

Q&A with Dr. Crystal Nyitray, Inventor, Founder and CEO of Encellin, Inc. developing a Ultra Thin-Film Cell Encapsulation and Delivery Device that will enable Type I Diabetes Patients to better Regulate Insulin



Dr. Crystal Nyitray
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CEOCFO: *Dr. Nyitray, the tagline on your site is, "Protecting cells, protecting people." What is the problem that you are addressing at Encellin Inc?*

Dr. Nyitray: Encellin is developing a cell encapsulation technology that is focused on allowing cells to do what they do best. When you think about it, the cell is the ultimate smart machine. Most, if not all, therapies are trying to recapitulate some function of the cell; either some protein or small molecule that the cell is secreting, or some feature that the cell is responding and reacting to. Our approach is to allow the cell to do what the cell does best. Our technology is built on allowing the cell to maintain its normal function. In the instance of diabetes, our investigational therapy is being developed to detect glucose and secrete insulin through the membrane, and at the same time protect those enclosed cells. In this way, you could create an approach where you would re-implant those missing cells in Type I diabetes.

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

Dr. Nyitray: Encellin is a preclinical stage biotechnology company. However, the technology itself has been under development for the past five plus years.

CEOCFO: *What is the science of how it works?*

Dr. Nyitray: For the most part, what we are doing is provide a platform technology that hides the cells from the body but lets them maintain their normal function. With cells inside of our platform technology, they would be able to interact with the body but could be protected from graft rejection.

CEOCFO: *Why does it work? Are other people trying to accomplish what you have been able to do?*

Dr. Nyitray: The field for encapsulation has been around for a while. One of the things that we are fundamentally doing differently is developing these therapies by thinking about the biology of this system. If you look back a couple of years you will see these really fantastic membranes, but these are stiff, rigid silica based membrane that, when you want to then implant in a person, are not very biocompatible. People are not machines, and we don't want to put computer chips inside a person without thinking about how that would respond within a human. We are focused on the patient, and developing towards the right cues to have complete patient satisfaction.

CEOCFO: *Would the device just need to be in one place or would it need to be in a number of locations?*

Dr. Nyitray: What is really nice about this therapy is that it consists of a very thin compliant material, meaning you can implant them a number of placed throughout the body. Practically, we have a couple of implant sites in mind that would enable the ease of access of the implantation.

CEO CFO: *What surprised you in the early testing?*

Dr. Nyitray: There were a couple of things that surprised me about this. I hit on this earlier, but I think it really speaks to the transition that we are seeing in biotech right now. You have the semi conductor world and the computer world to thank for all of this nano precision in chips and membranes. However, there was not a lot of transition from putting chips in computers to chips within a person. I was really surprised that there was not a more sophisticated approach for leveraging the nanotech world into biology. When you think about it, it seems sort of obvious that everyone has a preferred way that they organize their house and the type of style of their house. Is it modern? Is it country? Is it with everything really hot or cold? It was really surprising to me that those types of features were not considered in cell encapsulation. Everyone was just thinking about the door. True, you have got to get in the house and out of the house, but being happy inside of the house is kind of important.

CEO CFO: *Diabetes Type I is first. Where might you go next?*

Dr. Nyitray: We chose Type I Diabetes because of the huge unmet clinical need in Type I diabetes, for people to regulate their insulin. Also, we understand the biology really well and what needs to happen there. However, I think that after Type I, that an obvious transition would be to some populations of Type II as well as other metabolic diseases where you can envision the sophistication of the cells metabolism would be really beneficial.

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CEO CFO: *Funding is always an issue. Where are you looking at partnerships and investments? What is your status now?*

Dr. Nyitray: The technology itself during development had the benefit of grant support. As a company we have won a number of awards, which have provided fantastic services and resources. Right now we are working to raise our first round to support manufacturing towards First in Human studies.

CEO CFO: *Why are you confident deep down in your gut that you are in the right direction, that you have really hit on something?*

Dr. Nyitray: As a scientist, looking at the data gives me confidence, and I really hold a lot of stock in that. Fundamentally, we are addressing a biology problem with engineering. We know what needs to happen to treat this disease. We understand how much insulin needs to be secreted, when it needs to be secreted. When we look back into at current therapies, people have been implanting islets alone with immunosuppression into humans and getting a pretty decent response for insulin independence, and that is really huge.

CEO CFO: *There are so many new ideas in health. Why look at Encellin Inc?*

Dr. Nyitray: At the end of the day, we have a really different approach for this. We are coming at the biology first for cell encapsulation. There are many hidden or overlooked challenges that occur in encapsulation that we are specifically focusing on addressing. I talked a little bit about the protection of the cells. That is absolutely important if you want to have a cell therapy or a transplant without an immunosuppressant. However, one of the other really important things when you are thinking about doing an implant that not many people talk about is comfort. We want to develop a technology that is comfortable for the patient and not susceptible to massive scar tissue formation.

