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Q&A with Dr. Edward M. Rudnic, Ph.D., CEO of DisperSol Technologies, LLC developing their revolutionary KinetiSol® Technology that will make Insoluble Drugs Water Soluble leading to New and Better Medicines

Edward M. Rudnic, Ph.D.
Chief Executive Officer

DisperSol Technologies, LLC
www.DisperSoltech.com

Contact:
Raj Sheel
512-686-5185
raj.sheel@DisperSoltech.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Dr. Rudnic, what is the concept behind DisperSol Technologies, LLC?***
Dr. Rudnic: DisperSol has perfected a technology for making solid dispersions, which is to say solid solutions of insoluble drugs that help them absorb better in the body. There are a couple of technologies that are used commercially now to accomplish that. One is spray drying and another is called hot-melt extrusion. Both of those technologies have limitations which we do not have. Our technology has been developing over the last ten years. Through physical thermokinetic mixing, or extremely high shear, we have been able to liquefy water soluble polymers; not melt them but liquefy them, to a point where the drug dissolves in that soluble polymer. Then we take away the shear or the friction and the material solidifies at room temperature into a solid, where every molecule of the drug is surrounded by very soluble material. That whole process takes less than four seconds.

CEOCFO: ***Would you explain what is happening with KinetiSol®? How are you able to do it? What is the science?***
Dr. Rudnic: We employ something called high shear. Think friction. Think of a billion times more friction than you can get your head around. What happens is the soluble polymers liquefy under very high shear or friction. Then this very insoluble drug dissolves in that liquid polymer. When you take the shear or the friction away it solidifies and then we can mill it into a powder and directly compress tablets out of it. The fascinating thing is that the drugs remain quite stable both physically and chemically since no appreciable heat is involved.

CEOCFO: ***What creates the friction?***
Dr. Rudnic: We have lab-scale and production-scale machines that we have designed, patented and built; and we have many machines, that apply that friction. We have very specialized parts that spin at thousands of RPM and apply just an incredible amount of shear to the material.

CEOCFO: ***Have similar approaches been tried in the past?***
Dr. Rudnic: No.

CEOCFO: ***You have been involved with many different successful pharma ventures. Why did you decide to come onboard with DisperSol?***
Dr. Rudnic: Because it is very interesting. My background started out in the formulation sciences at big pharma and I kind of grew into a CEO role at a number of smaller companies, some public companies and some international public companies. When I look at the technologies for addressing these hard to dissolve and hard to absorb drugs, this is the only new technology that has come out in my entire career and it is exciting! I look at our ability to not only improve the delivery of drugs dramatically, but also to help patients by enabling drugs to be utilized that normally would not get to market because they are not being absorbed. I know that the phrase is over used, but this is a real game changer in that this technology can enable so many drugs for so many very critical diseases. I think it is exciting to be involved with a company that can make a real difference and really change things for patients. That, I think, has driven me more than anything else. This is a novel technology. It is widely applicable and with many cancer drugs, especially in the area of immune-oncology, many anti-viral drugs and many other anti-infective drugs. The newer ones that are coming through the discovery pipelines are incredibly insoluble and very poorly absorbed. So they just die, even though they look like they are pretty valuable drugs. They just get discarded because they are not orally active. We can change that. That has really made the difference for us and that is what has really excited me and caused me to come on board.

CEOCFO: ***Where are you in the development and commercialization process?***
Dr. Rudnic: We have one product in Phase II right now. In that program, we are treating patients with iron overload disorder, which occurs secondary to sickle cell disease and beta thalassemia treatment. We also have two more products that will be going in to Phase I in the next couple of months.

CEOCFO: ***Would drug companies eventually have the equipment and they would manufacture the drugs or are you looking to put out usable drugs, with your process?***
Dr. Rudnic: We have a balance in our business approach. Before I came on board we were very much a technology driven "service provider" company. Since I have come on board we have become much more balanced with a portfolio of external partnerships with big pharma's drugs and internal programs that we are developing for ourselves. Right now, we have eight products that we are developing ourselves, some of which we may decide to license out and some of which ultimately might go commercial internally as our products. However, we also have quite a few partnerships right now, that are in the evaluation stage with big pharmas and all of those are marquee names.

"Our technology ought to be frontline, because it gets you to the clinic faster, you get to a commercial formulation faster, your scale up challenges are significantly fewer and we can create a product that is unique and really maintains exclusivity for quite a while, far beyond any other formulation technology."- Edward M. Rudnic, Ph.D.

CEOCFO: ***You are approaching solutions from virtually every angle possible!***
Dr. Rudnic: Yes, and we will not sell machines to anyone. We own the machines. We own the technology. We will have machines in our R&D facilities to support R&D activities for our big pharma partners. We are about to sign and announce a global deal with a contract manufacturing organization that is very high profile in the solid dispersion space, with an impeccable regulatory history. We will have commercial machines in their facility so that a big pharma partner can see what is called "line of sight" from research and development all the way through to commercial manufacture.

CEOCFO: ***There are a tremendous amount of opportunities. How have you decided what to work on?***
Dr. Rudnic: We are looking at drugs that have some improvement that can be made in them. Some of these are new compounds. Some of these are existing compounds. In particular, in iron overload there is a drug called deferasirox, which is a drug product called Jadenu™. It is made by Novartis. About a third of patients do not adequately absorb the drug and as a result they do not get adequately treated. With sickle cell and beta thalassemia, these are patients that do not form very good red blood cells. Untreated, they will die very young, so they get blood transfusions. After about twenty transfusions you get so much iron that your body cannot handle, and it starts accumulating in your liver and your heart. Those patients will die by their thirties unless they start pulling some of the iron out. Since Novartis introduced Jadenu those patients can now live into their sixties. The problem is that about a third of those patients do not absorb the drug well and as a result they may die much earlier. Therefore, we thought there was an opportunity to treat those patients that are not adequately treated with the Novartis product.

CEOCFO: ***What has been the reaction from the medical community?***
Dr. Rudnic: I think that there is a pretty broad excitement in the pharmaceutical industry, because as I said, I have been around the formulation space for quite a while now and this is the only true innovation that has happened in the last forty

years. It is a proven technology, because it is ten years old, from concept and it has been perfected along the way. It has got a lot of patent life to it. It has got a way to really change the way the drug is absorbed. We have been able to go ten, fifteen times the absorption of some drugs, which is just astounding!

CEOCFO: ***Are you seeking funding or investments?***
Dr. Rudnic: In January we just concluded a twenty seven million dollar raise, so we are very well capitalized. We have raised almost fifty million dollars since inception. We have revenue coming in from our pharma partners and we are looking forward to having those transform into a real commercial deals in the very near future.

CEOCFO: ***What surprised you as you have begun testing different drugs? What have you learned?***
Dr. Rudnic: How poorly absorbed some drugs are. The bioavailability of some drugs is just so low. I guess I had not really appreciated how many drugs have such poor oral bioavailability.

CEOCFO: ***What should we expect in the next year or so from DisperSol Technologies?***
Dr. Rudnic: We have so many things going on! We are going in to the clinic in Phase II right now, on the iron overload product. We have a cancer drug and an anti-infective drug entering Phase I right now. We also have four big pharma's that are very excited about what they are seeing with our technology and they are preparing to go into Phase II. If they do it with our formulation that should translate into commercial deals with those big pharmas.

CEOCFO: ***What is your focus day to day as CEO?***
Dr. Rudnic: We have an excellent team here and we have many different things going on. Therefore, every day there is a challenge that needs to be overcome. However, we just keep focusing on our programs. The approach is sound. The technology is quite sound and the team is strong. We just keep executing on our plan and identifying new projects and new partners and we keep going with that.

CEOCFO: ***What, if anything, might people miss when they first look at DisperSol Technologies?***
Dr. Rudnic: Some people think that the technology is only something that they should evaluate when everything else has failed. I have been trying to educate the entire industry that this technology cannot be copied by any other technology. As a result the extension of intellectual property protection goes not only with our technology patents, but with the idea that this is a very difficult, if not impossible, technology to copy with spray drying or hot melt extrusion. Therefore, our technology ought to be frontline, because it gets you to the clinic faster, you get to a commercial formulation faster, your scale up challenges are significantly fewer and we can create a product that is unique and really maintains exclusivity for quite a while, far beyond any other formulation technology. I am amazed sometimes at how the formulation executives do not fully understand that. They are looking at it from a very limited, formulation science perspective. Some do. However, not all of them see that it is a strategic enabling technology to provide long-term exclusivity.