

EmCyte Corporation is leading the way in Regenerative Medicine developing products for autologous Platelet Rich Plasma, Bone Marrow Concentrate and Adipose Concentrate Biologics Therapies



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CEOCFO: Mr. Pennie, what is the idea behind EmCyte[®] Corporation today?

Mr. Pennie: The idea behind EmCyte Corporation is primarily to first be a leader in regenerative medicine. In regenerative medicine we are referring to therapies involving autologous Platelet Rich Plasma, Bone Marrow Concentrate and Adipose Concentrate biologics. Our aim is to create extraordinary products that lead to autologous therapies that positively impacts patient outcomes. This has led us to produce a family of biologics that are both clean and powerful. These are our PurePRP[®] Supraphysiologic Platelet Concentrating System, PureBMC[®] Supraphysiologic Bone Marrow Concentrating System, Progenikine[®] Adipose Concentrating System and ASPIRE Bone Marrow Harvesting System.

CEOCFO: When you say “clean format”, what do you mean?

Mr. Pennie: When I say “clean format” I mean autologous biologics that are devoid of the components that potentially cause pain, inflammation or discomfort, while significantly boosting its healing properties. For example, Platelet Rich Plasma’s powerful healing capability comes from a concentrated platelet population along with other cell mediators, however, typical platelet rich plasma also has a significant concentration of red blood cells which may lead to pain, or discomfort after application. The same is true for bone marrow and adipose concentrate products, as they have different forms of untoward ingredients.

The intellectual innovation of EmCyte devices allows us to isolate and collect the most powerful healing components of the biologic while leaving the unwanted components behind. Our PurePRP[®] Supraphysiologic system prepares platelet rich plasma without painful red blood cells or inflammatory granulocytes. Our PureBMC[®] Supraphysiologic prepares bone marrow concentrate without tissue destroying oxidative free hemoglobin. Our Progenikine[®] system prepares concentrated adipose without inflammatory lipid oil contaminants, and our ASPIRE bone marrow needle system collects bone marrow aspirate without the typical hemolysis or activation levels found in other needle systems. The ability to remove these components while preserving just about all of the growth factor and progenitor stem cell content in a treatment sample is an amazing accomplishment in product development and has led to the success of this company.

CEOCFO: How are you able to do that?

Mr. Pennie: We’ve devoted years of research and product development to accomplish this goal. From a clinical perspective I was fully aware of the impact this type of biologic would have on patients needing this therapy. I’ve been able to meet this goal with a proprietary product design which is embodied in our family of products. These products work

synergistically with a very specific centrifugation process and ultimately produces a powerful yet clean autologous biologic that's unlike any other. Patients' responses are phenomenal, which is a credit to our hard work.

CEOCFO: Does the industry or do potential customers recognize that there can be a better way and look to you for that or do people not yet realize it can be done in a cleaner and more effective way?

Mr. Pennie: That is the key. Most physicians are diligent and conscientious enough properly research and find products that deliver biologics that meet the clinical threshold, however there are some practitioners that are not fully aware of the importance of a good product review before considering it for use. We are educating physicians and the general public to have a better understanding of autologous biologics and realize that there are differences in PRP and bone marrow stem cell formulations. There are some PRP and bone marrow stem cell formulations that have absolutely no active ingredients. These systems tend to be cheaper and have no dedicated proprietary technology built into them. When the general public researches a PRP or bone marrow stem cell physician or clinic, they rarely encounter a physician discussing the quality of their PRP or bone marrow stem cell biologic. This should absolutely be a point of discussion during a patient's visit with their doctor. The physician should disclose the type of PRP or bone marrow stem cell biologic they are using and provide an independent review of its quality as it relates to the clinical threshold. This would provide the comfort of knowing they are getting a clinical dose of PRP or bone marrow stem cells. The accepted threshold for a powerful PRP biologic would be 5 times or greater platelet concentration and/or 80% or greater platelet yields in the final treatment sample. A powerful PRP biologic would have at least 1 billion platelets per milliliter. The more the better.

“EmCyte is important because we’re leading in product and treatment innovation and clinical education. We’re laser focused on patient outcomes and are looking to ways to continually improve in a safe and effective way. Our biologics are the most powerful point of care systems when independently compared to other leading brands in the market. Our products are also the best tolerated by the patient because our technology allows us to remove the deleterious components of the biologic while preserving clinical concentrations of the live active ingredients. Best of all, our products are made in the USA, in Fort Myers Florida, from raw materials to final packaging.”- Patrick Pennie

CEOCFO: Would you tell us about the launching of your Gulf Coast Biologics training center and how that will help educate?

Mr. Pennie: We're very excited about the Gulf Coast Biologics training center. Construction begins this summer with completion expected in the first quarter of 2020. The training center will educate physicians and the general public as well on the advances in regenerative medicine technologies and deliver evidence based clinical information to help define and direct the delivery of regenerative therapies. The goal is to build awareness and improve patient outcomes. Gulf Coast Biologics, will have between six and twelve training courses annually. We'll have the best minds in regenerative medicine to share their knowledge, expertise and experiences. We discuss the many potential uses and benefits of autologous biologics as well as the pitfalls and risky conducts to be aware of. The facility will be a beautiful, modern, state of the art facility with chandeliers, recessed lighting, glass entryways and large treatment demonstration rooms. We expect our attendees to have a substantive educational experience and leave enlightened in the field of regenerative medicine.

CEOCFO: How did you decide this was a good strategy for the company?

Mr. Pennie: Being an outcomes driven clinician, I knew this therapy would someday become a standard of care. It was my plan to get out in front of this and help direct the industry in a manner that would deliver results for the patient. My focus was always patient first. Our strategy was to develop products that would profoundly impact patient outcomes. We wanted to heal patients in an undeniable way. With this being the focus, everything done by EmCyte revolved around this centered concept. We are not profit driven, but our passion to impact patients has made us profitable. We spend less money on marketing and more on research, clinical trials and product development. We'll continue to engage the medical community and maintain great relationships with our physicians, medical practitioners and patients.

CEOCFO: Would you tell us about the recent FDA clearance?

Mr. Pennie: We have received our 4th 510k clearance from the FDA for our PureBMC® SupraPhysiologic bone marrow concentrating system. We are excited about this clearance because it allows us to continue to service our physicians and patients with advanced innovative technology. This device is a step up from its predecessor in that it significantly simplifies the preparation technique of the pure bone marrow concentrate biologic while improving the performance outcome. We will continue to work with the FDA for additional clearances of new technology and clinical trials.

CEOCFO: Are there products from EmCyte that do not get the attention you think they deserve?

Mr. Pennie: Biologics are hot and EmCyte is well known. We've had experiences where clients aggressively request products that we have in the development phase. I cannot say that our products are not getting the attention they deserve. We've worked hard to be a credible and trustworthy company. We have a robust manufacturing facility with a diligent quality department to ensure that we are delivering a quality product to our end users. This has led to a solid reputation and a coveted product line.

CEOCFO: Do you do clinical trials as well?

Mr. Pennie: Our clinical trials are done throughout the US and we have done a few internationally. We work with various institutes and various research physicians on many clinical projects. Our research projects involve treatment indications in various fields of use to include orthopedics, sports medicine, pain management, hair restoration, dermal rejuvenation and many others. Physicians conduct these research clinical trials with the full support of EmCyte Corporation as we continue to explore the vast uses and application of autologous regenerative biologics. The clinical trials have clinical protocols that are generally approved by an internal review board and the studies are managed by a principle investigator.

CEOCFO: With so much opportunity, how do you decide where to focus?

Mr. Pennie: We focus on the patient. This therapy has started with changing the lives of people who otherwise had no real option of improving their lives. We remain engaged with people that have conditions that can benefit from our products and therapies. With this in mind, we work to develop products and procedures that patients can truly respond to. We are a point of care autologous biologics company, which mean biologics derived from your blood, bone marrow or adipose tissue collected and processed at the point of care. We do not provide biologics that come from placenta, umbilical cord, or other sources derived from another person or animal. We are not convinced in the safety or efficacy of these products, with the understanding that the risk of cross contamination still exists along with other concerns raised by the FDA.

CEOCFO: How is business?

Mr. Pennie: Business is great! Again, we have been doing this for a long time. It has been very rewarding for me. We have been able to make a mark in the industry. We sell products throughout the US, Europe, South America, Canada and Asia. This would not happen if patients were not responding in a very positive way. We're proud of what we have accomplished so far and expect even greater accomplishments in the future.

CEOCFO: Why should people pay attention to EmCyte Corporation? Why is EmCyte so important?

Mr. Pennie: I think EmCyte is important because we're leading in product and treatment innovation and clinical education. We're laser focused on patient outcomes and are looking to ways to continually improve in a safe and effective way. Our biologics are the most powerful point of care systems when independently compared to other leading brands in the market. Our products are also the best tolerated by the patient because our technology allows us to remove the deleterious components of the biologic while preserving clinical concentrations of the live active ingredients. Best of all, our products are made in the USA, in Fort Myers Florida, from raw materials to final packaging. We're proud to be a major contributor in this industry for over 20 years and we're happy to continue to lead in a manner that benefits the patient first.

