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SpinalCyte chooses Fibroblasts over Stem Cells for Regenerative Medicine

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"When you look at medical device companies who are developing new products, you mostly find products which are enhanced from existing technologies. When you look at cell therapies, you will mostly find transformative technologies. SpinalCyte is a transformative technology with a broad cell platform which is emerging as a world leader in this space."- Pete O'Heeron

CEOCFO: ***Mr. O'Heeron, what is SpinalCyte, LLC?***
Mr. O'Heeron: SpinalCyte is a regenerative medicine company focused on the use of fibroblasts in regenerative medicine. We started in the spine space for degenerative disc disease. Our original patent was in that space and we have expanded our treatment platform to include other disease pathways. We filed our one hundred and fifty eighth patent last week. As we were discovering the benefits that we see in degenerative disc disease, we also found that fibroblasts are robust, potent and we think they are the future of regenerative medicine.

CEOCFO: ***What are fibroblasts?***
Mr. O'Heeron: Fibroblasts are regenerative cells, similar to stem cells. In the human body you have two cell types which can be used to regenerate tissue and organs. You can use stem cells or you can use fibroblasts. Most of the literature and articles you have read about or heard about over the last ten years, have focused on stem cells. Our focus is on fibroblasts and their broad regenerative characteristics.

We have worked on fibroblasts under the radar, and now we ready to show the world what we have developed with fibroblasts. The testing that we have done shows they are superior to stem cells, which puts us in a world leadership position for regenerative medicine using fibroblasts.

CEOCFO: ***Why do they work? How do they work?***
Mr. O'Heeron: My Chief Scientific Officer, Tom Ichim, Ph.D. can give you more technical terms, but in essence they have tremendous anti-inflammatory properties. Fibroblasts are the prototypic regenerative cell. They are involved in the major stages of wound healing. The main discovery we made is that not only can they produce new skin tissue,

but they produce growth factors that can help regeneration of a wide variety of tissues. Also, very interestingly, fibroblasts are capable of suppressing inflammation. The twin properties of stimulating regeneration while blocking inflammation, make them the ideal cell type for treatment of a variety of chronic diseases.

CEOCFO: ***You have programs for a number of different diseases, including MS, cancer, diabetes, pain and tissue regeneration. How do you work on so many programs at once or does the focus ebb and flow?***
Mr. O'Heeron: That is a great question. They are all in different stages of development. In degenerative disc we have FDA IND clearance and will be moving into humans in the U.S. soon, so that is the farthest along. Next up would be multiple sclerosis. We have done a lot of work in the lab where we have stopped degeneration of the myelin sheath and have actually stimulated regrowth of myelin producing cells in animal models using fibroblast-based therapies. We are working on putting together a clinical protocol to advance some research on that. All of those are in various stages of development. Some of our treatments are still early in the lab as we use fibroblasts to test regenerative capabilities for other therapeutic indications. As they ramp up, each one will take more time and resources, but right now we have degenerative disc disease and then right behind it would be multiple sclerosis and Parkinson's.

CEOCFO: ***Would you tell us about the Hong Kong patent regarding the HDFs and why do you need or want or have a Hong Kong patent?***
Mr. O'Heeron: We want worldwide protection on all of our patents. In the European Union you receive a patent which covers the entire European Union, but in some areas, you need individual coverage like India, Hong Kong and other parts of Asia. We try to make sure that we have coverage in areas we think are emerging markets so that we can protect them.

We certainly think Asia is an enormous market we want to be in long term. It is four times the size of the U.S., therefore, we want to protect it. We have patent protection in Mainland China, but also need it in Hong Kong, which has a separate intellectual property process from China. We have met with Chinese companies many times and the coverage is vitally important for us.

CEOCFO: ***What have you learned so far about what you are trying to do?***
Mr. O'Heeron: We have learned there are opportunities behind every clinical pathway. I have been doing research and development now for about twenty-eight years and I find that, usually, there are "nine closed doors for every one that opens", however, in regenerative medicine and in fibroblasts, it seems like every door we open is another possibility. We are excited about the potential and it feels like we are in a race to address these disease pathways as quickly as we can. We are intrigued about where fibroblasts can go. When we review all of the work we've done on them and the potency that we have seen with them, it is a

tremendous opportunity. Going forward, I think you will see some really exciting developments in the next three, four or five years.

CEOCFO: ***What has been the response from the medical community that is aware of the path you have taken?***
Mr. O'Heeron: The usual response is, "You are doing what!? You are using fibroblasts?" Sometimes we get meetings with people just because they did not know you could use fibroblasts for this. They will come to the meetings just to discuss the work we have done on fibroblasts. We did a revamping of our website a couple of months ago to address that. We want SpinalCyte to be the website you can go to if you do not know the full measure of fibroblasts' regenerative capabilities. You can read our four peer review papers, soon to be five, which are listed on the site. We also put anyone else's papers up there who are doing work with fibroblasts.

The Japanese are starting to do some exciting work in fibroblasts and reattachment of a severed spinal cord. This is an exciting area for anyone interested in fibroblasts. It is rewarding when you present to a room and they are eager to speak to you afterwards to learn more about fibroblasts. Most all of the clinical papers they have read, have really been about stem cells. Therefore, when we talk about fibroblasts, we talk to them about how easy they are to harvest, how they are found in much greater quantities and much less expensive than stem cells. They also appear to be more potent than stem cells. It is so new to them that their interest level is very high.

CEOCFO: ***Why has fibroblast been a stepchild for so long?***
Mr. O'Heeron: We like to say that fibroblasts are the B-side to the single. "We Will Rock You" was the B-side to "We Are The Champions". It's like sending out the main single and flipping it over and you say, "The real hit is on the B-side." That is how we joke around internally about the fibroblasts. They have actually been used as a control group in the past and have outperformed the therapeutic group. I do not have a good answer for why people have not explored fibroblasts. Maybe it is just an overabundance of people moving in the direction of stem cells. However, when we saw the regenerative capabilities of fibroblasts, we were hooked! We had to explore more and do more clinical work with them.

CEOCFO: ***Funding is most always an issue. Are you looking for investment, partnerships or funding of any kind?***
Mr. O'Heeron: Yes, we are. We are funded entirely by angels. We have a number of highly rated neurosurgeons across the country in the project. We also have other great angel investors in the project. We are looking for partnership opportunities and investment opportunities to continue this great work.

CEOCFO: ***Does the investment community understand?***
Mr. O'Heeron: I'm not sure if the investment community understands, because we have not gone down the path of the traditional institutional investment community or venture capital investing. We focus mainly on angels. A majority of the people in our project will be "end-users" of the product, which are neurosurgeons. I think we have been accepted so

well by the neurosurgeons because their existing product options and surgical approaches are not giving them or their patients the results they need. Therefore, I think there is a collective wisdom growing in the medical community that cell therapy will be the future of medicine. At times, there will still be a need for hardware, however, cell therapy will be what you will see going forward on most all disease pathways.

CEOCFO: ***What are the next steps?***
Mr. O'Heeron: The next step is to develop some partnerships, whether it be in the U.S. or overseas, to develop and further commercialize these product lines. We will be going into our IND trial for degenerative disc disease soon, so we are going to be excited to move down the commercialization path and we will continue to develop our other internal pipeline products?

CEOCFO: ***Do you see more interest from other countries than in the US or is there a particular region where you see more interest?***
Mr. O'Heeron: When you are from the U.S. and you present new clinical outcomes to other countries, they seem excited and interested to see what new developments are coming out of the U.S. Angel investors outside U.S. have been very excited and eager to participate in our new science. Institutional investors overseas also seem very interested in what we are doing. Anytime you have a new discovery about something that is a transformative technology, like we have, I think you get a lot of interest internationally.

CEOCFO: ***What is the interest in degenerative discs? Are people staying away from the surgery? Are people looking for alternative methods?***
Mr. O'Heeron: When you have degenerative disc disease, the chronic pain associated with that is a leading cause of opioid addiction in the country. Their addiction starts with chronic back pain. It is such a debilitating disease. In the human trials, we saw some of these people who had been largely immobile for decades, sitting on the couch and not being able to move and the condition continued to get worse. When we treated them with our fibroblasts, we had patients ask us if they could join a health club or gym. We have patients who were able to move around their house and began walking two miles a day.

Our studies showed when degenerative disc disease was treated with fibroblasts, it was a remarkable improvement. Degenerative disc disease is a chronic condition. I personally suffer from it and when you are in a pain cycle with your degenerative disc, you are looking for anything to stop the pain. It can be that debilitating! Therefore, I have sympathy for anybody who has degenerative disc disease. When the pain starts you just want it to stop!

CEOCFO: ***Why pay attention to SpinalCyte, LLC?***
Mr. O'Heeron: When you look at medical device companies who are developing new products, you mostly find products which are enhanced from existing technologies. When you look at cell therapies, you will mostly find transformative technologies. SpinalCyte is a transformative technology with a broad cell platform which is emerging as a world

leader in this space. Projects I have worked on in the past were improved over existing, functioning products and you can build value there. However, if you are looking for something that is transformative, a game changer, something that can take a second-tier spine company or pharmaceutical company from the second to the top tier, it is a company like SpinalCyte. SpinalCyte, is developing an entire cell platform that can be utilized across almost all disease pathways in the human body. Therefore, I would put SpinalCyte in a transformative category.