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## Q&A with Dr. Jake K. Lee, Ph.D., CEO of Human Biomed, Inc. developing Artificial Organ Devices offering a high efficiency Hemodialysis Device to Support Impaired Lung and Kidney Functions



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**CEOCFO: Dr. Lee, what is the concept behind Human Biomed, Inc?**

**Dr. Lee:** We are a biotech company developing artificial organ devices, which mean organs replacing devices. Specifically, we are developing a high efficiency hemodialysis device or a device to support impaired lung and kidney functions at the same time.

**CEOCFO: Why liver and kidney? What is it about what you understand that makes those appropriate areas for you?**

**Dr. Lee:** I studied artificial organ devices during my Ph.D. The high efficiency hemodialysis device is what I devised for the Ph.D. dissertation. After Ph.D., I had a chance to work in the dialysis industry as a marketing manager, and saw many kidney failure patients who are suffering from the insufficiency in dialysis dose with the current hemodialysis. I soon realized that there should be a way to improve the hemodialysis efficiency, especially the removal of middle-sized uremic toxin to relieve them from harsh dietary restrictions and high death rates. We need a new approach or a new device for those patients.

**CEOCFO: What is the new approach? How are you looking at the problem?**

**Dr. Lee:** We have developed novel technique to increase the hemodialysis efficiency. We applied a pulsatile dialysate flow to the dialysis stream so that we can increase the removal of medium-sized uremic toxins, because the medium sized uremic toxins are rarely removed by conventional hemodialysis devices. With the developed technology which was patented, we could increase the removal of such sized uremic toxins.

**CEOCFO: What is it that allows for that removal?**

**Dr. Lee:** The medium sized uremic toxins are usually removed by a phenomenon called filtration. However, with the conventional hemodialysis there is a limitation to increase the filtration volume. However, with the technology using pulsatile dialysate we developed, we could remarkably increase the filtration volume and consequently the removal of uremic toxins of medium size, while maintaining the entire system as a simple as a conventional hemodialysis device.

**CEOCFO: Where are you in the development process?**

**Dr. Lee:** We have experimental prototypes and finished blood experiment. We have a plan to conduct animal studies soon. In fact, we have developed several versions of the high-efficiency hemodialysis device and we've already done a small number of animal study with the prior version, developing a majority of animal study protocol.

**CEOCFO: What is the actual device? What is the size? Where does it go?**

**Dr. Lee:** The device has a moderate size, having 40 x 40 x 50 cm in size. Our eventual goal is to make it portable so that the patient can perform dialysis at any place. However, we are now focusing on improving the hemodialysis efficiency, i.e., the removal of the medium sized uremic toxins.

**CEOCFO: Has a similar idea been tried in the past or are there other people that you are aware of working on something similar today?**

**Dr. Lee:** Yes. For the dialysis industry, the hemodialysis has been the standard protocol for kidney failure patients. However, the configuration for hemodialysis has not been changed. In recent years, there has been a trial to develop a wearable dialysis device even though there is no such device clinically available to allow wearable hemodialysis. As far as I understand there are no companies trying to use pulsatile dialysis flow to increased hemodialysis efficiency.

**CEOCFO: You are on the third version. What did you learn from the first two versions to get you were you are today?**

**Dr. Lee:** In the initial version which is covered by Ph.D. thesis, I applied the pulsatile flow to both blood and dialysate to increase hemodialysis efficiency. It worked, and the results were published. However, during the animal trials I realized that pulsatile blood might be problematic. The instant suction of blood caused some problems. Therefore, we revised the pulsatile dialysis technique, in which we wanted to retain many aspects, e.g., to increase uremic toxin removal by increasing the filtration volume, but removed the pulsatile blood flow. Thus, we ended up with developing a new version, i.e., a technology called dual pulsation dialysate supply (DPDS) in which blood pulsation was removed while increasing the hemodialysis efficiency. We could improve the flow stability substantially as well with DPDS.

**“We are a biotech company developing artificial organ devices.”- Dr. Jake K. Lee, Ph.D.**

**CEOCFO: Would this device be used by anyone with dialysis? Are there particular cases where it might be more appropriate?**

**Dr. Lee:** Yes, this device can replace conventional hemodialysis devices in clinics and hospitals. That means the device can be used for any kidney failure patients.

**CEOCFO: Is there any potential downside that you are aware of, anything to be on the lookout for at this point? Are there any side effects?**

**Dr. Lee:** As far as what we experienced, we did not find any significant side effects.

**CEOCFO: What has been the reaction from people in the medical community that are aware of what you are doing?**

**Dr. Lee:** I had a chance to communicate with nephrologists about the device. They said they needed a device to increase the medium sized uremic toxin removal because, as one of the doctors said, it is important to remain a lower level of medium sized uremic toxins. We call it pre-dialysis concentration of the uremic toxin. That is, it is important to maintain the pre-dialysis concentration of uremic toxins as low as possible. With our device, the pre-dialysis concentration of medium size uremic toxins can be maintained at a lower level than the level with the conventional hemodialysis device.

**CEOCFO: Are you seeking funding, partnerships, investments?**

**Dr. Lee:** We have completed the prototype and blood experiments with government funding. Since we have a plan for animal study, we are seeking for fund.

**CEOCFO: There are so many companies with so many ideas in healthcare? How do you stand out?**

**Dr. Lee:** You are right. There are so many bio companies these days in the world. However, the truth is that I do not think you could find such a company developing artificial kidney or liver devices. That means there are many companies who are working on medical devices, but it is unlikely easy to see a company developing artificial organ devices. I believe we are developing unique therapeutic medical devices.

**CEOCFO: What, if anything, might people misunderstand when they first look at your company?**

**Dr. Lee:** We are developing a device which people consider can't be developed in a small company. Truth is that the hemodialysis devices are manufactured by large companies. Therefore, many people might think "Can you really develop such a device?" Of course, we can. I explained why or how we can develop this device.