021 and 2020 was $0.9 million and $0.7 million, respectively.

For the year ended December 31, 2021, $0.9 million and approximately $48,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss. For the year ended December 31, 2020, $0.6 million and approximately $55,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss.

The following table summarizes the option activity for the years ended December 31, 2021 and 2020:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	1,011, 082	$ 5.51
Options granted	291,648	7.01
Options forfeited or expired	(33,402)	8.60
Options exercised	(3,668)	2.84
Outstanding at December 31, 2020	1,265,660	$ 5.78
Options granted	391,156	7.81
Options forfeited or expired	(152,051)	6.71
Options exercised	(78,255)	4.79
Outstanding at December 31, 2021	1,426,510	$ 6.29

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2021 and 2020 (in thousands except per share prices):

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2020	814,160	$ 5.21
Vested and expected to vest at December 31, 2020	1,239,473	$ 5.76
Exercisable at December 31, 2021	877,633	$ 5.46
Vested and expected to vest at December 31, 2021	1,395,932	$ 6.26

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

	Option Pricing Assumptions	
Grant Year	2021	2020
Stock Price Volatility	70.62%	71.88%
Risk-Free Interest Rates	1.02%	0.41%
Expected Life (in years)	6.17	6.23
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 2021 and 2020 is $4.94 and $4.45, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2021 were $0.7 million and $0.8 million, 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, 2021 was 6.6 years.

The intrinsic values of stock options exercised were approximately $265,000 and $20,000 for the years ended December 31, 2021 and 2020.

As of December 31, 2021, there was $2.4 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 3.0 years.

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, 2021 and 2020:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2019	55,111	$ 8.57
Vested	(55,111)	8.57
Nonvested at December 31, 2020	-	-
Granted	83,513	8.07
Vested	(23,781)	8.06
Nonvested at December 31, 2021	59,732	$ 8.07

The total fair value of restricted stock that vested during the years ended December 31, 2021 and 2020 was $0.2 million and $0.5 million, respectively.

Total stock-based compensation expense for the restricted stock granted to employees and non-employee directors was approximately $333,000 for the year ended December 31, 2021 and is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. Total stock-based compensation expense for the restricted stock granted to employees and non-employee directors was approximately $52,000 for the year ended December 31, 2020. Approximately $42,000 and $10,000 is included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2020. Approximately $169,000 of restricted stock was granted to employees during the year ended December 31, 2021 for services rendered during the year ended December 31, 2020.

As of December 31, 2021, there was approximately $172,000 of unrecognized compensation expense related to the restricted stock awards which will be amortized over the weighted average remaining requisite service period of 2.5 years.

The aggregate shares of common stock legally issued and outstanding as of December 31, 2021 is greater than the aggregate shares of common stock outstanding for accounting purposes by the amount of unvested restricted shares.

SRP Equity Incentive Plan

SRP's 2019 Equity Incentive Plan was approved on May 7, 2019 under which 150,000 shares of SRP's common stock are reserved for the issuance of options and other awards. There were no SRP stock options granted during the year ended December 31, 2021. SRP stock options are being expensed over the respective vesting period, which is based on a service condition.

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	23,040	$ 5.00
Options forfeited or expired	(8,587)	5.00
Outstanding at December 31, 2020	14,453	$ 5.00
Options forfeited or expired	(9,173)	5.00
Outstanding at December 31, 2021	5,280	$ 5.00

Stock-based compensation expense related to the SRP stock options was approximately $3,000 for the year ended December 31, 2021 and is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. Stock-based compensation expense related to the SRP stock options was approximately $37,000 for the year ended December 31, 2020. For the year ended December 31, 2020, approximately $16,000 and $21,000 are included in selling, general and administrative expenses and research and development expenses, respectively, on the accompanying consolidated statement of operations and comprehensive loss.

Stock-based compensation expense related to the SRP stock options is presented by the Company as noncontrolling interest on the consolidated balance sheet as of December 31, 2021.

Note 17 - Stockholders' Equity

July 2021 Common Stock Issuance

On July 9, 2021, the Company issued 123,981 shares of common stock to acquire 100% of GenArraytion. The purchase price was $1.2 million, including transaction costs of approximately $49,000, and was allocated among the acquired assets based upon their relative fair values at the date of acquisition. Fifty percent of the 123,981 common shares issued were subject to a risk of forfeiture which lapsed during the three months ended September 30, 2021.

October 2020 Common Stock Issuance

On October 20, 2020, the Company issued 833,333 shares of the Company's common stock in a registered direct offering, resulting in gross proceeds to the Company of $5.0 million. The purchase price for each share was $6.00. Proceeds, net of equity issuance costs of $0.3 million, recorded as a result of the offering were $4.7 million. Of the 833,333 shares of the Company's common stock issued, 166,667 shares, resulting in proceeds of $1.0 million, were sold to the Company's largest stockholder.

February 2020 Common Stock Issuance

On February 4, 2020, the Company issued 937,500 shares of common stock through a confidentially marketed underwritten public offering resulting in gross proceeds to the Company of $7.5 million. The purchase price for each share was $8.00. Proceeds, net of equity issuance costs of $0.7 million, recorded as a result of the offering were $6.8 million.

Noncontrolling Interest

On September 5, 2018, SRP entered into a Series A Preferred Stock Purchase Agreement with certain purchasers pursuant to which SRP sold 600,000 shares of its Series A Preferred Stock ("Series A Preferred") for $5.00 per share. The aggregate purchase price was $3.0 million. The net proceeds from the issuance of the Series A Preferred are restricted to SRP expenses, and may not be used for the benefit of the Company or other affiliated entities, except to reimburse for expenses directly attributable to SRP. Following the Series A Preferred transaction, the Company retained a 62.5% ownership interest in SRP, holding 100% of the outstanding common shares, and holders of Series A Preferred retained a 37.5% interest in SRP on a fully diluted basis, holding 100% of the outstanding preferred shares. Of the 600,000 shares of Series A Preferred issued, the shares purchased by related parties comprised of persons controlled by members of management and by the Company's largest stockholder amounted to 18,000 and 400,000 shares, respectively.

Each share of Series A Preferred is initially convertible into one share of SRP common stock, subject to adjustment for stock splits and recapitalization events. Subject to customary exempt issuances, in the event SRP issues additional shares of its common stock or securities convertible into common stock at a per share price that is less than the original Series A Preferred price, the conversion price of the Series A Preferred will automatically be reduced to such lower price.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of SRP, the holders of the Series A Preferred are entitled to be paid out of the assets of SRP available for distribution to its stockholders or, in the case of a deemed liquidation event, out of the consideration payable to stockholders in such deemed liquidation event or the available proceeds, before any payment shall be made to the holders of SRP common stock by reason of their ownership thereof, an amount per share equal to one times (1x) the Series A Preferred original issue price, plus any accruing dividends accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon (the "Series A Liquidation Preference"). If upon any such liquidation, dissolution or winding up of SRP or deemed liquidation event, the assets of SRP available for distribution to its stockholders shall be insufficient to pay the Series A Liquidation Preference in full, the holders of Series A Preferred shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. After the full payment of the Series A Liquidation Preference, the holders of the Series A Preferred and the holders of common stock will share ratably in any remaining proceeds available for distribution on an as-converted to common stock basis.

Each share of Series A Preferred accrues dividends at the rate per annum of $0.40 per share. The accruing dividends shall accrue from day to day, whether or not declared, and shall be cumulative and shall be payable only when, as, and if declared by the Board. As of December 31, 2021, accrued dividends on the Series A Preferred was $0.8 million.

Holders of Series A Preferred shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series A Preferred held by such holder are convertible as of the record date for determining stockholders entitled to vote. Except as provided by law or by the other provisions, the holders of Series A Preferred vote together with the holders of common stock as a single class. Notwithstanding the foregoing, for as long as at least 150,000 shares of Series A Preferred are outstanding, SRP is required to obtain the affirmative vote or written consent of a majority of the Series A Preferred in order to effect certain corporate transactions, including without limitation, the issuance of any securities senior to or on parity with the Series A Preferred, a liquidation or deemed liquidation of SRP, amendments to SRP's charter documents, the issuance of indebtedness in excess of $250,000, any annual budget for the Company's operations, and the hiring or firing of any executive officers of SRP. In addition, the holders of the Series A Preferred are entitled to elect two members of SRP's board of directors.

The noncontrolling interest in SRP held by holders of the Series A Preferred has been classified as equity on the accompanying consolidated balance sheet, as the noncontrolling interest is redeemable only upon the occurrence of events that are within the control of the Company.

Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. As of December 31, 2021 and 2020, all of the Company's outstanding warrants are classified as equity.

The following table summarizes certain terms of all of the Company's outstanding warrants at December 31, 2021 and 2020:

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable as of December 31, 2021	Total Common Shares Issuable as of December 31, 2020
Equity-classified warrants					
June 2016 – Note and Warrant Agreement	6/7/2016	6/7/2021	$ 2.70	-	127,121
March 2017 – private placement warrants	3/22/2017	3/22/2022	$ 2.70	123,476	143,476

Warrants Exercised During 2021 and 2020

During the year ended December 31, 2021, the Company issued an aggregate of 120,966 shares of its common stock upon the exercise of outstanding warrants relating to an aggregate of 126,008 shares of common stock. Of such 120,966 shares issued, 110,003 were issued in cash exercises resulting in gross proceeds to the Company of $0.3 million (the "Cash Exercises") and 10,963 shares were issued in connection with cashless (net) exercises of outstanding warrant relating to 16,005 shares of common stock (the "Cashless Exercises"). Among the shares issued in connection with the Cash Exercises, 66,667 shares were issued to the Company's largest stockholder, which resulted in proceeds to the Company of $0.2 million. Among the Cashless Exercises, 4,570 shares of common stock were issued to persons affiliated with members of the Company's management upon the exercise of warrants relating to 6,669 shares.

During the year ended December 31, 2020, warrants to purchase 40,012 shares of the Company's common stock were exercised, resulting in proceeds of $0.2 million and the issuance of 40,012 shares of the Company's common stock. Of the warrants exercised during the year ended December 31, 2020, warrants to purchase 4,344 shares of the Company's common stock were exercised by members of management, resulting in proceeds of approximately $33,000.

Note 18 – 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 $92,000 and $89,000 to the SIMPLE IRA in 2021 and 2020, respectively.

Note 19 - Commitments and Contingencies

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 9 – License and Supply Agreement, net), the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2021, the Company agreed to make minimum annual aggregate purchases from Medica of €3.3 million (approximately $3.9 million). For the year ended December 31, 2021, the Company's aggregate purchase commitments totaled €3.5 million (approximately $4.2 million).

Note 20 – Segment Reporting

The Company has defined three reportable segments: Water Filtration, Pathogen Detection and Renal Products. The Water Filtration segment primarily develops and sells high performance water purification filters. The Pathogen Detection segment develops and sells portable, real-time water testing systems designed to provide actionable data on waterborne pathogens in approximately one hour. The Renal Products segment is focused on the development of medical device products for patients with renal disease, including a 2nd generation hemodiafiltration system for the treatment of patients with ESRD.

The Company's chief operating decision maker evaluates the financial performance of the Company's segments based upon segment revenues, gross margin and operating expenses which include research and development and selling, general and administrative expenses. Items below loss from operations are not reported by segment, since they are excluded from the measure of segment profitability reviewed by the Company's chief operating decision maker. The Company does not report balance sheet information by segment since such information is not reviewed by the Company's chief operating decision maker.

The accounting policies for the Company's segments are the same as those described in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates" of this Annual Report on Form 10-K and Note 2 – Summary of Significant Accounting Policies.

The tables below present segment information reconciled to total Company loss from operations, with segment operating loss including gross profit less direct research and development expenses and direct selling, general and administrative expenses to the extent specifically identified by segment (in thousands):

	Year Ended December 31, 2021			
	Water Filtration	Pathogen Detection	Renal Products	Nephros, Inc. Consolidated
Total net revenues	$ 10,217	$ 187	$ -	$ 10,404
Gross margin	5,641	102	-	5,743
Research and development expenses	1,251	668	247	2,166
Depreciation and amortization expense	200	2	-	202
Selling, general and administrative expenses	7,124	515	71	7,710
Total operating expenses	8,575	1,184	318	10,078
Loss from operations	$ (2,934)	$ (1,083)	$ (318)	$ (4,335)

	Year Ended December 31, 2020			
	Water Filtration	Pathogen Detection	Renal Products	Nephros, Inc. Consolidated
Total net revenues	$ 8,532	$ 29	$ -	$ 8,561
Gross margin	4,900	13	-	4,913
Research and development expenses	1,240	262	1,257	2,759
Depreciation and amortization expense	192	-	-	192
Selling, general and administrative expenses	5,693	468	305	6,466
Change in fair value of contingent consideration	(229)	-	-	(229)
Total operating expenses	6,896	730	1,562	9,188
Loss from operations	$ (1,996)	$ (717)	$ (1,562)	$ (4,275)

As of December 31, 2021, $0.2 million of total assets in the Renal Products segment consisted of cash received from the loan agreement between Nephros and SRP.

As of December 31, 2020, $0.2 million of total assets were in the Renal Products segment. The $0.2 million consisted of $0.1 million of remaining cash received from the sale of Series A Preferred during the year ended December 31, 2018 and prepaid expenses and other current assets of $0.1 million.

Note 21 – Subsequent Event

On February 1, 2022, SRP, the Company's majority-owned subsidiary, entered into a First Amendment to Series A Preferred Stock Purchase Agreement (the "Amendment") with the holders of SRP's outstanding shares of Series A Preferred Stock. The Amendment amended the terms of the Series A Preferred Stock Purchase Agreement, dated September 9, 2018, among SRP and the purchasers identified therein (the "SRP Purchase Agreement"), pursuant to which SRP had sold to such purchasers an aggregate of 600,000 shares of its Series A Preferred Stock at a price of $5.00 per share resulting in total gross proceeds of $3.0 million. The purpose of the Amendment was to permit SRP to sell up to an additional 100,003 shares of its Series A Preferred Stock at one or more closings to occur by February 28, 2022, and on the same terms and conditions as otherwise set forth in the SRP Purchase Agreement. Pursuant to the Amendment, on February 4, 2022, SRP conducted a closing in which it sold 100,003 shares of Series A Preferred Stock, resulting in gross proceeds of $500,015. The Company purchased 62,500 shares of SRP's Series A Preferred at such closing and, as a result, maintained its 62.5% stock ownership position in SRP. The other purchasers at the February 4, 2022 closing included the Company's Chief Executive Officer, who purchased 833 shares, and Lambda Investors LLC ("Lambda"), an affiliate of Wexford Capital, which beneficially owns approximately 36% of the Company's common stock, which purchased 29,938 shares of SRP Series A Preferred Stock. Such purchases were made on the same terms as all other purchasers.

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

There were no disagreements with the accountants during 2021 or 2020.

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, 2021. Based upon this evaluation, the Chief Executive Officer and Chief Financial Officer has concluded that the disclosure controls and procedures were effective as of December 31, 2021. 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, 2021 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 as of December 31, 2021, the internal control over financial reporting was effective as of December 31, 2021.

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

None.

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 2022 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption “Compensation Matters” in the 2022 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 2022 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 2022 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 2022 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, 2021 and 2020.
Consolidated statements of operations and comprehensive loss for the years ended December 31, 2021 and 2020.
Consolidated statements of changes in stockholders' equity for the years ended December 31, 2021 and 2020.
Consolidated statements of cash flows for the years ended December 31, 2021 and 2020.
Notes to consolidated financial statements.

(2) Exhibits:

Exhibit No.	Description
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	Form of Warrant, incorporated by reference to Exhibit 4.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on March 23, 2017.
4.4	Description of Capital Stock, incorporated by reference to Exhibit 4.5 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 27, 2020.
10.1	Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Amendment No. 1 to Registration Statement on Form S-1/A (Reg. No. 333-116162), filed with the SEC on July 20, 2004. †
10.2	Amendment No. 1 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 4.3 to Nephros, Inc.'s Registration Statement on Form S-8 (Reg. No. 333-127264), filed with the SEC on August 5, 2005. †
10.3	Amendment No. 2 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.7 to Nephros, Inc.'s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, filed with the SEC on November 13, 2007. †
10.4	Amendment No. 3 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit 10.51 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 31, 2009 †

10.5	Amendment No. 4 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Exhibit A to Nephros, Inc.'s Definitive Proxy Statement, filed with the SEC on December 2, 2010. †
10.6	Amendment No. 5 to Nephros, Inc. 2004 Stock Incentive Plan, incorporated by reference to Appendix A to Nephros, Inc.'s Definitive Proxy Statement, filed with the SEC on April 11, 2013. †
10.7	Amendment No. 6 to Nephros, Inc. 2004 Stock Incentive Plan, dated June 14, 2013, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed with the SEC on August 13, 2013. †
10.8	Nephros, Inc. 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.9	Form of Incentive Stock Option Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.10	Form of Non-Qualified Stock Option Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.11	Form of Restricted Stock Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.5 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.12	Form of Restricted Stock Unit Agreement under the 2015 Equity Incentive Plan, incorporated by reference to Exhibit 10.6 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 15, 2015. †
10.13	Nephros, Inc. Director Compensation Policy, incorporated by reference to Exhibit 10.15 to Nephros, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 26, 2018.
10.14	License Agreement, dated July 1, 2011, between the Registrant and Bellco S.r.l., incorporated by reference to Exhibit 10.62 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on June 27, 2011.
10.15	First Amendment to License Agreement, dated February 19, 2014, between the Registrant and Bellco S.r.l., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on February 25, 2014.
10.16	License and Supply Agreement, dated April 23, 2012, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 26, 2012.
10.17	Second Amendment to License and Supply Agreement, dated May 4, 2015, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 10, 2015.
10.18	Third Amendment to License and Supply Agreement, dated May 5, 2017, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on May 9, 2017.

10.19	Fourth Amendment to License and Supply Agreement, dated September 26, 2017, between the Registrant and Medica S.p.A., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on September 27, 2017.
10.20	Sublicense Agreement, dated May 6, 2015, between the Registrant and CamelBak Products, LLC, incorporated by reference to Exhibit 10.5 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 10, 2015.+
10.21	Second Amendment to Sublicense Agreement, dated January 30, 2019, between the Registrant and CamelBak Products, LLC, incorporated by reference to Exhibit 10.24 to Nephros, Inc's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 12, 2019.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	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.
10.27	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.
10.28	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.
10.29	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.
10.30	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.
10.31	Series A Preferred Stock Purchase Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018.

10.32	Amended and Restated Certificate of Incorporation for Specialty Renal Products, Inc., dated September 5, 2018, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018.
10.33	Amendment dated December 10, 2018, to Amended and Restated Certificate of Incorporation of Specialty Renal Products, Inc., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on December 10, 2018.
10.34	Investor Rights Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018.
10.35	Voting Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein, incorporated by reference to Exhibit 10.4 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018.
10.36	Right of First Refusal and Co-Sale Agreement, dated September 5, 2018, among Specialty Renal Products, Inc. and the Purchasers identified therein, incorporated by reference to Exhibit 10.5 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018.
10.37	Amended and Restated Loan and Security Agreement, dated May 26, 2020, by and between Tech Capital, LLC and the Registrant, incorporated by reference to Exhibit 10.2 to Nephros Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 5, 2020.
10.38	Amended and Restated Secured Promissory Note (Single Advance – Non-Revolving), dated May 26, 2020, issued by the Registrant, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 5, 2020.
10.39	Employment Agreement between the Registrant and Andrew Astor, dated August 23, 2020, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020. †
10.40	Consulting Agreement between the Registrant and Daron Evans, dated August 23, 2020, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020.
10.41	Consulting Agreement between Specialty Renal Products, Inc. and Daron Evans, dated August 26, 2020, incorporated by reference to Exhibit 10.3 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020.
10.42	Loan Agreement between the Registrant and Specialty Renal Products, dated October 7, 2020, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K filed with the SEC on October 13, 2020.
10.43	8% Convertible Promissory Note, from Specialty Renal Products, Inc. to the Registrant, dated October 7, 2020, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on October 13, 2020.
10.44	Form of Securities Purchase Agreement dated October 15, 2020, between the Registrant and the Purchasers, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K filed with the SEC on October 16, 2020.

10.45	Letter Agreement, dated November 30, 2020, between Wesley S. Lobo and the Registrant (incorporated by reference to Exhibit 10.55 to Nephros, Inc.'s Annual Report on From 10-K for the year ended December 31, 2020). †
10.46	Separation Agreement and Release, between the Company and Daniel DAgostino, dated January 28, 2021 (incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021).†
10.47	Asset Purchase Agreement between Nephros, Inc. and GenArraytion, Inc. dated July 9, 2021 (incorporated by reference to Exhibit 10.1 to Nephros Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021). *
21.1	List of Subsidiaries of Nephros, Inc. *
23.1	Consent of Baker Tilly US, LLP Independent Registered Public Accounting Firm. *
24.1	Power of Attorney (included on the signature page). *
31.1	Certification by the Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification by the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101	Interactive Data File. *
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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.

Date: March 3, 2022

NEPHROS, INC.

By: */s/ Andrew Astor*
Name: Andrew Astor
Title: President, Chief Executive Officer and Chief Financial Officer
(Principal Executive and Financial Officer)

POWER OF ATTORNEY

We, the undersigned directors and officers of Nephros, Inc., hereby severally constitute and lawfully appoint Andrew Astor, 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, 2021 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/ Andrew Astor Andrew Astor	President, Chief Executive Officer and Chief Financial Officer (Principal Executive and Financial Officer)	March 3, 2022
/s/ Arthur H. Amron Arthur H. Amron	Director	March 3, 2022
/s/ Oliver Spandow Oliver Spandow	Director	March 3, 2022
/s/ Alisa Lask Alisa Lask	Director	March 3, 2022
/s/ Thomas Gwydir Thomas Gwydir	Director	March 3, 2022

Exhibit 21.1

Subsidiaries of Nephros, Inc.

Name	Jurisdiction	Percentage Equity
Nephros International Limited	Ireland	100%
Biocon 1, LLC	Nevada	100%
Aether Water Systems, LLC	Nevada	100%
Specialty Renal Products, Inc.	Delaware	62.5%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements of Nephros, Inc. on Form S-8 (Nos 333-127264; 333-148236; 333-188592; 333-205167; 333-223849; 333-232707, 333-238563 and 333-256712) and on Form S-3 (Nos 333-225109, 333-232708, 333-234528 and 333-259370), of our report dated March 3, 2022, relating to the consolidated financial statements of Nephros, Inc. and Subsidiaries, as of and for the years ended December 31, 2021 and 2020, which appears in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Baker Tilly US, LLP

Tewksbury, Massachusetts
March 3, 2022

Exhibit 31.1

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

I, Andrew Astor, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Dated: March 3, 2022

/s/ Andrew Astor
Andrew Astor
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive and Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Nephros, Inc. (the "Company") for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Astor, President, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 3, 2022

/s/ Andrew Astor
Andrew Astor
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive and Financial Officer)