

**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, 2019

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
(State or Other Jurisdiction of
Incorporation or Organization)

13-3971809
(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
Non-accelerated filer

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 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, 2019, was approximately \$17,800,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the OTCQB on June 30, 2019. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2019.

As of February 20, 2020, there were 9,006,550 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 2020 Annual Meeting of Stockholders (the "2020 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2020 Proxy Statement will be filed within 120 days of December 31, 2019.

NEPHROS, INC. AND SUBSIDIARIES

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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 “FDCA”) 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 if and 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 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; and
- we may not be able to achieve sales growth in key geographic markets.

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

PART I

Item 1. Business

Overview

Nephros, Inc. (the “Company” or “we”) is a commercial-stage company that develops and sells high performance water solutions to the medical and commercial markets.

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

Our pathogen detection system is a portable, real-time system designed to provide actionable data for infection control teams on up to 15 different pathogens from a single water sample, in approximately one hour.

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 used in the health care, food service, hospitality, and convenience store markets.

The AETHER[®] brand was acquired on December 31, 2018, when we entered into a Membership Interest Purchase Agreement (the “Agreement”) with Biocon 1, LLC and Aether Water Systems, LLC (collectively, “Aether”), and Gregory Lucas, the sole member of Aether. Pursuant to the terms of the Agreement, we acquired 100% of the outstanding membership interests of Aether (the “Aether Acquisition,” which we have also previously referred to as the “Biocon Acquisition”).

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 OLpür 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.

Reverse Stock Split

On July 9, 2019, we effected a reverse stock split, in which every nine shares of our common stock issued and outstanding immediately prior to the effective time, which was 5:30 p.m. ET on July 9, 2019, were combined into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to \$5.58 per share for such fractional interests. The number of shares of our common stock issued and outstanding was reduced from approximately 69,000,000 to approximately 7,700,000.

All of the share and per share amounts discussed in this Annual Report on Form 10-K have been adjusted to reflect the effect of this reverse split.

Public Offering

On January 31, 2020, we announced the sale of 937,500 shares of common stock through a confidentially marketed underwritten public offering at a price of \$8.00 per share. The transaction closed on February 4, 2020 with aggregate proceeds of \$7,500,000 and net proceeds after underwriting discounts and offering expenses of approximately \$6,765,000. The shares were offered pursuant to an effective shelf registration statement on Form S-3 (File No. 333-234528) that was previously filed with the SEC and declared effective on December 6, 2019.

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 in 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 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 the year since we acquired the AETHER brand, we have seen some promising results in each of these strategies, but it is still too early to judge the likelihood or magnitude of their long-term success.

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 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.

According to the American Hospital Association, approximately 6,200 hospitals, with approximately 931,000 beds, treated over 36 million patients in the United States in 2017. The U.S. Centers for Disease Control and Prevention estimates that healthcare associated infections (“HAI”) occurred in approximately 1 out of every 31 hospital patients, or about 687,000 patients in 2015. 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 recently acquired AETHER® brand expands 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 in 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 a number of large commercial customers. We have recently added to our commercial sales team and, going forward, hope 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 (“IWT”) in both in-line and point-of-use configurations. Our IWT 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 IWT 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 IWT. 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. During the years ended December 31, 2019 and 2018, we recognized royalty revenue of approximately \$16,000 and \$100,000, respectively, related to this Sublicense Agreement. CamelBak product sales have been slower than originally hoped. However, military contracts often take years to close, and we remain optimistic about these products and markets.

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 amoebocyte 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 plan to launch the DiallyPath™ pathogen detection and endotoxin estimation system in the second quarter of this year. The DiallyPath system will mirror our PluraPath but include a gram-negative DNA marker test and test for six different gram-negative bacteria. The DiallyPath 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, we have been able to detect as many as 10 different bacteria families in a single sample. The potential for this kind of building biome mapping is enormous. We will have the ability to process as many as 96 samples in a single run, recognizing over 20,000 different bacteria reference sequences, in less than a day on site. We are currently working on the processes and procedures to provide this as a service, and eventually as a product that we can support with partners who have the in-house technical capabilities to manage this system. Additionally, we are working on drafting a white paper to provide guidance on how to operationalize this building biome mapping tool.

We expect to be able to launch the SequaPath™ system and building biome mapping service before the end of 2020. 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, then we believe that the SequaPath system has the potential to shift the building water testing paradigm across multiple markets and geographies.

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 on a daily basis, 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 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 work flow 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 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.

Once we have obtained FDA clearance for our second-generation device, we intend to launch it at a clinic with previous experience with our device. We plan to then expand our efforts, on a measured basis, to clinics that wish to provide HDF therapy to their patients. At this time, we do not believe making a rapid and broad push into the market would be optimal. Nephrologists in the United States are not trained on HDF therapy; however, many nephrologists want to explore the option and we believe that early adopters will want to perform studies to better understand the technology. We intend to support these investigator-initiated studies.

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, Nevada; Nashville, Tennessee; and Dublin, Ireland. For more information about Nephros, please visit our website at www.nephros.com.

Manufacturing and Suppliers

We do not, and do not intend to in the near future, manufacture any of our medical device products and components. We do manufacture some of our commercial products in our Aether facility in Las Vegas, Nevada.

With regard to 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.

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, 2019 and 2018, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2019	2018
A	19%	6%
B	17%	11%
C	10%	-%
D	10%	10%
E	4%	11%
Total	60%	38%

Due primarily to the success of two significant customer relationships (Customers A and B), concentration levels at our top five customers increased compared to 2018. We expect these two relationships to continue to grow, but that overall concentration levels will remain relatively stable, due to the expected growth of other customer relationships.

As of December 31, 2019 and 2018, the following customers accounted for the following percentages of our accounts receivable, respectively:

Customer	2019	2018
A	26%	5%
B	11%	1%
E	6%	11%
F	-%	15%
D	-%	11%
Total	43%	43%

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 OLPur 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, 2019, we had twelve U.S. patents, four Mexican patents, one South Korean patent, two Chinese patents, two French patents, two German patents, one Israeli patent, two Italian patents, one Spanish patent, two United Kingdom patents, one Canadian patent, one Swedish patent, and one patent in the Netherlands. In addition, we have two pending patent applications in the United States and one in Canada. Our pending patent applications relate to a range of filter technologies, including cartridge configurations, cartridge assembly, substitution fluid systems, and methods to enhance and ensure performance.

Trademarks

As of December 31, 2019, we secured registrations of the trademarks H2H, PATHOGUARD, NANOGUARD, NEPHROS HYDRAGUARD and OLPur in the European Union. In the United States, we secured trademark registrations for OLPur, HYDRAGUARD and NANOGUARD. We have also filed trademark applications for ENDOPUR, PLURAPATH, DIALYPATH, FILPATH and SEQUAPATH in the United States.

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 nation 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 will 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 Européenne, demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported to, or sold or distributed within, the European Union.

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 OLpür MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the Canadian approval of our OLpür 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, 2019, we employed a total of 25 full-time employees, including 8 employed in sales/marketing/customer support, 10 in general and administrative, and 7 in research and development.

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 Company

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, 2019, we had an accumulated deficit of approximately \$127,332,000 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 recent coronavirus outbreak in Italy may impact our supply chain, which could adversely affect our sales and revenues if we are unable to obtain sufficient inventory of products.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. As of February 2020, the virus has spread to Italy, which reportedly has the highest number of coronavirus infections outside Asia. We currently source substantially all of our products from Medica, which is located in Italy. As such, the outbreak of the coronavirus could have a material adverse effect on our business, financial condition and results of operations. These effects could include disruptions from the temporary closure of third-party supplier and manufacturer facilities, or restrictions on the export or shipment of products. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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.

Our Aether Acquisition may not produce the desired outcomes and expected value.

We purchased Aether to increase our revenues and to provide an entry to new markets, with particular focus on hospitality, food service, and convenience stores. However, any acquisition carries risks, including:

- Issues of concern that were missed during due diligence activities;
- Sales to existing Aether customers may not increase as planned;
- Our target markets may be more difficult to grow than anticipated;
- Difficulties could emerge while integrating the two companies and their work forces; and
- Key employees could leave.

As such, we cannot guarantee any specific results from the Aether Acquisition; and if the anticipated outcomes do not occur, our business, financial condition and results of operations may be materially impacted.

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.

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

We do not yet have an established market or customer base for our products. Acceptance of our 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, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform dialysis patients and nephrologists, dialysis clinics and other health care providers of the benefits of using our 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. Factors that may affect our ability to achieve acceptance of our chronic renal failure therapy products in the marketplace include whether:

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

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

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

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

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

We expect 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. Our manufacturers could experience manufacturing and control problems as they begin to scale-up our future manufacturing operations, if any, and we may not be able to scale-up manufacturing in a timely manner or at a commercially reasonable cost to enable production in sufficient quantities. If we experience any of these problems with respect to our manufacturers' initial or future scale-ups of manufacturing operations, then we may not be able to have our products manufactured and delivered in a timely manner. Our products are new and evolving, and our manufacturers may encounter unforeseen difficulties in manufacturing them in commercial quantities or at all.

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.

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 Européenne (“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.

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.

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

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

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.

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 12 granted U.S. patents will expire at various times from 2020 to 2027, 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.

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.

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 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 money. 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, 2019, our common stock has traded at prices ranging from a high of \$11.35 to a low of \$3.42 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 Lambda Investors LLC (“Lambda”) 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 20, 2020, Lambda, our largest stockholder, beneficially owned approximately 39% of our outstanding common stock. Collectively, Lambda, our directors and our executive officers beneficially owned approximately 45% of our outstanding common stock. As a result of this ownership, Lambda has the ability to exert significant influence over our policies and affairs, including the election of directors. Lambda, 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 Lambda, 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 Lambda 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 Lambda 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; 211 Donelson Pike, Suite #7, Nashville, Tennessee 37214; and 3221 Polaris Avenue, Las Vegas, Nevada 89118, and consist of approximately 16,000 total square feet of space. The New Jersey lease expires in November 2022 with a monthly cost of approximately \$11,000. The Nevada lease expires in August 2024 with a monthly cost of approximately \$15,000. We use these facilities to house our corporate headquarters, research, manufacturing, and distribution facilities.

Our office in Europe is currently located at Ulysses House, Foley Street, Dublin, Ireland. The lease agreement was entered into on August 1, 2019 and is for a twelve-month term.

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

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

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, 2019, there were approximately 62 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, 2019 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 2019.

Equity Compensation Plan Information

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

Item 6. Selected Financial Data

Not required for smaller reporting companies.

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

Our pathogen detection system is a portable, real-time system designed to provide actionable data for infection control teams on up to 15 different pathogens from a single water sample, in approximately one hour.

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 used in the health care, food service, hospitality, and convenience store markets.

The AETHER brand was acquired on December 31, 2018, when we entered into a Membership Interest Purchase Agreement (the “Agreement”) with Biocon 1, LLC and Aether Water Systems, LLC (collectively, “Aether”), and Gregory Lucas, the sole member of Aether. Pursuant to the terms of the Agreement, we acquired 100% of the outstanding membership interests of Aether (the “Aether Acquisition,” which we have also previously referred to as the “Biocon Acquisition”).

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 OLPür 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.

Revenue Recognition

We adopted Accounting Standards Codification (“ASC”) 606, Revenue from Contracts with Customers, as of January 1, 2018 using the modified retrospective method. 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.

We recognize 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. In addition to product revenue, we recognize revenue related to license, royalty and other agreements in accordance with the five-step model in ASC 606.

Stock-Based Compensation

The fair value of stock options is recognized as stock-based compensation expense in net loss. We calculate employee stock-based compensation expense in accordance with ASC 718. The fair value of our stock option awards is estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions 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

We account for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement.

Accounts Receivable

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

Inventory Reserves

Our inventory reserve requirements are based on various factors including product expiration date and estimates for the future sales of the product. If estimated sales levels do not materialize, we will reevaluate our assumptions for inventory reserve requirements.

Accrued Expenses

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

Noncontrolling Interest

We present the noncontrolling interest in SRP held by outside shareholders as stockholders' equity on the accompanying consolidated balance sheet, as the noncontrolling interest is redeemable only upon the occurrence of events that are solely within our control.

Segment Reporting

We have two reportable segments, Water Filtration and Renal Products. The Water Filtration segment includes both the medical device and commercial filtration product lines, and currently represents 100% of our consolidated revenues. The Renal Products segment is comprised of SRP, which is focused on the development of medical device products for patients with renal disease, including a second-generation HDF system for the treatment of patients with ESRD.

Our chief operating decision maker evaluates the financial performance of our segments based on revenues, gross margin (where applicable), research and development expenses (R&D), and sales, general, and administrative expenses. The accounting policies for our segments are the same as those described 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.

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, 2019 Compared to the Fiscal Year Ended December 31, 2018

The following table sets forth our summarized, consolidated results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		\$ Increase (Decrease)	% Increase (Decrease)
	2019	2018		
Total net revenues	\$ 10,334,000	\$ 5,687,000	\$ 4,647,000	82%
Cost of goods sold	4,250,000	2,484,000	1,766,000	71%
Gross margin	6,084,000	3,203,000	2,881,000	90%
Gross margin %	59%	56%	-	3%
Research and development expenses	3,090,000	1,539,000	1,551,000	101%
Depreciation and amortization expenses	186,000	163,000	23,000	14%
Selling, general and administrative expenses	6,119,000	4,517,000	1,602,000	35%
Change in fair value of contingent consideration	(156,000)	-	156,000	100%
Loss from operations	(3,155,000)	(3,016,000)	139,000	5%
Loss on extinguishment of debt	-	(199,000)	(199,000)	(100)%
Interest expense	(195,000)	(172,000)	23,000	13%
Interest income	-	4,000	(4,000)	(100)%
Other expense, net	(54,000)	(35,000)	19,000	54%
Loss before income taxes	(3,404,000)	(3,418,000)	(14,000)	(1)%
Income tax benefit	225,000	93,000	132,000	142%
Net loss	(3,179,000)	(3,325,000)	(146,000)	(4)%
Less: Undeclared deemed dividend attributable to noncontrolling interest	(241,000)	(77,000)	164,000	213%
Net loss attributable to Nephros, Inc. shareholders	<u>\$ (3,420,000)</u>	<u>\$ (3,402,000)</u>	<u>\$ 18,000</u>	<u>1%</u>

Water Filtration

The following table sets forth results of operations for the Water Filtration segment for the years ended December 31, 2019 and 2018:

	Fiscal Year Ended December 31,		\$ Increase (Decrease)	% Increase (Decrease)
	2019	2018		
Total net revenues	\$ 10,334,000	\$ 5,687,000	\$ 4,647,000	82%
Cost of goods sold	4,250,000	2,484,000	1,766,000	71%
Gross margin	6,084,000	3,203,000	2,881,000	90%
Gross margin %	59%	56%	-	3%
Research and development expenses	1,717,000	808,000	909,000	113%
Depreciation and amortization expenses	186,000	163,000	23,000	14%
Selling, general and administrative expenses	5,960,000	4,340,000	1,620,000	37%
Change in fair value of contingent consideration	(156,000)	-	156,000	100%
Loss from operations	<u>\$ (1,623,000)</u>	<u>\$ (2,108,000)</u>	<u>\$ (485,000)</u>	<u>(23)%</u>

Net Revenues

Total net revenues for the year ended December 31, 2019 were approximately \$10,334,000 compared to approximately \$5,687,000 for the year ended December 31, 2018. The increase of approximately \$4,647,000, or 82%, was driven by several factors:

- Recurring revenue in our customer base accounted for approximately \$6.4 million, or 62% of total revenues.
- Our customer retention rate was 94%, measured quarterly.
- New customer site acquisition averaged more than one per day in 2019.
- Revenue from responding to disease outbreaks increased approximately 142% over 2018, which we believe reflects our growing reputation for fast and effective outbreak control solutions.
- The Aether Acquisition drove approximately \$738,000 in incremental commercial revenues.

Cost of Goods Sold

Cost of goods sold was approximately \$4,250,000 for the year ended December 31, 2019 compared to approximately \$2,484,000 for the year ended December 31, 2018. The increase of approximately \$1,766,000, or 71%, was due to approximately \$1,879,000 in increased direct product costs in support of increased revenue, partially offset by volume manufacturing discounts of approximately \$135,000 and decreases of approximately \$113,000 in inventory reserves for expiring items and physical count inventory adjustments.

Gross Margin

Gross margin was approximately 59% for the year ended December 31, 2019 compared to approximately 56% for the year ended December 31, 2018. The increase of approximately 3% is primarily due to volume manufacturing discounts of approximately \$135,000 and decreases of approximately \$113,000 in inventory reserves for expiring items and physical count inventory adjustments.

Research and Development Expenses

Research and development expenses were approximately \$1,717,000 and \$808,000 for the years ended December 31, 2019 and December 31, 2018, respectively. This increase of approximately \$909,000, or 113%, was driven by investments in pathogen detection systems and increased headcount associated with filter research and development.

Depreciation and Amortization Expense

Depreciation and amortization expenses were approximately \$186,000 for the year ended December 31, 2019 compared to approximately \$163,000 for the year ended December 31, 2018. The increase of approximately \$23,000, or 14%, is primarily due to amortization of intangible assets recognized in the Aether Acquisition of approximately \$42,000 partially offset by a decrease in depreciation expense of approximately \$17,000 related to fully depreciated assets.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$5,960,000 for the year ended December 31, 2019 compared to approximately \$4,340,000 for the year ended December 31, 2018, representing an increase of \$1,620,000, or 37%. The increase was primarily due to increased headcount-related expenses of approximately \$889,000, increased stock based compensation expense of approximately \$198,000 (primarily related to performance based awards that vested upon our recent Nasdaq listing and certain revenue increases), increased professional and marketing expenses of approximately \$243,000 (including approximately \$66,000 of investor relations expenses primarily related to our recent Nasdaq listing), increased other expenses of approximately \$216,000 (primarily related to rent, insurance and warehouse expenses associated with the Las Vegas facility expansion), and increased travel expenses of approximately \$67,000 in support of increased sales.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was approximately \$156,000 for the year ended December 31, 2019, due to lower than expected Aether performance.

Interest Expense

Interest expense increased approximately \$23,000 primarily due to accretion expense of approximately \$51,000 related to contingent consideration, partially offset by a decrease in interest expense related to our outstanding credit facilities of approximately \$15,000 and a decrease in interest expense related to outstanding payables due to a vendor of approximately \$13,000.

Interest Income

There was no interest income for the year ended December 31, 2019. Interest income of approximately \$4,000 for the year ended December 31, 2018 was a result of interest income recognized on an equipment lease. This equipment lease was terminated as a result of the Aether Acquisition.

Other Expense, net

Other expense was approximately \$54,000 and \$35,000 for the years ended December 31, 2019 and 2018, respectively, as a result of losses on foreign currency transactions.

Income Tax Benefit

In the years ended December 31, 2019 and 2018, an income tax benefit of approximately \$225,000 and \$93,000, respectively, was recorded due to the sale of net operating loss and research and development credit carryforwards under the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program.

Renal Products

The following table sets forth results of operations for the Renal Products segment for the years ended December 31, 2019 and 2018:

	Years Ended December 31,		\$ Increase (Decrease)	% Increase (Decrease)
	2019	2018		
Research and development expenses	\$ 1,373,000	731,000	\$ 642,000	88%
Selling, general and administrative expenses	159,000	177,000	(18,000)	(10)%
Loss from operations	\$ (1,532,000)	\$ (908,000)	\$ 624,000	69%

Research and Development Expenses

Research and development expenses were approximately \$1,373,000 and \$731,000 for the years ended December 31, 2019 and 2018, respectively, an increase of approximately \$642,000 due to increased investment in the second-generation HDF product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$159,000 and \$177,000 for the years ended December 31, 2019 and 2018, respectively, a decrease of approximately \$18,000 primarily related to a decrease in legal expenses incurred as a result of the formation of SRP during the year ended December 31, 2018.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2019.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2019 and 2018 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and Capital Resources	December 31,	
	2019	2018
Cash	\$ 4,166	\$ 4,581
Other current assets	4,133	3,592
Working capital	5,871	5,519
Stockholders' equity	7,689	6,798

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, 2019, we had an accumulated deficit of approximately \$127,332,000, 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.

On February 4, 2020, we completed a confidentially marketed underwritten public offering whereby we sold 937,500 shares of our common stock for aggregate proceeds of approximately \$6,765,000. Based on cash that is available for our operations and projections of our future operations, we believe that our cash balances will be sufficient to fund our current operating plan through at least the next 12 months from the date of issuance of the 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 the possible inability of us 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 approximately \$2,276,000 for the year ended December 31, 2019 compared to approximately \$3,662,000 for the year ended December 31, 2018, a decrease of approximately \$1,386,000. This decrease is due to a combination of factors, primarily lower expenditures on inventory as a result of managing inventory levels and improvements in accounts receivable collections during the year ended December 31, 2019 compared to December 31, 2018.

Net cash used in investing activities was approximately \$151,000 for the year ended December 31, 2019 due to a working capital adjustment of approximately \$137,000 related to the Aether Acquisition and an equipment purchase of approximately \$14,000.

Net cash used in investing activities was approximately \$991,000 for the year ended December 31, 2018 as a result of the Aether Acquisition.

Net cash provided by financing activities of approximately \$2,017,000 for the year ended December 31, 2019 resulted from net proceeds from the issuance of common stock of approximately \$1,992,000, proceeds from the exercise of warrants of approximately \$731,000, proceeds from the exercise of stock options of approximately \$21,000, and proceeds from equipment financing of approximately \$14,000, partially offset by net payments on our secured revolving credit facility of approximately \$431,000, payments on our secured note payable of approximately \$214,000, payment of contingent consideration related to the Aether Acquisition of approximately \$94,000, and payments on a financing obligation of approximately \$2,000.

Net cash provided by financing activities of approximately \$7,047,000 for the year ended December 31, 2018 resulted from net proceeds from the issuance of common stock of approximately \$3,778,000, contributions from the sale of preferred stock of SRP to a noncontrolling interest of approximately \$3,000,000, proceeds from the issuance of a secured note payable of approximately \$1,187,000, proceeds from the exercise of warrants of approximately \$138,000, and net proceeds from our secured revolving credit facility of approximately \$280,000. These items were offset partially by payments on our secured note payable of approximately \$149,000 and payments on our unsecured long-term note payable of approximately \$1,187,000.

Contractual Obligations and Commercial Commitments

The following table summarizes our approximate minimum contractual obligations and commercial commitments as of December 31, 2019:

	Payments Due in Period				
	Total	Within 1 Year	Years 2 - 3	Years 4 - 5	More than 5 Years
Minimum Purchase Commitments ¹	\$ 24,000,000	\$ 3,500,000	\$ 7,600,000	\$ 8,400,000	\$ 4,500,000
Leases ²	1,339,000	339,000	662,000	338,000	-
Total	\$ 25,339,000	\$ 3,839,000	\$ 8,262,000	\$ 8,738,000	\$ 4,500,000

¹ Reflects minimum purchase commitments pursuant to our License and supply agreement with Medica.

² In addition to lease obligations for office space, these obligations include a lease for various office equipment which expires in 2020 and an automobile lease which expires in 2021.

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.
South Orange, New Jersey

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, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, 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.

/s/ Moody, Famiglietti & Andronico, LLP

We have served as the Company's auditor since 2015.
Tewksbury, Massachusetts
February 27, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	\$ 4,166	\$ 4,581
Accounts receivable, net	1,045	1,359
Inventory, net	2,562	1,864
Prepaid expenses and other current assets	526	369
Total current assets	8,299	8,173
Property and equipment, net	81	91
Operating lease right-of-use assets	1,106	-
Intangible assets, net	548	590
Goodwill	759	748
License and supply agreement, net	804	938
Other assets	32	18
TOTAL ASSETS	\$ 11,629	\$ 10,558
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Secured revolving credit facility	\$ 560	\$ 991
Current portion of secured note payable	211	195
Accounts payable	959	836
Accrued expenses	136	396
Current portion of contingent consideration	300	236
Current portion of operating lease liabilities	262	-
Total current liabilities	2,428	2,654
Secured note payable, net of current portion	613	843
Equipment financing, net of current portion	10	-
Contingent consideration, net of current portion	-	263
Operating lease liabilities, net of current portion	889	-
TOTAL LIABILITIES	3,940	3,760
COMMITMENTS AND CONTINGENCIES (Note 20)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018.	-	-
Common stock, \$.001 par value; 40,000,000 and 10,000,000 shares authorized at December 31, 2019 and 2018, respectively; 8,058,850 and 7,184,609 shares issued and outstanding at December 31, 2019 and 2018, respectively.	8	7
Additional paid-in capital	131,934	127,873
Accumulated other comprehensive income	65	71
Accumulated deficit	(127,332)	(124,153)
Subtotal	4,675	3,798
Noncontrolling interest	3,014	3,000
TOTAL STOCKHOLDERS' EQUITY	7,689	6,798
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 11,629	\$ 10,558

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,	
	2019	2018
Net revenue:		
Product revenues	\$ 10,182	\$ 5,457
Royalty and other revenues	152	230
Total net revenues	<u>10,334</u>	<u>5,687</u>
Cost of goods sold		
	4,250	2,484
Gross margin	<u>6,084</u>	<u>3,203</u>
Operating expenses:		
Research and development	3,090	1,539
Depreciation and amortization	186	163
Selling, general and administrative	6,119	4,517
Change in fair value of contingent consideration	(156)	-
Total operating expenses	<u>9,239</u>	<u>6,219</u>
Loss from operations	(3,155)	(3,016)
Other income (expense):		
Loss on extinguishment of debt	-	(199)
Interest expense	(195)	(172)
Interest income	-	4
Other expense, net	(54)	(35)
Loss before income taxes	(3,404)	(3,418)
Income tax benefit	225	93
Net loss	(3,179)	(3,325)
Less: Undeclared deemed dividend attributable to noncontrolling interest	(241)	(77)
Net loss attributable to Nephros, Inc. shareholders	<u>\$ (3,420)</u>	<u>\$ (3,402)</u>
Net loss per common share, basic and diluted		
	\$ (0.45)	\$ (0.50)
Weighted average common shares outstanding, basic and diluted	7,542,299	6,846,669
Comprehensive loss:		
Net loss	\$ (3,179)	\$ (3,325)
Other comprehensive loss, foreign currency translation adjustments, net of tax	(6)	(6)
Comprehensive loss	(3,185)	(3,331)
Comprehensive loss attributable to noncontrolling interest	(241)	(77)
Comprehensive loss attributable to Nephros, Inc. shareholders	<u>\$ (3,426)</u>	<u>\$ (3,408)</u>

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 Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Subtotal	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount						
Balance, December 31, 2017	6,143,663	\$ 6	\$ 122,973	\$ 77	\$ (121,106)	\$ 1,950	\$ -	\$ 1,950
Net loss					(3,325)	(3,325)		(3,325)
Noncontrolling interest							3,000	3,000
Cumulative effect of adoption of ASC 606					278	278		278
Net unrealized losses on foreign currency translation, net of tax				(6)		(6)		(6)
Issuance of common stock, net of equity issuance costs of \$19	937,846	1	3,777			3,778		3,778
Cashless exercise of options	2,471	-				-		-
Exercise of warrants	50,739	-	138			138		138
Noncash stock-based compensation			985			985		985
Balance, December 31, 2018	<u>7,134,719</u>	<u>\$ 7</u>	<u>\$ 127,873</u>	<u>\$ 71</u>	<u>\$ (124,153)</u>	<u>\$ 3,798</u>	<u>\$ 3,000</u>	<u>\$ 6,798</u>
Net loss					(3,179)	(3,179)		(3,179)
Net unrealized losses on foreign currency translation, net of tax				(6)		(6)		(6)
Issuance of common stock, net of equity issuance costs of \$8	493,827	1	1,991			1,992		1,992
Issuance of vested restricted stock	44,270	-				-		-
Exercise of warrants	327,351	-	731			731		731
Exercise of stock option	4,166	-	21			21		21
Aggregate fractional shares cancelled due to reverse stock split	(594)	-	-			-		-
Noncash stock-based compensation			1,318			1,318	14	1,332
Balance, December 31, 2019	<u>8,003,739</u>	<u>\$ 8</u>	<u>\$ 131,934</u>	<u>\$ 65</u>	<u>\$ (127,332)</u>	<u>\$ 4,675</u>	<u>\$ 3,014</u>	<u>\$ 7,689</u>

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,	
	2019	2018
OPERATING ACTIVITIES:		
Net loss	\$ (3,179)	\$ (3,325)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	24	29
Amortization of intangibles and license and supply agreement	176	134
Non-cash stock-based compensation, including stock options and restricted stock	1,332	985
Loss on extinguishment of debt	-	199
Inventory reserve	37	70
Allowance for doubtful accounts reserve	15	40
Amortization of debt discount	-	34
Change in fair value of contingent consideration	(156)	-
Accretion of contingent consideration	51	-
Loss on disposal of equipment	-	10
Loss on capital lease termination	-	11
Loss on foreign currency transactions	4	3
(Increase) decrease in operating assets:		
Accounts receivable	392	(391)
Inventory	(735)	(1,082)
Prepaid expenses and other current assets	(265)	(284)
Operating right-of-use assets and operating lease liabilities	51	-
Other assets	(21)	-
Increase (decrease) in operating liabilities:		
Accounts payable	119	(130)
Accrued expenses	(121)	35
Net cash used in operating activities	<u>(2,276)</u>	<u>(3,662)</u>
INVESTING ACTIVITIES:		
Purchase of equipment	(14)	-
Acquisition of Aether, net of cash acquired	(137)	(991)
Net cash used in investing activities	<u>(151)</u>	<u>(991)</u>
FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of equity issuance costs of \$8 and \$19, respectively	1,992	3,778
Net (payments) proceeds from secured revolving credit facility	(431)	280
Proceeds from sale of subsidiary preferred shares to noncontrolling interest	-	3,000
Proceeds from equipment financing	14	-
Principal payments on equipment financing debt	(2)	-
Payments on secured note payable	(214)	(149)
Payment of contingent consideration	(94)	-
Proceeds from issuance of secured note	-	1,187
Repayment of unsecured long term note payable	-	(1,187)
Proceeds from exercise of warrants	731	138
Proceeds from exercise of stock options	21	-
Net cash provided by financing activities	<u>2,017</u>	<u>7,047</u>
Effect of exchange rates on cash	<u>(5)</u>	<u>(7)</u>
Net (decrease) increase in cash	(415)	2,387
Cash, beginning of year	4,581	2,194
Cash, end of year	<u>\$ 4,166</u>	<u>\$ 4,581</u>
Supplemental disclosure of cash flow information		
Cash paid for interest expense	<u>\$ 139</u>	<u>\$ 150</u>
Cash paid for income taxes	<u>\$ 5</u>	<u>\$ 4</u>
Supplemental disclosure of noncash investing and financing activities		
Right-of-use asset obtained in exchange for lease liability	<u>\$ 800</u>	<u>-</u>
Fair value of contingent consideration related to the Aether Acquisition	<u>\$ -</u>	<u>\$ 499</u>
Reclassification of capital lease to equipment	<u>\$ -</u>	<u>\$ 39</u>

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 Company’s pathogen detection system is a portable, real-time system designed to provide actionable data for infection control teams on up to 15 different pathogens from a single water sample, in approximately one hour. The water filtration business is a reportable segment, referred to as the Water Filtration segment.

In July 2018, the Company formed a new subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of its second-generation hemodiafiltration (“HDF”) 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.

On December 31, 2018, the Company entered into a Membership Interest Purchase Agreement (the “Aether Agreement”) with Biocon 1, LLC and Aether Water Systems, LLC (collectively, “Aether”), and Gregory Lucas, the sole member of Aether. Pursuant to the terms of the Aether Agreement, the Company acquired 100% of the outstanding membership interests of Aether (the “Aether Acquisition”, which has also been previously referred to as the “Biocon Acquisition”).

The Company’s primary U.S. facilities are located at 380 Lackawanna Place, South Orange, New Jersey, 07079, and at 3221 Polaris Avenue, Las Vegas, Nevada 89102. 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

Reverse Stock Split

On May 22, 2019, the Company’s Board of Directors authorized a 1-for-9 reverse stock split and approved an amendment to the Company’s Certificate of Incorporation to affect the 1-for-9 reverse split of the Company’s common stock, which was effected at 5:30 p.m. ET on July 9, 2019. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to \$5.58 per share for such fractional interests. All of the share and per share amounts discussed in the accompanying consolidated financial statements have been adjusted to reflect the effect of this reverse split.

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 shareholders’ 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.

Reclassifications

Certain reclassifications were made to the prior year’s amounts to conform to the 2019 presentation. The receivable related to the income tax benefit of approximately \$93,000 recognized in the year ended December 31, 2018 previously presented in accounts receivable, net, at December 31, 2018 is now presented in prepaid expenses and other current assets.

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 approximately \$127,332,000 as of December 31, 2019. On February 4, 2020, the Company completed a confidentially marketed underwritten public offering whereby the Company sold 937,500 shares of its common stock for aggregate net proceeds of approximately \$6,765,000. The Company also has a loan agreement with a lender, which provides a secured asset-based revolving credit facility. This loan agreement was amended on December 20, 2019 to increase the borrowing capacity from \$1,000,000 to \$2,500,000.

In July 2018, the Company formed a new subsidiary, SRP, to drive the development of its second-generation HDF system and other products focused on improving therapies for patients with renal disease. 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 \$3,000,000. As of the date of issuance of the accompanying consolidated financial statements, SRP has approximately \$539,000 in cash. The proceeds of this private placement 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.

Based on cash that is available for Company operations and projections of future Company operations, the Company believes that its cash will be sufficient to fund the Company’s current operating plan through at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. Additionally, management’s operating plans are designed to help control operating costs, to increase revenue and to raise additional capital until such time as the Company generates sufficient cash flows from operations. If there were a decrease in the demand for the Company’s products due to either economic or competitive conditions, or management were unable to achieve its plan, there could be a significant reduction in liquidity due to the possible inability of the Company to cut costs sufficiently.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, “Leases,” (“ASC 842”) which discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. The Company adopted the guidance on January 1, 2019 using the transition method provided by ASU 2018-11, “Leases (Topic 842): Targeted Improvements.” Under this transition method, the Company applied the new requirements to only those leases that existed as of January 1, 2019, rather than at the earliest comparative period presented in the financial statements. Prior periods will be presented under existing lease guidance. Upon transition, the Company applied the package of practical expedients permitted under the ASC 842 transition guidance. As a result, the Company did not reassess (1) whether expired or existing contracts contain leases under the new definition of a lease, including whether an existing or expired contract contains an embedded lease, (2) lease classification for expired or existing leases and (3) any initial direct costs of existing leases. As a result of the adoption of this guidance on January 1, 2019, the Company recorded right-of-use assets of approximately \$613,000, net of approximately \$8,000 of deferred rent liability, and lease liabilities of approximately \$621,000. Adoption of the guidance did not have any impact on the Company’s consolidated statements of operations and comprehensive loss or cash provided by or used in operating, investing or financing activities on its consolidated statements of cash flows.

In June 2016, the FASB issued ASU 2016-13, “Measurement of Credit Losses on Financial Instruments,” which replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. The Company early adopted this guidance as of January 1, 2019 and the guidance did not have an impact on its consolidated financial statements.

In May 2018, the FASB issued ASU 2018-07, “Improvements to Nonemployee Share-Based Payment Accounting,” which expands the scope of Accounting Standards Codification (“ASC”) 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted this guidance as of January 1, 2019 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, 2019 and 2018, the following customers accounted for the following percentages of the Company’s revenues, respectively:

Customer	2019	2018
A	19%	6%
B	17%	11%
C	10%	-%
D	10%	10%
E	4%	11%
Total	60%	38%

As of December 31, 2019 and 2018, the following customers accounted for the following percentages of the Company’s accounts receivable, respectively:

Customer	2019	2018
A	26%	5%
B	11%	1%
E	6%	11%
F	-%	15%
D	-%	11%
Total	43%	43%

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 \$25,000 and \$15,000 as of December 31, 2019 and 2018, respectively. The increase of approximately \$10,000 to the allowance for doubtful accounts was primarily due to provision for bad debt expense of approximately \$15,000 for the year ended December 31, 2019 offset by write-offs of accounts receivable of approximately \$5,000 which were fully reserved. For the year ended December 31, 2018, provision for bad debt expense was approximately \$40,000.

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. As a result of the Aether Acquisition, 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.

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

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 10 – License and Supply Agreement, net for further discussion.

Patents

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. All costs and direct expenses incurred in connection with patent applications have been expensed as incurred and are included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

Leases

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

Operating lease ROU assets and operating 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 Accounting Standards Codification (“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, 2019 and 2018.

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.

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.

Shipping and Handling Costs

Shipping and handling costs charged to customers are recorded as cost of goods sold and were approximately \$90,000 and \$45,000 for the years ended December 31, 2019 and 2018, respectively.

Research and Development Costs

Research and development costs are expensed as incurred.

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.

Amortization of Debt Issuance Costs and Debt Discounts

The Company accounts for debt issuance costs in accordance with ASC 835 which requires that costs paid directly to the issuer of a recognized debt liability be reported in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company amortizes the debt discount, including debt issuance costs, in accordance with ASC 835 over the term of the associated debt. See Note 13 – Unsecured Promissory Notes and Warrants for a discussion of the Company's prior unsecured long-term note payable.

Other Expense, net

Other expense, net, of approximately \$54,000 and approximately \$35,000 for the years ended December 31, 2019 and 2018, respectively, is primarily due to foreign currency transaction gains and 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, 2019 and 2018.

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 2013. During the years ended December 31, 2019 and 2018, 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 Company recognized an income tax benefit of approximately \$225,000 and \$93,000 for the years ended December 31, 2019 and 2018, respectively, from the sale of net operating loss and research and development credit carryforwards under the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. These amounts are recorded on the consolidated financial statements as income tax benefit in the year they are earned. See Note 16 – Income Taxes for further discussion.

Net Income (Loss) per Common Share

Basic net income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted net income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants, 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,	
	2019	2018
Shares underlying options outstanding	1,011,082	826,061
Shares underlying warrants outstanding	378,924	738,070
Unvested restricted stock	55,111	49,890

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 Income (Loss)

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

Recent Accounting Pronouncements, Not Yet Effective

In January 2017, the FASB issued ASU 2017-04, “Simplifying the Test for Goodwill Impairment,” which simplifies the test for goodwill impairment. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual goodwill impairments tests after January 1, 2017. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Disclosure Framework-Changes to the Disclosure Requirements for the Fair Value Measurement,” which modifies the disclosure requirements on fair value measurements. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract,” which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, “Collaborative Arrangements: Clarifying the Interaction Between Topic 808 and Topic 606.” This guidance clarifies that, when the collaborative arrangement participant is a customer in the context of a unit-of-account, revenue from contracts with customers guidance should be applied, adds unit-of-account guidance to collaborative arrangements guidance, and requires, that in a transaction with a collaborative arrangement participant who is not a customer, presenting the transaction together with revenue recognized under contracts with customers is precluded. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on its consolidated financial statements.

In November 2019, the FASB issued ASU 2019-08, “Codification Improvements – Share-Based Consideration Payable to a Customer,” which requires that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on its consolidated financial statements.

In December 2019, the FASB issued 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 guidance is effective for the Company beginning in the first quarter of fiscal year 2021. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

Note 3 – Aether Acquisition

On December 31, 2018, the Company completed the Aether Acquisition, which included the acquisition of 100% of the outstanding membership interests of Aether. The purpose of the Aether Acquisition was to accelerate growth and to expedite entry into additional markets.

Transaction costs associated with the Aether Acquisition of approximately \$33,000 were recorded in selling, general and administrative expenses for the year ended December 31, 2018.

The Company has accounted for the Aether Acquisition as a business combination under the acquisition method of accounting.

The following is a summary of total consideration for the Aether Acquisition, including a final working capital adjustment during the year ended December 31, 2019 of approximately \$11,000:

	Total Consideration
Fixed purchase price	\$ 1,070,000
Acquisition date fair value of contingent consideration	562,000
Total consideration¹	\$ 1,632,000

¹Total consideration of \$1,632,000 consists of \$5,000 in accrued expenses, \$137,000 in working capital payments, \$499,000 of contingent consideration liabilities, and an upfront payment of \$991,000, of which \$250,000 was placed in escrow as of the date of the acquisition. Of the \$250,000 placed in escrow, \$187,000 and \$63,000 are included in fixed purchase price and acquisition date fair value of contingent consideration, respectively, in the total consideration table presented above.

The Company has allocated the total consideration for the transaction based upon the fair value of net assets acquired and liabilities assumed at the date of acquisition.

The following is a summary of the purchase price allocation for the Aether Acquisition. Changes to the purchase price allocation from amounts reported in the Company's consolidated financial statements for the year ended December 31, 2018 were due to the final working capital adjustment.

	Fair Values
Trade accounts receivable	\$ 164,000
Inventories	179,000
Equipment	39,000
Security deposit	7,000
Goodwill	759,000
Intangible assets	590,000
Total assets acquired, net of cash acquired	1,738,000
Accounts payable	91,000
Accrued expenses	15,000
Total liabilities assumed	106,000
Net assets acquired, net of cash acquired	\$ 1,632,000

Intangible Assets

The acquired intangible assets are being amortized over their estimated useful lives as follows:

	Fair Values	Weighted Average Useful Life (Years)
Tradenames, service marks and domain names	50,000	5
Customer relationships	540,000	17
Total intangible assets	\$ 590,000	

Estimated aggregate amortization expense for each of the next four years is estimated to be approximately \$42,000, followed by approximately \$32,000 in the fifth year.

The estimated fair value of the identifiable intangible assets was determined using the "income approach," which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. The assumptions, including the expected projected cash flows, utilized in the purchase price allocation and in determining the purchase price were based on the Company's best estimates as of December 31, 2018, the closing date of the Aether Acquisition.

Some of the more significant assumptions inherent in the development of those asset valuations include the estimated net cash flows for each year for each asset or product (including net revenues, cost of sales, research and development costs, selling and marketing costs and working capital / contributory asset charges), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream, as well as other factors. No assurances can be given that the underlying assumptions used to prepare the discounted cash flow analysis will not change. For these and other reasons, actual results may vary significantly from estimated results.

Goodwill

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized. Factors that contributed to the Company's recognition of goodwill include the Company's intent to expand its product portfolio. Goodwill has been allocated to the Water Filtration segment.

Unaudited Pro Forma Results of Operations

The following table reflects the unaudited pro forma combined results of operations for the year ended December 31, 2018 (assuming the closing of the Aether Acquisition occurred on January 1, 2017):

	Year Ended December 31, 2018	
Total revenues	\$	6,412,000
Net loss attributable to Nephros, Inc	\$	(3,158,000)

The pro forma results have been prepared for comparative purposes only and are not necessarily indicative of the actual results of operations had the closing of the Aether Acquisition taken place on January 1, 2017. Furthermore, the pro forma results do not purport to project the future results of operations of the Company.

The unaudited pro forma information reflects the following adjustments:

- Adjustment to amortization expense for the year ended December 31, 2018 of approximately \$21,000 related to identifiable intangible assets acquired;
- Adjustment, net of a reduction, to depreciation expense for the year ended December 31, 2018 of approximately \$10,000 related to equipment acquired and for which the capitalization policy and useful lives were adjusted based on the Company's policy;
- Adjustment to selling, general and administrative expense related to transaction costs directly attributable to the Aether Acquisition, including the elimination of \$33,000 of expenses incurred in the year ended December 31, 2018;
- Eliminate interest expense in the historical Aether results of operations and eliminate interest income in the Company's historical results of operations, each of which was approximately \$4,000 for the year ended December 31, 2018, which interest was related to a lease that was terminated as of the acquisition; and
- Eliminate sales, and related cost of goods, for products sold by Aether to the Company, with a gross margin impact of approximately \$5,000 for the year ended December 31, 2018.

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, 2019 or 2018. 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 revenue recognized for the years ended December 31, 2019 and 2018 is comprised of:

	Years Ended December 31,	
	2019	2018
Royalty revenue under the Sublicense Agreement with CamelBak ⁽¹⁾	\$ 16,000	\$ 100,000
Royalty revenue under the License Agreement with Belco	59,000	101,000
Other revenue	77,000	29,000
Total royalty and other revenue	<u>\$ 152,000</u>	<u>\$ 230,000</u>

- (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 are not met or exceeded, the Company was able to convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. In the first quarter of 2019, the Sublicense Agreement was amended to eliminate the minimum fee obligations starting May 6, 2018 and, as such, Camelbak has no further minimum fee 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 recognized as license revenue over the term of the License Agreement. As of the adoption of ASC 606, the remaining deferred revenue of approximately \$278,000 was recognized as a cumulative effect adjusted to accumulated deficit as of January 1, 2018 in accordance with ASC 606.

The License Agreement, as amended, also provides 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 will 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 \$1.95) per unit; thereafter, €1.25 (approximately \$1.40) per unit. The License Agreement also provides 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.

The Company recognized royalty income from Bellco pursuant to the License Agreement for the years ended December 31, 2019 and 2018 of approximately \$59,000 and \$101,000, respectively.

Note 5 – 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.

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, 2019:

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2019:				
Total contingent consideration liability	\$ -	\$ -	\$ 300,000	\$ 300,000

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, 2018:

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2018:				
Total contingent consideration liability	\$ -	\$ -	\$ 499,000	\$ 499,000

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, 2019:

	Contingent Consideration
Balance as of December 31, 2018	\$ 499,000
Payments against contingent consideration	(94,000)
Change in fair value of contingent consideration liability	(156,000)
Accretion of contingent consideration liability	51,000
Balance as of December 31, 2019	\$ 300,000

Accretion expense of approximately \$51,000 is included in interest expense on the accompanying consolidated statement of operation and comprehensive loss for the year ended December 31, 2019.

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, 2019.

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

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

The carrying amounts of the secured long-term note payable as of December 31, 2019 and 2018 and the carrying amounts of equipment financing debt and operating lease liabilities as of December 31, 2019 approximate fair value as of December 31, 2019 and 2018 because those financial instruments bear interest at rates that approximate current market rates for similar agreements with similar maturities and credit.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

See Note 3 – Aether Acquisition for the allocation of the total consideration for the Aether Acquisition based upon the fair value of net assets acquired and liabilities assumed at the date of acquisition.

Note 6 - Inventory, net

The Company’s inventory components as of December 31, 2019 and 2018 were as follows:

	December 31,	
	2019	2018
Finished goods	\$ 2,248,000	\$ 1,633,000
Raw material	359,000	280,000
Less: inventory reserve	(45,000)	(49,000)
Total inventory, net	<u>\$ 2,562,000</u>	<u>\$ 1,864,000</u>

Note 7- Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2019 and 2018 were as follows:

	December 31,	
	2019	2018
Prepaid insurance premiums	\$ 40,000	\$ 45,000
Deposit for future services	200,000	200,000
Receivable related to the sale of net operating loss and research and development credit carryforwards	225,000	93,000
Other	61,000	31,000
Prepaid expenses and other current assets	<u>\$ 526,000</u>	<u>\$ 369,000</u>

Note 8 - Property and Equipment, Net

Property and equipment as of December 31, 2019 and 2018 was as follows:

	Life	December 31,	
		2019	2018
Manufacturing equipment	3-7 years	\$ 782,000	\$ 768,000
Research equipment	5 years	37,000	37,000
Computer equipment	3-4 years	43,000	43,000
Furniture and fixtures	7 years	37,000	37,000
Property and equipment, gross		899,000	885,000
Less: accumulated depreciation		(818,000)	(794,000)
Property and equipment, net		\$ 81,000	\$ 91,000

Depreciation related to equipment utilized in the manufacturing process is recognized in cost of goods sold on the consolidated statements of operations and comprehensive loss. Depreciation expense for the years ended December 31, 2019 and 2018 was approximately \$24,000 and \$29,000, respectively. Approximately \$14,000 of depreciation expense has been recognized in cost of goods sold for the year ended December 31, 2019. There was no depreciation recognized in cost of goods sold for the year ended December 31, 2018.

Note 9 – 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, 2019:

	December 31, 2019		
	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net
Tradenames, service marks and domain names	\$ 50,000	\$ (10,000)	\$ 40,000
Customer relationships	540,000	(32,000)	508,000
Total intangible assets	\$ 590,000	\$ (42,000)	\$ 548,000

The Company recognized amortization expense of approximately \$42,000 for the year ended December 31, 2019 in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss.

As of December 31, 2019, future amortization expense for the next five years is estimated to be:

2020	\$ 42,000
2021	\$ 42,000
2022	\$ 42,000
2023	\$ 42,000
2024	\$ 32,000

The Company did not recognize any intangible asset impairment charges during the year ended December 31, 2019.

Goodwill

Goodwill had a carrying value on the Company's consolidated balance sheets of approximately \$759,000 and \$748,000 at December 31, 2019 and 2018, respectively. As a result of a final working capital adjustment, goodwill increased approximately \$11,000 during the year ended December 31, 2019. Goodwill has been allocated to the Water Filtration segment. The Company concluded the carrying value of goodwill was not impaired as of December 31, 2019 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 10 – 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 approximately \$2,250,000. License and supply agreement, net, on the consolidated balance sheet is approximately \$804,000 and \$938,000 as of December 31, 2019 and 2018, respectively. Accumulated amortization is approximately \$1,446,000 and \$1,312,000 as of December 31, 2019 and 2018, respectively. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Amortization expense of approximately \$134,000 was recognized in each of the years ended December 31, 2019 and 2018 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 year ended December 31, 2019. For the year ended December 31, 2018, approximately \$13,000 of interest expense was recognized on the consolidated statement of operations and comprehensive loss.

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. Approximately \$273,000 and \$161,000 for the year ended December 31, 2019 and 2018, respectively, was recognized as royalty expense and is included in cost of goods sold on the consolidated statement of operations and comprehensive loss. Approximately \$83,000 and \$50,000 are included in accounts payable as of December 31, 2019 and 2018, respectively.

Note 11 – Secured Revolving Credit Facility

On August 17, 2017, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Tech Capital, LLC ("Tech Capital"). The Loan Agreement initially provided for a secured asset-based revolving credit facility of up to \$1,000,000, which the Company may draw upon and repay from time to time during the term of the Loan Agreement. On December 20, 2019, the Company and Tech Capital entered into a First Modification to the Loan Agreement ("the Amendment"). The Amendment increased the senior secured asset-based revolving credit facility from \$1,000,000 to \$2,500,000.

The outstanding principal balance of the Loan Agreement was approximately \$560,000 and \$991,000 as of December 31, 2019 and 2018, respectively. The Company is using these proceeds for working capital and general corporate purposes.

The Loan Agreement has a term of 12 months and, as a result of the Amendment, will automatically renew for successive 12-month periods, measured from the date of the Amendment. Availability under the Loan Agreement will be based upon periodic borrowing base certifications valuing certain of the Company's accounts receivable and inventory. Outstanding borrowings under the Loan Agreement accrue interest, which is payable monthly based on the average daily outstanding balance, at a rate equal to 3.5% plus the prime rate per annum, provided that such prime rate is not less than 4.25% per annum and provided that such monthly interest payment is not less than \$6,500. As of December 31, 2019, the current interest rate was 8.25% per annum.

The Company also granted to Tech Capital a first priority security interest in its assets, including its accounts receivable and inventory, to secure all of its obligations under the Loan Agreement. In addition, Nephros International Limited, the Company's wholly-owned subsidiary, unconditionally guaranteed the Company's obligations under the Loan Agreement.

As a result of the Amendment, the Company was required to pay to Tech Capital 0.50% of the maximum amount of credit available under the Loan Agreement and on each anniversary thereof while there remain outstanding amounts under the Loan Agreement.

For the years ended December 31, 2019 and 2018, approximately \$67,000 and \$22,000, respectively, was recognized as interest expense on the consolidated statement of operations and comprehensive loss. Included in interest expense was approximately \$14,000 of fees related to the Amendment. As of December 31, 2019, approximately \$7,000 of the \$67,000 of interest expense incurred for the year ended December 31, 2019 is included in accrued expenses on the consolidated balance sheet. As of December 31, 2018, approximately \$2,000 of the \$22,000 of interest expense incurred for the year ended December 31, 2018 is included in accrued expenses on the consolidated balance sheet.

Note 12 – Secured Note Payable

On March 27, 2018, the Company entered into a Secured Promissory Note Agreement (the "Secured Note") with Tech Capital, LLC ("Tech Capital") for a principal amount of \$1,187,000. The Company used the proceeds from the Secured Note to repay the Company's 11% unsecured promissory notes issued in June 2016 pursuant to the Note and Warrant Agreement (see Note 13 – Unsecured Promissory Notes and Warrants). As of December 31, 2019 and 2018, the principal balance of the Secured Note was approximately \$824,000 and \$1,038,000, 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 11 – 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.

During the years ended December 31, 2019 and 2018, the Company made payments under the Secured Note of approximately \$289,000 and \$216,000, respectively. Included in the total payments made, approximately \$75,000 and \$67,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019 and 2018, respectively. Debt issuance costs of approximately \$6,000 were recognized as interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

As of December 31, 2019, future principal maturities are as follows:

2020	\$	211,000
2021		249,000
2022		269,000
2023		95,000
Total	\$	<u>824,000</u>

Note 13 - Unsecured Promissory Notes and Warrants

In June 2016, the Company entered into a Note and Warrant Agreement (the “Note and Warrant Agreement”) with new creditors as well as existing stockholders under which the Company issued unsecured promissory notes and warrants resulting in total gross proceeds to the Company of approximately \$1,187,000. The outstanding principal under the notes accrued interest at a rate of 11% per annum. The notes required the Company to make interest only payments on a semi-annual basis, with all outstanding principal under the notes being repayable in cash on the third anniversary of the date of issuance. In addition to the notes, the Company issued warrants to purchase approximately 300,000 shares of the Company’s common stock. The portion of the gross proceeds allocated to the warrants, approximately \$393,000, was accounted for as additional paid-in capital resulting in a debt discount. The debt discount, which included approximately \$9,000 of debt issuance costs in addition to the fair value of the warrants, was being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the Note and Warrant Agreement.

On March 30, 2018, the principal balance of the notes, along with the remaining accrued interest of approximately \$43,000, was repaid in full. Approximately \$30,000 of the approximately \$43,000 was recognized as interest expense on the Company’s consolidated statement of operations and comprehensive loss for the year ended December 31, 2018. The remaining approximately \$13,000 was accrued in the prior year. The remaining debt discount of approximately \$199,000 was recorded as loss on extinguishment of debt in the Company’s consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

For the year ended December 31, 2018, approximately \$34,000 was recognized as amortization of debt discount and is included in interest expense on the consolidated statement of operations and comprehensive loss.

For the year ended December 31, 2018, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda Investors, LLC, the Company’s largest stockholder, was approximately \$1,000.

Note 14 – 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 5 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 other assets on the consolidated balance sheet as of December 31, 2019 and 2018. The Company uses this facility to house its corporate headquarters and research facilities.

The Company entered into an operating lease that began in February 2019 for 211 Donelson Pike, Nashville, Tennessee 37214, for office space. The rental agreement expires in January 2021 with a monthly cost of approximately \$850. Approximately \$1,000 related to a security deposit for this office facility is classified as other assets on the consolidated balance sheet as of December 31, 2019.

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. The Company recognized a ROU asset and lease liability of approximately \$800,000 as a result of this lease. 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, 2019.

As of August 31, 2019, the Company terminated its rental agreement for 591 East Sunset Road, Henderson, Nevada 89011, which consisted of approximately 8,000 total square feet of space. In connection with the lease termination, the Company and the lessor agreed to a lease termination penalty of \$27,000. For the year ended December 31, 2019, the Company paid a lease termination liability of \$20,000, consisting of the \$27,000 lease termination penalty offset partially by a security deposit of \$7,000. The \$20,000 loss on lease termination is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

The lease agreement for the Company's office space in Ireland was entered into on August 1, 2019 and includes a twelve-month term.

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

Prior to the adoption of ASC 842, operating lease expense of approximately \$162,000 was recognized in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

Operating lease expense was approximately \$301,000 for the year ended December 31, 2019 in the Company's consolidated statement of operations and comprehensive loss and includes costs associated with leases for which ROU assets have been recognized as well as short-term leases.

Supplemental cash flow information related to leases was as follows:

	Year ended December 31, 2019
Operating activities:	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 251,000
Noncash investing and financing activities:	
ROU assets obtained in exchange for lease liability	
Operating leases	\$ 800,000

Supplemental balance sheet information related to leases was as follows:

	December 31, 2019
Operating ROU assets	\$ 1,106,000
Current portion of operating lease liabilities	\$ 262,000
Operating lease liabilities, net of current portion	889,000
Total operating lease liabilities	\$ 1,151,000
Weighted average remaining lease term, operating leases	4.0 years
Weighted average discount rate, operating leases	8.0%

As of December 31, 2019, maturities of lease liabilities were as follows:

2020	\$ 339,000
2021	333,000
2022	329,000
2023	201,000
2024	137,000
Total future minimum lease payments	1,339,000
Less imputed interest	(188,000)
Total	\$ 1,151,000

Note 15 - Accrued Expenses

Accrued expenses as of December 31, 2019 and 2018 were as follows:

	December 31,	
	2019	2018
Accrued legal	\$ 14,000	\$ 90,000
Accrued sales commission	50,000	42,000
Accrued research and development	-	65,000
Accrued accounting	-	8,000
Accrued interest	7,000	2,000
Accrued other	65,000	189,000
	<u>\$ 136,000</u>	<u>\$ 396,000</u>

Note 16 - Income Taxes

The income tax benefit attributable to loss before income taxes for the years ended December 31, 2019 and 2018 is as follows:

	Years Ended December 31,	
	2019	2018
Current:		
State	\$ (225,000)	\$ (93,000)
Total current tax benefit	(225,000)	(93,000)
Total deferred tax benefit	-	-
Income tax benefit	<u>\$ (225,000)</u>	<u>\$ (93,000)</u>

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, 2019 and 2018 is as follows:

	Years Ended December 31,	
	2019	2018
U.S. federal statutory rate	21.00%	21.00%
State taxes	(8.30)%	5.25%
Sale of NJ NOLS and credits	5.22%	(2.78)%
Expired NOLs and credits	(31.19)%	-%
Stock based compensation	(3.21)%	(1.96)%
Federal research and development credits	4.93%	2.28%
Other	(2.96)%	(0.11)%
Valuation allowance	21.12%	(26.46)%
Effective tax rate	<u>6.61%</u>	<u>(2.78)%</u>

Significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carry forwards	\$ 18,060,000	\$ 18,671,000
Research and development credits	1,459,000	1,399,000
Nonqualified stock option compensation expense	515,000	497,000
Other temporary book - tax differences	28,000	58,000
Total deferred tax assets	20,062,000	20,625,000
Deferred tax liabilities:		
Fixed and intangible asset basis difference	(134,000)	(21,000)
Total deferred tax liabilities	(134,000)	(21,000)
Deferred tax assets (liabilities), net	19,928,000	20,604,000
Valuation allowance for deferred tax assets	(19,928,000)	(20,604,000)
Deferred tax assets (liabilities), net after valuation allowance	\$ -	\$ -

During the years ended December 31, 2019 and 2018, the Company recorded an income tax benefit of approximately \$225,000 and \$93,000, respectively, due to the sale of net operating loss and research and development credit carryforwards under the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. These amounts are recorded in the consolidated financial statements as an income tax benefit in the year they are earned. As a result of the sale of net operating loss and research and development credit carryforwards during these years, the Company's deferred tax assets decreased by approximately \$239,000 and \$99,000, respectively. The gross amounts of the net operating loss and research and development credit carryforwards that were sold during the years ended December 31, 2019 and 2018 were approximately \$2,193,000 and \$613,000, respectively, and \$41,000 and \$44,000, respectively.

A valuation allowance has been recognized to offset the Company's net deferred tax asset as it is more likely than not that such net asset will not be realized. The Company primarily considered its historical loss and potential Internal Revenue Code Section 382 limitations to arrive at its conclusion that a valuation allowance was required. The Company's valuation allowance decreased approximately \$676,000 from December 31, 2018 to December 31, 2019.

At December 31, 2019, the Company had Federal income tax net operating loss carryforwards of \$78,650,000 and New Jersey income tax net operating loss carryforwards of \$35,000. Foreign income tax net operating loss carryforwards were \$7,286,000 as of December 31, 2019. The Company had Federal research and development tax credit carryforwards of \$1,289,000 and \$1,330,000 at December 31, 2019 and 2018, respectively. The Company also had state research and development tax credit carryforwards of \$78,000 and \$42,000 at December 31, 2019 and 2018, respectively. 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, it 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 \$3,015,000 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 2020 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 2015 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 17 - Stock Plans and Share-Based Payments

Stock Plans

In 2015, the Board of Directors adopted the Nephros, Inc. 2015 Equity Incentive Plan (“2015 Plan”) and reserved and authorized 777,777 shares of common stock for issuance pursuant to stock options, restricted stock and other equity incentive awards to the Company’s employees, directors and consultants. In December 2017, the Board of Directors approved an amendment to the 2015 Plan increasing the number of shares of common stock authorized thereunder to 1,111,110 shares and in May 2019, the Board of Directors approved an amendment to the 2015 Plan increasing the number of shares of common stock authorized thereunder to 1,333,332. The maximum contractual term for stock options granted under the 2015 Plan is 10 years.

As of December 31, 2019, options to purchase 892,926 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 16, 2029. As of December 31, 2019, options to purchase 3,334 shares of common stock issued to non-employees under the 2015 Plan were outstanding and will expire on May 31, 2021. Taking into account all options and restricted stock granted under the 2015 Plan, there are 29,516 shares available for future grant under the 2015 Plan. Options currently outstanding are fully vested or will vest upon a combination of the following: immediate vesting, performance-based vesting or straight-line vesting of two or four years. Of the 896,260 options outstanding as of December 31, 2019, 130,354 options vested on February 1, 2020 as specified performance criteria were met as of December 31, 2019.

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, 2019, options to purchase 65,097 shares of common stock had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between January 8, 2020 and March 26, 2024. As of December 31, 2019, 49,725 options had been issued to non-employees under the 2004 Plan and were outstanding. Such options expire at various dates between March 24, 2021 and November 17, 2024. 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, 2019 and 2018 was approximately \$867,000 and \$525,000, respectively.

Approximately \$802,000 and \$500,000 has been recognized in selling, general and administrative expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2019 and 2018, respectively. Approximately \$65,000 and \$25,000 has been recognized in research and development expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2019 and 2018, respectively.

The following table summarizes the option activity for the years ended December 31, 2019 and 2018:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2017	752,367	\$ 4.91
Options granted	126,952	5.57
Options forfeited or expired	(42,147)	4.14
Options exercised	(11,111)	2.70
Outstanding at December 31, 2018	826,061	\$ 5.04
Options granted	218,290	7.26
Options forfeited or expired	(29,103)	6.72
Options exercised	(4,166)	5.13
Outstanding at December 31, 2019	1,011,082	\$ 5.51

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2019 and 2018:

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2018	297,532	\$ 5.82
Vested and expected to vest at December 31, 2018	795,406	\$ 5.10
Exercisable at December 31, 2019	551,948	\$ 5.20
Vested and expected to vest at December 31, 2019	984,452	\$ 5.50

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.

Grant Year	Option Pricing Assumptions	
	2019	2018
Stock Price Volatility	81.73%	92.42%
Risk-Free Interest Rates	1.93%	2.71%
Expected Life (in years)	6.13	6.15
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 2019 and 2018 is \$5.05 and \$4.32, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2019 were approximately \$4,532,000 and \$4,423,000, respectively. A stock option has intrinsic value, at any given time, if and to the extent that the exercise price of such stock option is less than the market price of the underlying common stock at such time. The weighted-average remaining contractual life of options vested or expected to vest as of December 31, 2019 was 6.89 years.

During the year ended December 31, 2019, stock options to purchase 4,166 shares of the Company's common stock were exercised by a member of management for proceeds of approximately \$21,000, resulting in the issuance of 4,166 shares of the Company's common stock.

The aggregate intrinsic values of stock options outstanding and of stock options vested or expected to vest as of December 31, 2018 were approximately \$441,000 and \$421,000, respectively. The weighted-average remaining contractual life of options vested or expected to vest as of December 31, 2018 was 7.24 years.

During the year ended December 31, 2018, stock options to purchase 11,111 shares of the Company's common stock were exercised in a cashless exercise, resulting in the issuance of 2,471 shares of the Company's common stock.

As of December 31, 2019, there was approximately \$1,424,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans which will be amortized over the weighted average remaining requisite service period of 2.9 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, 2019 and 2018:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2017	88,821	\$ 4.50
Granted	49,890	5.58
Vested	(83,725)	4.50
Forfeited	(5,096)	4.50
Nonvested at December 31, 2018	49,890	5.58
Granted	55,111	8.57
Vested	(45,160)	5.58
Forfeited	(4,730)	5.58
Nonvested at December 31, 2019	<u>55,111</u>	\$ 8.57

The total fair value of restricted stock that vested during the years ended December 31, 2019 and 2018 was approximately \$252,000 and \$377,000, respectively.

Total stock-based compensation expense for the restricted stock granted to employees and non-employee directors was approximately \$451,000 and \$460,000, respectively, for the years ended December 31, 2019 and 2018. Approximately \$367,000 and \$416,000 is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss for the years ended December 31, 2019 and 2018, respectively. Approximately \$84,000 and \$44,000 is included in research and development expenses on the accompanying consolidated statement of operations and comprehensive loss for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was approximately \$52,000 of unrecognized compensation expense related to the restricted stock awards, which is expected to be recognized over the next six months.

The aggregate shares of common stock legally issued and outstanding as of December 31, 2019 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. During the year ended December 31, 2019, SRP granted stock options to purchase 23,040 shares of common stock to its directors and one employee. These stock options are being expensed over the respective vesting period, which is based on a service condition. The fair value of the stock options granted during the year ended December 31, 2019 was approximately \$88,000.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The below weighted average assumptions for the risk-free interest rates, expected dividend yield, expected lives and expected stock price volatility were utilized for the stock options granted by SRP during the year ended December 31, 2019.

Weighted Average Assumptions for Option Grants

Stock Price Volatility	92.4%
Risk-Free Interest Rates	2.3%
Expected Life (in years)	6.10
Expected Dividend Yield	-%

Stock-based compensation expense related to the SRP stock options was approximately \$14,000 for the year ended December 31, 2019, respectively. For the year ended December 31, 2019, approximately \$4,000 and \$10,000 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, 2019.

Note 18 - Stockholders' Equity

Reverse Stock Split

On July 9, 2019, the Company effected a reverse stock split, in which every nine shares of its common stock issued and outstanding immediately prior to the effective time, which was 5:30 p.m. ET on July 9, 2019, were combined into one share of common stock. Fractional shares were not issued and stockholders who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split received an amount in cash equal to \$5.58 per share for such fractional interests. The number of shares of Company common stock issued and outstanding was reduced from approximately 69,000,000 to approximately 7,700,000.

May 2019 Private Placement

On May 15, 2019, the Company entered into a Stock Purchase Agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 493,827 shares of the Company's common stock resulting in gross proceeds to the Company of approximately \$2,000,000. The purchase price for each share was \$4.05. Proceeds, net of equity issuance costs of \$8,000, recorded as a result of the private placement were approximately \$1,992,000. Of the 493,827 shares of the Company's common stock issued, 12,346 shares, resulting in proceeds of approximately \$50,000, were sold to a member of management.

April 2018 Private Placement

On April 10, 2018, the Company entered into a Stock Purchase Agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 726,735 shares of the Company's common stock resulting in gross proceeds to the Company of approximately \$2,943,000. The purchase price for each share was \$4.05. Proceeds, net of equity issuance costs of \$19,000, recorded as a result of the private placement were approximately \$2,924,000. Of the 726,735 shares of the Company's common stock issued, 24,331 shares, resulting in proceeds of \$98,550, were sold to members of management, including immediate family members.

July 2015 Purchase Agreement and Registration Rights Agreement

On July 24, 2015, the Company entered into both a securities purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Under the terms and subject to the conditions of the securities purchase agreement, the Company had the right to sell to Lincoln Park, and Lincoln Park was obligated to purchase, up to \$10.0 million in shares of the Company's common stock, subject to certain limitations, from time to time, over the 36-month period commencing on September 4, 2015. Pursuant to the securities purchase agreement, during the nine months ended September 30, 2018, the Company issued and sold approximately 211,111 shares of its common stock to Lincoln Park. The issuance of the common shares to Lincoln Park resulted in gross proceeds of \$854,000 for the nine months ended September 30, 2018. The securities purchase agreement expired on September 4, 2018.

Noncontrolling Interest

In July 2018, the Company formed a new, wholly-owned subsidiary, SRP, to drive the development of its second-generation HDF system and other products focused on improving therapies for patients with renal disease.

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, or aggregate gross proceeds of \$3,000,000. SRP incurred transaction-related expenses of approximately \$30,000, which were included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2018. 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 Lambda Investors, LLC, 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 is 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 are insufficient to pay the Series A Liquidation Preference in full, the holders of Series A Preferred will 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 accrue from day to day, whether or not declared, and are cumulative and are payable only when, as, and if declared by the Board.

Holders of Series A Preferred are 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, 2019 and 2018, 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, 2019 and 2018:

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable as of December 31,	
				2019	2018
Equity-classified warrants					
May 2015 – private placement warrants	5/18/2015	5/18/2020	\$ 7.65	89,438	101,917
June 2016 – Note and Warrant Agreement	6/7/2016	6/7/2021	\$ 2.70	127,121	253,790
March 2017 – private placement warrants	3/22/2017	3/22/2022	\$ 2.70	162,365	382,363
Total				<u>378,924</u>	<u>738,070</u>

The weighted average exercise price of the outstanding warrants was \$3.87 as of December 31, 2019 and \$3.38 as of December 31, 2018.

Warrants Exercised During 2019 and 2018

During the year ended December 31, 2019, warrants to purchase 359,146 shares of the Company's common stock were exercised, resulting in proceeds of approximately \$731,000 and the issuance of 327,351 shares of the Company's common stock. Of the warrants exercised during the year ended December 31, 2019, warrants to purchase 111,114 shares of the Company's common stock were exercised in a cashless exercise, resulting in the issuance of 79,316 shares of the Company's common stock. Of the warrants exercised during the year ended December 31, 2019, warrants to purchase 4,444 shares of the Company's common stock were exercised by members of management, resulting in proceeds of approximately \$12,000.

During the year ended December 31, 2018, warrants to purchase 50,739 shares of the Company's common stock were exercised, resulting in proceeds of approximately \$138,000 and the issuance of 50,739 shares of the Company's common stock. Of the warrants exercised during the year ended December 31, 2018, warrants to purchase 8,147 shares of the Company's common stock were exercised by members of management, resulting in proceeds of approximately \$22,000.

Note 19 – 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 \$69,000 and \$52,000 to this plan in 2019 and 2018, respectively.

Note 20 - Commitments and Contingencies

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 10 – 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, 2019, the Company agreed to make minimum annual aggregate purchases from Medica of €3,000,000 (approximately \$3,400,000). For the year ended December 31, 2019, the Company’s aggregate purchase commitments totaled approximately €5,699,000 (approximately \$6,382,000).

Contractual Obligations and Commercial Commitments

The following table summarizes the Company’s approximate minimum contractual obligations and commercial commitments as of December 31, 2019:

	Payments Due in Period				
	Total	Within 1 Year	Years 2 - 3	Years 4 - 5	More than 5 Years
Minimum Purchase Commitments ¹	\$ 24,000,000	\$ 3,500,000	\$ 7,600,000	\$ 8,400,000	\$ 4,500,000
Leases ²	1,339,000	339,000	662,000	338,000	-
Total	<u>\$ 25,339,000</u>	<u>\$ 3,839,000</u>	<u>\$ 8,262,000</u>	<u>\$ 8,738,000</u>	<u>\$ 4,500,000</u>

¹ Reflects minimum purchase commitments pursuant to the License and Supply agreement with Medica.

² In addition to lease obligations for office space, these obligations include a lease for various office equipment which expires in 2020 and an automobile lease which expires in 2021. See Note 14 – Leases for further discussion.

Note 21 – Segment Reporting

The Company has defined its two reportable segments as Water Filtration and Renal Products. The Water Filtration segment develops and sells high performance liquid purification filters. The Renal Products segment is focused on the development of medical device products for patients with renal disease, including a second-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.

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:

	Year Ended December 31, 2019		
	Water Filtration	Renal Products	Nephros, Inc. Consolidated
Total net revenues	\$ 10,334,000	\$ -	\$ 10,334,000
Gross margin	6,084,000	-	6,084,000
Research and development expenses	1,717,000	1,373,000	3,090,000
Depreciation and amortization expense	186,000	-	186,000
Selling, general and administrative expenses	5,960,000	159,000	6,119,000
Change in fair value of contingent consideration	(156,000)	-	(156,000)
Total operating expenses	7,707,000	1,532,000	9,239,000
Loss from operations	\$ (1,623,000)	\$ (1,532,000)	\$ (3,155,000)

	Year Ended December 31, 2018		
	Water Filtration	Renal Products	Nephros, Inc. Consolidated
Total net revenues	\$ 5,687,000	\$ -	\$ 5,687,000
Gross margin	3,203,000	-	3,203,000
Research and development expenses	808,000	731,000	1,539,000
Depreciation and amortization expense	163,000	-	163,000
Selling, general and administrative expenses	4,340,000	177,000	4,517,000
Total operating expenses	5,311,000	908,000	6,219,000
Loss from operations	\$ (2,108,000)	\$ (908,000)	\$ (3,016,000)

As of December 31, 2019, approximately \$945,000 of total assets are in the Renal Products segment. The \$945,000 consists primarily of the remaining cash received of approximately \$733,000 from the sale of Series A Preferred during the year ended December 31, 2019 and prepaid expenses and other current assets of approximately \$200,000.

As of December 31, 2018, approximately \$2,500,000 of total assets are in the Renal Products segment. The \$2,500,000 consisted of the remaining cash received of approximately \$2,300,000 from the sale of Series A Preferred during the year ended December 31, 2018 and prepaid expenses and other current assets of approximately \$200,000.

Note 22 – Subsequent Event

On January 31, 2020, the Company announced the sale of 937,500 shares of common stock through a confidentially marketed underwritten public offering at a price of \$8.00 per share. The transaction closed on February 4, 2020 with aggregate proceeds of \$7,500,000 and net proceeds after underwriting discounts and offering expenses of approximately \$6,765,000. The shares were offered pursuant to an effective shelf registration statement on Form S-3 (File No. 333-234528) that was previously filed with the Securities and Exchange Commission and declared effective on December 6, 2019.

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

There were no disagreements with our accountants during 2019 or 2018.

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 our 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 our 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, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2019. Based upon this evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019. Accordingly, management believes that the financial statements included in this Annual Report on Form 10-K present fairly in all material respects our financial position, results of operations and cash flows for the period presented.

Management's Report on Internal Control Over Financial Reporting

Our 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 our internal control over financial reporting as of December 31, 2019 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework". Based on our assessment, management concluded that as of December 31, 2019, our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our 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 2020 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption “Compensation Matters” in the 2020 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 2020 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 2020 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 2020 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.

Consolidated balance sheets as of December 31, 2019 and 2018.

Consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018.

Consolidated statements of changes in stockholders' equity for the years ended December 31, 2019 and 2018.

Consolidated statements of cash flows for the years ended December 31, 2019 and 2018.

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 to Purchase Common Stock issued to various investors, incorporated by reference to Exhibit 4.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on May 18, 2015.
4.3	Form of Common Stock Purchase Warrant issued June 3 and 9, 2016, incorporated by reference to Exhibit 4.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on June 14, 2016.
4.4	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.
4.5	Description of Capital Stock. *
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 [Employment Agreement, dated April 15, 2015, between the Registrant and Daron Evans, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 21, 2015. †](#)
- 10.14 [First Amendment to Employment Agreement, dated April 15, 2019, between the Registrant and Daron Evans, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2019. †](#)
- 10.15 [Letter Agreement dated February 10, 2017, between Andrew Astor and the Registrant, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on February 14, 2017. †](#)
- 10.16 [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.](#)
- 10.17 [License Agreement, dated October 1, 2007, between the Trustees of Columbia University in the City of New York, and the Registrant incorporated by reference to Exhibit 10.41 to Nephros, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the SEC on March 31, 2008.](#)

- 10.18 [License Agreement, dated July 1, 2011, between the Registrant and Belco 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.](#)
- 10.19 [First Amendment to License Agreement, dated February 19, 2014, between the Registrant and Belco 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.](#)
- 10.20 [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.](#)
- 10.21 [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.](#)
- 10.22 [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.](#)
- 10.23 [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.](#)
- 10.24 [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.+](#)
- 10.25 [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.](#)
- 10.26 [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.](#)
- 10.27 [Form of Registration Rights Agreement, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.28 [Registration Rights Agreement, dated February 4, 2013, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.29 [First Amendment to Registration Rights Agreement, dated May 23, 2013, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.30 [Registration Rights Agreement, dated November 12, 2013, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.31 [First Amendment to Registration Rights Agreement, dated April 14, 2014, between the Registrant and Lambda Investors LLC, 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.](#)

- 10.32 [Registration Rights Agreement, dated August 29, 2014, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.33 [First Amendment to Registration Rights Agreement, dated September 23, 2014, between the Registrant and Lambda Investors LLC, 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.](#)
- 10.34 [Securities Purchase Agreement, dated May 12, 2015, among the Registrant and various accredited investors, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on May 18, 2015.](#)
- 10.35 [Form of Note and Warrant Purchase Agreement entered into on June 3, 2016, between the Registrant and the purchasers of the Notes and Warrants sold by the Registrant on June 3 and 9, 2016, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on June 14, 2016.](#)
- 10.36 [Securities Purchase Agreement dated March 17, 2017, among the Registrant and the Purchasers identified therein, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on March 23, 2017.](#)
- 10.37 [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.](#)
- 10.38 [Loan and Security Agreement dated August 17, 2017, between the Registrant and Tech Capital, LLC, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on August 23, 2017.](#)
- 10.39 [First Modification to Loan and Security Agreement, dated December 20, 2019, between the Registrant and Tech Capital, LLC, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on December 26, 2019.](#)
- 10.40 [Secured Promissory Note dated March 27, 2018, between the Registrant and Tech Capital, LLC, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on March 30, 2018.](#)
- 10.41 [Form of Stock Purchase Agreement, dated April 10, 2018, among the Registrant and the Purchasers identified therein, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 11, 2018.](#)
- 10.42 [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.](#)
- 10.43 [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.](#)
- 10.44 [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.](#)

- 10.45 [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.](#)
- 10.46 [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.](#)
- 10.47 [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.](#)
- 10.48 [Membership Interest Purchase Agreement, dated December 31, 2018, by and among the Registrant, Biocon 1, LLC, Aether Water Systems, LLC, and Gregory Lucas, incorporated by reference to Exhibit 10.48 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.+](#)
- 10.49 [Stock Purchase Agreement dated May 15, 2019, among the Registrant and the purchasers identified therein, incorporated by reference to Exhibit 10.1 of Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on May 16, 2019.](#)
- 21.1 [List of Subsidiaries of Nephros, Inc.](#) *
- 23.1 [Consent of Moody Famiglietti & Andronico, LLP Independent Registered Public Accounting Firm.](#) *
- 24.1 [Power of Attorney \(included on the signature page\).](#) *
- 31.1 [Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#) *
- 31.2 [Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#) *
- 32.1 [Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#) *
- 32.2 [Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#) *
- 101 Interactive Data File. *

* Filed herewith.

† Management contract or compensatory plan arrangement.

+ Confidential treatment has been granted for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Date: February 27, 2020

NEPHROS, INC.

By: /s/ Daron Evans

Name: Daron Evans

Title: President and Chief Executive Officer (Principal Executive Officer)

POWER OF ATTORNEY

We, the undersigned directors and officers of Nephros, Inc., hereby severally constitute and lawfully appoint Daron Evans, 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, 2019 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Daron Evans</u> Daron Evans	Director, President and Chief Executive Officer (Principal Executive Officer)	February 27, 2020
<u>/s/ Andrew Astor</u> Andrew Astor	Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2020
<u>/s/ Arthur H. Amron</u> Arthur H. Amron	Director	February 27, 2020
<u>/s/ Paul A. Mieyal</u> Paul A. Mieyal	Director	February 27, 2020
<u>/s/ Malcolm Persen</u> Malcolm Persen	Director	February 27, 2020
<u>/s/ Oliver Spandow</u> Oliver Spandow	Director	February 27, 2020
<u>/s/ Alisa Lask</u> Alisa Lask	Director	February 27, 2020
<u>/s/ Thomas Gwydir</u> Thomas Gwydir	Director	February 27, 2020

**Description of the Registrant's Securities
Registered Pursuant to Section 12 of the
Securities Exchange Act of 1934**

As of December 31, 2019, Nephros, Inc. (the "Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): Common Stock.

Description of Common Stock

The following description of the Company's Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Fourth Amended and Restated Certificate of Incorporation, as amended to date (the "Certificate of Incorporation"), and our Second Amended and Restated By-Laws (the "Bylaws"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K to which this description is also an exhibit.

Authorized Capitalization

The Company's authorized capital stock consists of (i) 40,000,000 shares of common stock, par value \$0.001 per share (the "Common Stock") and (ii) 5,000,000 shares of preferred stock, par value \$0.001 per share.

Voting Rights

Holders of Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of Common Stock entitled to vote in any election of directors may elect all of the directors standing for election.

Dividend and Liquidation Rights

Apart from preferences that may be applicable to any holders of preferred stock outstanding at the time, holders of Common Stock are entitled to receive dividends, if any, ratably as may be declared from time to time by the Company's Board of Directors (the "Board") out of funds legally available therefor. Upon the Company's liquidation, dissolution or winding up, the holders of Common Stock are entitled to receive ratably the Company's net assets available after the payment of all liabilities and liquidation preferences on any outstanding preferred stock.

Other Rights

Holders of Common Stock have no preemptive, subscription, redemption or conversion rights, and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which the Company may designate and issue in the future.

Anti-Takeover Provisions

The Certificate of Incorporation and the Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of the Company. These provisions are as follows:

- special meetings of stockholders may be called only by the Board, the Chairman of the Board, the President or any Vice President;
- the Board is a classified board, with three separate classes of directors each serving a three-year term; and
- the Company may issue, without stockholder approval, up to 5,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of Common Stock.

The Company is subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation 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 the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who owns 15% or more of the voting stock of a corporation, or any affiliate or associate of a corporation who, within three years prior, did own 15% or more of the voting stock of that corporation.

Listing

The Common Stock is listed on the Nasdaq Capital Market under the symbol "NEPH."

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is V Stock Transfer, LLC.

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%

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Nephros, Inc.
South Orange, New Jersey

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) and on Form S-3 (Nos 333-225109; 333-232708; 333-234528), of our report dated February 27, 2020, relating to the consolidated financial statements of Nephros, Inc. and Subsidiaries, as of and for the years ended December 31, 2019 and 2018, which appears in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Moody Famiglietti & Andronico, LLP

Tewksbury, Massachusetts
February 27, 2020

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

I, Daron Evans, 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: February 27, 2020

/s/ Daron Evans

Daron Evans
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF THE 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: February 27, 2020

/s/ Andrew Astor

Andrew Astor
Chief Operating Officer & Chief Financial Officer
(Principal Financial and Accounting Officer)

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

In connection with the Annual Report on Form 10-K of Nephros, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daron Evans, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2020

/s/ Daron Evans

Daron Evans
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report on Form 10-K of Nephros, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Astor, 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: February 27, 2020

/s/ Andrew Astor

Andrew Astor
Chief Operating Officer & Chief Financial Officer
(Principal Financial and Accounting Officer)
