NEPHROS INC
Form 10-K
March 12, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

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

For the transition period from to

Commission File Number 001-32288

NEPHROS, INC.

(Exact name of registrant specified in its charter)

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

380 Lackawanna Place

South Orange, NJ 07079

(Address of Principal Executive Offices)

(201) 343-5202

(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act: **None**

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

Common Stock, $.001 par value per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

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 [X]

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

Large accelerated filer [ ] Accelerated filer [ ]
Non-accelerated filer [X] Smaller reporting company [X]
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 [X]

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2018, was approximately $19,500,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the OTCQB on June 30, 2018. 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, 2018.

As of March 10, 2019, there were 64,611,300 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 SEC in connection with the 2019 Annual Meeting of Stockholders (the "2019 Proxy Statement"), are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2019 Proxy Statement will be filed within 120 days of December 31, 2018.

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," "proj "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarante 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 could adversely affect our potential sales and revenues;
- product-related deaths or serious injuries or product malfunctions could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products;
- we face potential liability associated with the production, marketing and sale of our products, and the expense of defending against claims of product liability could materially deplete our assets and generate negative publicity, which could impair our reputation;
- to the extent our products or marketing materials are found to violate any provisions of the U.S. Food, Drug and Cosmetic Act (the "FDC Act") or any other statutes or regulations, we could be subject to enforcement actions by the U.S. Food and Drug Administration (the "FDA") or other governmental agencies;
- we may not be able to obtain funding 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.

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PART I

Item 1. Business

Overview

We are a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters. Our filters, which are generally classified as ultrafilters, are primarily used in hospitals for the prevention of infection from water-borne 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 subsidiary, Specialty Renal Products, Inc. ("SRP"), is a development-stage medical device company focused primarily on developing hemodiafiltration ("HDF") technology. SRP is developing a second generation of the OLpūr H2H Hemodiafiltration System, the only FDA 510(k)-cleared medical device that enables nephrologists to provide HDF treatment to patients with end stage renal disease ("ESRD").

On December 31, 2018, we entered into a Membership Interest Purchase Agreement (the "Agreement") with Biocon1, LLC, a Nevada limited liability company ("Biocon"), Aether Water Systems, LLC, a Nevada limited liability company ("Aether"), and Gregory Lucas, the sole member of each of Biocon and Aether ("Lucas"). Pursuant to the terms of the Agreement, we acquired 100% of the outstanding membership interests of each of Biocon and Aether.

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

Our Products

We develop and sell liquid filtration products used in both medical and commercial applications, employing multiple filtration technologies.

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 water-borne 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.

In commercial markets, with our recent addition of the Aether product line, 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 sales strategy is a combination of direct selling to end customers and indirect selling through value-added resellers ("VARs"). Leveraging VARs has enabled us to expand rapidly our access to target customers in the medical market 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.

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. According to the American Hospital Association, approximately 5,700 hospitals, with approximately 915,000 beds, treated over 35 million patients in the United States in 2013. 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.

The Affordable Care Act, passed in March 2010, puts in place comprehensive health insurance reforms that aim to lower costs and enhance quality of care. With its implementation, healthcare providers have substantial incentives to deliver better care or be forced to absorb the expenses associated with repeat medical procedures or complications like HAIs. As a consequence, hospitals and other healthcare facilities are proactively implementing strategies to reduce HAI potential. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the points of delivery, such as ice machines, sinks and showers.

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 is an in-line, 0.005-micron ultrafilter that provides dual-stage protection from water borne pathogens. The DSU H is 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 when used in a hospital setting.

The SSU H is an in-line, 0.005-micron ultrafilter that provides single-stage protection from water borne pathogens. The SSU H is primarily used to filter potable water feeding sinks, showers and medical equipment. The SSU H has an up to 3-month product life when used in a hospital setting.

The S100 is a point-of-use, 0.01-micron microfilter that provides protection from water borne 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 water borne 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.

We received FDA 510(k) clearance to market the HydraGuard™ in December 2016 and began shipping it in July 2017. We began shipping the HydraGuard™ - Flush in September 2017. The DSU H, SSU H, and S100 products received FDA 510(k) clearance in prior years.

The 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. 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 6,300 dialysis clinics in the United States servicing approximately 430,000 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 available in 10”, 20”, and 30” configurations.

The EndoPur is a cartridge-based, “plug and play” market entry that requires no plumbing at installation or replacement. In March 2017, we received FDA 510(k) clearance to market the EndoPur filter. We began shipping the EndoPur 10”

filter in July 2017 and the 20” and 30” versions in September 2017.

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. Our recent acquisition of Biocon and Aether – marketed under the AETHER® brand – expands our product line to include additional water filtration and purification technologies, primarily focused on improving odor and taste and on reducing scale and heavy metals from filtered water.

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

The NanoGuard®-D is an in-line, 0.005-micron ultrafilter that provides dual-stage retention of any organic or inorganic particle larger than 15,000 Daltons.

The NanoGuard®-S is an in-line, 0.005-micron ultrafilter that provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons.

The NanoGuard®-E is a 0.005-micron ultrafilter cartridge that plugs into an Everpure® filter manifold and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons.

The NanoGuard®-C is a 0.005-micron cartridge ultrafilter that fits with most 10”, 20”, 30” and 40” cartridge housings and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons.

The NanoGuard®-F is a 0.005-micron flushable cartridge ultrafilter, available in 10” or 20” sizes and provides single-stage retention of any organic or inorganic particle larger than 15,000 Daltons.

The AETHER® Sediment filter provides a 1-micron barrier to retain sediment, dirt, rust particles and other solids in potable water.

The AETHER® Carbon Block filter is a carbon-based filter to improve and taste and odor and reduce levels of chlorine and heavy minerals.

The AETHER® Scale filter uses proprietary technology to reduce the development of lime scale build-up in downstream equipment and surfaces.

The AETHER® Carbon + Scale filter combines a carbon-based filter with the AETHER® Scale technology in a single filter.

The Nephros Lead Filter System filters both particulate lead and soluble lead, tested to reduce 99% of 150ppb soluble lead in potable water.

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. AETHER® and NanoGuard® products are targeted primarily at the food service, hospitality, convenience store and industrial markets.

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

In May 2015, we entered into a Sublicense Agreement (the “Sublicense Agreement”) with CamelBak Products, LLC (“CamelBak”). Under this Sublicense Agreement, we granted CamelBak an exclusive, non-transferable, worldwide (with the exception of Italy) sublicense and license, in each case solely to market, sell, distribute, import and export the IWTD. In exchange for the rights granted to CamelBak, CamelBak agreed, through December 31, 2022, to pay us a percentage of the gross profit on any sales made to a branch of the U.S. military, subject to certain exceptions, and to pay us a fixed per-unit fee for any other sales made. CamelBak was also required to meet or exceed certain minimum annual fees payable to us, and, if such fees are not met or exceeded, we may convert the exclusive sublicense to a non-exclusive sublicense with respect to non-U.S. military sales. During the years ended December 31, 2018 and

December 31, 2017, Camelbak met its minimum fee payments, and we recognized royalty revenue of $100,000 and $25,000, respectively, related to this Sublicense Agreement. 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.

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, 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.

Leveraging the results of our evaluations, we recently completed development of a second-generation HDF machine prototype. We believe that the design changes will enable our HDF machine to better align with clinical work-flow practices, to be highly reliable, to simplify the training required for proficiency, and to have a dramatically lower cost of goods. We have filed for patent protection on key features of our updated design.

During 2018, we formed a new subsidiary, Specialty Renal Products, Inc. ("SRP"), to drive the development of this second-generation HDF system. A prototype of the new second-generation HDF system has been constructed. We intend to fund the HDF program primarily with funds directly raised into SRP, including a $3 million Series A financing round completed in September 2018. Pending FDA clearance, we believe we can return to the market with our HDF system in late 2019 or early 2020.

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 Henderson, Nevada 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 Biocon/Aether facility in Henderson, 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 Licenses 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 office 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 Biocon 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 SRP subsidiary is driving the development of our second-generation HDF system.

Major Customers

For the years ended December 31, 2018 and 2017, the following customers accounted for the following percentages of our revenues, respectively:

Customer	2018	2017
A	11 %	13 %
B	11 %	20 %
C	10 %	1 %
Total	32 %	34 %

As of December 31, 2018 and December 31, 2017, the following customers accounted for the following percentages of our accounts receivable, respectively:

Customer	2018	2017
D	15 %	- %
A	11 %	18 %
C	11 %	- %
E	2 %	11 %
Total	39 %	29 %

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

Intellectual Property

Patents

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

We believe that our patent strategy will provide a competitive advantage in our target markets, but our patents may not be broad enough to cover our competitors' products, and may be subject to invalidation claims. Our U.S. patents for the "Method and Apparatus for Efficient Hemodiafiltration" and for the "Dual-Stage Filtration Cartridge" have claims that cover the OLpūr MDHDF filter series and the method of hemodiafiltration employed in the operation of the products. Technological developments in ESRD therapy could reduce the value of our intellectual property. Any such reduction could be rapid and unanticipated. We have issued patents on our water filtration products and applications in process to cover various applications in residential, commercial, and remote environments.

As of December 31, 2018, 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, 2018, we secured registrations of the trademarks H2H, PATHOGUARD, NANOGUARD, NEPHROS HYDRAGUARD and OLpūr in the European Union. In the United States, we secured trademark registrations for OLpūr, HYDRAGUARD and NANOGUARD. We have also filed a trademark application for ENDOPUR 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 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, FDA clearance of a pre-market notification under Section 510(k) of the FDC Act or FDA clearance of a pre-market approval application under Section 515 of the FDC Act must be obtained. A Section 510(k) clearance will be granted if the submitted information establishes that the proposed device is “substantially equivalent” to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not called for pre-market approval under Section 515. The Section 510(k) pre-market clearance process is generally faster and simpler than the Section 515 pre-market approval process.

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

In July 2009, we received FDA clearance of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures.

In April 2012, we announced that 510(k) clearance was received from the FDA to market 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.

In October 2014, we announced that we received 510(k) clearance from the FDA to market our DSU H and SSU H ultrafilters; in April 2016, we announced that we received 510(k) clearance from the FDA to market our S100 point-of-use filter; in December 2016, we announced that we received 510(k) clearance from the FDA to market our HydraGuard 10” ultrafilter; and in March 2017, we announced that we received 510(k) clearance from the FDA to market our EndoPur 10” ultrafilter.

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

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

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

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

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

European Union

The European Union began to harmonize national regulations comprehensively for the control of medical devices in member 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.

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

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

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

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.

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

We also plan to sell our ESRD therapy products in foreign markets outside the United States that are not part of the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase, with no assurance that such approval will be obtained. Our ability to export into other countries may require compliance with ISO 13485, which is analogous to compliance with the FDA's QSR requirements. In November 2007 and May 2011, the Therapeutic Products Directorate of Health Canada, the Canadian health regulatory agency, approved our OLpūr MD220 Hemodiafilter and our DSU, respectively, for marketing in Canada. Other than the Canadian approval of our OLpūr MD220 Hemodiafilter and DSU products, we have not obtained any regulatory approvals to sell any of our products outside of the United States and the European Union and there is no assurance that any such clearance or certification will be issued.

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, 2018, we employed a total of 18 full-time employees, including 6 employed in sales/marketing/customer support, 7 in general and administrative, and 5 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 Securities and Exchange Commission (“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.

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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, 2018, we had an accumulated deficit of approximately $124,153,000 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.

In the event that revenue does not grow sufficiently, and we are not able to reduce expenses sufficiently, there could be substantial doubt about our ability to continue as a going concern.

As of the date of this Annual Report on Form 10-K, we expect that our existing cash balances and projected increases in product sales will allow us to fund our current operating plan through at least the next twelve months. In addition, should sales not achieve planned levels, management has plans in place to reduce personnel and other discretionary expenditures to maintain sufficient cash balances to fund our operating plan.

If sales do not achieve planned levels, however, and if we are not able to reduce expenditures sufficiently, there could be doubt about our ability to continue as a going concern. We believe our plans are sufficient to alleviate such doubt.

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 recent acquisition of Biocon/Aether may not produce the desired outcomes and expected value.

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

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

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

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.

The recently passed Tax Cuts and Jobs Act of 2017 may have a material impact on our financial condition and results of operations.

The Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law on December 22, 2017. The Tax Act made numerous changes to U.S. federal corporate tax law and is expected to reduce our effective tax rate for fiscal year 2018 and future periods. Effective January 1, 2018, the Tax Act lowers the U.S. corporate tax rate from 35% to 21% and prompts various other changes to U.S. federal corporate tax law. We have completed our analysis of the Tax Cuts and Jobs Act during the year ended December 31, 2018. There were no significant adjustments to the provisional amounts recorded during the year-ended December 31, 2017.

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 2019 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

There currently is a limited trading market for our common stock.

We do not currently meet all of the requirements for initial listing of our common stock on a registered stock exchange. Our common stock is quoted on the OTCQB. Trading in our common stock on the OTCQB has been very limited. As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our common stock, and our common stock may be less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes. There is no guarantee

that we will ever become listed on The Nasdaq Stock Market, the NYSE American, or any other exchange, or that a liquid trading market for our common stock will develop.

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, 2018, our common stock has traded at prices ranging from a high of $0.73 to a low of $0.18 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.

Because we are subject to the "penny stock" rules, investors may have difficulty selling our common stock.

Our common stock is subject to regulations of the SEC relating to the market for penny stocks. Penny stock, as defined by the Penny Stock Reform Act, is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The penny stock regulations generally require that a disclosure schedule explaining the penny stock market and the risks associated therewith be delivered to purchasers of penny stocks and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. The broker-dealer must make a suitability determination for each purchaser and receive the purchaser's written agreement prior to the sale. In addition, the broker-dealer must make certain mandated disclosures, including the actual sale or purchase price and actual bid offer quotations, as well as the compensation to be received by the broker-dealer and certain associated persons. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit an investor's ability to sell our securities in the secondary market.

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 March 1, 2019, Lambda, our largest stockholder, beneficially owned approximately 47% 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.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after holding their shares for six months and affiliates may sell freely after holding their shares for one year, in each case, subject to current public information, notice and other requirements. Any substantial sales of our common stock pursuant to Rule 144 may have a material adverse effect on 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 and 591 East Sunset Road, Henderson, Nevada 89011, and consist of approximately 16,000 total square feet of space. The current rental agreement in New Jersey expires in November 2022 with a monthly cost of approximately $11,000. The Nevada lease expires in November 2020 with a monthly cost of approximately $6,000. 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, 2018 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 OTCQB under the symbol "NEPH". Any over-the-counter market quotations for our common stock reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

As of December 31, 2018, there were approximately 65 holders of record and approximately 2,100 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 security during the year ended December 31, 2018 that was 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 2018.

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 liquid purification filters for both medical device and commercial markets.

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

Our commercial filter products employ a diverse set of filtration technologies – including ultrafiltration, carbon block filtration, and chemical-based filtration – to deliver a broad range of water purity solutions. Our primary target markets include the food service, hospitality, and convenience store industries. Our solutions address problems that are important to these markets, including:

Bacteria and other pathogen control;
Taste and odor reduction/improvement;
Lead removal;
Lime scale prevention and control; and
Chlorine and heavy minerals reduction.

We were founded in 1997 by healthcare professionals affiliated with Columbia University Medical Center/New York-Presbyterian Hospital to develop and commercialize hemodiafiltration (HDF), an alternative method to standard hemodialysis (HD). Our subsidiary, Specialty Renal Products, Inc. ("SRP") is a development-stage medical device company that continues to carry forward our focus on this mission. SRP is developing a second-generation OLpūr H2H Hemodiafiltration System, the only U.S. Food and Drug Administration ("FDA") 510(k) cleared medical device that enables nephrologists to provide HDF treatment to patients with end stage renal disease ("ESRD").

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, which is incorporated herein by reference.

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 evaluate 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, 2018 Compared to the Fiscal Year Ended December 31, 2017

The following table sets forth our summarized, consolidated results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,			
	2018	2017	$ Increase (Decrease)	% Increase (Decrease)
Total net revenues	$5,687,000	$3,809,000	$1,878,000	49 %
Cost of goods sold	2,484,000	1,517,000	967,000	64 %
Gross margin	3,203,000	2,292,000	911,000	40 %
Gross margin	56 %	60 %	-	(4 %)
Research and development expenses	1,539,000	1,002,000	537,000	54 %
Depreciation and amortization expense	163,000	218,000	(55,000)	(25 %)
Selling, general and administrative expenses	4,517,000	3,298,000	1,219,000	37 %
Loss from operations	(3,016,000)	(2,226,000)	790,000	35 %
Loss on extinguishment of debt	(199,000)	-	199,000	100 %
Interest expense	(172,000)	(302,000)	(130,000)	(46 %)
Interest income	4,000	4,000	-	- %
Other expense	(35,000)	(74,000)	(39,000)	(52 %)
Loss before income taxes	(3,418,000)	(2,598,000)	820,000	32 %
Income tax benefit	93,000	1,789,000	(1,696,000)	(95 %)
Net loss	(3,325,000)	(809,000)	2,516,000	(311 %)
Less: Undeclared deemed dividend attributable to noncontrolling interest	(77,000)	-	77,000	100 %
Net loss attributable to Nephros, Inc.	$(3,402,000)	$(809,000)	$(2,593,000)	(321 %)

Water Filtration

The following table sets forth results of operations for the Water Filtration segment for the fiscal years ended December 31, 2018 and 2017:

	Fiscal Year Ended December 31,			
	2018	2017	$ Increase (Decrease)	% **Increase (Decrease)**
Total net revenues	$5,687,000	$3,809,000	$1,878,000	49 %
Cost of goods sold	2,484,000	1,517,000	967,000	64 %
Gross margin	3,203,000	2,292,000	911,000	40 %
Gross margin	56 %	60 %	-	(4 %)
Research and development expenses	808,000	970,000	(162,000)	(17 %)
Depreciation and amortization expense	163,000	218,000	(55,000)	(25 %)
Selling, general and administrative expenses	4,340,000	3,286,000	1,054,000	32 %
Loss from operations	$(2,108,000)	$(2,182,000)	$(74,000)	(3 %)

Net Revenues

Total net revenues for the year ended December 31, 2018 were approximately $5,687,000 compared to approximately $3,809,000 for the year ended December 31, 2017. The increase of approximately $1,878,000, or 49%, was driven by an increase in sales to new customers and expansion within existing customer accounts.

Cost of Goods Sold

Cost of goods sold was approximately $2,484,000 for the year ended December 31, 2018 compared to approximately $1,517,000 for the year ended December 31, 2017. The increase of approximately $967,000, or 64%, was due to approximately $867,000 in increased direct product costs in support of increased revenue, approximately $70,000 in inventory reserves for expiring items, and approximately $30,000 in physical count inventory adjustments.

Gross Margin

Gross margin was approximately 56% for the year ended December 31, 2018 compared to approximately 60% for the year ended December 31, 2017. The decrease of approximately 4% is primarily due to certain inefficiencies in the manufacturing and distribution processes noted in the cost of goods sold discussion above.

Research and Development Expenses

Research and development expenses were approximately $808,000 and $970,000 for the years ended December 31, 2018 and December 31, 2017, respectively. This decrease of approximately $162,000, or 17%, reflects lower expenditures on new filter development.

Depreciation and Amortization Expense

Depreciation and amortization expense was approximately $163,000 for the year ended December 31, 2018 compared to approximately $218,000 for the year ended December 31, 2017. The decrease of approximately $55,000, or 25%, is due to lower amortization expense for the year ended December 31, 2018 resulting from an amendment to our License and Supply Agreement with Medica in September 2017, which extended the term from December 31, 2022 to December 31, 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $4,340,000 for the year ended December 31, 2018 compared to approximately $3,286,000 for the year ended December 31, 2017, representing an increase of $1,054,000, or 32%. The increase was primarily due to increased headcount-related expenses of approximately $485,000, an increase in stock-based compensation expenses of approximately $179,000 due to increased headcount, an increase in marketing expenses of approximately $104,000, an increase in rent, warehousing, and shipping expenses of approximately $84,000, an increase in bad debt expense of approximately $40,000, and an increase in other expenses of approximately $162,000.

Interest Expense

The table below summarizes interest expense for the years ended December 31, 2018 and 2017:

	2018	2017	**$ Increase**	**% Increase**

			(Decrease)	(Decrease)
Interest related to unsecured long-term note payable	$30,000	$133,000	$(103,000)	(77%)
Amortization of debt discount - unsecured long-term note payable	34,000	116,000	(82,000)	(71%)
Interest - outstanding payables due to a vendor	13,000	24,000	(11,000)	(46%)
Interest related to secured note payable	73,000	-	73,000	100%
Interest on secured revolving credit facility	22,000	29,000	(7,000)	(24%)
Total interest expense	$172,000	$302,000	$(130,000)	(43%)

Interest expense decreased approximately $130,000 due to interest and related debt discount on the unsecured long-term note payable that was outstanding for the year ended December 31, 2017 but was paid off in the first quarter of 2018. This decrease related to the unsecured long-term note payable was partially offset by interest expense on the secured note payable of approximately $73,000 that was not outstanding during the year ended December 31, 2017.

Interest Income

Interest income of approximately $4,000 for each of the fiscal years ended December 31, 2018 and 2017 is as result of interest income recognized on the investment in lease, net.

Other Income/Expense

Other expense of approximately $35,000 and $74,000 for the years ended December 31, 2018 and 2017, respectively, is primarily a result of gains and losses on foreign currency transactions. The decrease of 50% is primarily due to improvements in foreign currency exchange rates.

Income Tax Benefit

In the fiscal years ended December 31, 2018 and 2017, an income tax benefit of approximately $93,000 and $1,789,000, 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, 2018 and 2017:

	Years Ended December 31,				
	2018	2017	**$ Increase (Decrease)**	**% Increase (Decrease)**	
Research and development expenses	$731,000	32,000	$ 699,000	2,184	%
Selling, general and administrative expenses	177,000	12,000	165,000	1,375	%
Loss from operations	$(908,000)	$(44,000)	$ 864,000	1,964	%

Research and Development Expenses

Research and development expenses were approximately $731,000 and $32,000 for the years ended December 31, 2018 and 2017, respectively, an increase of approximately $699,000 due to increased investment in the second-generation HDF product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $177,000 and $12,000 for the years ended December 31, 2018 and 2017, respectively, an increase of approximately $165,000 due to increased investment in the second-generation HDF product.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2018 or December 31, 2017.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2018 and 2017 and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,	
Liquidity and Capital Resources	**2018**	**2017**
Cash	$4,581	$2,194
Other current assets	3,592	1,615
Working capital	5,519	1,938
Stockholders' equity	6,798	1,950

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:

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

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, 2018, we had an accumulated deficit of approximately $124,153,000, 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.

As of the date of this Annual Report on Form 10-K, we expect that our existing cash balances and projected increases in product sales will allow us to fund our current operating plan through at least the next twelve months. In the event that sales increases are below planned levels, we believe we have sufficient flexibility in discretionary expenditures and personnel efficiencies to alleviate any substantial doubt as our ability to continue as a going concern.

Our cash flow currently is not, and historically has not been, sufficient to meet our obligations and commitments. We may need to seek and obtain additional financing to fund our operations. If so, and if we cannot raise sufficient capital, whether in connection with offerings of our common stock or through other means, we would be forced to curtail our planned activities and operations or cease operations entirely and you will lose all of your investment in us. We cannot ensure that we could raise sufficient capital on a timely basis or on satisfactory terms or at all.

Net cash used in operating activities was approximately $3,662,000 for the year ended December 31, 2018 compared to approximately $77,000 for the year ended December 31, 2017, an increase of approximately $3,585,000. In addition to losses from operations, the following are key factors contributing to this net increase in cash used in operating activities:

Through the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program, we received cash in exchange for New Jersey state income tax credits during 2017 in the amount of approximately $1,789,000, compared to zero in 2018;

We spent cash to increase our inventory levels approximately $1,082,000 during 2018 compared to an increase of approximately $195,000 during 2017, in order to accommodate increased sales volume and to build stock levels for anticipated future sales volume increases;

Accounts payable decreased approximately $130,000 during 2018 compared to an increase of approximately $268,000 during 2017, due primarily to catch-up payments for vendor invoices, which were completed early in 2018; and

Prepaid expenses and other current assets increased approximately $191,000 during 2018 compared to a decrease of approximately $30,000 during 2017, as a result of timing of payments.

Net cash used in investing activities was approximately $991,000 for the year ended December 31, 2018 as a result of the acquisition of Biocon/Aether. There was no cash used in investing activities for the year ended December 31, 2017.

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.

Net cash provided by financing activities of approximately $1,990,000 for the year ended December 31, 2017 resulted from net proceeds from the issuance of common stock of approximately $1,179,000, net proceeds from our secured revolving credit facility of approximately $711,000, and proceeds from the exercise of warrants of approximately $100,000.

Contractual Obligations and Commercial Commitments

The following table summarizes our approximate minimum contractual obligations and commercial commitments as of December 31, 2018:

	Payments Due in Period				
	Total	Within 1 Year	Years 2 - 3	Years 4 - 5	More than 5 Years
Minimum Purchase Commitments[1]	$28,700,000	$3,500,000	$7,600,000	$8,400,000	$9,200,000
Leases[2]	696,000	213,000	347,000	136,000	-
Employment Contract[3]	117,000	117,000	-	-	-
Total	$29,513,000	$3,830,000	$7,947,000	$8,536,000	$9,200,000

[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.

[3] Relates to an employment agreement with Daron Evans, our President and Chief Executive Officer, entered into on April 15, 2015 for a term of four years.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

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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, 2018 and 2017, 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, 2018 and 2017, and the results of their operations and their 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
March 12, 2019

NEPHROS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$4,581	$2,194
Accounts receivable, net	1,452	836
Investment in lease, net-current portion	-	20
Inventory, net	1,864	674
Prepaid expenses and other current assets	276	85
Total current assets	8,173	3,809
Property and equipment, net	91	52
Investment in lease, net-less current portion	-	39
Intangible assets	590	-
Goodwill	748	-
License and supply agreement, net	938	1,072
Other asset	18	11
Total assets	$10,558	$4,983
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Secured revolving credit facility	$991	$711
Current portion of secured note payable	195	-
Accounts payable	836	872
Accrued expenses	396	218
Current portion of contingent consideration	236	
Deferred revenue, current portion	-	70
Total current liabilities	2,654	1,871
Secured note payable, net of current portion	843	-
Contingent consideration, net of current portion	263	-
Unsecured long-term note payable, net of debt issuance costs and debt discount of $0 and $233, respectively	-	954
Long-term portion of deferred revenue	-	208
Total liabilities	3,760	3,033
Commitments and Contingencies (Note 19)		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding at December 31, 2018 and 2017.	-	-
	64	55

Common stock, $.001 par value; 90,000,000 shares authorized at December 31, 2018 and 2017; 64,616,031 and 55,293,267 shares issued and outstanding at December 31, 2018 and 2017, respectively.		
Additional paid-in capital	127,816	122,924
Accumulated other comprehensive income	71	77
Accumulated deficit	(124,153)	(121,106)
Subtotal	3,798	1,950
Noncontrolling interest	3,000	-
Total stockholders' equity	6,798	1,950
Total liabilities and stockholders' equity	$10,558	$4,983

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,	
	2018	2017
Net revenue:		
Product revenues	$5,457	$3,544
License, royalty and other revenues	230	265
Total net revenues	5,687	3,809
Cost of goods sold	2,484	1,517
Gross margin	3,203	2,292
Operating expenses:		
Research and development	1,539	1,002
Depreciation and amortization	163	218
Selling, general and administrative	4,517	3,298
Total operating expenses	6,219	4,518
Loss from operations	(3,016)	(2,226)
Loss on extinguishment of debt	(199)	-
Interest expense	(172)	(302)
Interest income	4	4
Other expense, net	(35)	(74)
Loss before income taxes	(3,418)	(2,598)
Income tax benefit	93	1,789
Net loss	(3,325)	(809)
Less: Undeclared deemed dividend attributable to noncontrolling interest	(77)	-
Net loss attributable to Nephros, Inc.	(3,402)	(809)
Other comprehensive income (loss), foreign currency translation adjustments, net of tax	(6)	10
Total comprehensive loss attributable to Nephros, Inc.	$(3,408)	$(799)
Net loss per common share, basic and diluted	$(0.06)	$(0.02)
Weighted average common shares outstanding, basic and diluted	61,620,423	52,935,728

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

NEPHROS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In Thousands, Except Share Amounts)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated		Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Subtotal	Interest	Equity
Balance, December 31, 2016	49,782,797	$ 50	$ 120,835	$ 67	$ (120,285)	$ 667	$ -	$ 667
Net loss					(809)	(809)		(809)
Cumulative effect of change in accounting principle			12		(12)	-		-
Net unrealized gains on foreign currency translation, net of tax				10		10		10
Issuance of common stock, net of equity issuance costs of $152	4,359,994	4	1,175			1,179		1,179
Issuance of restricted stock	750,099	1				1		1
Restricted stock issued to settle liability	67,045	-	30			30		30
Exercise of warrants	333,332	-	100			100		100
Noncash stock-based compensation			772			772		772
Balance, December 31, 2017	55,293,267	55	122,924	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	8,440,669	9	3,769			3,778		3,778
Cashless exercise of stock options	22,245	-				-		-
Exercise of warrants	456,666	-	138			138		138

Noncash stock-based compensation			985			985		985
Balance, December 31, 2018	64,212,847	$ 64	$ 127,816	$ 71	$ (124,153)	$ 3,798	$ 3,000	$ 6,798

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,	
	2018	2017
Operating activities		
Net loss	$(3,325)	$(809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	29	28
Amortization of license and supply agreement	134	190
Non-cash stock-based compensation, including stock options and restricted stock	985	772
Loss on extinguishment of debt	199	-
Inventory reserve	70	-
Provision for bad debt expense	40	-
Amortization of debt discount	34	116
Loss on disposal of equipment	10	-
Loss on capital lease termination	11	-
Loss on foreign currency transactions	3	19
(Increase) decrease in operating assets:		
Accounts receivable	(484)	(416)
Inventory	(1,082)	(195)
Prepaid expenses and other current assets	(191)	30
Other asset	-	(10)
Increase (decrease) in operating liabilities:		
Accounts payable	(130)	268
Accrued expenses	35	-
Deferred revenue	-	(70)
Net cash used in operating activities	(3,662)	(77)
Investing activities		
Biocon Acquisition, net of cash acquired	(991)	-
Net cash used in investing activities	(991)	-
Financing activities		
Proceeds from issuance of common stock, net of equity issuance costs of $19 and $152, respectively	3,778	1,179
Net proceeds from secured revolving credit facility	280	711
Proceeds from sale of subsidiary preferred shares to noncontrolling interest	3,000	-
Payments on secured note payable	(149)	-
Proceeds from issuance of secured note	1,187	-
Repayment of unsecured long term note payable	(1,187)	-
Proceeds from exercise of warrants	138	100

Net cash provided by financing activities	7,047	1,990
Effect of exchange rates on cash	(7)	6
Net increase in cash	2,387	1,919
Cash, beginning of year	2,194	275
Cash, end of year	$4,581	$2,194
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$150	$148
Cash paid for income taxes	$4	$7
Supplemental disclosure of noncash investing and financing activities		
Fair value of contingent consideration related to the Biocon Acquisition	$499	-
Reclassification of capital lease to equipment	$39	$-
Purchase of equipment in accrued expenses	$-	$10
Restricted stock issued to settle liability	$-	$30

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. Today, the Company has two FDA 510(k)-cleared products in the hemodiafiltration (“HDF”) market that deliver therapy to ESRD patients: the OLpūr mid-dilution HDF filter or “dialyzer,” designed expressly for HDF therapy, and the OLpūr H2H HDF module, an add-on module designed to allow the most common types of hemodialysis machines to be used for HDF therapy.

Beginning in 2009, Nephros introduced an additional, complementary business developing and marketing 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 water-borne pathogens, such as legionella and pseudomonas, and in dialysis centers for the removal of biological contaminants from water and bicarbonate concentrate. The Company is also exploring water purification applications in several commercial markets, including food and beverage, data center cooling, and military field applications.

In July 2018, the Company formed a new, wholly-owned subsidiary, Specialty Renal Products, Inc. (“SRP”), to drive the development of its second-generation 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 September 5, 2018, SRP completed a private placement transaction whereby SRP sold preferred shares equivalent to 37.5% of its outstanding equity interest for aggregate proceeds of $3,000,000.

On December 31, 2018, the Company entered into a Membership Interest Purchase Agreement (the “Agreement”) with Biocon 1, LLC, a Nevada limited liability company (“Biocon”), Aether Water Systems, LLC, a Nevada limited liability company (“Aether”), and Gregory Lucas, the sole member of each of Biocon and Aether (“Lucas”). Pursuant to the terms of the Agreement, the Company acquired 100% of the outstanding membership interests of each of Aether and Biocon (the “Biocon Acquisition”).

The U.S. facilities, located at 380 Lackawanna Place, South Orange, New Jersey, 07079, and at 591 East Sunset Road, Henderson, Nevada 89011, are used to house the Company's corporate headquarters, research, manufacturing, and distribution facilities.

Note 2 - Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nephros, Inc. and its subsidiaries, including the entity in which a controlling interest is maintained. For the consolidated subsidiary in which the Company's ownership is less than 100% but greater than 50%, the outside shareholders' interest is shown as noncontrolling interest. All intercompany accounts and transactions were eliminated in the preparation of the accompanying consolidated financial statements.

Use of Estimates in the Preparation of Financial Statements

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

Liquidity

The Company has sustained operating losses and expects such losses to continue over the next several quarters. In addition, net cash from operations has been negative since inception, as have been net losses from operations, generating an accumulated deficit of approximately $124,153,000 as of December 31, 2018. Also, the Company has a loan agreement Tech Capital, which provides a secured asset-based revolving credit facility of up to $1,000,000. This loan agreement will automatically renew on August 17, 2019, although this renewal is not guaranteed.

In July 2018, the Company formed a new, wholly-owned subsidiary, Specialty Renal Products, Inc. (“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. 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 twelve months from the date of issuance of the accompanying consolidated financial statements. In the event that operations do not meet expectations, the Company will reduce discretionary expenditures such as additional headcount, new R&D projects, and other variable costs to alleviate the substantial doubt as to the Company’s ability to continue as a going concern.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” related to revenue recognition. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to be entitled to in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in prior accounting guidance. ASU 2014-09 provides alternative methods of initial adoption and was to be effective for fiscal years beginning after December 15, 2016 and interim periods within those annual periods. Early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date.” This ASU deferred the effective date of ASU No. 2014-09 for all entities for one year. In March, April and May 2016, the FASB issued ASU No. 2016-08, ASU No. 2016-10 and ASU No. 2016-12, respectively, which clarified implementation guidance, including the guidance on principal versus agent considerations, performance obligations and licensing and assessments of collectability and noncash considerations. Public business entities, certain not-for-profit entities, and certain employee benefit plans are required to apply the guidance in ASU 2014-09 to fiscal years beginning after December 15, 2017, including interim reporting

periods within that fiscal year. The Company adopted the new revenue recognition standard as of January 1, 2018 using the modified retrospective method, which requires the cumulative effect of adoption, if any, to be recognized as an adjustment to opening accumulated deficit in the period of adoption. The majority of the Company's revenue relates to the sale of finished products to various customers and the adoption did not have any impact on revenue recognized from these transactions. The Company completed its analysis of the impact on certain less significant transactions involving third-party arrangements and as a result of the analysis, the Company accelerated the remaining approximately $278,000 of deferred revenue to be recognized under the License Agreement with Bellco as of December 31, 2017 and recorded a cumulative effect adjustment to opening accumulated deficit as of January 1, 2018.

In January 2016, the FASB issued ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years and interim periods within those years, beginning after December 15, 2017, and early adoption was permitted. The Company adopted this guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Classification of Certain Cash Receipts and Cash Payments,” which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have a significant impact on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, “Restricted Cash,” which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, “Clarifying the Definition of a Business,” which clarifies the definition of a business in a business combination. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption was permitted. The Company adopted the guidance as of January 1, 2018 and the guidance did not have an impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation,” which requires modification accounting to be used on share-based payment awards if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. The Company adopted the guidance as of January 1, 2018 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 year ended December 31, 2018 and 2017, the following customers accounted for the following percentages of the Company’s revenues, respectively:

Customer	2018		2017	
A	11	%	13	%
B	11	%	20	%
C	10	%	1	%
Total	32	%	34	%

As of December 31, 2018 and December 31, 2017, the following customers accounted for the following percentages of the Company’s accounts receivable, respectively:

Customer	2018		2017	
D	15	%	-	%
A	11	%	18	%
C	11	%	-	%
E	2	%	11	%
Total	39	%	29	%

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 $15,000 and $1,000 as of December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, provision for bad expense was approximately $40,000 of which $14,000 was an increase to the allowance for doubtful accounts. Of the remaining $26,000, $1,000 was write-offs of accounts receivable related to a prior period. There was no allowance for sales returns at December 31, 2018 or 2017. During the year ended December 31, 2017, there were write-offs of accounts receivable of approximately $42,000, which were fully reserved.

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 Biocon Acquisition, some commercial products will be 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 9 – 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.

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, 2018 and December 31, 2017.

Intangible Assets

The Company's intangible assets include finite lived assets. Finite lived intangible assets, consisting of customer lists, 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, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. 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.

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 $45,000 and $35,000 for the years ended December 31, 2018 and 2017, 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 employee stock-based compensation expense in accordance with ASC 718. The Company accounts for stock option grants to consultants under the provisions of ASC 505-50, and as such, these stock options are revalued at each reporting period through the vesting period. 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.

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, “Interest”, 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, Interest, 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 Income (Expense), net

Other expense of approximately $35,000 and approximately $74,000 for the years ended December 31, 2018 and 2017, 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, 2018 and 2017.

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, 2018 and 2017, 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 approximately $93,000 and $1,789,000 in the years ended December 31, 2018 and 2017, 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 15 – 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,	
	2018	2017
Shares underlying options outstanding	7,434,561	6,770,777
Shares underlying warrants outstanding	6,642,344	7,099,010
Unvested restricted stock	449,043	799,387

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 February 2016, the FASB issued ASU No. 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 guidance is effective for the Company beginning in the first quarter of 2019. The Company plans to adopt the standard using the transition method provided by ASU 2018-11, "Leases (Topic 842): Targeted Improvements". Under this method, the Company will apply the new requirements to only those leases that exist 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 plans to apply the package of practical expedients permitted under ASC 842 transition guidance. As a result, the Company is not required to 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. While the Company is still finalizing the potential impacts of the

standard, it currently expects the most significant impact will be the recognition of right-of- use assets and lease liabilities for operating leases. The Company estimates adoption of the standard will result in the recognition of right-of-use assets and lease liabilities for operating leases ranging from approximately $500,000 to $750,000 as of January 1, 2019. The Company does not expect the adoption will have a material impact on its consolidated statements of operations and comprehensive loss.

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 adoption of this guidance on January 1, 2019 will not have a significant impact on the Company’s consolidated financial statements.

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 is assessing the impact of adopting this guidance on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, “Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception” which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features and recharacterizes the indefinite deferral of certain provisions within the guidance for distinguishing liabilities from equity. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. The adoption of this guidance on January 1, 2019 will not have a significant impact on the Company’s consolidated financial statements.

In May 2018, the FASB issued ASU 2018-07, “Improvements to Nonemployee Share-Based Payment Accounting,” which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. The adoption of this guidance on January 1, 2019 will not have a significant impact on the Company’s 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 is assessing the impact of adopting this guidance 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 is assessing the impact of adopting this guidance 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.” The new 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 is assessing the impact of adopting this guidance on its consolidated financial statements.

Note 3 – Biocon Acquisition

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

For the year ended December 31, 2018, transaction costs associated with the Biocon Acquisition of approximately $33,000 were recorded in selling, general and administrative costs.

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

The following is a summary of total consideration for the Biocon Acquisition:

	Total **Consideration**
Fixed purchase price	$ 1,059,000
Acquisition date fair value of contingent consideration	562,000
Total consideration[1]	$ 1,621,000

[1]Total consideration consists of an upfront payment of $991,000 which includes $250,000 held in escrow, $131,000 in accrued expenses and $499,000 of contingent consideration liabilities.

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 preliminary purchase price allocation for the Biocon Acquisition:

	Fair Values as of December 31, 2018
Trade accounts receivable	$164,000
Inventories	179,000
Equipment	39,000
Security deposit	7,000
Goodwill	748,000
Intangible assets	590,000
Total assets acquired, net of cash acquired	1,727,000
Accounts payable	91,000
Accrued expenses	15,000
Total liabilities assumed	106,000
Net assets acquired, net of cash acquired	$1,621,000

Intangible Assets

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

	Preliminary 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 five years is estimated to be approximately $42,000.

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 preliminary 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 Biocon 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 years ended December 31, 2018 and 2017 (assuming the closing of the Biocon Acquisition occurred on January 1, 2017):

	Year Ended December 31, 2018	December 31, 2017
Total revenues	$6,412,000	$4,236,000
Net loss attributable to Nephros, Inc	$(3,158,000)	$(855,000)

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 Biocon 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:

- Adjustments to amortization expense for each of the years ended December 31, 2018 and 2017 of approximately $21,000 related to identifiable intangible assets acquired;
- Adjustments, net of a reduction, to depreciation expense for each of the years ended December 31, 2018 and 2017 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;
- Adjustments to selling, general and administrative expense related to transaction costs directly attributable to the Biocon Acquisition, including the elimination of $33,000 of expenses incurred in the year ended December 31, 2018 which have been included in the year ended December 31, 2017;
- Eliminate interest expense in the historical Biocon results of operations and eliminate interest income in the Company's historical results of operations, each of which was approximately $4,000 for each of the years ended December 31, 2018 and 2017, 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 Biocon to the Company, with a gross margin impact of approximately $5,000 and $10,000 for the years ended December 31, 2018 and 2017, respectively.

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. In addition to product revenue, the Company recognizes revenue related to license, royalty and other agreements in accordance with the five-step model in ASC 606. License, royalty and other revenue recognized for the years ended December 31, 2018 and 2017 is comprised of:

	Years Ended December 31,	
	2018	2017
Royalty revenue under the Sublicense Agreement with CamelBak [1]	$100,000	$25,000
Royalty revenue under the License Agreement with Bellco	101,000	140,000
License revenue under the License Agreement with Bellco	-	70,000
Other revenue	29,000	30,000
Total license, royalty and other revenue	$230,000	$265,000

(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 is 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 may 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 with expires on December 31, 2021. During the year ended

December 31, 2017, approximately $70,000, respectively, was recognized as license revenue. See “ASC 606 Adoption” below for a discussion of the impact of ASC 606 on the recognition of this license revenue.

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 $2.10) per unit; thereafter, €1.25 (approximately $1.50) 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, 2018 and 2017 of approximately $101,000 and $140,000, respectively.

ASC 606 Adoption

In accordance with the adoption of ASC 606, the remaining deferred revenue of approximately $278,000 related to license revenue as of December 31, 2017 was recognized as a cumulative effect adjustment to accumulated deficit as of January 1, 2018.

The following tables present the Company's revenue for the year ended December 31, 2018 under the ASC 606 model as compared to revenue under the previous accounting guidance:

	Year Ended December 31, 2018		
	Revenue as reported	Revenue under previous accounting guidance	Difference
Product revenue	$5,457,000	$5,457,000	$ -
Royalty revenue under the Sublicense Agreement with CamelBak	100,000	100,000	-
Royalty revenue under the License Agreement with Bellco	101,000	101,000	-
License revenue under the License Agreement with Bellco [(1)]	-	70,000	(70,000)
Other revenue	29,000	29,000	-
Total net revenues	$5,687,000	$5,757,000	$ (70,000)

(1) Under ASC 606, amounts received related to the license under the License Agreement with Bellco would have been recognized as revenue at the time that the license was transferred, which was at the time the payments were received by the Company. Under previous accounting guidance, amounts received under the License Agreement with Bellco were deferred and recognized as revenue over the term of the License Agreement.

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, 2018 (there were no assets or liabilities that were measured at fair value on a recurring basis as of December 31, 2017):

	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:				
Current portion of contingent consideration	-	-	$ 236,000	$236,000
Contingent consideration, net of current portion	-	-	263,000	263,000
Total contingent consideration liability	$ -	$ -	$ 499,000	$499,000

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, 2018.

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 investment in lease, net, the secured long-term note payable and the unsecured long-term note payable approximate fair value as of December 31, 2018 and December 31, 2017 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 – Biocon Acquisition for the allocation of the total consideration for the Biocon 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, 2018 and 2017 were as follows:

	December 31,	
	2018	2017
Finished goods	$1,633,000	$654,000
Raw material	280,000	51,000
Less: inventory reserve	(49,000)	(31,000)
Total inventory, net	$1,864,000	$674,000

Note 7- Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2018 and 2017 were as follows:

	December 31,	
	2018	2017
Prepaid insurance premiums	$45,000	$39,000
Deposit for future services	200,000	-
Security deposit	-	20,000
Other	31,000	26,000

Prepaid expenses and other current assets	$276,000	$85,000

Note 8 – Investment in Lease, net

On October 8, 2015, the Company entered into an equipment lease agreement with Biocon. The lease commenced on January 1, 2016 with a term of 60 months and monthly rental payments to the Company of approximately $1,800. At the completion of the lease term, Biocon was to own the equipment provided under the agreement. An investment in lease was established for the direct financing lease receivable at the present value of the future minimum lease payments. Interest income was recognized monthly over the lease term using the effective-interest method. Cash received was applied against the direct financing lease receivable and was presented within changes in operating assets and liabilities in the operating section of the Company's consolidated statement of cash flows. At lease inception, an investment in lease of approximately $92,000 was recorded, net of unearned interest of approximately $14,000. Approximately $4,000 and $4,000, respectively, was recognized in interest income during each of the years ended December 31, 2018 and 2017.

As a result of the Biocon Acquisition on December 31, 2018, the equipment lease was terminated. The equipment is now included in property and equipment, net on the consolidated balance sheet as of December 31, 2018. The equipment will be depreciated over four years.

Note 9 – License and Supply Agreement, net

On April 23, 2012, the Company entered into a License and Supply Agreement (the "License and Supply Agreement") with Medica S.p.A. ("Medica"), an Italy-based medical product manufacturing company, for the marketing and sale of certain filtration products based upon Medica's proprietary Medisulfone ultrafiltration technology in conjunction with the Company's filtration products, and for an exclusive supply arrangement for the filtration products. Under the License and Supply Agreement, as amended, 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 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 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 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 $938,000 and $1,072,000 as of December 31, 2018 and December 31, 2017, respectively. Accumulated amortization is approximately $1,312,000 and $1,178,000 as of December 31, 2018 and December 31, 2017, respectively. The intangible asset is being amortized as an expense over the life of the License and Supply Agreement. Approximately $134,000 and $190,000 has been

charged to amortization expense for the years ended December 31, 2018 and 2017, respectively, 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. For the years ended December 31, 2018 and 2017, approximately $13,000 and $24,000 of interest, respectively, was recognized as interest expense.

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 $161,000 and $98,000 for the years ended December 31, 2018 and 2017, respectively, was recognized as royalty expense and is included in cost of goods sold on the consolidated statement of operations and comprehensive loss. Approximately $50,000 and $34,000 in royalties are included in accounts payable as of December 31, 2018 and December 31, 2017, respectively.

Note 10 - Property and Equipment, Net

Property and equipment as of December 31, 2018 and 2017 was as follows:

		December 31,	
	Life	2018	2017
Manufacturing equipment	3-7 years	$768,000	$700,000
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		885,000	817,000
Less: accumulated depreciation		794,000	765,000
Property and equipment, net		$91,000	$52,000

Depreciation expense for the years ended December 31, 2018 and 2017 was approximately $29,000 and $28,000, respectively.

Note 11 – 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. As of December 31, 2018, the principal balance of the Secured Note was approximately $1,038,000. 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).

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 and Security Agreement between the Company and Tech Capital, dated August 17, 2017 and all of the riders and amendments thereto (the "Loan Agreement") (see Note 12 – Secured Revolving Credit Facility). An event of default under such Loan Agreement would 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 would also be due.

During the year ended December 31, 2018, the Company made payments under the Secured Note of approximately $216,000. Approximately $67,000 of the total payments made was recognized as interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2018. 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, 2018, future principal maturities are as follows:

2019	$195,000
2020	230,000
2021	249,000
2022	269,000
2023	95,000
Total	$1,038,000

Note 12 – Secured Revolving Credit Facility

On August 17, 2017, the Company entered into the Loan Agreement with Tech Capital. The Loan Agreement provides 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. The outstanding principal balance of the Loan Agreement was approximately $991,000 and $711,000 as of December 31, 2018 and 2017, respectively. The Company is using these proceeds for working capital and general corporate purposes.

The Loan Agreement has a term of 12 months, which automatically renewed on August 17, 2018 and will automatically renew for successive 12-month periods unless cancelled. Availability under the Loan Agreement is 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 will not be less than 4.25% per annum. As of December 31, 2018, the current interest rate was 9.00% 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 unconditionally guaranteed the Company's obligations under the Loan Agreement.

For the year ended December 31, 2018, approximately $22,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss. As of December 31, 2018, approximately $2,000 of such interest expense incurred is included in accrued expenses on the consolidated balance sheet.

For the year ended December 31, 2017, approximately $29,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss, which includes the debt issuance costs of approximately $12,000 in addition to interest expense incurred of approximately $17,000 on the revolving facility. As of December 31, 2017, approximately $4,000 of such interest expense incurred is included in accrued expenses on the consolidated balance sheet.

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 2.4 million 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. As of December 31, 2017, the portion of the outstanding notes held by related parties comprised of persons controlled by a member of management and by Lambda Investors LLC ("Lambda"), a significant shareholder, amounted to $30,000 and $300,000, respectively. On March 30, 2018, the principal balance of the notes, along with the remaining accrued interest of approximately $43,000, was repaid in full. While the notes were outstanding, approximately $195,000 of interest was paid to noteholders. The remaining debt discount of approximately $199,000 was recorded as loss on extinguishment of debt in the Company's consolidated statements of operations and comprehensive loss.

For the years ended December 31, 2018 and 2017, approximately $34,000 and $116,000, respectively, was recognized as amortization of debt discount and is included in interest expense on the consolidated statement of operations and comprehensive loss.

For the years ended December 31, 2018 and 2017, approximately $30,000 and $133,000, respectively, of interest expense was incurred.

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 was approximately $1,000 and $8,000, respectively. For the year ended December 31, 2017, the amount of interest expense recognized related to related parties comprised of entities controlled by a member of management and by Lambda was approximately $3,000 and $33,000, respectively.

Note 14 - Accrued Expenses

Accrued expenses as of December 31, 2018 and 2017 were as follows:

	December 31,	
	2018	2017
Accrued legal	$90,000	$90,000
Accrued sales commission	42,000	40,000
Accrued research and development	65,000	-
Accrued accounting	8,000	11,000
Accrued interest	2,000	18,000
Accrued other	189,000	59,000
	$396,000	$218,000

Note 15 - Income Taxes

The income tax benefit attributable to loss before income taxes for the years ended December 31, 2018 and 2017 is as follows:

	Years Ended December 31,	
	2018	2017
Current:		
State	$(93,000)	$(1,789,000)
Total current tax benefit	(93,000)	(1,789,000)
Total deferred tax benefit	-	-
Income tax benefit	$(93,000)	$(1,789,000)

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, 2018 and 2017 is as follows:

	Years Ended December 31,	
	2018	2017
U.S. federal statutory rate	21.00 %	35.00 %

State taxes	5.25 %	(21.84)%
Sale of NJ NOLS and credits	(2.78)%	(68.91)%
Change in federal statutory rate	- %	(441.07)%
Stock based compensation	(1.96)%	(5.48)%
Other permanent difference due to sale of NJ NOLs and credits	- %	(24.12)%
Federal research and development credits	2.28 %	2.24 %
Other	(0.11)%	(12.46)%
Valuation allowance	(26.46)%	467.73 %
Effective tax rate	(2.78)%	(68.91)%

Significant components of the Company's deferred tax assets as of December 31, 2018 and 2017 are as follows:

	December 31, 2018	2017
Deferred tax assets:		
Net operating loss carry forwards	$18,671,000	$17,907,000
Research and development credits	1,399,000	1,322,000
Nonqualified stock option compensation expense	497,000	453,000
Other temporary book - tax differences	58,000	125,000
Total deferred tax assets	20,625,000	19,807,000
Deferred tax liabilities:		
Fixed and intangible asset basis difference	(21,000)	-
Total deferred tax liabilities	(21,000)	-
Deferred tax assets (liabilities), net	20,604,000	19,807,000
Valuation allowance for deferred tax assets	(20,604,000)	(19,807,000)
Deferred tax assets (liabilities), net after valuation allowance	$-	$-

The Tax Cuts and Jobs Act of 2017 (the "Tax Act"), which was signed into law on December 22, 2017, resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of the Company's foreign subsidiary to U.S. taxation as global intangible low-taxed income. The Company has completed its analysis of the Tax Cuts and Jobs Act during the year ended December 31, 2018. There were no significant adjustments to the provisional amounts recorded during the year-ended December 31, 2017.

The Tax Act also includes a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings. For tax years beginning after December 31, 2017, taxpayers must include in taxable income their share of Global Intangible Low Taxed Income (GILTI) from foreign controlled corporations. The Company has elected to treat income from GILTI as a period cost.

Changes in tax rates and tax laws are accounted for in the period of enactment.

During the years ended December 31, 2018 and 2017, the Company recorded an income tax benefit of approximately $93,000 and $1,789,000, 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 on the consolidated financial statements as income tax benefits in the year they were 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 $99,000 and $1,903,000, respectively. The gross amounts of the net operating loss and research and development credit carryforwards that were sold during the years ended December 31, 2018 and 2017 were approximately $613,000 and $19,233,000, respectively, and $44,000 and $170,000, 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 increased approximately $797,000 from December 31, 2017 to December 31, 2018.

At December 31, 2018, the Company had Federal income tax net operating loss carryforwards of $82,241,000 and New Jersey income tax net operating loss carryforwards of $2,244,000. Foreign income tax net operating loss carryforwards were $7,903,000 as of December 31, 2018. The Company had Federal research tax credit carryforwards of $1,330,000 and $1,220,000 at December 31, 2018 and 2017, respectively. The Company also had state research tax credit carryforwards of $42,000 and $45,000 at December 31, 2018 and 2017, respectively. The Company's net operating losses and research 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. The Federal and New Jersey net operating loss carryforwards and Federal and New Jersey tax credit carryforwards will expire at various times between 2019 and 2038 unless utilized. The 2018 Federal net operating loss carryforward of $2,780,000 has an indefinite carryover period.

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 2013 and does not anticipate a change in its uncertain tax positions within the next twelve months. The Company’s policy is to report interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Note 16 - Stock Plans, Share-Based Payments and Warrants

Stock Plans

In 2015, the Board of Directors adopted the Nephros, Inc. 2015 Equity Incentive Plan ("2015 Plan") and reserved and authorized 7,000,000 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 10,000,000 shares. The maximum contractual term for stock options granted under the 2015 Plan is 10 years.

As of December 31, 2018, options to purchase 6,369,425 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 31, 2028. As of December 31, 2018, options to purchase 30,000 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 460,917 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 6,399,425 options granted, 1,845,447 options will vest when specified performance criteria are met.

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, 2018, options to purchase 1,035,136 shares of common stock had been issued to employees under the 2004 Plan and were outstanding. The options expire on various dates between January 6, 2019 and March 26, 2024. As of December 31, 2018, 447,500 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.

Share-Based Payments

Expense related to share-based payments is recognized over the vesting period of the options. The Company has elected to recognize forfeitures as they occur. Stock-based compensation expense recognized for the years ended December 31, 2018 and 2017 was approximately $525,000 and $456,000, respectively.

Approximately $500,000 and $426,000 has been recognized in selling, general and administrative expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2018 and 2017, respectively. Approximately $25,000 and $30,000 has been recognized in research and development expenses on the consolidated statement of operations and comprehensive loss for the years ended December 31, 2018 and 2017, respectively.

The following table summarizes the option activity for the years ended December 31, 2018 and 2017:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2016	4,592,347	0.60
Options granted	2,311,542	0.44
Options forfeited or expired	(133,112)	0.77
Outstanding at December 31, 2017	6,770,777	$ 0.55
Options granted	1,143,034	0.62
Options forfeited or expired	(379,250)	0.46
Options exercised	(100,000)	0.30
Outstanding at December 31, 2018	7,434,561	$ 0.56

The following table summarizes the options exercisable and vested and expected to vest as of December 31, 2018 and 2017:

	Shares	Weighted Average Exercise Price
Exercisable at December 31, 2017	2,271,527	$ 0.65
Vested and expected to vest at December 31, 2017	6,509,821	$ 0.55
Exercisable at December 31, 2018	3,221,236	$ 0.61
Vested and expected to vest at December 31, 2018	7,190,188	$ 0.57

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

	Option Pricing Assumptions	
Grant Year	2018	2017
Stock Price Volatility	92,42%	104.56%
Risk-Free Interest Rates	2.71 %	2.19 %
Expected Life (in years)	6.15	6.11
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 2018 and 2017 is $0.48 and $0.36, respectively. The aggregate intrinsic values of stock options outstanding and stock options vested or expected to vest as of December 31, 2018 were approximately $441,000 and $425,000, 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, 2018 was 7.25 years.

The aggregate intrinsic values of stock options outstanding and of stock options vested or expected to vest as of December 31, 2017 were approximately $170,000 and $162,000, respectively. The weighted-average remaining contractual life of options vested or expected to vest as of December 31, 2017 was 7.8 years.

As of December 31, 2018, there was approximately $1,311,000 of total unrecognized compensation cost related to unvested share-based compensation awards granted under the equity compensation plans. Approximately $230,000 of the $1,311,000 total unrecognized compensation will be recognized if and when certain performance conditions are met. The remaining approximately $1,081,000 will be amortized over the weighted average remaining requisite service period of 2.2 years.

Restricted Stock Issued to Employees and Directors

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, 2018 and 2017:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2016	957,336	$ 0.35
Granted	817,144	0.50
Vested	(975,093)	0.35
Nonvested at December 31, 2017	799,387	0.50
Granted	449,043	0.62
Vested	(753,528)	0.50
Forfeited	(45,859)	0.50
Nonvested at December 31, 2018	449,043	$ 0.62

The total fair value of restricted stock that vested during the years ended December 31, 2018 and 2017 was approximately $377,000 and $345,000, respectively.

Total stock-based compensation expense for the restricted stock granted to employees and non-employee directors was approximately $460,000 and $316,000, respectively, for the years ended December 31, 2018 and 2017. Approximately $416,000 and $264,000 is included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss for the years ended December 31, 2018 and 2017, respectively. Approximately $44,000 and $52,000 is included in research and development expenses on the accompanying consolidated statement of operations and comprehensive loss for the years ended December 31, 2018 and 2017, respectively. Approximately $30,000 of stock-based compensation expense was recognized in the year ended December 31, 2017 related to restricted stock granted to employees in 2017 to settle liabilities for services incurred in prior years. As of December 31, 2018, there was approximately $87,000 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, 2018 is greater than the aggregate shares of common stock outstanding for accounting purposes by the amount of unvested restricted shares.

Note 17 - Stockholders’ Equity

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 6,540,669 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 $0.45. Proceeds, net of equity issuance costs of $19,000, recorded as a result of the private placement were approximately $2,924,000. Of the 6,540,669 shares of the Company's common stock issued, 219,000 shares, resulting in proceeds of $98,000, were sold to members of management, including immediate family members.

March 2017 Private Placement

On March 17, 2017, the Company entered into a securities purchase agreement with certain accredited investors identified therein pursuant to which the Company issued and sold in a private placement 4,059,994 units of its securities, resulting in gross proceeds to the Company of approximately $1,218,000. Each unit consisted of one share of the Company's common stock and a five-year warrant to purchase one additional share of common stock. The purchase price for each unit was $0.30. The warrants are exercisable at a price of $0.30 per share and are indexed to the Company's common stock; therefore, the Company is accounting for the warrants as a component of equity. The portion of the gross proceeds received from certain members of management and existing shareholders amounted to $315,000. Proceeds, net of equity issuance costs of $152,000, recorded as a result of the private placement were approximately $1,066,000. In addition to the equity issuance costs incurred as a result of the private placement, the Company also issued a warrant to purchase 81,199 shares of its common stock to the placement agent engaged in connection with the private placement. The form and terms of the placement agent warrant are substantially the same as the form of warrants issued to the investors under the securities purchase agreement, except that the exercise price is $0.33 per share.

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 years ended December 31, 2018 and 2017, the Company issued and sold 1,900,000 and 300,000 shares of its common stock, respectively, to Lincoln Park. The issuance of the common shares to Lincoln Park resulted in gross proceeds of $854,000 and $113,000 for the years ended December 31, 2018 and 2017, respectively. 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. The aggregate purchase price was $3,000,000. SRP incurred transaction-related expenses of approximately $30,000, which are included in selling, general and administrative expenses on the accompanying consolidated statement of operations and comprehensive loss. 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 amounted to 18,000 and 400,000 shares, respectively.

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

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

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

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

The noncontrolling interest in SRP held by holders of the Series A Preferred has been classified as equity on the accompanying consolidated interim 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, 2018 and 2017, 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, 2018 and 2017:

Title of Warrant	Date Issued	Expiry Date	Exercise Price	Total Common Shares Issuable as of December 31, 2018	2017
Equity-classified warrants					
May 2015 – private placement warrants	3/18/2015	3/18/2020	$ 0.85	917,149	917,149
June 2016 – Note and Warrant Agreement	6/7/2016	6/7/2021	$ 0.30	2,284,000	2,374,000
March 2017 – private placement warrants	3/22/2017	3/22/2022	$ 0.30	3,441,195	3,807,861
Total				6,642,344	7,099,010

The weighted average exercise price of the outstanding warrants was $0.38 as of December 31, 2018 and $0.37 as of December 31, 2017.

Warrants Exercised During 2018 and 2017

During the year ended December 31, 2018, warrants to purchase 456,666 shares of common stock were exercised, resulting in proceeds of approximately $138,000 and the issuance of 456,666 shares of the Company's common stock. During the year ended December 31, 2017, warrants to purchase 333,332 shares of common stock were exercised, resulting in proceeds of approximately $100,000 and the issuance of 333,332 shares of the Company's common stock.

Note 18 – Savings Incentive Match Plan

On January 1, 2017, the Company established a Savings Incentive Match Plan for Employees Individual Retirement Account (SIMPLE IRA), which covers all employees. The SIMPLE IRA Plan provides for voluntary employee contributions up to statutory IRA limitations. The Company matches 100% of employee contributions to the SIMPLE IRA Plan, up to 3% of each employee's salary. The Company contributed and expensed approximately $52,000 and $39,000 to this plan in 2018 and 2017, respectively.

Note 19 - Commitments and Contingencies

Purchase Commitments

In exchange for the rights granted under the License and Supply Agreement with Medica (see Note 9 – License and Supply Agreement, net), the Company agreed to make certain minimum annual aggregate purchases from Medica over the term of the License and Supply Agreement. For the year ended December 31, 2018, the Company has agreed to make minimum annual aggregate purchases from Medica of €2,500,000. As of December 31, 2018, the Company's aggregate purchase commitments totaled approximately €2,500,000 (approximately $2,900,000).

Contractual Obligations

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, 2018 and 2017. The Company uses these facilities to house its corporate headquarters and research facilities.

The Company also has a rental agreement for 591 East Sunset Road, Henderson, Nevada 89011 which consists of approximately 16,000 total square feet of space. The Nevada lease expires in November 2020 with a monthly cost of approximately $6,000.

The lease agreement for the office space in Ireland was entered into on August 1, 2018 and includes a twelve month term.

Rent expense for the years ended December 31, 2018 and 2017 totaled $162,000 and $131,000, respectively.

As of December 31, 2018, minimum lease payments are as follows:

2019	$204,000

2020	197,000
2021	145,000
2022	136,000

Contractual Obligations and Commercial Commitments

The following table summarizes our approximate minimum contractual obligations and commercial commitments as of December 31, 2018:

	Payments Due in Period				
	Total	Within 1 Year	Years 2 - 3	Years 4 - 5	More than 5 Years
Minimum Purchase Commitments[1]	$28,700,000	$3,500,000	$7,600,000	$8,400,000	$9,200,000
Leases[2]	696,000	213,000	347,000	136,000	-
Employment Contract[3]	117,000	117,000	-	-	-
Total	$29,513,000	$3,830,000	$7,947,000	$8,536,000	$9,200,000

[1] License and supply agreement with Medica.

[2] In addition to lease obligations for office space, obligations include a lease for various office equipment which expires in 2020.

[3] Relates to employment agreement with Daron Evans, our President and Chief Executive Officer, entered into on April 15, 2015 for a term of four years.

Note 20 – Segment Reporting

During the year ended December 31, 2018, the Company began reporting the results of SRP as a new segment. Prior to the formation of SRP, the Company had only a single operating segment. The Company has reflected these new segment measures beginning in the year ended December 31, 2018 and prior periods have been restated for comparability.

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, 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)

	Year Ended December 31, 2017		
	Water Filtration	Renal Products	**Nephros, Inc.** **Consolidated**
Total net revenues	$3,809,000	$-	$3,809,000
Gross margin	2,292,000	-	2,292,000
Research and development expenses	970,000	32,000	1,002,000
Depreciation and amortization expense	218,000	-	218,000
Selling, general and administrative expenses	3,286,000	12,000	3,298,000
Total operating expenses	(4,474,000)	(44,000)	(4,518,000)
Loss from operations	$(2,182,000)	$(44,000)	$(2,226,000)

As of December 31, 2018, approximately $2,500,000 of total assets are in the Renal Products segment. The $2,500,000 consists 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. There were no assets allocated to the Renal Products segment as of December 31, 2017.

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

There were no disagreements with our accountants during 2018 or 2017.

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, 2018. 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, 2018. 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, 2018 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, 2018, our internal control over financial reporting was effective as of December 31, 2018.

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 “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2019 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information set forth under the caption “Compensation Matters” in the 2019 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 2019 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 2019 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 2019 Proxy Statement is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report:

(1) Consolidated Financial Statements of Nephros, Inc.

Reports of independent registered public accounting firms.
Consolidated balance sheets as of December 31, 2018 and 2017.
Consolidated statements of operations and comprehensive loss for the years ended December 31, 2018 and 2017.
Consolidated statements of changes in stockholders' equity for the years ended December 31, 2018 and 2017.
Consolidated statements of cash flows for the years ended December 31, 2018 and 2017.
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; and March 11, 2011; incorporated by reference to Exhibit 3.1 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.
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 (SEC File No. 001-32288).
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 Unsecured Promissory Note issued June 3 and 9, 2016, incorporated by reference to Exhibit 4.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on June 14, 2016.

4.4	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.
4.5	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.
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 (SEC File No. 001-32288). †

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 (SEC File No. 001-32288). †
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 (SEC File No. 001-32288). †
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	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. †
10.15	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.
10.16	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 (SEC File No.

001-32288).

10.17 License Agreement, dated July 1, 2011, between the Registrant and Bellco S.r.l., incorporated by reference to Exhibit 10.62 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on June 27, 2011 (SEC File No. 001-32288).

10.18	First Amendment to License Agreement, dated February 19, 2014, between the Registrant and Bellco S.r.l., incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on February 25, 2014.
10.19	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 (SEC File No. 001-32288).
10.20	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.
10.21	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.
10.22	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.
10.23	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.+
10.24	Second Amendment to Sublicense Agreement, dated January 30, 2019, between the Registrant and CamelBak Products, LLC.*
10.25	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 (SEC File No. 001-32288).
10.26	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.
10.27	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.
10.28	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.
10.29	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.
10.30	

	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.
10.31	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.

10.32	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.
10.33	Securities Purchase Agreement, dated May 12, 2015, among the Company 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.
10.34	Purchase Agreement, dated July 24, 2015, between the Registrant and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 10.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on July 27, 2015.
10.35	Registration Rights Agreement, dated July 24, 2015, between the Registrant and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 10.2 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on July 27, 2015.
10.36	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.
10.37	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.
10.38	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.
10.39	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.
10.40	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.*++
14.1	Code of Ethics and Business Conduct, as amended through April 2, 2007, incorporated by reference to Exhibit 14.1 to Nephros, Inc.'s Current Report on Form 8-K, filed with the SEC on April 6, 2007 (SEC File No. 001-32288).
21.1	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.
++	Confidential treatment has been requested 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.

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SIGNATURES

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

NEPHROS, INC.

Date: March 12, 2019

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, 2018 of Nephros, Inc. and any and all amendments thereto, and to file the same with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	**Title**	**Date**
/s/ Daron Evans Daron Evans	Director, President and Chief Executive Officer (Principal Executive Officer)	March 12, 2019
/s/ Andrew Astor Andrew Astor	Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2019
/s/ Arthur H. Amron Arthur H. Amron	Director	March 12, 2019
	Director	March 12, 2019

Paul A. Mieyal

/s/ Malcolm Persen Malcolm Persen	Director	March 12, 2019
/s/ Oliver Spandow Oliver Spandow	Director	March 12, 2019
/s/ Alisa Lask Alisa Lask	Director	March 12, 2019