

## US Kidney Research Corp – Developing the First Waterless Blood Purification Device to Replace Dialysis Machines Worldwide



**Roland Ludlow**  
**Founder/CEO**  
**US Kidney Research Corp**

**Interview conducted by:**  
**Lynn Fosse, Senior Editor**  
**CEOCFO Magazine**

**CEOCFO: Mr. Ludlow: what is the focus at US Kidney Research Corp today?**

**Mr. Ludlow:** Prior to developing an implantable artificial kidney, our primary focus is to finish developing our flagship waterless blood purification device that can potentially replace dialysis machines worldwide. Dialysis, as

it stands today, is the only available option for patients who require blood purification, and its methodology has remained unchanged since its invention by Willem Johan Kolff in 1943. Dialysis is water dependent and has remained fundamentally unchanged for over 80 years. While technical improvements have been made, the core methodology has stayed the same. A shift to a portable, water-free solution would fundamentally reshape the market, and will provide substantial improvements over current dialysis treatments. This innovation is a major leap forward in renal patient care.

One of the key challenges with dialysis is its reliance on water, which presents a significant limitation. Due to its water dependency and reliance on a disposable dialyzer and dialysate solution, dialysis methodology cannot be used to create an implantable artificial kidney, which is our ultimate goal. Our novel waterless technology eliminates this shortcoming.

While our current focus is on creating a standalone waterless blood purification device to replace current dialysis machines, the next step in the process will be miniaturizing the components to fit into an implantable design.

**CEOCFO: Would you explain the current dialysis procedure and how the waterless procedure works?**

**Mr. Ludlow:** Our waterless blood purifying device has several key components, each designed to replicate a specific function of the native kidney. First, we use a specially designed ultrafilter that removes proteins, as well as white and red blood cells, and returns them to the body. The remaining concentrate then moves through the rest of the device. The reason we remove these elements upfront is that they could coagulate inside the device. So, we make sure to filter them out right away.

Next, we use a nano filter that retains glucose because it's vital to return glucose to the body. If we were to remove it, it would be extremely detrimental to the patient. After that, the Electrodeionization (EDI) component comes into play, which is really the heart of the device. It is an ion transport system. This component separates ions like potassium, magnesium, sodium, and others. It then transports the excess ions to the urine stream as waste and returns the necessary levels of ions back to the bloodstream. This is crucial for maintaining physiological balance, and is similar to how a native kidney works. Diet affects the ion levels in the body. For example, if someone eats a lot of bananas, their potassium levels would rise, and the kidney would remove that excess before they reach toxic levels. The EDI ion transport system mimics this process.

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To manage this effectively, a programmed computer chip controls the timing and quantity. The final step of the device uses reverse osmosis to handle excess water, which is also sent to the urine stream. There are other processes taking place, such as removing some uremic toxins, but the main components are there to mimic the native kidney and help restore physiological balance to the body.

Comparatively, a dialysis machine relies on purified water, a dialyzer, and a dialysate solution to draw out toxins from the blood. Toxins are removed through diffusion. The blood flows on one side of a permeable membrane, while the dialysate flows on the other in the opposite direction. The membrane ensures that the two never mix directly, but substances can transfer across the membrane based on concentration gradients. As blood passes by the membrane, waste products diffuse into the dialysate. Substances like red blood cells and proteins are too large to pass through and are retained in the blood.

**CEOCFO: *What have you created now regarding the ion transport system?***

**Mr. Ludlow:** As I previously mentioned, the EDI ion transport system is the heart of our device, and responsible for separating and transporting ions to either the bloodstream or the urine stream. While others have tried to create an implantable kidney device, they've always encountered challenges with this key aspect. No one has ever successfully created a functioning ion transport system, and we have now broken through that barrier.

**"Today, we are very close to completing our novel waterless blood purifying device, which can replace traditional dialysis machines worldwide." Roland Ludlow**

Recently, after years of research, our team made a groundbreaking discovery in this area. While the details are proprietary, this breakthrough took us 9 years to achieve, and it's what truly differentiates our device. The ion transport system is essential for maintaining the body's physiological functions, and without it, this device wouldn't be possible. The other components of the device are relatively simple in comparison. There's still work to be done to complete the transport system, but we now have a clear solution to move forward.

**CEOCFO: *Why did it take so long?***

**Mr. Ludlow:** The kidney is incredibly complex. It is the most intricate organ in the human body. When scientists developed an artificial heart, it was essentially just a pump, sophisticated, but not nearly as scientifically challenging to create. In contrast, replicating the kidney's functions is a major hurdle, which is why no one has successfully created an implantable artificial kidney device.

**CEOCFO: *What are some of the advantages in having a waterless machine?***

**Mr. Ludlow:** On the practical side, there are many advantages to having a waterless machine. Unlike conventional dialysis systems that rely on water, disposable dialyzers, dialysate solutions, and a complex water purification infrastructure, our waterless blood purification device eliminates these costly necessities, leading to substantial savings for healthcare providers. For nurses and technicians, it will simplify the entire procedure by reducing the steps prior to the blood purifying process.

**CEOCFO: *Are you incorporating other new technologies and if so, what are they?***

**Mr. Ludlow:** Yes, our device will incorporate novel technology such as real-time patient monitoring, which is something you cannot do with dialysis. Before a dialysis session, blood is tested to measure various levels, and then it's checked again afterward to ensure the results fall within the acceptable safety ranges. If everything is within those ranges, the treatment is considered successful. With our device, we'll be able to monitor the process in real-time, allowing us to have precise control over electrolyte balance and fluid removal. This will help us target those ranges more toward dead center, improving patient outcomes. Additionally, the monitoring could be done remotely, offering added flexibility.

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**CEOCFO: *Are there advantages outside of the medical benefits?***

**Mr. Ludlow:** I'm glad you asked. There are several advantages. In the USA alone, 6.2 billion gallons of contaminated water resulting from hemodialysis enters the drainage system yearly. Our waterless device would greatly reduce this number. Additionally, the large carbon footprint generated by the dialysis industry caused by electricity utilization in sending water to the clinics, purifying water during reverse osmosis, manufacturing and transport of dialyzers and dialysate, could be eliminated. Also, our device could be used in areas of the world where water is scarce or the water purifying equipment needed for dialysis is unavailable.

**CEOCFO: *Is the medical community excited?***

**Mr. Ludlow:** We've received an overwhelmingly positive response from the medical community, which has been closely following our progress. One example is the KidneyX competition, a prestigious innovation challenge backed by the U.S. Congress, the American Society of Nephrology, and the U.S. Department of Health and Human Services. We participated in their very first contest and won, receiving a \$75,000 award. A couple of years later, they held an international competition for innovation, and we were among the winners again, this time earning \$650,000.

Thus, our work has been recognized by both the American Society of Nephrology and the U.S. Department of Health and Human Services, and we're featured on the KidneyX website. Additionally, we were invited as guest speakers at the International Federation for Artificial Organs. We had the opportunity to present our research there twice, once in June 2020 and again in June 2021, where our team engaged with global experts in the field. Additionally, our chief doctors and researchers have written scientific articles about our technology that were published in *Nature*, the world's leading scientific journal.

**CEOCFO: *Are you seeking funding today?***

**Mr. Ludlow:** Yes, like all emerging scientific research companies, we are always seeking funding. We were one of the lucky ones, because early on we had someone come in and make a significant investment and that got us started.

Today, we are very close to completing our novel waterless blood purifying device, which can replace traditional dialysis machines worldwide. After years of development, we estimate that we are about two years away from reaching Proof-of-Concept, which is the critical stage just before applying to the FDA for clinical trials. Currently we have raised 6 million dollars. Additional funding would be used to accelerate our progress and potentially shorten our timeline. Also, it would be used to advance the development of our portfolio of associated renal care products. Some are in advance stages and very near completion. For companies like ours, funding is an essential element in bringing new technologies to market.

**CEOCFO: *What have you learned from your past experiences as CEO that is helpful to you for this venture?***

**Mr. Ludlow:** Being a CEO of a corporation is a continual learning experience. No one person knows everything. Experience teaches you to adapt to changes in the industry, new regulations, and unforeseen setbacks. It has taught me to look ahead and prepare in advance for upcoming challenges. I have learned to keep a close eye on competition, changes in the industry, and to listen to relevant advice and ideas from others. Running an effective team, creating harmony, good communication between team members, and problem solving are skills that can always be further developed. Strategic planning and implementation are also key, and honing these skills is an on-going process.

**CEOCFO: *What you are developing is exciting! Is it frustrating with the long process to get it going?***

**Mr. Ludlow:** Yes, it can be frustrating at times. A lot of patience is required. We've been committed to this for a long time, and we're still pushing forward. We're very optimistic about our progress and are well on our way, having overcome many significant hurdles. Concerning our flagship waterless blood purifying device, the ion transport system was a major challenge and a source of frustration, but we've made a tremendous breakthrough in that area, which will help us complete the project.

Our researchers are confident that we can wrap up this portion of our project within 18 months to two years. However, I'm cautious about setting firm deadlines in science, as unexpected challenges or unsuccessful experiments can sometimes delay progress. That said, they're hopeful that within a couple of years, we'll be ready to move into FDA

clinical trials. Reaching the clinical trial stage is often when companies start considering an exit strategy. However, we'll address that when the time comes!