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The Most Powerful Name in Corporate News

Nanotechnology Platform for DDFP-Based Oxygen Therapeutics

Dr. David Wilson
Chief Business Officer

About NuvOx Pharma
NuvOx Pharma is a biotechnology company based in Tucson, Arizona with a novel patent portfolio allowing it to develop an innovative platform of dodecafluoropentane (DDFP)-based oxygen therapeutics to treat a host of human conditions. Founded in 2008, NuvOx Pharma has demonstrated therapeutic feasibility in radiation-resistant cancer, hemorrhagic shock, traumatic brain injury, myocardial infarction, retinopathy and stroke. Due to inherent structure of DDFP, a very stable and relative lack of inter-molecular attractive forces, this perfluorocarbon is known to carry large payloads of oxygen in the bloodstream. The main advantage to using DDFP is that it is a liquid at room temperature, but expands to the gas state in the body. Therefore, upon intravenous injection the transition of DDFP from a liquid to a gas in the bloodstream allows for ~200 times increased oxygen transport compared to Hemoglobin.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: ***Dr. Wilson, what is the concept at NuvOx Pharma?***
Dr. Wilson: It is a very interesting concept in that this is the first technology that I have seen where you can intravenously administer a drug that safely increases the concentration of oxygen in the body. This has a variety of therapeutic applications that you might imagine. In the case of heart attack, when the heart is starved for oxygen you have heart muscle damage. If you can increase the amount of oxygen in the limited blood that the heart is receiving, then you can mitigate the damage due to that heart attack. We have seen this in experimental animal studies. We are in human clinical trials in brain cancer right now. It is a nanotechnology platform that serves to increase the concentration of oxygen in the tissues of the body where it low.

CEOCFO: ***How?***
Dr. Wilson: It uses a molecule. The active pharmaceutical ingredient is a perfluorocarbon. I do not want to get too technical for your readers, but it is dodecafluoropentane. It is a small molecule. It binds oxygen with two hundred times the capacity of hemoglobin. Therefore, when you inject this molecule into the blood stream, as the molecule passes through the capillaries in your lungs it picks up oxygen and delivers it to the tissues where oxygen is low.

CEOCFO: ***How does it pick up oxygen? How is it accomplished?***
Dr. Wilson: It is one of the properties of the molecule. Oxygen fits into a binding pattern or a binding configuration associated with this molecule. It was discovered many, many years ago where people were focused on blood substitutes as a replacement for plasma. However, there were many, many safety problems and toxicities associated with that. Maybe fifteen or twenty years ago, I remember seeing on television, as a younger man, someone immersing a rat into a liquid, but the rat was able to breathe under liquid. It was not water. It was a perfluorocarbon. It was saturated with oxygen so that you can take it in very easily. However, our particular molecule is very different from those others in that ours is eliminated from the body by exhaling it through the lungs. Therefore, once is has bound the oxygen it circulates around and the half life is about ninety minutes in the human body. It releases oxygen into tissues that are starved for oxygen. Do not get me wrong; when I tell this story oftentimes people think that athletes can use this to improve their performance. However, that is not the focus or the point. It will not increase your oxygen levels beyond normal. However, if you have low oxygen it will serve to compensate for the lack of oxygen.

CEOCFO: ***Why intravenous? Is it the length of time that it takes or the properties?***
Dr. Wilson: Yes. You want to get it into the circulation quickly to put it into vasculature.

CEOCFO: ***You mentioned that you are starting first clinical trials regarding the brain. Why that as a beginning?***
Dr. Wilson: Why brain cancer? That is a great question. There is a disease called glioblastoma multiforme. Once this disease is diagnosed, if left untreated you die in four months. If you undergo brain surgery to remove as much tumor as possible, six weeks of radiation and chemotherapy after that, then you have increased your chances of survival, so that

five percent of the people that go through that course of therapy live beyond three years. Therefore, it is a significant area of unmet medical need. Regulatory authorities like the US FDA or the European authorities are very supportive of therapeutic developments in these areas. When there are diseases in need of potentially effective treatments they work with you as a partner. That is because they want to bring potential new innovation and therapy to areas where there is not much hope for patients. That is our goal. It is that we believe that we can really prolong the life of patients in a variety of diseases just by increasing the concentration of oxygen in their body safely. If you just inject oxygen into a blood vessel you get clotting and eventually can die. However, this actually holds it in a molecular form and acts as if it is like hemoglobin, carrying it throughout the body. Then when it encounters a region where there is low oxygen it seems to dissipate into it. We demonstrated this in animals where we stick an oxygen probe into a hypoxic tumor. It is a little complicated here, but we put a human tumor into a specific laboratory animal, in this case a rat, and then put an oxygen probe into that tumor. You can show that it has very little oxygen going to that tissue. It is really starving for oxygen. Then after getting our drug it increases the concentration of oxygen up to about half of what it would normally be from virtually nothing.

"The NuvOx nanotechnology platform will revolutionize how hypoxic cancers and ischemic diseases like heart and stroke are treated. We will see reduced disability, shortened recovery time and increased effectiveness in treating solid tumors. Our goal is to bring cost effective therapeutics to benefit patients." - Dr. David Wilson

CEOCFO: ***Have similar approaches been tried?***
Dr. Wilson: Yes. There are other oxygen therapeutics and there are companies out there that have been working on this. However, they have seen toxicity upon administration, because the doses that they use are quite high. In fact, they are about two hundred times higher than what we use for our particular molecule, which is patented every which way come Sunday, so to speak. I also wanted to add that this particular molecule was previously reviewed by the Food and Drug administration and the European Regulatory Authorities as an ultrasound contrast imaging agent. Therefore, it was approved in Europe and was approvable by the FDA. However, the company that invested nearly one hundred million dollars to develop the diagnostic agent decided that being fourth to market was not a good commercial strategy, so they never launched the product. However, the FDA has given us the right of reference or permission to reference that new drug application that they have on file. Therefore, NuvOx has a tremendous advantage in referencing a lot of the preclinical and the human data that has already been generated while it was being reviewed as a diagnostic imaging agent. That is why I joined NuvOx. I invested in NuvOx as well. NuvOx had been going about five years at that point. In addition to putting in money I spoke to the founder, Evan Unger, who is the CEO and President of NuvOx and said, “I might also be able to bring some drug development skills that you might be able to use, because of my twenty year career in the pharmaceutical industry.”

CEOCFO: ***Is the medical community, or at least people that should know, aware of what you are doing? Is it still too early?***
Dr. Wilson: We have several publications on our website, and have presented at the American Society of Clinical Oncology. We will continue to present at a variety of scientific conferences. Actually Evan Unger, the President, is on the road right now trying to raise another round of financing for us, so that we can continue our development efforts. Therefore, we are trying to get the name out there. However, you know there is a lot of competition and many good ideas floating around. It is a challenge and takes a huge effort to make sure that your company, your position and your technology platform are viewed and is known by the public. We do the best we can. We only have seven employees at this point. Therefore, most of our work is done through contracts and collaborators and many late night telephone meetings.

CEOCFO: ***Different medical conditions and different medical concepts are in and out of favor with the investment community at different points in time. What is the feeling about your area? Is there interest today?***
Dr. Wilson: It is a great concept and it is a good question, Lynn. That is because the thing that I like about what we do is that it is so simple. It is a simple intravenous injection; one syringe. However, it seems like most of the big pharma companies are going after the sexy new technology, targeted immuno therapies and immuno modulators, things of that sort that are really quite complex. In my view they have a much longer product development timeline. Our particular product has the potential to serve billion dollar markets. However, it has really been difficult to get the attention of big pharma or potential corporate partners that, in my view, have sufficient infrastructure to fully develop a product and bring it to commercialization. NuvOx, as I said; we are a small company. We struggle over every nickel that we spend in order to invest properly. Therefore, to get the attention of big pharma, I think we have not had the sizzle that they are looking for. I am not sure why that is. In my view, it might be too simple. We are currently generating human data that I am confident will get the attention of potential partners.

CEOCFO: ***How do you and the whole team deal with the frustration of knowing that you have something that could potentially help and yet it is such a struggle to get it on the map, even in the early stages?***
Dr. Wilson: You have to believe. You have to have passion for what it is and you have to believe in and visualize the outcome. Our goal is really to help patients. That may sound trite, but in my entire working career, every product that I have ever been a part of developing has provided benefit to someone, to people, saved lives, improved their diagnostic capabilities and protected them from disease. When you do that you feel really good about what you are doing and the money comes. The frustration; I just suppress it and slog on, because I believe in the potential of this platform. I do not know how else to say it.

CEOCFO: ***Why take note of NuvOx Pharma?***
Dr. Wilson: NuvOx Pharma has the lowest risk drug development option or opportunity that I have ever seen in my twenty years of being in the pharmaceutical business. It is the fact that it has already been tested in two thousand people as an ultrasound contrast imaging agent. It is the fact that another company invested one hundred million dollars in the product development that was never brought the market, but the FDA has given us access to all of that historical record and documentation, which saves us a lot of time and money. We have spent about five million dollars total to date to get to this point. To be in a clinical trial after only having spent five million is pretty darn good! We just got a one million dollar grant from the NCI that I should mention, that will help in the radiation sensitization or brain cancer work that we are doing. We seem to be getting government recognition of the work that we are doing, which is definitely a start. That will help us begin to publish and just to keep putting our name out there until people start to pay attention. It takes time. There are many smart people in my business that work very hard and have much at risk. Therefore, it is highly competitive for the dollars out there. What can I say, you just have to believe in what you do and that is what we are doing right now. We just extended our intellectual property position for another seventeen years or so at this point with an important composition of matter patent. We continue to generate intellectual property. We have patent applications for stroke, heart attack, transplantation, and things of that sort. The other thing that I want to mention is that two important product development paths are being taken on by the Navy and the Air Force. They are looking at our product and are quite enthusiastic about it for traumatic brain injury and hemorrhagic shock. Imagine being out in the battle field and being able to triage a soldier and give that injured person some more time so they can get them to a facility where they can be taken care of properly, just by increasing the concentration of oxygen in their body. I mean, we are going to help a lot of people in this world! It will be very cost effective. The sexy products that people seem to focus on today are quite expensive. Ours; on the commercial scale we ought to be able to sell it for about one thousand dollars a dose. To mitigate your heart or stroke damage by eighty five percent for one thousand dollars; that is just nothing! The pharmacoeconomics work in our favor. I just believe in it so strongly. At this point it is just a question of us executing and finding the resources that we need to do it as efficiently and as quickly as possible and then find a big partner to work with us that can help us cultivate it into a full blown product portfolio.

BIO: Dr. Wilson is a senior executive with extensive Domestic and International experience leading Biotech/Pharm Corporate Development, Operations, Product Development, Project and Alliance Management, Regulatory Affairs in startup and mid-size life science companies with an excellent track record of bringing new products through different phases of Research, Development and Commercialization. He has demonstrated successes in 5 biotechnology companies that have directly resulted in increased valuation by subsequent acquisition or IPO. He has had increasing executive leadership roles in MAST Immunosystems (now Hitachi Medical), Aviron (now Medimmune/Astra Zeneca), Medarex (now Bristol Myers Squibb), Molecular Profiling Institute (now Caris Dx), Advanced Biologics (China), and now NuvOx Pharma. Strengths are strategic planning and resourceful, hands-on tactical management in focused product development from laboratory to launch, creation of operational infrastructure to support technology development, and leading multifunctional teams to optimize the value of their science.

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