CEO CFO

RCLL RegenoCELL

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Using their Adult Blood Stem Cell Therapy, RegenoCELL Therapeutics, Inc. is Giving Hope to No-Option Congestive Heart Failure Patients

Healthcare
Biological Products
(RCLL-OTCBB)

RegenoCELL Therapeutics, Inc.

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James F. Mongiardo
Chairman, President, CEO, CFO and Director

BIO:
Mr. Mongiardo has extensive experience in building companies and in the investment banking business. He has served as Chief Executive Officer for public biotechnology and healthcare services companies and as head of United States Marketing for Schering-Plough Corporation. He has raised capital for clients through institutional private placements, directed business start-ups from concept to marketing, completed a successful turnaround, designed operative business plans, raised venture and public equity financing, created marketing and promotional plans for new products, directed acquisitions and divestitures, developed and administered sales budgets over $ 300 million and managed corporate and legal services.

Among the companies Mr. Mongiardo has headed are Epigen, Inc., an oncology company which he brought public and raised additional capital through PIPE's (private investment in a public company). Epigen is developing treatments and diagnostic tests for the early detection of carcinomas. He served as Chief Executive Officer of Medivix, Inc., a public health care services company for which he completed a secondary offering and raised capital through a debt placement. Medivix provided mail order prescription services for employers and unions. In addition, Mr. Mongiardo served as Chief Executive Officer of CardioBioMedical Corporation, a medical device company which non-invasively determines whether a patient has coronary artery disease. He raised capital and obtained 510 (k) clearance from the Food and Drug Administration (FDA) to market this device. Mr. Mongiardo also served as President and Chief Operating Officer of Photec Diagnostics, a venture capital financed diagnostic company. Mr. Mongiardo completed additional rounds of financing for Photec and within 18 months from concept received 510(k) clearance from the FDA to market the company's first product.

Mr. Mongiardo also served as Chief Operating Officer of Total ReCord, Inc., a regenerative medicine tissue engineering company with a product to treat spinal cord injury. He completed a six million dollar financial restructuring of the company and finalized an agreement to raise capital on the AIM market with a major AIM Nomad/broker. He also served as Vice President of Corporate Development for Organogenesis where he completed a $ 4.5 million PIPE and obtained favorable tax free status for building a new corporate facility in Massachusetts. While head of United States marketing for the pharmaceutical division of Schering-Plough, he introduced 12 new over-the-counter and prescription products.

For five years, he served as Managing Director of LBC Capital Corporation and in 2000 formed the Homewood Capital Group, LLC, an investment advisory firm specializing in institutional private placements for emerging companies. Mr. Mongiardo is a graduate of Johns Hopkins University (B.A.), Harvard Law School (J.D.) and the Columbia University Executive Program in Business Administration.

Company Profile:
The mission of RegenoCELL Therapeutics, Inc. (OTC BB: RCLL) is to bring stem cell therapy treatments to the market as quickly as possible. Stem cells have the ability to produce other cells identical to themselves or to differentiate into specific cell lineages which can be used in the regeneration and repair of damaged tissue. RCLL is utilizing adult stem cells, those derived from the patient's own blood, which eliminates the ethical and safety concerns associated with embryonic and umbilical cord blood stem cells.

RCLL's therapy utilizes a process to identify adult stem cells found in a patient's blood. In circulating blood, the numbers of adult stem cells present are less than 1% of 1% of all the cells found in the blood. At the Company's manufacturing operations in Israel, sufficient stem cells are segregated from less than a half liter of blood drawn from the patient and then rapidly grown from tens of thousands into many millions over a five day period. This occurs in a standard class 10,000 clean room with the handling of the cells under a class 100 hood.

The adult stem cells and other mature cells extracted from the circulating blood have been selected because of their ability to differentiate into angiogenic precursor cells, or blood vessel forming cells. When these angiogenic precursor cells are administered to the patient, they are primed to form new blood vessels.

Currently congestive heart failure pa-

tients cleared for treatment have less than one-half liter of blood drawn which is sent to the Company's cell processing facility in Israel. After the adult stem cells in the patient's blood have been extracted and grown into large numbers of angiogenic precursor cells, they are sent to Thailand, the Dominican Republic, Greece and other locations where importation of the autologous stem cell therapy product is permitted for infusion into the patient in a minimally invasive procedure. The stem cell therapy product is either delivered through a catheter or injected directly into the myocardium. All patients are private pay.

RCLL's primary asset is Regenocell Laboratories, Ltd., a wholly owned Israeli corporation, which is manufacturing the stem cell therapy product used to treat congestive heart failure and peripheral artery disease. Marketing of the stem cell therapy product either directly or through distributors is done by Regenocell, Ltd., a wholly owned Antigua and Barbuda corporation.

RCLL's plan to further build its business is to submit an IND to the Food and Drug Administration and its equivalent to the European Medicines Agency to initiate clinical trials in order to apply and obtain approval for the treatment of peripheral artery disease in the United States and Europe. There are over ten million people suffering from the lack of sufficient blood flow to the extremities in the United States and an equal number in Europe. This disease is most often experienced by diabetics in their toes and lower legs. Pilot studies have demonstrated that there is new blood vessel formation which saves the patient from what would progress to amputation.

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

CEOCFO: Mr. Mongiardo, you have a long and varied business history in the industry, what is special about RegenoCELL to you personally?

Mr. Mongiardo: I have been involved with start up life and sciences companies since 1984 and have led companies in a variety of disciplines, several in tissue engineering. When I came across this opportunity with the technology that RegenoCELL Therapeutics has, I was convinced that this was a company that had really great upside potential and something I wanted to get involved with.

CEOCFO: Would you explain RegenoCELL's technology?

Mr. Mongiardo: What we are doing today is treating patients who are no-option congestive heart failure patients. These are patients who have run out of treatment options and basically have three to six months to live if they cannot get a heart transplant. There is a very low probability of a heart transplant. The patient decides to get our therapy. We extract from them less than a half liter of blood, which is like a Red Cross donation. The blood is then transported to our cell processing facility, which is in Israel, and there we extract the patient's stem cells as well as some other mature cells found in the patient's blood. Over the course of the next five days we grow this mixture from tens of thousands into many, many millions, and that net result is a mixture of stem cells, which believes that their function in the body is angiogenesis or blood vessel formation. The patient then goes to a jurisdiction where autologous therapy is permitted. Autologous therapy is a therapy that involves taking cells out of a patient, multiplying them outside the patient, but then putting them back into the same patient so you are not concerned about any kind of immunological response. The patient goes to a jurisdiction where autologous therapy is permitted and goes to a hospital that has a catherization laboratory. A cath lab is where they do angioplasty, because you deliver this therapy very similar to how you remove a blockage in the arteries. You start with a catheter in the femoral artery in the leg and instead of the catheter going to the blockage and getting rid of it, it goes to the left ventricle of the heart and the stem cells are released. Patients then recover like they normally would from angioplasty and after a couple days fly back to their homes. What we have found in treating over 500 patients since 2005 is that patients start feeling better almost immediately, but the full benefits of this therapy occurs over the first three months after receipt. These patients go from being totally debilitated to leading a much more normal life for their particular age. In addition while almost all these patients had a very short life expectancy of three to six months before they got the treatment, after the treatment over 90% are still alive two years later. Just about everyone who got the original treatment in the first rounds of treatment in 2005 are still alive today.

This whole area of regenerative medicine and being able to use cells to rebuild what has gone wrong in a patient, is going to experience explosive growth. We are in the stem cell area where everyone understands that there are significant possibilities and fortunately we are in the adult stem cell area so there are no ethical issues that anyone has to be concerned with. Finally, what we have done is show that our product works so that there is less of a chance when we go into clinical trials that we will have a surprise. Very importantly, while we are going through that lengthy regulatory process we are at the same time generating revenues to help support the company. - James F. Mongiardo

CEOCFO: Is it something that you add or do to the cells once you extract them that allow them to work when you put them back in the patient?

Mr. Mongiardo: There are a couple parts to this. The first part is we are taking normal circulating blood out of the patient to extract the stem cells the bone marrow is producing. The issue with congestive heart failure is that you do not have enough normal circulating stem cells to do the repair necessary. It is very difficult to extract stem cells from normal circulating

blood, because less than 1% of 1% of the cells found in your normal circulating blood are stem cells. Most extraction technologies have to boost the immune system to increase the number of stem cells and that causes complications. We do not do that. The other part is we are extracting the stem cells and there are different categories of stem cells, so we are extracting the different categories, but also some mature cells also found in that patient's blood. We are growing this mixture and have set our product release specifications to get the kind of benefits we want.

CEOCFO: Is there an FDA process and clinical trials that RegenoCELL will have to go through to use your therapy in the U.S.?
Mr. Mongiardo: What you have to understand is that the United States treats stem cells differently depending upon their use. If you are going to use stem cells for the treatment of cancer, the FDA does not regulate it. However, if you are going to use stem cells for any other kind of use, such as we are doing for congestive heart failure or peripheral artery disease, then the FDA does regulate it. Therefore, we plan to file an IND with the FDA and its equivalent in Europe the EMEA, in order to get the product approved in the United States and in Europe. We understand that it is a lengthy process, so at the minimum we are talking about is five years before we would get approval to market the product in the United States and/or Europe.

CEOCFO: How onboard is the medical community?
Mr. Mongiardo: We have to educate the medical community. What we find is that there is a great deal of skepticism, but as soon as a patient gets the treatment and their physician sees the results, they are convinced. The plan is for us to begin these clinical trials and in the course of conducting the clinical trials generate the kind of scientific literature that physicians in the United States are used to reading. We believe that once they start reading that literature, we will convince them that this is a very safe and effective treatment for congestive heart failure and peripheral artery disease.

CEOCFO: How does RegenoCELL recruit potential patients?
Mr. Mongiardo: We have been marketing our product through a wholly owned foreign subsidiary Regenocell Ltd. We have been using distributors who obtain patients either through the internet or through medical seminars that the distributor conducts. Usually, attending these medical seminars are patients who have received the treatment which permits the person thinking about the treatment to talk to someone who has already had the treatment.

CEOCFO: How costly is the RegenoCELL therapy?
Mr. Mongiardo: Our distributors are charging $54 thousand for this treatment.

CEOCFO: How involved are you with the labs that are actually doing it at the other end; are they working with you?
Mr. Mongiardo: We control the whole process. The patient is first found and approved by the distributor, but we have final approval to insure that the patient meets the qualifications set forth in our protocol which has inclusion and exclusion criteria. The blood draw taken from the patient is sent to our cell processing facility in Israel. Again, this is a wholly owned foreign subsidiary Regenocell Laboratories Ltd. There we control the technology and we manufacture the product under good manufacturing practices standards, so there is a protocol followed to manufacture and release the product. You go through standard quality control testing, which is done throughout the entire process and there are final release specifications which must be met. We are doing this like any biological product that is approved and sold in the United States. The only difference is that we are doing it outside of the United States through our foreign subsidiaries.

CEOCFO: What is the financial picture like for RegenoCELL Therapeutics today?
Mr. Mongiardo: The premise of RegenoCELL Therapeutics is that we are going to access the public markets as an OTC Bulletin Board company and use the public markets to raise capital. Unfortunately, we began this whole operation in July of 2008, just before the greatest economic recession since the great depression. Therefore, we were delayed for a long time in trading and by the time we were ready to trade, new rules had come into effect and we had to comply with those new rules. It really was not until July of this year that we became a very actively traded company, and now we are in the process of raising funds. We believe that there will be a lot of interest in the market for our business plan because we are a life sciences company in this very interesting area of stem cells and stem cell treatments. What is different about us is that not only are we going to take our product through the regulatory process, but also at the same time we are earning revenues through our treating of patients in jurisdictions where autologous therapy is permitted.

CEOCFO: Do you find that the interest in personalized medicine is helping RegenoCELL?
Mr. Mongiardo: This is the ultimate in personalized medicine, because we are taking cells from a person and multiplying them and putting them back into the same person. We have taken this to the far end of where personalized medicine is going.

CEOCFO: How do you get past any kind of skepticism?
Mr. Mongiardo: There are unfortunately many companies claiming things with stem cells and offering treatments for which there really is no basis for what they are doing. We have a record of accomplishment over six years now for successfully treating patients with congestive heart failure and peripheral artery disease and we know that with over five hundred patients treated there has never been a serious adverse effect and that our product is efficacious. If someone is skeptical then we will put them in touch with someone who has received the treatment so they can learn first hand about the benefits. In the final analysis, if someone who has already received it, can say what their experience has been, that is important to someone who is concerned as

to whether the product will be a benefit to them.

CEOCFO: Are most of RegenoCELL's patients from the United States?
Mr. Mongiardo: Yes, most of our patients are from the United States. There are patients from overseas but the vast majority, are from the United States.

CEOCFO: Why should potential investors choose RegenoCELL?
Mr. Mongiardo: When you are looking at a start-up life sciences company, you are looking for an area that will hopefully have explosive growth, and this whole area of regenerative medicine and being able to use cells to rebuild what has gone wrong in a patient, is going to experience explosive growth. We are in the stem cell area where everyone understands that there are significant possibilities and fortunately we are in the adult stem cell area so there are no ethical issues that anyone has to be concerned with. Finally, what we have done is show that our product works so that there is less of a chance when we go into clinical trials that we will have a surprise. Very importantly, while we are going through that lengthy regulatory process we are at the same time generating revenues to help support the company.

CEOCFO: Final thoughts, what should people remember most about RegenoCELL Therapeutics?
Mr. Mongiardo: It is rewarding to me to be CEO of this business because every week I know that we are saving someone's life. That has been a great motivational tool to keep working with this company and building it. We believe that anyone who gets involved with us or decides that they have interest in investing will be equally rewarded because we are saving peoples lives. At the same time, we have a business model that can generate a great deal of revenues and income and therefore a very successful company.

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