NEPHROS INC
Form 424B3
April 25, 2017

Filed pursuant to Rule 424(b)(3)
PROSPECTUS
Registration No. 335-205169

NEPHROS, INC.

2,751,448 Shares of Common Stock

The selling stockholders identified beginning on page 21 of this prospectus are offering on a resale basis a total of 2,751,448 shares of our common stock, of which 917,149 are issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Shares of our common stock are quoted on the OTCQB Marketplace operated by the OTC Markets Group, Inc., or OTCQB, under the ticker symbol "NEPH." On April 19, 2017, the closing sales price for our common stock was $0.34 per share. The shares of common stock issued upon the exercise of warrants will also be quoted on the OTCQB under the same ticker symbol. The warrants are not listed for trading on any stock exchange or market or quoted on the OTCQB.

Investing in our common stock involves substantial risks. See "Risk Factors" beginning on page 8 of this prospectus to read about important factors you should consider before purchasing our common stock.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 20, 2017.

NEPHROS, INC.

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ABOUT THIS PROSPECTUS

We refer to Nephros, Inc. and its consolidated subsidiary as “Nephros”, the “Company”, “we”, “our”, and “us”. This prospectu is part of a registration statement that we have filed with the Securities and Exchange Commission, which we refer to as the SEC or the Commission, utilizing a registration process. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus before making a decision whether to invest in the common stock. You should also read and consider the information contained in the exhibits filed with our registration statement, of which this prospectus is a part, as described in “Where You Can Find More Information” in this prospectus.

You should rely only on the information contained in this prospectus and any applicable prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. We are not offering to sell or soliciting offers to buy, and will not sell, any securities in any jurisdiction where it is unlawful. You should assume that the information contained in this prospectus or any prospectus supplement, as well as information contained in a document that we have previously filed or in the future will file with the SEC is accurate only as of the date of this prospectus, the applicable prospectus supplement or the document containing that information, as the case may be.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. For a more complete understanding of our business, you should read this summary together with the more detailed information and financial statements for the years ended December 31, 2016 and 2015, and related notes appearing elsewhere in this prospectus. You should read this entire prospectus carefully, including the “Risk Factors” section beginning on page 8 and the “Special Note Regarding Forward-Looking Statements” section beginning on page 19. This prospectus contains important information that you should consider when making your investment decision.

About the Company

Nephros is a commercial stage medical device and commercial products company that develops and sells high performance liquid purification filters and hemodiafiltration (“HDF”) systems. Our filters, which are generally classified as ultrafilters, are primarily used in dialysis centers for the removal of biological contaminants from water and

bicarbonate concentrate, and are used in hospitals for the prevention of infection from water-borne pathogens, such as legionella and pseudomonas. 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 OLpūr H2H Hemodiafiltration System, used in conjunction with a standard hemodialysis machine, is the only FDA 510(k) cleared medical device that enables nephrologists to provide hemodiafiltration treatment to patients with end stage renal disease ("ESRD"). Additionally, we sell hemodiafilters, which serve the same purpose as dialyzers in an HD treatment, and other disposables used in the hemodiafiltration treatment process.

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 ("HD"). We have extended our filtration technologies to meet the demand for liquid purification in other areas, in particular water purification.

Our Products

Presently, we have two core product lines: HDF Systems and Ultrafiltration Products.

HDF Systems

The current standard of care in the United States for patients with chronic renal failure is HD, a process in which toxins are cleared via diffusion. Patients typically receive HD treatment 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 performed on a daily basis, and typically takes 12-24 hours.

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 much more prevalent in Europe and is performed in 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 HF, HDF can be resource intensive and can require a significant amount of time to deliver one course of treatment.

We have developed a modified approach to HDF that we believe is more patient-friendly, is less resource-intensive, and can be used in conjunction with current HD machines. We refer to our approach as an online mid-dilution hemodiafiltration ("mid-dilution HDF") system and it consists of our OLpūr H2H Hemodiafiltration Module ("H2H Module"), our OLpūr MD 220 Hemodiafilter ("HDF Filter") and our H2H Substitution Filter ("Dialysate Filter").

The H2H Module utilizes a standard HD machine to perform on-line hemodiafiltration 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 is

connected 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 HDF System is cleared by the FDA to market for use with an ultrafiltration 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. Our on-line mid-dilution HDF system is the only on-line mid-dilution HDF system of its kind to be cleared by the FDA to date.

Vanderbilt University began treating patients with our HDF Systems early in 2017. Our goal over the next 12-18 months is to develop a better understanding of how our system best fits into the current clinical and economic ESRD treatment paradigm with the ultimate goals of (a) improving the quality of life for the patient, (b) reducing overall expenditure compared to other dialysis modalities, (c) minimizing the impact on nurse work flow at the clinic, and (d) demonstrating the pharmacoeconomic benefit of the HDF technology to the U.S. healthcare system, as has been done in Europe with other HDF systems. In addition, we are in the process of developing version 2.0 of our HDF System, which will enable us to manufacture at scale, as well as potentially reduce the per treatment cost of performing HDF.

Ultrafiltration Products

Our ultrafiltration products target a number of markets:

Hospitals and Other Healthcare Facilities: Filtration of water to be used for patient washing and drinking as an aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeons' hands.
Dialysis Centers - Water/Bicarbonate: Filtration of water or bicarbonate concentrate used in hemodialysis devices.
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.
Commercial Facilities: Filtration of water for washing and drinking including use in ice machines and soda fountains.

Our Target Markets

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 25 hospital patients. HAIs affect patients in a hospital or other healthcare facility, 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 waterborne bacteria and viruses that can thrive in aging or complex plumbing systems often found in healthcare facilities. The Affordable Care Act, which was 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 the potential for HAIs. Our ultrafilters are designed to aid in infection control in the hospital and healthcare setting by treating facility water at the point of delivery, for example, from sinks and showers.

On October 28, 2014, we announced that we received 510(k) clearance from the FDA to market our DSU-H and SSU-H Ultrafilters as medical devices for use in the hospital setting. The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters also produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of a surgeon's hands. The filters are not intended to provide water that can be used as a substitute for United States Pharmacopeia ("USP")

sterile water.

In May 2015, we received a warning letter from the FDA resulting from an October 2014 inspection. In the letter, the FDA alleged deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter did not restrict our ability to manufacture, produce or ship any of our products, nor did it require the withdrawal of any product from the marketplace. In August 2015, we received a subsequent letter from the FDA noting that it had received our response correspondence detailing our completed corrective actions. The corrective actions included revisions to our standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483's, cited at the conclusion of the inspection. In April 2016, we received a third letter from the FDA noting that the FDA had completed its evaluation of our corrective actions and that, based on its evaluation, it appeared that we had addressed the deficiencies specified in the May 2015 warning letter.

In June 2015, the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (“ASHRAE”) approved Standard 188-2015, “Legionellosis: Risk Management for Building Water Systems”. We believe the approval of ASHRAE 188-2015 (“S188”) as a national standard will have a positive impact on point of delivery filtration market. The S188 applies to any human occupied building that is not a single family residence; requires the building to have a plan to control for waterborne infection; requires heat, chemical or both cleaning in the event of a suspected or confirmed presence of legionella; and recommends point-of-use filters in areas of high risk. We are enhancing our efforts to support our distributors by developing and delivering focused sales training to their sales forces on the use of our filters to support an overall program of infection risk prevention; and by, whenever possible, doing joint sales calls with our distributors on potential hospital customers to both serve as a product expert and to field train their sales representatives.

In April 2016, we announced that we received 510(k) clearance from the FDA to market our S100 Point of Use filter. We began shipping our S100 Point of Use in the third quarter of 2016, and ramped up to full production by the end of 2016.

In December 2016, we announced that we received 510(k) clearance from the FDA to market our HydraGuard™ 10” Ultrafilter. We expect to begin shipping HydraGuard™ 10” Ultrafilter in the second quarter of 2017, ramping to full production in the third quarter of 2017.

In the third quarter of 2017, we expect to launch a flushable version of the HydraGuard™ 10” Ultrafilter.

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, or incorporating it by reference into, this report.

Dialysis Centers - Water/Bicarbonate. To perform hemodialysis, all dialysis clinics have dedicated water purification systems to produce water and bicarbonate concentrate. Water and bicarbonate concentrate are 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 U.S. 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.

Published studies have shown that the use of ultrapure dialysate can reduce the overall need for erythropoietin stimulating agents (“ESA”), expensive drugs used in conjunction with HD. By reducing the level of dialysate contaminants, specifically cytokine-inducing substances that can pass into a patient’s blood stream, the stimulation of inflammation-inducing cytokines is reduced, thus reducing systemic inflammation. When inflammation is low, inflammatory morbidities are reduced and a patient’s responsiveness to erythropoietin (“EPO”) is enhanced, consequently the overall need for ESAs is reduced.

We believe that our DSU-D and SSU-D ultrafilters are attractive to dialysis centers because they exceed currently approved and newly proposed standards for water and bicarbonate concentrate purity, assist in achieving those standards and may help dialysis centers reduce costs associated with the amount of ESA required to treat a patient. These in-line filters are easily installed into the fluid circuits supplying water and bicarbonate concentrate just prior to entering each dialysis machine, or are installed as polishing filters for portable reverse osmosis (“RO”) water systems.

In March 2016, we launched the SSUmini product, developed to provide a lower cost ultrafiltration solution for water and bicarbonate flowrates of 0.5 gallons per minutes (“GPM”) or less. The SSUmini can be used as a polish filter for small, portable RO water systems or on bicarbonate concentrate lines in dialysis clinics with centralized bicarbonate concentrate systems.

In March 2017, we announced that we received 510(k) clearance from the FDA to market our EndoPur™ 10” Endotoxin filter, which is designed to fit in the existing cartridge hosing of a dialysis clinic’s large RO water system. We expect to begin shipping the EndoPur™ 10” Endotoxin filter in the second quarter of 2017, and the 20” and 30” versions of the filter by the third quarter of 2017.

Military and Outdoor Recreation. Water is a key requirement for the soldier to be fully mission-capable. The availability of water supplies and immediate on-site water purification is critical to enhance the ability to operate in any environment. Currently, the military is heavily reliant on the use of bottled water to support its soldiers in the field. Bottled water is not always available, is very costly to move, is resource intensive, and is prone to constant supply disruptions. Soldiers conducting operations in isolated and rugged terrain must be able to use available local water sources when unable to resupply from bulk drinking water sources or bottled water. Therefore, the soldier needs the capability to purify water from indigenous water sources in the absence of available potable water. Soldiers must have the ability to remove microbiological contaminants in the water to Environmental Protection Agency (“EPA”) specified levels.

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 fresh water source. This enables the soldier to remain hydrated, which will maintain mission effectiveness and unit readiness, and extend mission reach. Our IWTD is one of the few portable filters that has been validated by the military to meet the NSF Protocol P248 standard. It has also been approved by U.S. Army Public Health Command and U.S. Army Test and Evaluation Command for deployment.

On May 6, 2015, we entered into a 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 is 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 fiscal year ended December 31, 2016, we recognized royalty revenue of $10,000 related to the Sublicense Agreement with CamelBak.

In 2015, we began working with multiple companies developing portable water purification systems designed to provide potable water in remote locations. Specifically, we have provided flushable filter prototypes to these companies for validation as one potential component in systems that employ multiple technologies to purify water from streams, lakes and rivers.

*Commercial and Industrial Facilitie*s. In 2014, we launched NanoGuard-D and NanoGuard-S in-line ultrafilters for the filtration of water to be used for non-medical drinking and washing in non-transient non-community water systems, or commercial facilities. The NanoGuard-D and NanoGuard-S trap particulates greater than 0.005 microns in size and can be used as a component of a facility water treatment system, or to filter water used in ice machines and soda fountains.

In November 2015, we announced a strategic partnership with Biocon 1, LLC. Biocon 1's AETHER® Water Systems technology, which includes patented water filtration media and water filtration products, provides solutions for customers to address all contaminate issues and to provide clean-tasting, sediment-free, scale-free, and bacteria-free water for the food service industry. AETHER® Water Systems are used with ice machines, coffee stations, and soda fountains in hotels, casual dining restaurants, fast food restaurants and convenience stores. As part of the collaboration, we have access to Biocon 1's anti-scale and related water filtration technology to develop filter products for the medical industry. In March 2016, we shipped the first lot of filter cartridges to Biocon 1 for inclusion with its AETHER® line of filtration products.

While our EndoPur™ ultrafilter cartridge platform was designed initially for use in the dialysis setting, we are working with our distributors to identify other opportunities for our ultrafilters to provide value to customers in multiple commercial and industrial settings. The NanoGuard-C, a cartridge ultrafilter that inserts into standard 10", 20", 30" and 40" housings, is now available; and we expect that the NanoGuard-F, a flushable cartridge ultrafilter available in 10" and 20" sizes, will be available for broad distribution in the second quarter of 2017.

Many potential customers in the commercial and industrial space currently utilize an Everpure® manifold system. The NanoGuard-E, a version of our ultrafilter that plugs into an Everpure® housing system, is now available.

Over the last few years, we have been developing a high-throughput, auto-flushing filter system capable of handling 25 GPM, or greater, through our proprietary 0.005 micron fiber membrane. The flushable filter system is designed to remove submicron particulates in closed loop water systems, including cooling systems for data centers and hot water return loops in commercial buildings. Initial data suggests the ability to remove both organic and inorganic particulates. We have released a limited number of systems to specific customers for additional testing and validation.

Small, flushable 2.5 and 5 GPM filter systems have potential utility as a point-of-entry water purification system in restaurants, convenience stores and households. We offered flushable systems to a limited set of customers in 2016, and expect to offer these system to a broad set of commercial and industrial customers starting in the second quarter of 2017.

In the third quarter of 2017, we expect to launch a lead filtration system that will address both soluble and particulate lead in potable water, with the ability to treat up to 10,000 gallons of water between filter change-outs.

Going forward, as we grow our water filtration business, we will be exploring opportunities for new applications for our filter products and will be open to evaluating new potential partnerships to expand our water filtration foot print. Our strategic distribution partners who place our filters in hospitals and medical facilities, also support a wide range of commercial and industrial customers. We believe that our existing distributor relationships will facilitate growth in filter sales outside of the medical industry.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 1997. Our principal executive offices are located at 41 Grand Avenue, River Edge, New Jersey, 07661, and our telephone number is (201) 343-5202. We also have an office in Dublin, Ireland. For more information about Nephros, please visit our website at www.nephros.com.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred significant losses in operations in each quarter since inception. In addition, we did not generate positive cash flow from operations for the years ended December 31, 2016 and 2015. To become profitable, we must increase revenue substantially and achieve and maintain positive gross and operating margins. If we are not able to increase revenue and gross and operating margins sufficiently to achieve profitability, our results of operations and financial condition will be materially and adversely affected.

There can be no assurance that our future cash flow will be sufficient to meet our obligations and commitments. If we are unable to generate sufficient cash flow from operations in the future to service our commitments, we will be required to adopt alternatives, such as seeking to raise debt or equity capital, curtailing our planned activities or ceasing our operations. There can be no assurance that any such actions could be effected on a timely basis or on satisfactory terms or at all, or that these actions would enable us to continue to satisfy our capital requirements.

Recent Developments

On March 17, 2017, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement, referred to as the 2017 Private Placement, a total of 4,059,994 units of our securities, each unit consisting of one share of our common stock and a five-year warrant to purchase one share of our common stock, referred to as the 2017 Warrants. The closing of the 2017 Private Placement occurred on March 22, 2017. The purchase price for each unit was $0.30. The 2017 Warrants are exercisable at a price of $0.30 per warrant share and will be exercisable for a five-year term. The sale of the shares and 2017 Warrants resulted in aggregate gross proceeds of approximately $1.218 million, before deducting expenses. Additionally, we entered into a registration rights agreement with such purchasers, pursuant to which we agreed to file a registration statement with the SEC covering the resale of the shares of common stock and shares issuable upon the exercise of the 2017 Warrants within thirty days of the closing date. Maxim Group LLC acted as the sole placement agent for the offering, and we paid Maxim a cash fee equal to 7.5% of the aggregate gross proceeds of the offering, to reimburse Maxim for certain expenses, and granted Maxim a warrant to purchase 81,199 shares of common stock, upon substantially the same terms as the 2017 Warrants, except that the warrant issued to Maxim has an exercise price of $0.33 per share.

Where You Can Find More Information

We make available free of charge on our website (http://www.nephros.com) our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. We provide electronic or paper copies of filings free of charge upon request. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street N.E. Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC at http://www.sec.gov.

The Offering

The following summary describes the principal terms of the offering, but is not intended to be complete.

Securities Offered	2,751,448 shares of common stock, including 917,149 shares of common stock issuable upon exercise of certain outstanding warrants.

Use of Proceeds	We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which we expect to use to further develop our products and for general working capital purposes.
Risk Factors	The acquisition of our common stock involves substantial risks. See “Risk Factors” beginning on page 8 of this prospectus.
OTCQB Symbol	NEPH

RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus, before you decide whether to buy our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Company

Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. However, there can be no assurance that we will be able to do so. Our recurring losses and difficulty in generating sufficient cash flow to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern, and our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on our current cash flow projections and the approximately $1.2 million raised in a private placement offering in March 2017 and projected increase in product sales from the launch of new products we may be able to fund our operations at least into 2018, if not longer, depending on the timing and market acceptance of our new products. If we are unable to generate cash flow from our operating activities by such time, we will need to raise additional funds through either the licensing or sale of our technologies or the additional public or private offerings of our securities. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we may be required to cease operations.

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

As of December 31, 2016, we had an accumulated deficit of approximately $120,285,000, 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, We may continue to incur additional losses in the future depending on the timing and marketplace acceptance of our new 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 which exceed our per unit costs; and
- our ability to continue to develop products and maintain a competitive advantage in our industry.

If we violate any provisions of the FDCA 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 U.S. Food, Drug and Cosmetic Act, or the FDCA, 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.

On May 28, 2015, we received a warning letter from the FDA resulting from an October 2014 inspection. In the letter, the FDA alleged deficiencies relating to our compliance with the quality system regulation and the medical device reporting regulation. The warning letter did not restrict our ability to manufacture, produce or ship any of our products, nor did it require the withdrawal of any product from the marketplace. On August 12, 2015, we received a subsequent letter from the FDA noting that it had received our response correspondence detailing our completed corrective actions. The corrective actions included revisions to our standard operating procedures relating to purchasing and supplier controls, adverse event reporting, and complaint handling and monitoring. In February 2016, the FDA performed another on-site inspection. There were no observations, or 483’s, cited at the conclusion of the inspection. In April 2016, we received a third letter from the FDA noting that the FDA had completed its evaluation of our corrective actions and that, based on its evaluation, it appeared that we had addressed the deficiencies specified in the May 2015 warning letter.