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

TABLE OF CONTENTS

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.

3

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: