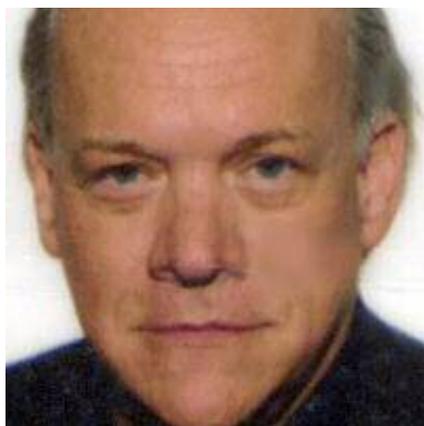


Q&A with Mark S. Miller, Co-founder, Chairman and CEO of BirchBioMed Inc. developing an Antifibrotic Therapeutic for the Prevention of Scarring and Breaking Down Existing Scars and an Autoimmune Platform for reversing Type I Diabetes



Mark S. Miller
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CEOCFO: *Mr. Miller, would you tell us the concept behind BirchBioMed?*

Mr. Miller: A startup / spin-off of the University of British Columbia, BirchBioMed holds the exclusive license to antifibrotic and autoimmune platforms that use scarring as their proof-of-concept. The first prevents the formation of scars and breaks down existing scars, and it does so on the molecular level, and there is nothing out there that does that, despite the many anti-scarring ointments and other products that do little more than moisturize. As for our autoimmune platform, we are reversing Type I diabetes and alopecia in Gold Standard animal models.

CEOCFO: *What is the connection between scarring and Type I diabetes?*

Mr. Miller: While our antifibrotic therapeutic, FS2, works at the molecular level to stop the formation of scars, it also has been effective, when administered in combination with cell therapy, in reversing certain autoimmune diseases, as previously mentioned. In effect, when we inject allogeneic cells in combination with FS2 into a subject in the throes of an autoimmune reaction, the subject's autoimmune system essentially redirects its focus. In the case of Type I diabetes, the autoimmune system is attacking the subject's pancreas and – ultimately – the pancreas' ability to produce insulin. While the autoimmune system erroneously reacts to the body's pancreas as foreign, it ultimately reacts to the allogeneic cells as even more foreign. It begins to attack the alien cells and encounters our therapeutic, FS2, which was co-administered with the alien cells, and essentially resets itself.

CEOCFO: *Would you explain the relation between autoimmune disease and scarring?*

Mr. Miller: Initially, Dr. Aziz Ghahary, cofounder of our therapeutics and a member of our Science Advisory Board, and his team – including Dr. Ryan Hartwell, also a co-founder and BirchBioMed's Chief Science Officer – were looking for a therapy with immunosuppressant qualities (with the intent of preventing transplant rejection). They started by investigating characteristics of pregnancy, because a fetus is both similar to an organ transplant and heals without scars. As they got into it further they discovered efficacious antifibrotic agents, one of which is FS2.

The team then extrapolated that FS2, already in high concentrations in amniotic fluid, might also play a role in keeping the body's autoimmune system from attacking the fetus. Since the fetus is composed of both the mother's DNA and the father's DNA, it seemed logical that the mother's immune system would see the fetus as foreign (causing miscarriage). So why wasn't it?

Dr. Reza Jalili, another team member and subsequent member of BirchBioMed's Science Advisory Board, postulated that FS2's immune-modulating qualities might be at work in preventing fetus rejection. So, the team then tested FS2 in combination with cell therapy in order to mimic pregnancy and proved that it reversed Type I diabetes and led to regeneration of the pancreases in Gold Standard animal models (mice bred to have Type I diabetes). At the same time, it also reversed alopecia (disfiguring hair loss) in mice bred to have alopecia. Simply put, the bald mice all regrew their fur.

CEO CFO: *What have you learned in the trials so far?*

Mr. Miller: We completed Phase I trials, which test tolerability and safety. The results, published recently in The Journal of Pharmaceutical Sciences (<https://www.sciencedirect.com/science/article/pii/S0022354918300662>) showed that FS2 is safe and tolerable at therapeutic dosages. Since then, we have been approved for Phase II trials in Canada and are also starting a Phase II trial in the U.S., testing the efficacy of our topical FS2 on humans. At the same time, we are poised to begin a Phase I/IIA trial of AI001, our autoimmune therapeutic.

CEO CFO: *What has been the reaction of the people in the medical community?*

Mr. Miller: Our team recently returned from a number of conferences, including the South Beach Symposium on Clinical and Aesthetic Dermatology and the American Academy of Dermatology's (AAD) annual meeting in San Diego, where we were very positively received. At the South Beach Symposium, we held an advisory board with some of the top names in dermatology, who expressed significant encouragement and interest in our research and development.

Coinciding with the AAD convention in San Diego in February, we announced a collaboration with Sensus Healthcare, Inc. (NASDAQ: SRTS), a leader in the use of Superficial Radiation Therapy (SRT) to treat keloid scars. Keloids are often horribly disfiguring scars, which are almost tumor-like in appearance. Doctors generally treat keloids by surgically excising them. The problem is that in many cases, keloids grow back to an even greater extent. Through our collaboration with Sensus Healthcare, we believe BirchBioMed's anti-scarring therapeutic, FS2, in combination with Sensus Healthcare's SRT, will essentially prevent the return of keloids and other scars.

"What we want to ensure is that ours will be a successful product – the first of many innovations that will not be defined solely by a regulatory path, or by the need for therapeutic indication. That first innovative product will be one with minimal barriers in demonstrating efficacy in a patient population."- Mark S. Miller

CEO CFO: *Are you funded for your next steps?*

Mr. Miller: We are in the process of completing funding for our trials.

CEO CFO: *You have been involved in many ventures. What have you learned on what to do as you are developing a product and eventually going to market, and maybe what not to do as well?*

Mr. Miller: People view startups as either a labor of love or an exercise in masochism. So, if you aren't made for startups, my advice is to get out early. BirchBioMed, however, is made up of people who understand the challenges that startups face and welcome those challenges. For a company with disruptive platforms such as ours, the process is particularly motivating, because the therapeutics hold the promise of truly making a world-changing difference. That said, funding is always a challenge.

BirchBioMed began with the advantage of therapeutics bearing the imprimatur of the University of British Columbia and benefitting from more than \$6 million in government grants and private donations for preclinical development and Phase I trials. Since then, we have raised approximately \$3 million in investment that has allowed us to begin Phase II trials. We also have focused on a new approach that we think could change the way startups can combat what has been a risk-averse and prohibitively costly road to development.

The key for us is collaboration -- and we have been doing that from the start. Beginning with our collaboration with the University of British Columbia, we took well-funded and established research from the University and coupled it with the experts and talent necessary to take these discoveries to the next level. Our collaborative model has been to work with established leaders in healthcare who have proven track records in innovative commercialization. Collaboration enables us to decide where best to focus our efforts and resources. That means early collaboration and choosing the right partners who can help us focus on the most promising aspects of our R&D that lend themselves to successful commercialization.

CEOCFO: *Do I see another venture coming out of this for you?*

Mr. Miller: We are a tech-transfer company, so we have a number of other projects coming and in development. Deploying our antifibrogenic products in collaboration with Sensus Healthcare, as well through a more recent collaboration with Neutraderm, a Los Angeles-based pioneer in medical grade skincare products, is the first of many clinical options in our pipeline. These are tested companies that recognize our value, and that enables us to hone in on our strengths and move to market faster. After all, there are many different routes we can take and many different applications on which we can focus – whether it's topical, 510Ks, ethical drug, or medical device, to name a few. What we want to ensure is that ours will be a successful product – the first of many innovations that will not be defined solely by a regulatory path, or by the need for therapeutic indication. That first innovative product will be one with minimal barriers in demonstrating efficacy in a patient population.

