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Interviews & News!

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Stem Cell Therapeutics Is Building The Leading Product-Based Neurological Company

Healthcare
Biotechnology
(SSS: TSX-Venture)

Stem Cell Therapeutics Corp.

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Dr. Alan F. Moore
President and CEO

BIO: Dr. Alan Moore obtained a Ph.D. in pharmacology in 1974 from the University of Aston in Birmingham, England. He completed a postdoctoral fellowship at the Cleveland Clinic from 1974 to 1977. From 1977 to 1979 he was Assistant Professor of Pharmacology at the Institute for Cardiovascular Studies and Department of Pharmacology at the University of Houston. From 1979 to 1982 he was Unit Leader, Pharmacology and Senior Research Scientist at Norwich Eaton Pharmaceuticals. Following the acquisition of Norwich Eaton by Procter & Gamble, Dr. Moore held increasingly senior positions as Section Chief, Director of Research, and then Director of New Drug Development before assuming his most recent role there from 1998 to 2002 as General Manager, Cardiac R&D.

Prior to joining Stem Cell Therapeutics Corp., Dr. Moore was Executive VP, Clinical Development and Regulatory Affairs at Cardiome Pharma Corp. (TSX: COM) from 2002 through end of 2004, where he was responsible for all clinical and regulatory activities. Most recently, Dr. Moore was Chief Clinical and Regulatory Officer for Stem Cell Therapeutics, responsible for moving NTx™-265 from preclinical through phase I and into early phase II clinical studies, and exploring new therapeutic applications. He has 28 years of senior management experience in pharmaceutical research and development including 23 years with increasingly senior responsibilities at Procter & Gamble.

During his extensive working history, Dr. Moore has completed 12 investigational new drug (IND) applications or supplemental INDs, 16 Phase I studies, 12 Phase II studies, 9 Phase III studies and 2 New Drug Applications. One of Dr. Moore's completed Phase III studies enrolled 4,000 patients and included centers in 26 countries.

Company Profile:
Stem Cell Therapeutics Corp. is a Canadian public biotechnology company (TSX VENTURE: SSS) focused on the development and commercialization of drug-based therapies to treat central nervous system diseases. SCT is a leader in the development of therapies that utilize drugs to stimulate a patient's own resident stem cells. The company's programs aim to repair neurological function lost due to disease or injury. The company's extensive patent portfolio of owned and licensed intellectual property supports the potential expansion into future clinical programs in numerous neurological diseases.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Moore, what was your vision when you became CEO and how has that developed?
Dr. Moore: "My idea was to develop this company into the leading drug-based neurological company in the area of brain regeneration. If you lose brain function because of loss of tissue after a stroke or brain trauma, then our company takes the lead in developing a therapeutic regimen to amplify the natural repair process to replace the damaged tissue and restore lost function. Consequently that is the technical vision, we also have a commercial vision to put drugs on the market in that area, and then overall the vision would be to return shareholder equity and to make the company a more valuable commodity."

CEOCFO: Please tell us about your ideas and technology that enable you to do this.
Dr. Moore: "What we have is actually the smart scientist whose work founded the Company, a neurobiologist named Dr. Samuel Weiss from the University of Calgary as well as Director of the Hotchkiss Brain Institute. He is the person who developed this technology. He was study-

ing how adult stem cells grow into the parent (surrounding) tissue itself. We all have adult stem cells in the brain that, if stimulated, differentiate into brain tissue. These are different from fetal stem cells because when you stimulate fetal (or embryonic) stem cells they can grow into any tissue such as a big toe or a nose or into an entire fetus. In the case of adult stem cells, when you stimulate the cells they only grow into the tissue that they are surrounded by. An adult stem cell in the heart will grow into the heart tissue, it will not grow into brain tissue or the adult stem cell in the brain will grow into more brain tissue, it will not grow into a nose. Dr. Weiss has been working with these types of adult stem cells and studying the pharmacology of them. He has been studying what makes them divide, what makes them multiply and what makes them differentiate into the adult tissue they should become. In other words, what makes them go from a stem cell, a precursor cell, to the actual tissue itself such as a nerve or brain tissue. Dr. Weiss had been studying brain tissue in animal stroke models and applying two parts of the regimen to them. He applied the drug that he thought would cause the cells to divide and multiply and then drug that would make them differentiate and grow into new brain tissue. What he found was exactly what he hypothesized. Initially, when you looked at the animal model, there was a hole in the brain (dead tissue due to lack of blood flow) and when you looked ninety days later in the treated animals, the hole was no longer there. The bottom line from his findings was that he had an approach that worked in rats and when the regimen was given directly into the brain, it would make hole in the brain disappear, a very exciting concept."

CEOCFO: And your progress since that time?

Dr. Moore: "When I first joined the Company, we were at the animal data stage and the question really was how do we move forward from here. We had to determine which drugs to use in the clinic that would work the same as in the animal studies but could instead be given peripherally into an arm or a leg rather than directly into the brain. People do not like have drugs injected into their brain. What we did was look around at very similar drugs, also covered by our patents, which would cause this increase in the numbers of the adult stem cells and then made them divide and differentiate into new brain tissue. What we settled on were two drugs, both of which are marketed for other indications. The first drug, human Chorionic Gonadotropin (hCG), causes these adult stem cells to divide and the second drug, Erythropoietin (EPO), causes the newly divided cells to differentiate into the new brain tissue. The first thing we did was develop an animal model of stroke, followed the same regimen as before but gave the drugs peripherally instead of directly into the brain to determine if they crossed the blood brain barrier. The answer was yes, they do. The second question was whether is would work in people. We actually had a new neurologist, Dr. Steven Cramer from the University of California, Irvine, help us complete those rat studies. He said that one of the reasons unapproved drugs appear to fail, particularly in stroke, is because the trial protocol changes when graduating from animal models to human clinical trials. Dr. Cramer did not want the trial design to change from animal models to human trials so we used the same protocol for the human trials. The first drug that causes the cells to multiply, hCG, is given intramuscularly (IM) 24-48 hours after a stroke on days 1, 3, and 5 and on days 7, 8, and 9, the drug that causes the newly divided cells to differentiate into brain tissue, EPO, is given intravenously (IV). We reported interim Phase IIa clinical results in April of this year on five patients who had enrolled into the stroke study, NTx™-265. Four of whom we had data on (as there is a 90-day review period) and we announced that each one of those patients showed benefits according to our criteria, which was through scores of industry standard stroke tests. That was clinically significant."

"We recently completed our Phase IIa study. This is where we enrolled a small number of stroke victims to determine that this drug regimen was working and there were no serious side effects. Given that so many drugs developed for a stroke treatment have failed, except tPA, we needed a patient database to confirm we should be moving forward. We will be reporting the data from that Phase IIa trial formally at the end of February at the American Stroke Association's International Stroke Conference and we will be holding a symposium there as well. The next trial for the stroke treatment, the Phase IIb, will be a multi-site, double-blind, placebo-controlled, enrolling approximately 120 patients and this will be the definitive study of efficacy. We have filed a CTA (Clinical Trial Application) with Health Canada in order to initiate the Phase IIb trial. The CTA is the Canadian equivalent of the IND in the US. We received the NOL (No Objection Letter) from Health Canada in early December and that is the green light to begin enrolling patients in the Phase IIb study at the approved sites."

- Dr. Alan F. Moore

CEOCFO: Are there any major side effects that you found so far?

Dr. Moore: "No, interestingly enough we haven't. These drugs, hCG and EPO, are marketed for other purposes so they have a fairly well defined safety profile. Our regimen is an acute therapy so we are using only three doses of each drug. We are using them within the approved dosage guidelines so we do not expect to see many unknown side effects. In fact we haven't seen any to date."

CEOCFO: Will using the known drugs make it easier to get regulatory approval?

Dr. Moore: "I hope so but there is no guarantee on that. The argument supporting that is they have been in hundreds of

thousands of people so you pretty much know what the safety profile is. The argument against that is that they usually used for different indications. Human Chorionic Gonadotropin (hCG) is a profertility drug that is used in fertility clinics to make men and women more fertile. You can imagine not many of those people have had a stroke so this is kind of a new population for the use of that drug. Erythropoietin (EPO), the second drug, is approved to treat anemia for renal dialysis or cancer patients. Generally, that is an older population group more akin to the stroke population. In most conditions, both drugs are given chronically over weeks, months, or years. We are only using three doses per drug within in a span of 9 days. Hopefully the drugs known safety profiles will make it easier for regulatory approval but really there is no guarantee."

CEOCFO: How do you go forward?
Dr. Moore: "We recently completed our Phase IIa study. This is where we enrolled a small number of stroke victims to determine that this drug regimen was working and there were no serious side effects. Given that so many drugs developed for a stroke treatment have failed, except tPA, we needed a patient database to confirm we should be moving forward. We will be reporting the data from that Phase IIa trial formally at the end of February at the American Stroke Association's International Stroke Conference and we will be holding a symposium there as well. The next trial for the stroke treatment, the Phase IIb, will be a multisite, double-blind, placebo-controlled, enrolling approximately 120 patients and this will be the definitive study of efficacy. We have filed a CTA (Clinical Trial Application) with Health Canada in order to initiate the Phase IIb trial. The CTA is the Canadian equivalent of the IND in the US. We received the NOL (No Objection Letter) from Health Canada in early December and that is the green light to begin enrolling patients in the Phase IIb study at the approved sites."

CEOCFO: Did you recently raise some money?
Dr. Moore: "We have and that was deliberately to fund the Phase IIb stroke study. We raised gross proceeds of $12.075 million through a bought deal which was lead by Dundee Securities Corp."

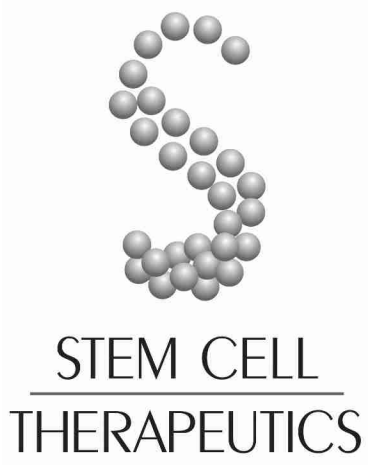
CEOCFO: You have recently added a couple new board members.
Dr. Moore: "Yes, we added two new board members. First was Mr. Scott Tannas, who is a local financial expert. He is the Founder, President & CEO of Western Financial Group Inc. Secondly, the person I am most excited about, was Dr. Francesco Bellini, who is the President & CEO of Neurochem Inc. in Montreal. He is a very good scientist and a very successful and savvy businessman. The last company that he developed, BioChem Pharma, he merged with Shire Pharmaceuticals Group, for $5.9 billion."

CEOCFO: What is the market and potential?
Dr. Moore: "It is at least a billion dollar market for stroke. We have two other indications that we are working on, traumatic brain injury (TBI) which is like having a stroke but it is caused by an external blow to the head such as in a car accident or a soldiers on the front line in Iraq. We are using the same therapy, the NTx™-265 regimen, and that should work equally as well in TBI because the first animal model we looked at was the model of traumatic brain injury. There are approximately 1 million new cases of TBI each year in the US and there currently is no drug treatment for TBI. We are also working in the area of Multiple Sclerosis, which is an unpredictable, often disabling disease of the central nervous system. The disease attacks the protective myelin covering of the central nervous system, causing inflammation and often destroying the myelin in patches. Dr. Samuel Weiss has recently been working in that area with a closely related drug to hCG, Prolactin. This drug stimulates the myelin sheath that surrounds the nerve endings to grow back again. Dr. Weiss' work is in early stages of animal studies now. No one knows exactly how many people have MS. It is estimated that there are currently about 250,000 to 350,000 people in the United States and 55,000-75,000 Canadians who have been diagnosed with multiple sclerosis. This estimate suggests that approximately 200 new cases are diagnosed each week. Interferon is one of the few drugs that is standard of care but that is to control inflammation where as our treatment would be to help 'cure' the patient and there is nothing else like it on the market."

CEOCFO: Does the company then have expertise on both the medical and business side?
Dr. Moore: "Yes, but I think the balance is more towards the technical. What I have been trying to do is add more on the board who have a strategic combination of business and technical particular to biotech. We have two CEOs on the board in addition to myself. One is Dr. Jim DeMesa, President & CEO of Migenix. He is an MD with a lot of business experience and he has been quite successful with that company. The latest one is Dr. Francesco Bellini, President & CEO of Neurochem Inc. who just joined us and he is a PhD and a chemist. He is a very smart businessman and a strategic thinker. I think that technical experts combined with the financial experts on the board are a good addition to the existing expertise on the management team."

CEOCFO: In closing, why should potential investors pick Stem Cell Therapeutics out of the crowd?
Dr. Moore: "There are a couple of reasons, we are working with marketed drugs and the advantages of that is if you look at drug development, drugs fail for two reasons, either they do not work or they are not safe. In this situation, really the only concern we have is that they might not work because the pharmaceutical companies that market these drugs have addressed the safety issue. You are not going to come across anything unexpected with these so that really takes away 50% of the risk, plus the initial data that we have in the human trials supports that the regimen is safe so I think there is an enormous risk reduction. I think the upside here is that we are working in an area where there is nothing else and a lot of new stroke drugs have already failed so you can look upon that as an area for concern but also an area of future opportunity. The bad news is everyone else has failed trying to approve new stroke therapies, but the good news is it is a wide open market place. The third point is that

as a Canadian company, we are very undervalued. The stock is in the thirty-cent range right now and I have been told by others in the industry that if we were physically in the US we could be a three-dollar stock right now. How true that is I do not know. The bottom line is that by its location and nature the company is undervalued, so the potential for upside is huge."



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