

CEOCFO Magazine

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Q&A with Phillip Larson, President of Axolotl Biologix, Inc. developing Regenerative Medicine to help Patients with Tendon, Ligament and Cartilage Damage Heal Faster and Wound Care Products that can Close Wounds that have been Open for Years

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CEOCFO: Mr. Larson, what is the concept behind Axolotl Biologix, Inc?

Mr. Larson: Axolotl Biologix is a biotechnology company that focuses on developing regenerative medicine to help patients heal faster. Our product line allows physicians and wound care specialists to treat patients who have damaged or diseased tissues, such as tendons, ligaments and cartilage. These treatment options work by regenerating and restoring cells and can be applied quickly at an out-patient facility.

We also have products which can close wounds that have been open for years, which is not uncommon among people with diabetes. Axolotl's membrane products and fluids can heal these wounds in a matter of weeks, saving the patient from more drastic measures like amputation. Therefore, we save limbs and basically we save lives, because once you have an amputation due to a diabetic foot ulcer you have a life expectancy of two to five years. Our advanced products not only close chronic wounds, but also combat pain management without just masking it with opiates.

CEOCFO: What do you understand on a very basic level about regenerative medicine that perhaps other people in health, as well as the general public, do not understand?

Mr. Larson: Most people do not fully understand that regenerative fluid is derived from the amniotic components of the placenta that is collected after a Caesarean section, when mother and baby are happily celebrating. We do not use stem cells and there are no active cells in our products. We use donated afterbirth that is considered biological waste to be disposed and we process it aseptically in accordance with all FDA guidelines in a controlled environment. This fluid contains select growth factors and cytokines, and we harness their potential to regenerate and grow tissues to improve patient outcomes.

CEOCFO: You mentioned being able to fix or help on chronic wounds? How can you do that and why have the wounds been allowed to get to the chronic state if you do have something to fix them?

Mr. Larson: Chronic wounds are seen in people with diabetes and other vascular disorders. They may start off with a blister on their foot or another minor injury, but not even realize it because they have neurological disorders where they cannot even feel their feet. Sometimes they go a while without even noticing the blister and will try to treat the wound themselves. Unfortunately, if the wound remains unhealed for too long it can become infected, which can lead to a foot ulcer and they may eventually have to get the foot amputated. But if doctors can get to the wound on time using Axolotl fluids and membranes, they can have a better chance to heal the wound rather quickly and without surgery. Regenerative

medicine is still somewhat new, but as more physicians learn about the benefits and ease of use and more patients become educated on all their treatment options, we expect to see a dramatic rise in its use.

CEOCFO: Are you suggesting that a diabetic with a wound that is not going away is going to the drug store to ask for something rather than consulting a doctor?

Mr. Larson: It depends on where you are in the country. For example, in major metropolitan areas, patients have greater access to healthcare and are more likely to see a doctor or specialist who is fully aware of the benefits of regenerative medicine. However, if you go to a small rural town, there are fewer options for medical care and the patient may not be able to travel to get to the nearest doctor as often. If they do see a doctor who is not aware of regenerative medicine treatments, he or she will just provide traditional standard wound care.

Patients with these chronic wounds will usually treat it by wearing a boot and then using wound dressings and wound wrappings. They will also often be taking opiates, not necessarily for the wound, but the other neurological pain that is caused from the co-morbidities associated with it and with the condition. Therefore, it is just a vicious cycle. They start to feel hopeless and when you are about to lose a portion of your body to an amputation it is pretty miserable. Our therapy alone is not a miracle cure, but it is far, far superior to traditional care.

Physicians are becoming more and more aware of our products. When these doctors enroll in continuing education, they are hearing about regenerative medicine and it is becoming more popular, but it is still an expensive therapy and they are cost conscious.

"Our dedicated research team uses new and impressive technologies to drive true innovation that helps us create life-changing treatments for people who need them, and that is already having an incredible impact in our community."- Phillip Larson

CEOCFO: Would you tell us about the different products from Axolotl and what they do?

Mr. Larson: We currently have five products - two membrane products and three fluids that work in different ways to heal wounds. AxolotI Graft[™] (https://www.axobio.com/axobiomembrane/) is our dehydrated allograft membrane patch that advances wound repair, skin replacement and reconstruction. We also just launched our new AxolotI DualGraft[™] membrane which creates a natural scaffold for the cells to hang on to during healing, while also inhibiting the growth of bacteria and reducing the rate of infection.

Our fluids include AxolotI Ambient[™] (https://www.axobio.com/axobiofluida/) the first room temperature regenerative fluid product that has enormous benefits for doctors and patients experiencing issues with tendons and ligaments. Since it can be stored at room temperature, physicians don't need a special freezer, they don't have to wait around for the product to thaw and they don't lose the product if a patient cancels their appointment. For the patient, a room temperature fluid is much more comfortable upon injection and they can get a treatment the same day as their consultation. We also just launched AxolotI Shot[™] which is a pre-loaded syringe containing our regenerative fluid that makes it even easier for doctors to administer. We also offer AxolotI Cryo[™] (https://www.axobio.com/axobiofluidc/) which is our cryopreserved liquid allograft that many physicians still prefer to use.

Many of our predecessors touted stem cell counts and different things, so the doctors think there are actual benefits to having cryo-preserved cells in the fluid – which is not true. So, we try to educate them and tell them that the cells are not the active ingredient; it is the growth factors and the different things that are released into the fluid.

Now, all our products are very significant in the sense that our competitors that create a fluid product are aspirating out amniotic fluid from the womb at the point of cesarean section and then taking some of the membrane from the placenta, micronizing it and sprinkling it in to this fluid. However, over the last nine months that fluid has been having its growth potential taken away by a single cell organism that goes from a single cell to a living being in that nine-month cycle. Plus, they are releasing waste products in to the womb as they are getting close to birth, so you have to then filter out ureic acid and other things, because the baby urinated and defecated in the womb. That additional growth potential is being robbed even further by that filtering process, whereas with our product, we take the amnion lining of the placenta and we extract the cells that actually created the amniotic fluid to being with and we create brand new amniotic fluid through cell culture. We are able to have those cells release all those growth factor cytokines, so we have this ultra-pure product that also has tremendous growth potential and growth factor profile. It really is a superior product to our competitor's. As I said, we have the ambient temperature product, plus we also have the dye within our fluid that will change from pink to straw yellow if

the product goes bad on the shelf or is contaminated in any way. Therefore, we have added safety and efficacy in our products.

CEOCFO: How did you get to the point where you recognized this was the way to do it?

Mr. Larson: My business partner and I started with an idea, or rather half of an idea. We were able to run with that and evolve it by bringing in a team of experts who were working on advanced research in this field. One of our first investors was attending John Hopkins University for his Masters in Biomedical Engineering and his insight helped us create our first product that was unlike anything else on the market. As soon as we had our first product out, we began improving upon it immediately and had a couple of iterations. We did not have an overnight success on our very first version, but we have made dramatic progression throughout the product's life cycle. Our third version is a really amazing product, but it came to be from a team effort from some of the most brilliant people I have had the pleasure to work with.

CEOCFO: Where are you today with product availability?

Mr. Larson: It is interesting. Today, we are able to offer our product in every state in the nation, except for New York. They are the last one and we are working diligently to get our state tissue banking license, which we expect will happen very soon. We are also available in Puerto Rico and Guam.

CEOCFO: Would the doctor get it from you? Is it in the pharmacy for an average person if they wanted to try to use it? What is the distribution method? Is it prescription?

Mr. Larson: This is not a medication. It is a therapy that a doctor must administer during treatment. For wound care, the physician would have to debride the wound; take all the dead necrotic tissue out of the wound and then put on one of our patches. Depending on the use of the product, it can be applied in a surgical suite to wrap a tendon, ligament or nerve. In other cases, it is just a topical application. Our fluid product can be injected both pre-operatively and post-operatively. There are many applications, but it is always done by a physician, whether it is in his clinic or a surgical suite.

CEOCFO: Is there much training for the physician or is it intuitive?

Mr. Larson: If the physician is using anything from Hyaluronic acid to corticosteroids, then he already knows how to use our product. They are just substituting it for the existing products that are currently being used, so it does not require much training. However, we do train our physicians to know who is a candidate for our product and if they are a candidate, what adjunct therapies have to be done beforehand to give the patient the best possible outcome. Therefore, we do offer some training to help the physicians identify the right patient population and how to best administer the whole treatment.

CEOCFO: How are you reaching out to the medical community? When you are at a conference how do you stand out among so many companies with lots of ideas?

Mr. Larson: We believe distributors are the best way to reach physicians and educate them. That is because many physicians just simply do not have the time to learn about new products and new companies. There are so many companies that are hitting the market and trying to compete for their time, that they use their distributors as a way of vetting out new technologies and they trust their distributors to only carry the best product lines.

Within conferences, no one notices the new exhibit at the exhibit hall. They notice who is up at the podium, where physicians speak passionately about their experience with new products and treatments. It is the best way to reach physicians, and as more and more doctors adopt our products, we will have more people that want to speak to colleagues about the benefits of Axolotl. But we want it to be something that happens organically, where a physician will spend the money to buy the product, take the time to study it on their patients and publish a paper on their findings.

CEOCFO: Are you seeking funding, investment or partnerships?

Mr. Larson: Yes, we are in the process of seeking funding. We are currently speaking to a couple of tribal nations where diabetes and wound care are a big concern. Native American populations have the highest propensity for diabetes. We do not just want to prolong life. We want to improve the quality of life. Therefore, part of that is by being able to provide greater access to these treatments while also letting tribal nations share in the economic development these products will bring. We have several tribes that are interested in investing in Axolotl, however, we have been speaking to other private equity firms as a backup. We also offer internships for Native Americans at our Phoenix headquarters.

CEOCFO: Why is Axolotl Biologix important?

Mr. Larson: Our dedicated research team uses new and impressive technologies to drive true innovation that helps us create life-changing treatments for people who need them, and that is already having an incredible impact in our community. While there are other competitors in the regenerative medicine space, AxolotI has a next generation set of

products that make our current products look like child's play. We are using new technology to develop products with Tropoelastin, which is a precursor to elastin. By the time we turn twelve, our bodies stop producing elastin. By the age of seventy, over half of our elastin is gone which is why our skin wrinkles, our blood pressure goes up, and our tendons and ligaments get injuries. Without enough elastin, our tissues can no longer stretch as needed.

Axolotl is working on a fluid that will be enhanced by the use of Tropoelastin, a water-soluble version of elastin. With it, we can print custom scaffoldings, such as skin scaffoldings, heart patches and blood vessels that are a perfect match for the patient. This is a highly scientific process that uses collagen and fiber in the Tropoelastin to build the scaffolding that will impact healthcare tremendously.