



## Avita Medical Shareholder Update

27 May 2015

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### Letter from the CEO

Dear Shareholders

This is my first communication to you all as CEO, and I felt it important that you hear from me direct now that I have had one month in the job. To state my intentions at the onset, I embark on my job with great excitement for a variety of reasons, but one is more important than all others. That is, the technology works. ReCell<sup>®</sup> is a powerful and proven means for treating skin wounds, and should be standard treatment across the world. Now we all know that the company has not yet achieved the recognition that it deserves, and that the dream of mass ReCell<sup>®</sup> treatment remains (mostly) unrealised. So I would like to take this chance to convey to you some of my ideas for getting this recognition, and what the team plans to do to get commercial traction.

But firstly, I would like to summarise five recent key commercial events of recent months.

#### **1. Next Generation Product**

We have achieved CE Mark approval to market and sell a next generation version of ReCell<sup>®</sup> in Europe, capable of treating a broader range of wounds, scars and skin defects. The new CE Mark moves ReCell<sup>®</sup> to treating a skin area of up to 1920 cm<sup>2</sup>. The previous version covered only 320 cm<sup>2</sup>. This improvement means ReCell<sup>®</sup> can treat an area of skin six times larger than was previously possible.

This augurs very well for our commercial prospects in this key marketing region as we are now able to treat patients with bigger disfigurements. In particular, it is better aligned to meet grafting requirements of burns patients, and the new product is in direct response to feedback from medical professionals. This new variant has already been used in the US in leading burns centers, where it has treated selected patients under the Burns and Compassionate Use IDE programs.

#### **2. Share Placement**

We had a successful capital raising earlier this year. In March, we raised more than \$5,042,280 via a share placement to sophisticated and institutional investors, with a further \$1,135,100 raised a month later in a Share Purchase Plan to existing investors. Under the plan 18,314,508 new shares were issued at 0.062 cents per share.

Our cash position was further bolstered late last year with an Australian R&D Tax Incentive payment of \$1.4 million.

All funds will contribute to our clinical trial program in the United States and to execute our commercial strategy in other key sales and marketing regions.

Naturally, we would like to thank all those who participated.

### **3. Key US regulatory study of ReCell®**

The first 10 patients have now been enrolled in a ReCell® Phase III trial, to be run at 6 leading burns centres, to assess the safety and effectiveness of ReCell® in patients requiring skin grafts due to burn injuries. A total of five of the six centres are now in play, and up to 30 subjects will eventually participate in the trial, which will be presented to the FDA so that the device can be approved for sale in the US. The programme is on track, and under our timelines, approval would come in 2017.

Under the protocol, each subject is his/her own control, with a portion of an injury randomly allocated to receive skin grafting (control) and a similar portion of the injury randomly allocated to receive ReCell® treatment in combination with meshed skin grafting.

The co-primary effectiveness endpoints will compare the donor site to treatment area expansion ratios and the incidence of complete closure assessed eight weeks after treatment by personnel blinded to the treatment.

In addition to supporting an application for FDA approval, this study data will support worldwide commercialisation, particularly in the UK.

### **4. Strong Interest in Avita technology from US Military**

We recently met high-ranking US government officials in Washington DC to discuss how our novel technology may be used for the treatment of burns, wounds and other skin conditions for wounded US service personnel.

Both COO Tim Rooney and myself visited Washington on April 28-30 to meet representatives from the US Department of Defense's Clinical and Rehabilitative Medicine Research Program (CRM RP), the US Army Medical Research and Materiel Command (USAMRMC) and the Armed Forces Institute of Regenerative Medicine (AFIRM). The company also met with the US Senate Veterans Affairs Committee to discuss possible treatments for veterans with both chronic and acute wounds, and we visited the leading military hospital, the Walter Reed National Military Medical Center (Bethesda). Here, we spoke in detail with surgeons who successfully treated a US wounded warrior with ReCell® under an FDA compassionate use protocol.

Further meetings on Capitol Hill were with US Senator Jack Reed (D-RI), US Senator Richard Burr (R-NC), US Senator Mark Kirk (R-IL) and US Senator Sheldon Whitehouse (D-RI). The company also had a breakfast meeting with US Congressman Jim McDermott (D-WA) and met with senior staff in the offices of US Senator Diane Feinstein (D-CA), US Congressman Brad Sherman (D-CA), US Congressman Mac Thornberry (R-TX) and US Congressman Trent Franks (R-AZ).

In the civilian arena, meetings were held with the National Institute of Health's Arthritis and Musculoskeletal and Skin Diseases division, and the US Department of State, Global Partnerships.

## **5. ReCell® presented at US Government Symposium on Disaster Preparedness**

Just last week, we gave an invited presentation at a key US Government Symposium focused on Emergency Preparedness. Andy Quick, our VP for Research and Technology, presented to an influential group of delegates on how ReCell® could be a versatile and effective treatment for burns and skin wounds in a mass casualty event.

The Symposium on Accessibility and Development of Tissue Products for Emergency Preparedness was held May 11-12 at the National Archives in Washington DC. The event was sponsored by the US Department of Health and Human Services, and was organized by the Office of the Assistant Secretary for Health and the Office of the Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and development Authority (BARDA), in collaboration with the Department of Defense.

Collectively, Avita is becoming known at high levels of the US government, and we will inform you of progress as we engage with these parties.

### **Internally.... Key Management Changes**

As you have probably gathered, I took over the CEO role in April, with our interim CEO Tim Rooney resuming his role as the company's Chief Financial Officer and Chief Operating Officer.

My background is as a marketing executive and entrepreneur, with a strong track record creating and building life science companies. In 2000 I founded UK-based life sciences company Equazen Limited, a leading omega-3 and omega-6 supplement company whose lead product eye q™ for lipid deficiencies linked to learning conditions, was sold to Galencia of Switzerland in 2007. Eye q™ at the time was marketed in 16 countries.

Further, in 2006 I started UK-based Equateq Limited, a cGMP-certified manufacturer providing super-pure fatty acids for the nutritional, pharmaceutical and research sectors. Equateq was sold to BASF in 2012.

I must here thank Tim for his time as helmsman, in which he deftly navigated the company through a challenging period. Tim's expertise in finance and operations will be crucial to our commercial strategy going forward.

### **Avita Medical has Powerful assets .....**

Before exploring our commercialisation strategy, I wanted to first explain what drew me to the company, as an entrepreneur.

My due diligence concluded that the company has very strong assets.

Firstly, as said above, the technology works: the many accounts of patient recovery are completely compelling. Some of the most important conversations I had were with clinicians who really could not do without our esteemed device. ReCell® has become a crucial part of their standard of care, and they have treated patients thousands of times to great benefit. It struck me that the offering was created by innovative clinicians, namely the remarkable

Professor Fiona Wood, purely to treat patients. This is quite a difference in the Medtech or Biotech space, where many offerings are from labs or institutes, and are often overly complicated, non-commercial or just plain weird.

Secondly, a lot of positive work had been done by the company, but in my view, this was not being effectively communicated. Our scientific bibliography has some 60 published papers, a body of work that other companies of our size would dearly love to have. The R&D strategy is now well focused, under the guidance of Andy Quick, and we are on track to deliver strong RCTs in all our chosen treatment areas. And even more crucial, we have approval in significant markets – the EU, China and Australasia – and there is no regulatory obstacle to us selling.

Thirdly, in terms of requirement, this needed a straight commercialisation play. It does not require massive capital expenditure; say to build a proprietorial cGMP manufacturing plant, with all of those attendant joys. It required a rethink, and a redirection and a fresh approach to the market.

Fourthly, and by no means least, Team Avita has shown themselves to be a highly motivated group. There is no shortage of brain cells amongst my staff, and they are genuinely motivated to get this company to succeed so that more patients can benefit. Altruism and enthusiasm are a contagious mix.

#### **.... But the Company Now Needs to Re-orient itself**

And now you say, that is all very nice, but we have heard similar messages before. How will you bring shareholder value? My simple equation for this is:

*Commercial traction + Hitting Milestones = Higher Share price*

In terms of focus, we are placing our efforts into the UK and Australia, to prove market penetration in our two core markets. We will achieve commercial traction, customer by customer. And we are actively engaging with significant sector partners, many of whom, it is clear to see, have a gap in their portfolio where our offering sits.

An observation of our current customers is that wherever ReCell® is used, is part of standard treatment, and has shown itself to benefit patients; there is fervent belief amongst clinicians. But there is an understandable resistance amongst those who have been doing treatments in a certain way, and are being asked to change. We will endeavour to convert the latter to the former by:

- Clearer communication of our scientific credentials
- Re-orienting the device away from being a replacement to standard care, to being an adjunct to standard care. Our research supports that ReCell® is even further optimised if used in conjunction with grafts and dermal sheets
- Increasing usability. Genuinely interested clinicians can now road-test donated devices under a structured partnership scheme. A Centre of Excellence project is being enacted with key hospitals, under which we will offer preferential pricing in return for being incorporated into their local standard of care

Avita is a busy little company, and in terms of upcoming milestones, some will be transformational, such as FDA approval. So one of my tasks internally is to free up key staff, to ensure that they are adequately resourced and not distracted from the main game. There is a healthy pipeline of positive events on the way, and we need to give this our complete focus.

### **And what is this RES all about?**

Some of you will have already seen communications about RES™ -- our trademark for Regenerative Epithelial Suspension. RES™ is the resultant product that our regenerative devices create and is then applied onto patients. This new positioning is the result of an internal discussion about explaining the mechanism within our suspension. I wanted us to drill down, and explain why ReCell® works, as it was not clear to me from the messaging to date. We sell a device that enables medical professionals to make RES™, which is the real 'magic' being offered by Avita. The RES™ message allows us to communicate effectively across our various condition areas and emerging brands. We articulate that RES™ is *Activated, Available, Autologous and Complete*, to give some explanation to the mechanism.

So far, the new messaging has been well received by the trade, at least to gauge from responses at such major professional conferences such as the recent European Wound Management Association in London, or the British Burns Association meeting in Birmingham. Our website will soon be re-launched, and then the messaging will be clear to all.

### **In Conclusion**

I must finally ask for some more patience, as it will take time to get results in the marketplace. This is not a quick-fix company, and of course, it is a complicated sell, requiring agreement of patient, clinician and procurement. But we have a great product and a strong team. With our new direction and fresh approach to the market, Avita will be on the move again.

Avita will continue aggressively achieving milestones as the year progresses. On behalf of the Avita Medical team, I thank shareholders for your ongoing loyalty and look forward to reporting more progress in coming months.

*Adam Kelliher*

CEO

**ABOUT AVITA MEDICAL LIMITED**

Avita Medical (<http://www.avitamedical.com/>) develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary tissue-culture, collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's lead product, ReCell®, is used in a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell is patented, CE-marked for Europe, TGA-registered in Australia, and CFDA-cleared in China. ReCell is not available for sale in the United States; in the United States, ReCell is an investigational device limited by federal law to investigational use. A Phase III FDA trial is in process.

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