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RepliCel -- Treating Functional Cellular Deficits. An Interview with CEO, David Hall

Despite us both living in the Vancouver area and both being involved in cell therapy, I didn't meet David Hall until we were both in La Jolla late last year for the Alliance for Regenerative Medicine's Stem Cell on the Mesa meeting. Since then we've been keeping in close contact and I have had opportunity to learn a lot more about him, his team, RepliCel, and the company's technology.

The company is by all appearances a company on the tail end of a number of significant transitions in terms of its structure, finance, clinical pipeline, and even the breadth of its underlying technology. The company is now unveiling RepliCel 2.0 (my term, not theirs) which builds on the company's core expertise and platform technology but combines newly added assets and clinical strategies that create end-to-end solutions and multiple pillars around which shareholder value is being created.

David presents a sound logic for the transitions through which he has taken the company in the past 18 months and the pace of that change. He does, perhaps more than many CEO's I have had the opportunity to interview, present a strong and focused vision for the company with a clear goal and a well-defined pathway for how he intends to get the company there. From my vantage point, this vision permeates into most aspects of the company from clinical trial design, to patent strategy, to defining collaborations, and even recruiting.

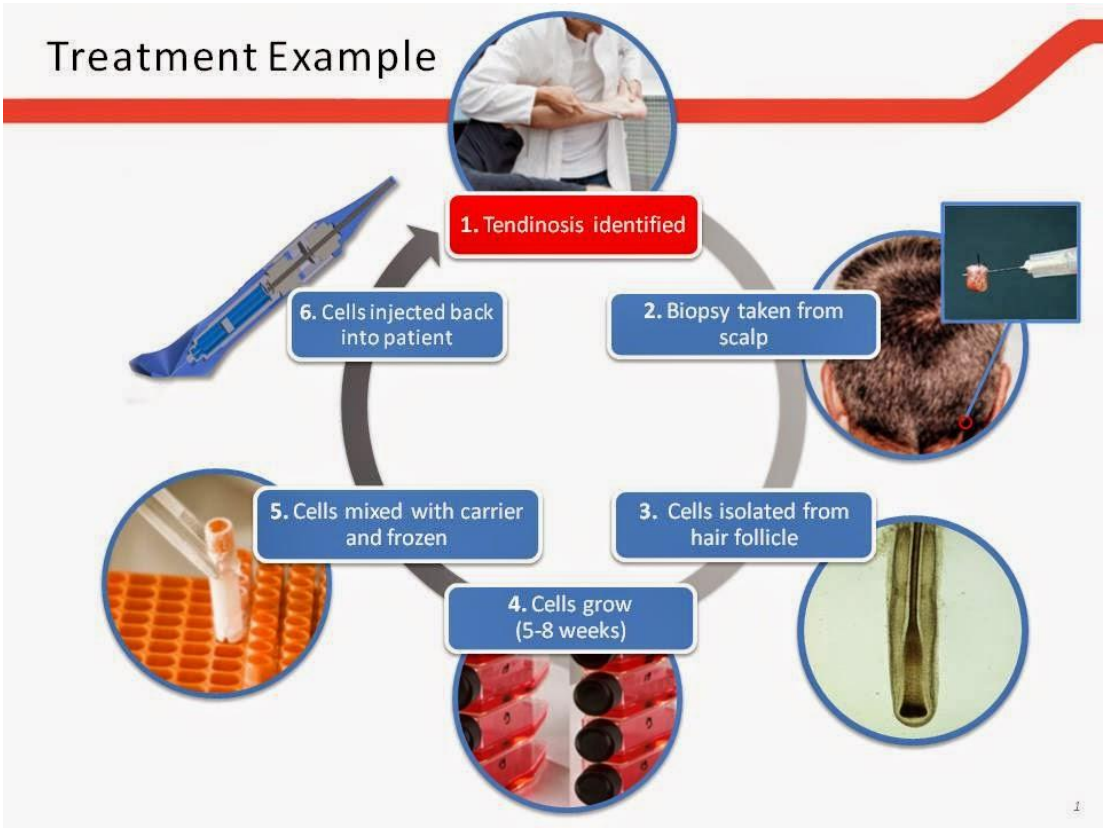
Suffice it to say I have been increasingly impressed by what I see and welcome the opportunity to share the interview below with you. I hope you enjoy learning a little more about RepliCel as much as I have.

CTB: Tell us a little about your background, David, and how you got involved in a cell therapy company?

DH: My initial career was in finance working on both sides of the street as a money manager and as a banker and analyst. It was as a banker that I came to join ID Biomedical which then led to my joining Angiotech Pharmaceuticals not long after it was started. During my time there I

served as Chief Financial Officer, Chief Compliance Officer and Treasurer and Corporate Secretary. After 20 years in life sciences, I spent time focused on public policy in BC and Canada as it related to developing our BC life sciences industry. During that time I was approached to look at a cell therapy company developing a treatment for pattern baldness. Despite my lack of empathy at that time for pattern baldness as a disease, I was struck by the elegance of this group's scientific approach and how that might be expanded into other treatments where there was a deficit of healthy active cells.

CTB: Can you give us a snapshot of RepliCel as a company?

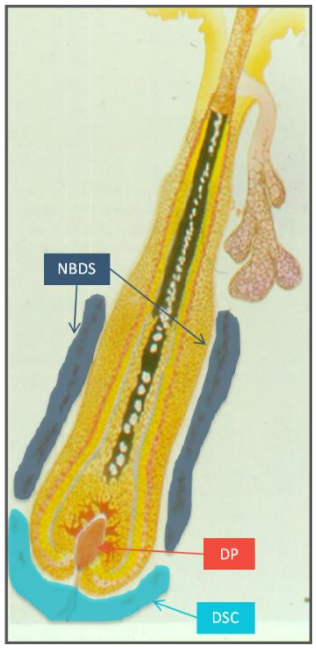


DH: RepliCel is treating cellular deficits in two main areas. The first is addressing conditions where there is a deficit of healthy functioning fibroblasts such as chronic tendinosis and damaged skin.

The second is in treating pattern baldness where there is a deficit of dermal sheath cup cells that are responsible for maintaining a hair follicle cycle of fiber production.

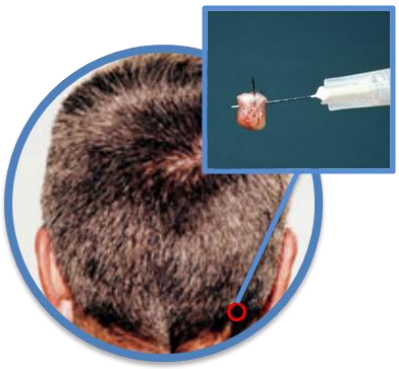
In addition, we have developed cell manufacturing technology and procedures to support the potential commercialization of these indications as well as specialised delivery devices which in themselves are unique and have the potential for licensing for other medical and cosmetic uses. We believe the manufacturing and delivery assets are very important to the company as you need to be able to demonstrate scalability and commercial delivery.

CTB: What is the company's technology?



DH: RCH-01 is our treatment for pattern baldness. This technology specifically focuses on replacing a deficit of healthy active dermal sheath cup cells (DSCs). Our product thesis is that these DSC cells control and maintain the population of dermal papillae (DP) cells in a hair follicle and the number of DPs determine the length and thickness of the hair fibre. In patients with pattern baldness (men and women), DSCs are compromised by the androgen hormone for no known reason. It is kind of like the reverse of unwanted or aggressive hair growth. Some people have five-o-clock shadows when they are 15 and others don't shave until they are 20+. In pattern baldness, the androgen hormone compromises hair growth. RCH-01 addresses the deficit of the active DSC cells in the areas of pattern baldness in the scalp.

The RCT family of products* are for the treatment of chronic tendinosis including Achilles, patellar and both golfer's and tennis elbow. In each case we are addressing a deficit of healthy active fibroblasts. The scientific thesis is that this chronic disease is the result of incomplete healing cycles due to a deficit of healthy functioning fibroblasts. Our early human clinical work on chronic tendinosis was done by our collaborator, Dr. David Connell, using fibroblasts isolated from the dermis. Our program is based on using fibroblasts isolated from the hair follicle due to their ability to express higher levels of type I collagen than dermal fibroblasts. Type I collagen is the main cell constituent of a tendon. (*RCT-A-01, RCT-P-01, RCT-G-01 and RCT-T-01)



RCS-01 is focused on replacing damaged or non-functioning fibroblasts in the dermis. Fibroblasts damaged by UV irradiation, smoking and other factors stop producing healthy amounts of collagen and the constituents of the skin's extracellular matrix. As a result, the skin loses its texture. Similarly, acne and burn scars are targets for us to deliver highly expressive fibroblasts to initiate remodelling of the damaged skin.

The supporting manufacturing technology is also a critical asset to the company as we believe our process is scalable.

In addition, we have developed a very unique injection cell injection device for dermal injections for both our derm and pattern baldness program. This device minimizes shear force, optimizes staged cell delivery, and has a built in freezing element that obviates the need for any kind of anesthetic and can control both volume and depth of injection.

CTB: Where are you doing your trials? Why Europe and Canada?

DH: All of our trials are being conducted under the terms of reference from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Each trial is designed to meet these international standards of which all of the western nations are members. As such, all of our data up to Phase 2 are admissible towards Phase 3 pivotal programs in each jurisdiction.

Our RCS-01 trial is being done in Germany. The co-founder of the Company Dr. Rolf Hoffmann, is located in Germany and he is leading this initiative. Similarly, our RCH-1 treatment is being conducted in Germany at the Charité Hospital in Berlin. The Charité is one of the largest teaching and research hospitals in Europe. In addition, the technology itself was first developed in Dr. Hoffmann and Dr. McElwee' s lab at the University of Marburg in Germany. There is history with these technologies in Germany and in addition, the cells are being processed by our contract manufacturer in Austria.

The clinical trial for RCT-A-01 will be conducted at the University of British Columbia because it is a world centre of excellence for sports medicine research including tendinosis. We have three very special advisers leading the development of the clinical trial protocol including Dr. Ross Davidson, Dr. Jack Taunton and Dr. David Connell. Each of them are key opinion leaders in sports medicine. It is also convenient to have this trial in our own city, but it was not the deciding factor. Reputation, skills and the ability to recruit patients were the deciding factors. The cells will be processed in Austria; however, we are moving to bring online a second contract facility validated in North America at the Centre for Commercialization for Regenerative Medicine in Toronto.

CTB: What is the strategy for the U.S. market?

DH: The US market will be addressed from two angles. First, we are presenting our fibroblast program to the US military under their peer reviewed medical research program. The DoD has a great interest in musculoskeletal research to deal with damaged tendons and skin. We believe our programs are ideally suited for their needs and are preparing filings for funding for clinical programs both in Canada and the US. The second approach is to undertake phase 2 clinical work on other target tendons in the US after we have gotten our RCT-A-01 program launched. Importantly, all of our trials are being conducted under ICH standards with the US regulatory pathways in mind.

CTB: Tell us about the deal you did recently with Shiseido and what your drivers were for that kind of deal?

DH: In 2013 we completed a geographic license with the Shiseido Company. Shiseido has its own hair research lab and they had come to the conclusion that our approach was the leading cell therapy technology for treating pattern baldness.

We were interested in doing a geographic license for Japan and parts of Asia for three main reasons. The first was to have a third party validation of our science and technology which is always important to a start-up company. The second was to be partnered with a large company whom had the resources (both human and financial) to conduct their own clinical program which along with our program would more than double the data being collected as we work towards establishing our dosing and other protocols for the technology in humans. Thirdly, Shiseido has committed to cell therapy in a significant manner including having commissioned and now opened a purpose-built cell processing centre in Kobe Japan, in the heart of the country's regenerative medicine initiative.

Our ongoing collaboration will see technology improvements shared between parties. Financially, we received $4 million up front, future milestones totaling approximately $30 million as well as middle single digit royalties on sales. We are very pleased with our collaboration with Shiseido. They are a focused and dependable collaborator.

CTB: From our perspective, the company is significantly under-exposed both in the regenerative medicine industry and investment communities. Can you give us a sense of why you think that might be and your plans in that regard?

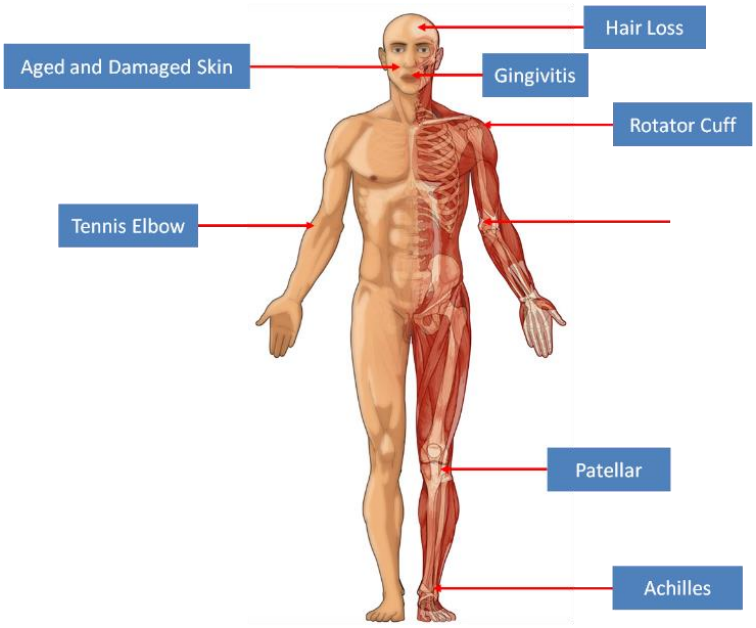
DH: Every company has its own chronological pathway to develop a profile in its industry and in the public domain. During the later stages of 2012 and through 2013 RepliCel was very concentrated on completing the Shiseido transaction as well as completing the filing of PCT patent applications on its fibroblast platform. Until we had completed the task of protecting our expanded technology, it did not serve the company to disclose these activities.

Now in 2014, we are completing the next round of financing, pushing hard on our clinical filings to launch 3 clinical trials and now have the freedom to discuss our programs. As such, we are going to be out in the public domain at conferences and doing roadshows in order to get the RepliCel story known and followed both in industry and in the capital markets.

CTB: While many of the companies in the cell therapy sector are focused on indications like cardiovascular disease, oncology, autoimmune disorders, or diseases of the central nervous system, RepliCel is going after sports injuries, baldness, and wrinkles. Do you see these indications as low-hanging fruit? Do these indications battle problems of lower-margin and/or reimbursement challenges?

DH: I would agree that our programs are low hanging fruit in the regenerative medicine business and that is an attractive distinction. Furthermore, as an autologous therapy, there is less risk of rejection than an allogeneic therapy.

Our therapies are designed to simply multiply a patient's particular cells that are in deficit and then deliver it to the area of deficit. We are not differentiating or inducing cell change, we are simply letting the cells do what they normally do when placed in the area of the wound or damage.



A lot of regenerative medicine is focused on very complex processes that take a source cell and then engage in extensive cell manipulation and/or differentiation. While these treatments are going to arrive in the future, today they are very difficult therapies to perfect both in assuring that the cell differentiations are exact and controlled and that the cells are delivered in volume and stay and function where they are needed. Our process is just simpler. So, yes, this is low hanging fruit in terms of safety risk and the commercial development timeline.

In terms of margins, we are quite confident in our ability to demonstrate manufacturing scalability. In terms of reimbursement, initially we have only one product that would need pharmacoeconomic validation and that is the tendon program. However, we know that we can replicate and deliver a tendon program at a reasonable cost and that there is no current clinically established solution for chronic tendinosis. Therefore, we do not anticipate any problem pricing at a good margin. In terms of the derm program, the initial focus is a cosmetic therapy and I think pricing a solution for sun damaged skin, wrinkles, etc. should not be an issue. A treatment with good efficacy will have no problem getting a premium price. In terms of margins on a treatment for pattern baldness, it would be priced against the current standard of care which is hair transplant surgery. And at that price, we can make good margins.

CTB: Many of the cell therapy products already approved are in the musculoskeletal, dermatology, and wound repair space and none are a run-away success. Does it worry you to be also focused on these areas for your near-term opportunities?

DH: That is a statement on the relative efficacy and difficulty of delivery. Approval does not necessarily equate to commercial success. We believe that our programs will have significant efficacy for their targeted indications, be easily delivered and they will become the gold standards. But that is the nature of product development; you have go out and demonstrate efficacy! One comment on wound repair is that we are not at this time interested in pursuing open wound repair as that space has many solutions ranging from complex cell therapies to medical devices. It is a crowded space and we prefer at this time to prove our platforms where we are confident in our success and are not populated by other treatments.

CTB: Your initial focus is on autologous applications of the hair follicle-derived cells, what are plans to address some of the commercial (cost) challenges presented by autologous cell therapies already on the market?

DH: As mentioned above, we are focused in parallel to our clinical development programs, on developing a scalable process for our cell manufacturing. We see this as a process engineering program and not a development process requiring scientific breakthroughs. This development program is underway. It is also true that we believe that our hair follicle derived cells are immune privileged and that in the future, our technologies could well become an allogeneic offering. But that is down the road.

CTB: Few companies of RepliCel's size and market cap are simultaneously tackling multiple products in clinical trials let alone also the concurrent development of a proprietary delivery device. Some might argue it would be more prudent to preserve capital to ensure you have what it takes to move one product further down the line. Can you give us a sense of your why you prefer this multi-pronged strategy?

DH: Our programs are inherently cheaper to develop and test than more complex cell therapies and for that matter, new chemical entities or biologics. We are simply expanding a patient's cells and giving them back to them. It is just cheaper to do than other therapies. As such, we can undertake more programs and I would argue that for shareholders, more shots on goal helps to mitigate risks associated with clinical programs. We believe we have a single focus on leveraging our core expertise around cells derived from the hair follicle organ and finding meaningful clinical applications for those cells. Optimizing the manufacturing and delivery of those cells just makes sense as part of the risk mitigation and value optimization of those assets.

CTB: To those investors interested in the regenerative medicine and cell therapy sector, where does RepliCel fit in the industry and how do you think it stacks up against sector comparables as an investment opportunity?

DH: I would characterize RepliCel as a mid-stage development company that exists between earlier approved products like Apligraf and Dermagraft for wound healing, and much more complex cell therapy clinical development programs. There are other mid-stage programs like Athersys' MultiStem and Mesoblast's Mesenchymal Precursor Cells. However, I would argue that our simple cell replication process of a target cell deficit is simpler to manufacture and deliver than many cell therapies. So, I would characterize our development programs as lower risk. Nevertheless, I would also say to investors that regenerative medicine is going to be a huge field in the future as science and technologies evolve. This industry will be delivering incredible medical solutions for patients in the future.

CTB: Talk to us a little about the stock. It's very lightly traded on both the Toronto venture exchange and over-the-counter bulletin board. What's the plan going forward in terms of its listing and liquidity?

DH: Yes, it is true our trading has been low. That is a direct function of our tightly held stock, (management, founders, etc., own approximately 45% of the stock) and the fact that we were very focused in 2103 on our partnership and the patent filings. As discussed above, we are now launching our story on a focused basis that will see the company out on road shows delivering its message to potential investors. We think that RepliCel is an attractive and unknown story which will have a good reception. That effort is focused on addressing the valuation and liquidity. In

terms of listing, the natural progression as we develop assets and valuation is to up list which we will be pursuing.

CTB: Where do you see RepliCel in 18-24 months?

DH: On a clinical basis, we will have data in both our tendon and derm programs and will be closing in on the clinical trial data for our treatment for pattern baldness. We should at that time be initiating at least one other tendon program and a phase 2 derm program. We will have developed clinical protocols for two new indications for our fibroblast platform (not yet being disclosed due to patent work) and we will have demonstrated scalability of our manufacturing platform. If we accomplish this as planned, we will have established an extremely valuable group of assets.

CTB: Thank you, David, for the opportunity to spend some time learning more about RepliCel and your plans for the company.

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