

# Avita Medical Shareholder Update

22 July 2015

# Letter from the CEO

Highlights:

- Additional share authorization requested to support a new direction for Avita Medical towards commercialization in the U.S. market
- Objective is to ensure access to resources required to bolster the company's commercialization strategy and support growing links in the U.S. at a governmental level
- A U.S. stock listing planned in 2016
- Taiwan Waterpark disaster update; 50 kits and support on the ground, 100 more kits ordered
- Avita meets the Irish Prime Minister

#### Dear Shareholder

#### **Future Capital Markets Initiatives**

Following on from this communication, you will see some materials explaining the legal and commercial structure for a new capital raise. I would like to provide some more details on the rationale behind this plan, so that you have the full picture about Avita Medical's new direction of travel, which is to expand our commercial base in the U.S. We will keep our strong pedigree within Australia, but there are three very good reasons why we are now looking towards the U.S.

Firstly, from a commercial position, it is vital that we establish our foundations in the world's largest economy. As we work towards U.S. FDA approval of ReCell<sup>®</sup>, we are building credibility with leading burns surgeons, many of whom have seen our ReCell<sup>®</sup> device successfully at work for treating patients, whether under a clinical trial setting, or under compassionate use dispensations. The burns sector is small compared with others within wound care, but it is of a significant size in the U.S. where we believe Avita will be a robust business if we can 'own this space'. We must commit now so that we are ready to run once we get U.S. FDA approval, with a fully resolved sales and marketing strategy supported by a robust supply chain and quality systems.

Secondly, we believe we have a strong opportunity for success as a result of our efforts in the U.S. on a governmental level. Many of you will have seen earlier communications regarding visits to Washington DC by CFO/COO Tim Rooney and myself. This is a strategic approach, to let the relevant people within the U.S. government and legislative branches know the Avita story. And I must report that our offering has resonated well with all of those we have spoken with. I point you all to the latest article within *Army Technology* Magazine, which highlighted ReCell® as an example of an innovative treatment that the U.S. Department of Defense 'wants to use.' Our device has been presented to leading officials tasked to prepare the nation for large-scale disasters. We have met many leading political figures who are actively engaged in the American programme to treat their wounded warriors. And there have been formal interactions with BARDA, a federal body assigned to ensure the U.S. is well prepared in the event of a public health medical emergency. So while we cannot say exactly where this part of the journey will lead, my view is that acceptance of our offering by any of these parties may be transformational for the company.

And this leads to my third and most significant point. Avita now needs to be properly capitalized, if it is to move to a higher plateau, not only within the US, but in the other markets too. We would like to now add additional institutional investors to our shareholder register. As you are aware, biotechnology is potentially lucrative, but capital intensive business and we will need to look outside Australia to raise funds to meet our needs. Our objective is to ensure that we have the required human and financial resources to enable implementation of the commercialization strategy beyond the next financial year. With that accomplished, our team can focus on achieving commercial traction without the distractions of continuously needing to raise money. We can already point to some early successes: ReCell<sup>®</sup> sales are up 25%, and these numbers have been subsequent to the new messaging and focus of the sales teams in the EU and Australia. It is early days yet, but our sales staff are bringing in new medical professionals who have become 'true believers' in the product after using it successfully. Already some of these new customers are giving us that most wonderful thing: the repeat order.

And where does all of this lead? The vital next step is that within the timeframe of the 2016 financial year, we intend to also resolve timings for a listing on a U.S stock exchange; the NASDAQ or NYSE. The U.S. is by far, the largest and most sophisticated biotech market in the world. A U.S. listing is expected to result in increased awareness and better liquidity for investors as well as improved access and lower cost of capital for your company. This action will cement our credentials within the U.S. market, and open us up to a far greater reach in terms of investors. Here I will nail my flag firmly to the mast and declare official exasperation with the current Avita valuation on the ASX, given the stream of positive news that we are generating.

We believe that the new commercialization initiatives and additional capital raising will be transformational programmes for the company but not the only emphasis. The influx of new capital will also allow us to engage in the necessary clinical and regulatory work to pursue additional indications in the U.S. for the very large chronic wounds and aesthetics markets. We also have a focus on reimbursement in our key markets while continuing our research and development work for our regenerative platform technology.

So the potential upside, I trust, I have also made clear: our plan should put Avita on a firm footing to execute its strategy and achieve its commercialization goals. My view is that the company now needs to grow beyond Australian shores, to achieve true value recognition for the company's technology and for the hard work that the Avita team has done over the years.

#### Taiwan

No doubt many of you will have already read or seen on TV the stories about our response to the disaster in Taiwan, where some 500 people, mostly youngsters, sustained horrific burns due to an explosion of inflammable dust. As soon as we heard about it, we knew that we had to respond as a company, and I am pleased to be able to report to you that our donated devices have been actively used to treat the injured. We donated a total of 50 devices, and crucially, my staff, Lorraine Glover and Phil de Dubois, were on hand to train personnel unacquainted with ReCell<sup>®</sup>.

To date, about 20 people have been treated with ReCell<sup>®</sup>. We also now have a follow-on order for 100 devices, which are currently being shipped to Taiwan. We will keep you updated as this situation unfolds.

#### Ireland

As part of our commercialization efforts, we have been exploring ways to introduce ReCell® to senior government members, and in this way, Avita does punch above its weight. With pleasure, I was able to recently meet the Irish Prime Minister Enda Kenny. The prime minister, or Taoiseach, was available for an hour, and I was able to brief him on our plans for expansion into Ireland and beyond. We have recently appointed a sales executive in Dublin, and the Prime Minister was also interested in our longer term manufacturing plans, when production increases. Ireland has proven itself to be a strong supporter of life science companies, and many companies have shown strong growth after basing themselves in the Emerald Isle.

#### Conclusion

Avita is moving aggressively forward on all fronts and achieving significant progress. The Avita team is energized by the commercial programs that are being put in place and by the lives that have been transformed by our wonderful technology. The time is now for us to globally capitalise on the large body of case-studies, clinical trials, and compassionate use data... but more significantly, the fantastic outcomes experienced by patients in need throughout Australia, Europe, and China.

# Adam Kelliher

CEO

# ABOUT AVITA MEDICAL LIMITED

Avita Medical develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's lead product, ReCell<sup>®</sup>, is used in the treatment of a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell<sup>®</sup> is patented, CE-marked for Europe, TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell<sup>®</sup> is an investigational device limited by federal law to investigational use. A pivotal U.S. trial is underway, with patient enrollment completion anticipated by the end of 2015. To learn more, visit <u>www.avitamedical.com</u>.

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### FOR FURTHER INFORMATION:

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