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Bridge to Life is a “Solution” provider



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CEOCFO: *Mr. Schweighardt, what is the concept behind Bridge to Life, Ltd?*

Mr. Schweighardt: Bridge to Life was founded to transform organ preservation with a new additive that would extend organ life and the quality of the transplant. The additive showed promise in that it would increase the viability and number of transplantable organs. In addition, the company also worked on creating a more user-friendly packaging system as it was also developing its Belzer UW® solutions. Our additive eventually failed to deliver on its promise. However, we continued on with our significantly improved packaging system for our Belzer UW solutions which has now become the dominant product form worldwide.

Bridge to Life is now an international company, providing organ preservation solutions to over 50 countries. Our solutions lead the worldwide market under the names of Belzer UW® and Belzer MPS®. We have been providing our transplant solutions for over 12 years at this point. As I said, our solutions lead the world market today. We continue to research and develop technology to improve organ preservation. We have now added organ perfusion devices to our portfolio of products. The addition of perfusion technology provides for more and better-quality organs to the transplant community worldwide.

The demand for organs continues to outpace the supply in all parts of the world. Organ transplantation will grow exponentially as more countries increase their support for organ transplantation. Both the Biden and previous administration have given strong support to increasing the number of transplants in the US. (The Chinese government has a stated goal to increase the number of transplant centers from 178 to 300 in the next few years.) There is a long waiting list of people waiting to receive organs, because the incidence of organ failure continues to grow in livers, hearts, lungs and kidneys. For example, in the US there are 120,000 people on the waiting list for a kidney. In China there are 450,000 on the waiting list for a kidney.

CEOCFO: *How are organs currently preserved? What is it about your solution that is different and better than others?*

Mr. Schweighardt: Our solution was invented by Folkert Belzer, M.D., at the University of Wisconsin, and therefore we call it the Belzer UW® solution. This unique solution was a major breakthrough in organ preservation. All the studies have shown that it is superior to the other organ preservation solutions and is considered the gold standard.

It is the unique combination of components that help maintain the viability of the organ. There are some simpler and less effective formulations available. However, once you get beyond 4 hours of preservation time, the formulation developed by Dr. Belzer is superior in preserving an organ.

In addition to our Belzer solution business, Bridge to Life over the last three years has developed organ perfusion devices to improve outcomes for organs currently not considered viable for transplantation. We are currently selling VitaSmart® our multipurpose (liver and kidney) perfusion pump in Europe and other parts of the world. We are also developing a heart perfusion device which received a "breakthrough device designation" from the FDA and through our merger with a Canadian company, Tevosol we are developing a breakthrough lung perfusion device.

CEOCFO: *How many transplants are there annually? What is the market?*

Mr. Schweighardt: In the US, there were 33,000 transplants from donated organs in 2020. Half of the donated kidneys are referred to as "live donations," where a family member or friend donates one of their kidneys to a loved one or another family member. There is a huge backlog of about 120,000 people on the waiting list just for a kidney transplant, let alone a significant latent demand for all organs. This does not count the people trying to qualify to be on the waiting list for an organ.

"Our company culture is attuned to the transplant community's needs. We do provide corresponding services, so if they run into a problem and have an emergency situation with a perfusion or have run out of solution, we will do everything possible to get them the solution and trouble shoot or answer questions 24/7. I believe this separates us from many of the other companies that are selling the transplant community products. We are a trusted supplier." Stevan Schweighardt

CEOCFO: *Have transplants become safer and safer each year or somewhat static? Where do you see things going?*

Mr. Schweighardt: Organ transplants are safe and are considered the standard of care for end-stage organ disease. Where things are going in organ transplantation is that there are a number of organs that are not used that are classified as extended criteria or marginal organs that would potentially put the recipient at high risk. Therefore, many of those organs are not being used now. We are developing perfusion devices that will help improve those organs that are currently considered marginal or not usable. That is really the next real phase in organ preservation. There will be better devices and methods to use organs that are currently discarded.

CEOCFO: *Are there newer technologies that will help create these new devices or is it more that people have become smarter and can figure it out?*

Mr. Schweighardt: Part of it is the research in this area that shows what type of organ perfusion is better. It was initially thought that perfusing the organ at normal body temperatures would be better for the organ. However, in many cases there is no advantage to perfusing the organ at body temperature. I need to walk you through the process of organ preservation. A donor organ is typically cooled down and flushed with a cold preservation solution, like our Belzer UW®. The blood is washed out and then the organ is stored in cold solution to lower the cellular activity just above the freezing point.

People thought that if we perfuse the organ normothermic or at body temperature it would be better. It has turned out not to be the case for a number of organs. For example, new data coming in from Europe has shown that with high oxygenation and when one perfuses the organs at cold temperature they will do as good as, and sometimes better, than if you perfuse them at body temperature with blood. Further, if you store the organ at body temperature with blood, it is a more complicated and expensive process. These concepts have taken some time to work out. The benefits of how to best preserve an organ is becoming clearer at this point in time.

CEOCFO: *When you are selling your products to different organizations, are these for one-time use or would someone reuse the container or certain components of it? Would you tell us a little but about the physical products?*

Mr. Schweighardt: The nature of preservation solutions lend themselves to one time use only. This also applies to the disposable liver and kidney kits used in our VitaSmart® perfusion device. The reason is the need for complete sterility to prevent any cross contamination.

In terms of the physical product, our solutions are used to flush, cold store and transport the donated organ. This process is important to ensure the organ is viable when it arrives at the recipient's transplant center. Alternatively, if a perfusion device is used, then it requires our Belzer MPS®, Machine Perfusion Solution. The solution is pumped by the perfusion device such as the VitaSmart and the organ is continuously perfused for 2-6 hours or more, resulting in an optimized organ.

The VitaSmart pump/perfusion device is a fixed component. The disposable kit/tubing set and the Belzer UW® solutions are one-time use items.

CEO CFO: *Is it the same for each organ or does it depend on what organ is being transplanted or how far the organ is being moved?*

Mr. Schweighardt: Each organ has a unique profile and need. For example, the kidney is a hardier organ versus the liver. But the kidney may require longer perfusion times to achieve a beneficial effect. On livers, you can pump both the portal vein and the artery, however, it has been shown in livers that you can get the same results by perfusing the portal vein as you would perfusing both the artery and the vein. These are all new concepts that are just being developed that simplify the organ preservation process. Back to your earlier question, it has taken significant time and research to develop all of these concepts and processes of how to best preserve a particular organ.

A heart has a very different requirement from a liver, from a kidney or from a lung. For example, you can cold store a kidney for up to 16 hours with our Belzer UW® solution, whereas you can only store a heart up to between 4 and 5 hours. After that point in time the heart has deteriorated so badly that it is discarded. Therefore, there is a lot of work being done in that area and we at Bridge to Life working in this area to show that perfusing a heart with a perfusion device can extend the time for up to 12 to 16 hours to be able to transport the heart and still have a viable heart. One can store a donated liver for up to 6 to 8 hours without any problems. After about 8 hours livers begin to deteriorate. These are just some of the differences between the organs.

We have two breakthrough perfusion devices to address the organ transport problems. Our LifeCradle® heart perfusion device has received the "Breakthrough Device" designation from the FDA. We merged last year with a Canadian company, Tevosol. This brought in the EVOSS® Lung, the first portable lung perfusion device already in clinical trials.

CEO CFO: *Do you sell directly to hospitals? Is it that specific doctors might request your system? Do you work through distributors?*

Mr. Schweighardt: Bridge to Life has its own sales and marketing organizations in the US and Europe. In the rest of the world, we use distributors for our Belzer UW® solutions and perfusion device. Here in the US, we work directly with transplant centers and OPOs. OPOs or Organ Procurement Organizations are government funded entities. There are 58 OPO regions in the US. The OPOs are responsible for the retrieval of organs in their region, but even more important, they manage and coordinate the priority list for organ transplants in their area and nationally.

When an organ becomes available in their area the call goes to the OPO. The OPO processes the availability, puts out a notice to find the closest matches available for that organ. They also arrange for the transportation of the organ and at times the organ retrieval process.

CEO CFO: *Does the industry recognize that Bridge to Life has a superior solution or is there still education involved for you?*

Mr. Schweighardt: It has been well established that the Belzer UW®, the original formulation by Dr. Belzer, is still the best and leading solution on the market. A number of other companies have made imitations, but they have had limited impact in the market, because the Belzer UW® is the superior product.

CEO CFO: *Is there a price difference? Why would anyone want any other solution than the best in such a delicate situation?*

Mr. Schweighardt: If you are only going to store an organ for 3 hours or just flush it and are able to transplant it immediately, the difference may not be that pronounced under those circumstances. The difference comes in, and the studies have shown both in Europe and the US, once you go beyond a certain period of time for an organ. Then the quality of the organ deteriorates very quickly, and this is where our solution provides an important safety margin that the others do not provide. You want that safety margin, particularly if you are in a transport situation or other time constraint. If the organ is transported by airplane or driven a distance, traffic jams and other things happen, so it is good to have that margin of safety. That is one of the reasons.

CEOCFO: *How is business these days?*

Mr. Schweighardt: We had been affected by COVID as far as the number of transplants not just in the US, but worldwide. However, at this point in time in 2021, I believe, particularly in the US, that the OPOs and transplant centers know how to manage the COVID situation going forward. They have made remarkable efforts in adapting to the Covid environment. and the number of organ transplants are continuing to increase despite the COVID situation.

CEOCFO: *Why is Bridge to Life an important company?*

Mr. Schweighardt: We provide a very important service and product. We are customer-focused and understand that our customers have very challenging jobs. They are on call 24/7. They must travel and retrieve organs at all hours of the day. Transplants are done not when it is necessarily convenient to the surgical teams since it is about the quality of the organ. An organ only lasts so long and must be transplanted within a specific time.

We recognize these demands on our customer. Our company culture is attuned to the transplant community's needs. We do provide corresponding services, so if they run into a problem and have an emergency situation with a perfusion or have run out of solution, we will do everything possible to get them the solution and trouble shoot or answer questions 24/7. I believe this separates us from many of the other companies that are selling the transplant community products. We are a trusted supplier.

