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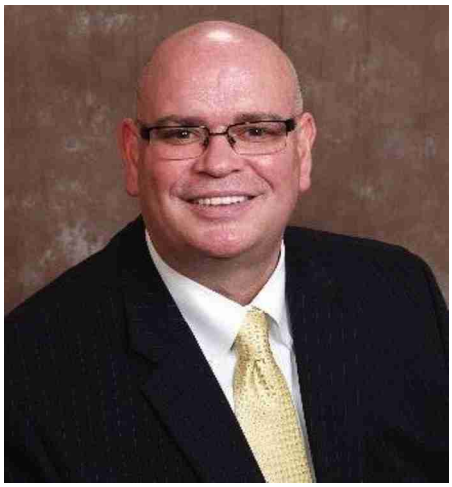
Using Polymers as a Platform Technology, InVivo Therapeutics Holdings Corp. has invented a Biodegradable Material that Does Not Inflame the Nervous System and has shown promise in the Treatment of Patients with Spinal Cord Injuries

Healthcare
Spinal Cord Injury

InVivo Therapeutics Holdings Corp.
One Kendall Square
Building 1400 East, 4th Floor
Cambridge, MA 02139
617-863-5599
www.invivotherapeutics.com



Frank Reynolds
CEO

BIO:
Frank Reynolds founded InVivo Therapeutics in 2005 and he serves as Chairman of the Board, CEO and CFO. In October 2010, Mr. Reynolds successfully took the company public through an Alternative Public Offering (InVivo Therapeutics Holdings Corp. is currently traded under stock symbol NVIV).

Mr. Reynolds is a co-inventor on four of InVivo's patents and he is co-author and winner of the "2011 David F. Apple Award" given by the American Spinal Injury Association to the top published paper in the world for SCI research. He is the former Director of Global Business Development at Siemens Corporation where he had global responsibility for business development. He has over 25 years of executive management experience and was the founder & CEO of ExpandThe Knowledge, Inc., an IT consulting company with a focus on life sciences. He is an Executive Board Member of the Irish American Business Chamber and has served on the board of the Special Olympics of Massachusetts, Philadelphia Cares, and Wharton Consulting Partners. He was awarded the 2010 Irish Life Science 50 Award by the President of Ireland, Mary McAleese, The 2008 Top 40 Irish-American Executives Award, Siemens 2005 Global Presidential Award, and the Siemens 2004 Top+ USA Strategy Award. He was featured in the March 2010 and October 2009 issues of Inc. Magazine.

Mr. Reynolds suffered a paralyzing injury to his spine in December 1992. While recovering from this injury he spent years gaining subject matter expertise on the spine and spinal cord. He holds a Master of Business Administration from the Sloan Fellows Program in Global Innovation and Leadership - Massachusetts Institute of Technology; a Master of Science in Engineering – University of Pennsylvania; he is an alumni of the Executive Masters of Technology Management - Wharton School of Business; a Master of Science in Management Information Systems – Temple University; a Master's of Science in Health Administration – Saint Joseph's University; and a Master's of Science in Counseling Psychology – Chestnut Hill College. He also has a Bachelor of Science in Marketing - Rider University. He's a Moore Fellow of the School of Engineering: University of Pennsylvania, and an IT Fellow of Fox School of Business: Temple University.

About InVivo (OTCBB:NVIV)
InVivo Therapeutics Holdings Corp. is utilizing polymers as a platform technology to develop treatments to improve function in individuals paralyzed from traumatic spinal cord injuries. The company was founded in 2005 based on proprietary technology co-invented by Robert S. Langer, ScD., Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, M.D., who is affiliated with Massachusetts General Hospital. In 2011, the company earned the prestigious 2011 David F. Apple Award from the American Spinal Injury Association for its outstanding contribution to spinal cord injury medicine. The publicly traded company is headquartered in Cambridge, MA.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Reynolds, what is the vision at InVivo?
Mr. Reynolds: We founded InVivo back in 2005 based on technology from Robert S. Langer's lab at MIT. Bob Langer co-founded the field of regeneration and tissue engineering with some people from Harvard and MIT over thirty years ago.

I met Bob back in 2005. He talked about having a treatment for spinal cord injuries. I had actually had a spinal cord injury back in 1992 myself and spent over five years in a body brace from my knees to my neck. I was curious about what Bob was doing, so he explained how the technology worked and asked how I recovered. I discussed the fact that I had spared tissue in my spinal cord and I was able to take advantage of that tissue. Bob mentioned that he could spare tissue in the spinal cord. I told him "if you can spare tissue in the spinal cord; that is the Holy Grail for recovery." There are patients in wheelchairs that have one hundred percent scarring across the cord; no spare tissue is available in their situation. He said "I do have the technology that can spare tissue." We founded InVivo to bring these technologies that can spare nervous system tissue, whether it is in the spinal cord or somewhere else in the nervous system, to market. In this way, we can give a new path to recovery through different types of neuroplasticity and rehabilitation programs, which allows patients to recover more functioning than they would have, of course, without these interventions. Today, there are no materials that can be implanted into a spinal cord that can do this. Yet people say "It sounds simple, why has it not been done in the past?" That is because the materials did not exist, we invented them at MIT. We have been working on this for over six years now, very steadily. We are excited to start human studies in early 2013. We have been meeting with the FDA and are finalizing our documentation for that right now. I get to "wear a new hat," it is called neuroprotection. The world of research around spinal cord injuries has been focused on stem cell research and regeneration research. Probably a good ninety five to ninety eight percent of all research dollars go that way. We have come up with a new approach to neuroprotection where we can actually give patients a chance to recover. It turns out that about ninety percent of spinal cord injury patients that are arriving in the emergency room are not paralyzed for life. Many are suffering spinal shock; they cannot move or feel, and their spinal cord is going to continue to bleed and inflame over the next twenty one days. It is a few weeks' process. What we will do is intervene in a day or two after an injury to prevent or reduce that bleeding and inflammation, and then the patient will, of course, have more spared tissue. They will have less scarring and with that spared tissue, through the rehabilitation program that they are going through as a result of their injuries, they regain levels of function that were not possible before intervention.

CEOCFO: What is it that you have figured out, as far as what types of materials and how to implant them that others have not?

Mr. Reynolds: Bob Langer is probably the number one biomedical engineer in the world. I would say, as a chemical engineer, the body has different ways of adapting to foreign materials. We have invented a biodegradable material that does not inflame the nervous system. Throughout history all materials have had some type of inflammatory reaction when put into the cord. However, we have invented materials that do not at all. We have really created some new materials that do not cause inflammation in and of themselves. The most important part, of course, is having the greatest chemical engineers in the world develop safe materials for the nervous system.

CEOCFO: Are you able to tell me what is in the materials that makes the difference or is that the "secret sauce"?

Mr. Reynolds: We have over one hundred patents, so we are certainly not afraid to discuss it. We use a PLGA material. It is a material that is very well known to people. It has been used in biodegradable sutures for close to thirty years. That was something I discussed with Bob when founding InVivo. I had a great job at the time and was concerned about taking such a big risk. Bob explained that, as former head of the science advisory board at the FDA, he had determined which materials he felt we could get through the FDA fastest. Therefore, when I decided to found InVivo, we had materials that we felt the FDA was going to be comfortable with, and it is. We are now using them in a way that they have never been used before. We are preparing our final First-in-man studies right now to prove the materials that we manufacture in our facility will be non-toxic and that we can manufacture a safe product in our new facility. We just did a ribbon cutting last week on our brand new facility in Cambridge, Massachusetts, and we are preparing to be cGMP compliant for the FDA and get started early next year.

CEOCFO: Why do you feel this approach has been overlooked when regeneration is where most of the research is? How did you know it was the right way to go?

Mr. Reynolds: I became a spine injury patient myself in 1992 and I was obviously very obsessed with it and I kind of understood it as an engineer. I am also an engineer with a degree in engineering from the University of Pennsylvania. I knew as an engineer that structural support to the spinal cord in addition to cellular activity was going to be very important. To an engineer that makes sense; if you are building something you want structural support. It is interesting that when we build homes we will build scaffolding, build the home and take the scaffolding down. In the spinal cord, we literally call our devices scaffolds. Therefore, after an injury we take the scaffolding material and support the structure of the spinal cord itself. Then, once the spinal cord can maintain itself and does not get inflamed as much and begins to recover, the device is actually designed to dissolve and literally leaves your system through blood and urine. It is a different approach that, as an engineer, made sense to me. Providing structural support to the spinal cord after an injury sounded better than doing nothing. Right then we were doing nothing. If you could, with structural support, mitigate some inflammation and bleeding, it would make sense to then apply anti-inflammatory drugs and time release them through the devices and achieve a better therapeutic effect. That is exactly what we found. Our structural support

scaffolds provide a therapeutic effect, but if you could use biomaterials that time release anti-inflammatories you defeat the inflammation even better. It makes sense. What is interesting on top of that is if you added some stem cells you would think the device would have the best therapeutic effect and in our studies we absolutely see that. Therefore, along the continuum of product development, we have a scaffold without drugs and cells that can get through the FDA very quickly with enough structural support to provide therapeutic effect. As we advance our technologies into the injectables, we can then time release drugs and cells. We can provide more improvement to our patients.

We have two products at the FDA right now and are beginning discussions to get them through the FDA. We have another few that are in our pipeline that we expect to be ready next year. By the end of 2013 I would expect that we will have as many as five products under review at the FDA, all based on this continuum of trying to provide structural support in order to spare tissue in different parts of the body, and then, of course, using anti-inflammatories to improve that sparing of the tissue and allowing the patients to recover greater function. Then ultimately, we are working with our stem cell partners with the long-term plans that they have. They have long paths through the FDA, over a decade. Concurrently, we will be developing our products in-house. Why was regeneration number one? It was where the funding was coming from. NIH and government funding really does dominate how science is conducted throughout the world. Many times I have looked at how these funding mechanisms have evolved. I believe it was two years ago when eighty-one million dollars were spent by the US government on spinal cord injury research, but there was thirty nine billion (with a 'b') spent on care for spinal cord injury patients and only eighty one million spent on research. Therefore, there has been an imbalance and research dollars are all going to stem cells. However, we did win the Apple Award last year for spinal cord injury research. That was for our first four-monkey study and now we have over forty monkeys in our studies and we are seeing similar results in all the treated monkeys in just a few weeks.

CEOCFO: You mentioned your new facility and you have added a number of people to your team. What will the additions and new facility bring to the table for you?

Mr. Reynolds: Not just us, but really every spinal cord injury patient in the world should be really happy that we put together the team that is going to build the perfect technology for anyone that gets a spinal cord injury. We have scaffolds, drugs, cells and we believe that five to ten years down the road the perfect treatment would be some type of biomaterial that time releases drugs for a few weeks, then time releases cells for maybe up to nine months; we will have to see. We have all the patents already put in place for that product. That is the ultimate product. I mentioned the product continuum earlier; biomaterials alone, then biomaterials to release the anti-inflammatories and then biomaterials that support cells for regeneration. Along the way, we can get those first products to market. We will be starting patients early next year. That first product could be approved in 2014. It is a very fast pace through the FDA. We have a verbal agreement right now for orphan status and we are compiling the paperwork to get that orphan status confirmed. Moreover, we have a low threshold for approval for the FDA. Our new center will provide us with the ability to do that. It has been interesting to try and find a facility where all these spinal cord injury studies can be done. There are very few labs. Personally, I believe there are less than ten that can do a high quality spinal cord injury study. We knew that there was a real shortage of that skill out in the world and we built our lab to bring it here, to really give the patients a new chance, a new option. Actually, in all of our research we had to bring most of our own team into other facilities to do the research, using just their facilities. We have now brought their facilities into us and continued to use our own internal skill sets. The facility has a vivarium with an over four hundred rodent capacity. We already have over one hundred rats in the study and we just did the ribbon cutting last week. We will have over four hundred rats at a time in the study. Then we have a chemical lab for all of our hydrogels and scaffolding inventions and discoveries. We have a cell lab for all of our stem cell work and all the different types of cells that we work with. Of course, we have a biology lab and all of the team behind it. We have pharmacologists, stem cell people, chemical engineers; all the different disciplines of science to treat the spinal cord injury are under that one roof. I can tell you that, depending on the technology, it takes a good eight to fourteen fields of medicine and science to develop just one of these technologies. Therefore, it is important to have them all under one roof. Finally, I should mention that we have our clean room, which will be FDA approved. We are going to be doing all of our FDA manufacturing in-house. We can manufacture all of our scaffolds and all of our hydrogels in the one facility in our clean room; invent it there, make it there and send it right into the treatment center. Our patients get a very cost effective model and they get the first real research facility that we think can provide them with the best new options for spinal cord injury and different types of neurotrauma. It is a win-win for everyone.

"It turns out that about ninety percent of spinal cord injury patients that are arriving in the emergency room are not paralyzed for life. We have scaffolds, drugs, cells and we believe that five to ten years down the road the perfect treatment would be some type of biomaterial that time releases drugs for a few weeks, and then time releases cells for maybe up to nine months. That is the ultimate product."

- Frank Reynolds

CEOCFO: Has the medical community been paying attention?

Mr. Reynolds: Yes, definitely! We have received a lot of respect and we did start getting awards. There has been a range of awards over the years given to InVivo and a number of our different staff. Actually, one of our newer surgeons, Dr. Amir Khalil, just won a grant for some of the work that we are doing. We are excited. There have been rumors of global awards and we are excited that some of the work that we are doing is, we think, of course groundbreaking. I can tell you that with the group of scientists leading this study, there are no roadmaps to follow in these areas. When you are thinking at night, you are thinking things that no one has ever thought before. For example, we trained monkeys to run on treadmills, which is difficult to do. We got some quotes saying that to train just four monkeys would take up to a year, so we had to develop some new ways to train monkeys faster and now we are able to get monkeys trained in just a matter of a month. It took a lot of time out of the process, but it is just being innovatively creative. It is a very interesting process.

CEOCFO: Is InVivo Therapeutics Holdings funded to go through the next steps?

Mr. Reynolds: Absolutely, yes! We have funding right now and about two more years of cash. We have a very low burn rate. We are somewhere usually around eight hundred to nine hundred thousand dollars a month. I believe we last reported about eighteen million in cash, so we have plenty of cash. We can get through as many as three human studies. The FDA has told us that our first study is only going to be five patients. That study is going to cost fewer than one million dollars and like I said, we have eighteen million in cash left. As the CEO and CFO I am very proud of the way we have managed our money. We have spent about sixteen million dollars and our market cap is about seven or eight times that. We are very proud of the return we have given to our investors. We are well funded and well positioned to take multiple products to the FDA.

CEOCFO: Why should investors pay attention to InVivo Therapeutics Holdings?

Mr. Reynolds: We just ran through a retrenchment. We heard that there were some rumors out there but operations are on track and on time. The stock recently pulled back from $2.50 to around $1.50 and we think this is really screaming a buying opportunity. As I told you, we have taken probably about sixteen million dollars to over one hundred million dollars in market cap. We have returned it to our investors to date. We were probably at $1 just about a year and a half ago; we are sitting at $1.50 right now. Again, there has been a drop in recent months, but we know that we will continue on track in the next few months and really importantly, we have human studies that are going to be beginning. We will have very important clinical data coming out on multiple products that we are working on, including chronic pain products, and including an additional injectable hydrogel for spinal cord injury treatments. We know the coming months are going to be very important. We think our shareholders should be buying now. It is a huge buying opportunity.

InVivo Therapeutics Holdings Corp.
One Kendall Square
Building 1400 East, 4th Floor
Cambridge, MA 02139