



Dear Friends and Shareholders,

With the turn of the new year, we are writing to provide a comprehensive update about Nephros and our plans for the future.

In the two years since our last shareholder letter, we have grown revenues over 200%, redesigned our Hemodiafiltration (HDF) Assist Device, purchased Aether Water Systems to pursue large opportunities in the commercial filtration market, up-listed our stock to the Nasdaq Capital Market, and recently launched a new pathogen detection system to further support our infection control customers.

Working closely with our strategic partners, we have executed on the strategy and tactics we first described in 2015, focusing on the needs of our customers in infection control and dialysis. We have also methodically expanded our product portfolio to better meet those needs, built an operational infrastructure to support our rapid growth, and passed the \$10 million annual revenue mark in 2019.

Key Business Areas

Infection Control: Over the past few years, our strategic partners and customers have made great strides creating and optimizing the water safety management programs that protect patients from the risks of water-borne pathogens. Those programs generally incorporate routine water testing, secondary disinfection efforts, and point-of-use filtration in high-risk areas. Nephros point-of-use filters are a leading tool used to provide proactive protection to patients in high-risk areas (e.g., ice machines, surgical rooms, NICU's, etc.) and reactive protection to patients in broader areas during periods of water pathogen outbreaks. Our products are currently used in hundreds of medical facilities to proactively and reactively aid in infection control, with new customers deploying our filters every week.

We have now expanded our portfolio of solutions with the recent introduction of our PluraPath™ pathogen detection system, which represents a significant growth opportunity for Nephros.

While providing filters during pathogen outbreaks, we observed a gap in both the timing and depth of data needed by infection control teams. They did not have the data needed to help them make real-time treatment decisions. We also recognized an almost singular focus on *Legionella*; yet we observed that many other bacterial and viral pathogens cause patient issues.

We developed the PluraPath™ pathogen detection system to bridge this data and timing gap. We integrated our ultrafilter technology with emerging, quantitative polymerase chain reaction (qPCR) technology and real-time analytics. We chose a portable, open-source qPCR platform



that allows us to parallel-processes up to 15 different bacteria and virus assays. We worked with industry experts to select and develop DNA- and RNA-based assays that could meet our goals of providing quantitative precision within one hour. We also developed a mobile application to extract and process the data real-time. Furthermore, we designed the system so that anyone can perform qPCR testing, not just someone with training in microbiological laboratory techniques.

Over the course of 2020, we plan to work with our strategic partners and industry experts to develop white papers and case studies to highlight methodologies that integrate real-time qPCR data into water safety management processes. We intend to submit select studies to peer-reviewed journals to contribute to the global dialogue on water-borne pathogen testing.

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

The PluraPath™ system does not replace culture-based assays, which are the current regulatory requirements for confirmation in testing for water-borne pathogens. Rather, we believe PluraPath™ will become a valuable tool in the arsenal of defense, permitting faster decision making about a larger target population of pathogens.

Our objective is to provide our customers and strategic partners with a user-friendly system that delivers dependable, actionable data to infection control teams in less than an hour. If we can succeed in this, we believe the PluraPath™ system could be used to help support infection control teams in every facility that currently deploys Nephros filtration products to aid in infection control. If made easy and economical, then we believe tracking the levels of multiple pathogens in a building could become standard protocol.

Dialysis Water: In the dialysis water market, Nephros ultrafiltration products are among the highest performing products on the market today. The DSU-D, SSU-D and the SSUmini have become the standard endotoxin filter in many portable reverse osmosis systems. The EndoPur®, our large-format ultrafilter targeted at dialysis clinic water systems, provides the smallest pore size available. Following a long pilot project at a major dialysis provider, we are now seeing growth in the use of this product. In addition, we aim to expand EndoPur's® usage into heat-disinfected water systems, which will further open the market for this product.



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

To provide a real-time solution for this testing paradigm, we plan to launch the DiallyPath™ pathogen detection and endotoxin estimation system in the second quarter this year. The DiallyPath™ system will mirror our PluraPath™ but include a gram-negative DNA marker test and test for 6 different gram-negative bacteria. The DiallyPath™ system is designed to provide data on two test samples in one run in less than one hour. The system will provide an estimate of the overall endotoxin in the sample, as well as estimated levels of six specific endotoxin-generating bacteria known to be frequent invaders of dialysis clinic water systems.

These real-time data will enable dialysis clinics to more quickly diagnose and solve urgent endotoxin issues that have the potential to close clinics and disrupt patient treatments. We believe the DiallyPath™ has the potential to be a game changer for the technicians tasked with solving the critical issues that disrupt patient treatments. We plan to work with major dialysis service providers to optimize its use into their current workflows.

Commercial Markets: Our commercial market focus is in the hotel, restaurant, and convenience store markets. For many years, these customers essentially had two filter options to improve taste, reduce odor, and reduce scale build-up in water for soda, coffee, tea and ice: Cuno® (3M) and Everpure® (Pentair). We believe the capabilities of our products will create opportunities to disrupt this oligopoly.

We purchased the Aether® brand at the end of 2018 to expedite our access to commercial markets and to expand our filtration expertise and capabilities. In the first year post-acquisition, we upgraded the Aether® facilities to increase production and logistics capacity, integrated Aether® products into the Nephros infection control product portfolio, and initiated sales efforts with a number of large commercial customers. We have recently added to our commercial sales team and, going forward, hope to close on one or more large contracts that may result in step-change increases in commercial market revenue.

Over time, we believe that the same water safety management programs currently underway at medical facilities will migrate to commercial markets. As the epidemiology of waterborne pathogens expands, links to contamination sources will become more efficient and the data more readily available. In cases in which those sources are linked to restaurants, hotels, office



buildings and residential complexes, the corporate owners of those facilities will likely face increasing liability exposure. We expect that building owners will come to understand ASHRAE-188, which outlines risk factors for buildings and their occupants, and provides water safety management guidelines. For example, (a) a 10-story condominium with (b) a centralized water system and (c) that houses residents over 65 years of age, would have three factors of increased risk (a, b, and c). If someone becomes ill from a pathogen linked to that building's water system, and the building management failed to take appropriate precautionary measures, then building management will face a very real risk of potential liability for damages. We believe, in time, most commercial buildings will need to follow the basic requirements of ASHRAE-188: create a water management plan, perform routine testing, and establish a plan to treat the building in the event of a positive test.

As demand for water testing and microbiological filtration grows, we will be ready to deploy our expertise and solutions based on years of experience servicing the medical market. We believe that we have an opportunity to offer unique expertise and products to the commercial market, and that our future revenue from the commercial market could even surpass our infection control revenue.

The Building Biome Project

Dr. Gomilla et. al.¹ showed that bacterial contaminants in dialysis water systems originate from over 200 different bacterial families. The technology now exists to reproduce that kind of water system biome mapping in real-time, on-site. Using an enhanced form of the portable PluraPath™ system and a bioinformatics database, we have been able to detect as many as 10 different bacteria families in a single sample. The potential for this kind of building biome mapping is enormous. We will have the ability to process as many as 96 samples in a single run, recognizing over 20,000 different bacteria reference sequences, in less than a day on site. We are currently working on the processes and procedures to provide this as a service, and eventually as a product that we can support with partners who have the in-house technical capabilities to manage this system. Additionally, we are working on drafting a white paper to provide guidance on how to operationalize this building biome mapping tool.

We expect to be able to launch the SequaPath™ system and building biome mapping service before the end of 2020. While this service could be of value to the management of any water system in any building in any part of the world, we will first focus on the hospital customers of our strategic partners. Once proven in the hospital space, then we believe that the SequaPath™ system has the potential to shift the building water testing paradigm across multiple markets and geographies.



Hemodiafiltration (HDF):

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

In 2018, we spun-off the development of the HDF Assist Device into Specialty Renal Products, Inc. (SRP). We raised \$3 million of outside capital directly into SRP to fund the second-generation development described above. Nephros maintains a 62.5% ownership stake in the subsidiary. The reasons for this spin-off were twofold.

First, HDF is a very different business than water filtration, with different customers, different investors, and potentially different acquirers. The water filtration business has become a rapidly growing, revenue-generating business while the HDF program is at an earlier stage. Separating the businesses acknowledged these differences.

A second reason for the spin-off was to highlight the HDF program and create a potential opportunity for the market to value it more highly. Prior to some of the struggles to achieve clearance from the FDA and before a worldwide financial collapse, Nephros – which was primarily an HDF company at the time – had a market capitalization which reflected a value of over \$70 million. The promise of HDF created significant value and we believe that keeping HDF as a separate and distinct subsidiary provides the best chance for realizing a comparable valuation range for this business. We expect to file for clearance of the second-generation device under the FDA's Special 510(k) Program in the summer of 2020.

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

While a number of studies have been performed in Europe, the body of evidence for optimal use of HDF needs to be built in the U.S. treatment setting. According to European data from Fresenius, over 15% of dialysis treatments are HDF. That could translate to over 10 million individual treatments if HDF achieved that level of penetration in the U.S. We do not believe that



the U.S. will instantaneously mirror Europe. However, we do believe that HDF therapy has a place in the treatment landscape for patients with end-stage renal disease in the U.S., and we look forward to enabling this pathway.

Closing Thoughts

Both we and our partners are excited by the continued growth of Nephros. With the launch of the new pathogen detection systems, we intend to transform Nephros from a “water filter” company to a “water solutions” company. As we effect that transformation, we expect to grow our revenue by at least 50% per year for the foreseeable future, while maintaining our current gross margins. On its own, our core filtration business is profitable. As a company, however, we have been prioritizing revenue growth over profitability, building a scalable infrastructure and focusing on product development. We believe our 82% revenue growth in 2019 was largely a result of our prioritization and hyper-focus on execution and customer engagement.

We believe that we are in the early stages of expansion on our value-creating journey for Nephros, our strategic partners, and our shareholders. We thank you for your ongoing support.

All the best,

Daron and Andy

¹Gomilla et. al. *FEMS Microbiology Ecology* 52 (2005) 101–114.

Note Regarding Forward-Looking Statements

This letter contains forward-looking statements that are subject to various risks and uncertainties. Such statements include statements regarding the expected growth in demand and sales of our products, , potential benefits of our water filtration products compared to competitors’ products, expected timing of the launch of additional Nephros products in the restaurant and other non-hospital markets, potential benefits of the design of our next generation HDF system, our expected revenue growth, and other statements that are not historical facts, including statements which may be accompanied by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Actual results could differ materially from those described in these forward-looking statements due to certain factors, including uncertainty in clinical outcomes, potential delays in the regulatory approval process, changes in business, economic and competitive conditions, the availability of capital when needed, our dependence on third party manufacturers and researchers, regulatory reforms, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in our reports filed with the U.S. Securities and Exchange



*Commission, including our Annual Report on Form 10-K for the year ended December 31, 2018.
We do not undertake any responsibility to update the forward-looking statements in this letter.*