

Avita Medical Fiscal Year 2015 Corporate Review

Australia 29 September 2015 - Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine company specializing in the treatment of wounds and skin defects, today provided a review of its fiscal year 2015 accomplishments.

Fiscal 2015 was a year of significant change and progress for Avita Medical. The year began with the July 2014 appointment of Lou Panaccio as Chairman of the Board of Directors, and with Adam Kelliher joining the Company as Chief Executive Officer in April of this year. Both Messrs. Panaccio and Kelliher bring significant experience to Avita and are helping to reshape the future of the Company as the management team works to continue implementing its strategy, which is focused around the successful commercial ramp-up of the ReCell® technology in the markets where it is approved and securing the necessary regulatory approvals in other strategic markets, most notably the U.S.

Commercial Developments

The Company has expanded the regenerative product platform and reworked the messaging around the three clinical indications of acute injuries, chronic wounds, and repigmentation. Part of this effort has been towards better communication packages to clinicians surrounding the mechanism of action of the Regenerative Epithelial Suspension (RES™). A recently re-launched website has been a further step in this commercialization progression. A full suite of presentation materials has been distributed to sales personnel with the new messaging, including a health economics tool to demonstrate how the use of ReCell® can typically save an institution money and treatment time, as well as delivering improved outcomes.

The Company has historical approvals for 32 territories, but an absence of commercial presence in all these markets, so management has increased its engagement with prospective distributors and partners to widen its sales footprint. In tandem with this process, sales grew in territories covered by staff sales personnel : Germany, France and the UK. The Company has appointed a representative in Dublin, and was honoured to meet the Prime Minister of Ireland, Enda Kenny, to discuss its long-term plans. In Australia, two sales staff have been recruited on the east coast with a mandate to gain traction in the main population centres. In China, sales were secured at beachhead hospitals in Beijing, Shanghai and Guangzhou, and a more ambitious roll-out is planned now that in-country trials have been completed. An opening pipeline order was generated from Saudi Arabia with a newly appointed distributor.

The commercial opportunity for Avita's ReCell® technology continues to develop, having achieved a key milestone with the Company's receipt of CE Mark approval for a next-generation version of the ReCell® device offering an expanded area of coverage of six times the skin surface of the previous version. With this approval, which will enable the Company to market ReCell® throughout Europe and in a number of other countries, Avita is now able to treat a much larger surface area for patients and has significantly increased its addressable market. This product enhancement coupled with last year's approval for an ambient-stored device are key commercial actions in response to clinician feedback.

As Avita works to establish its footprint in the U.S., it has been focused on securing protection for its novel technology. During the recent fiscal year, the Company was granted two new patents in the U.S., which provide further protections of its intellectual property and greater control over the future direction of this innovative product.

Clinical Developments

The Company has been proactively engaged with key opinion leaders across all of our focused indications in burns, chronic wounds, and aesthetics/repigmentation. Last October, the ReCell® technology platform was prominently featured at the International Society for Burn Injuries' (ISBI) 17th Biennial Congress in Sydney. Positive clinical outcomes were featured in five accepted presentations from thought-leaders attending the conference from Germany, Turkey, UK, US, and Australia. ReCell® inventor and non-executive Director Dr. Fiona Wood FRACS, AM was a keynote speaker, symposium co-chair and panellist at the prestigious event.

In April, Avita held its Skin Regeneration Symposium at Cambridge University. A higher than expected attendance of more than 80 clinicians from around the globe participated in a series of keynote presentations and panel discussions all focused on using the Regenerative Epithelial Suspension (RES™) that clinicians can generate from the ReCell® platform.

The Company had research published in the *Journal of the American Academy of Dermatology*, which demonstrated a 78% repigmentation in [lesions of patients with vitiligo and piebaldism](#), compared to 0% in control groups. In addition to repigmentation, ReCell® was shown to be well-tolerated and free of any long-term side effects.

The British Journal of Surgery in January published results of a randomized controlled trial conducted by Chinese researchers, involving 88 patients suffering from chronic wounds. The authors reported a faster rate of wound closures amongst the 44-patient active group treated with ReCell®, and observed superior outcomes.

Avita has entered into a partnership with England's University of Huddersfield to explore the mechanism of RES™ to better understand its ability to effectively treat burns, hard-to-heal wounds and other skin trauma. This research is expected to provide a more complete assessment of the cellular interactions taking place in RES™ and the role of these interactions in the regeneration of healthy skin. A better understanding of how the technology works will allow Avita to better educate clinicians who may use the product to treat patients, enabling a more precise identification of those most likely to benefit from the device.

Researchers in the UK conducting a venous leg ulcer pilot study are following up the last of the 52 subjects enrolled in the study aimed at comparing outcomes with ReCell® combined with standard wound dressings versus standard dressings alone. Target enrolment was adjusted to 52 subjects in order to complete subject follow-up and data analysis by the end of the calendar year.

Progress in bringing ReCell® to the U.S. market has been moving forward rapidly, with most progress in the clinical realm. The next-generation product has been used to treat patients in the U.S. under Burns and Compassionate Use IDE programs, and efforts to gain FDA approval are ongoing. Early this year, the FDA approved the proposed modifications to the pivotal trial protocol, and to-date, 19 patients out of a targeted 30 have been enrolled in the Phase III trial of ReCell® taking place at six burn centers in the U.S. With the new trial protocols, the Company believes that it is on track for potential FDA approval in 2017. ReCell® technology has gained increased exposure among key decision makers in the U.S. government as Avita was invited to present at a Symposium focused on Emergency Preparedness, and was also highlighted in the *Army Technology* magazine as an innovative way to treat soldiers who have been wounded in combat. The traction at the government level demonstrates the significant interest from

this market and the potential opportunity as the Company works toward FDA approval to enable broader U.S. penetration. Additionally, the Company has held discussions with government officials in the U.S., including the Biomedical Advanced Research and Development Authority (BARDA), as well as political figures whom are responsible for programs dedicated to helping wounded service personnel. In addition to growing its market presence, Avita remains focused on using its unique technology for humanitarian efforts. During the year, the Company was able to assist in the treatment of burn patients following a mass casualty explosion in Taiwan, which led to additional orders for the Company's devices.

Financial Performance

The Company further strengthened its balance sheet by raising a total of over \$6 million during the year. This will support its ongoing global expansion efforts, including the commercial ramp of ReCell®. With its proven access to capital, the Company is better positioned as it considers a future uplisting to a senior U.S. stock exchange, which would enable the Company to build greater awareness and credibility not only among members of the financial community but clinicians and patients who could potentially benefit from this technology.

Year-over-year sales of ReCell® increased 25% while total revenues for the year were \$2,750,176, an increase of 2.5% over the previous year (\$2,683,133). The strong ReCell® results were driven by a focused sales effort in our key markets, including an increase of 28% in the United Kingdom, 13% in Australia & New Zealand, 81% in Germany and 88% in China.

A 6% increase in expenses (\$9.8m vs \$9.3m) aimed at driving long-term growth, resulting in an increase in pre-tax losses of 17%, when compared to the previous year.

Sales and marketing costs increased 22% as the Company expanded its salesforce in Germany, Australia and China as it ramps its marketing efforts in these countries.

Research and Development expenses were also higher owing to an increase of clinical trials underway, while the Company also increased its administrative expenses with the hiring of a new chief executive officer.

ABOUT RECELL® AND RES™

ReCell® is Avita Medical's unique proprietary technology that enables a clinician to rapidly create, at point of care in approximately 30 minutes, Regenerative Epithelial Suspension (RES™) using a small sample of the patient's skin. RES™ is an autologous suspension comprising the cells and wound healing factors necessary to regenerate natural, healthy skin. RES™ has a broad range of applications and can be used to restart healing in unresponsive wounds, to repair burns using less donor skin yet with improved functional and aesthetic outcomes, and to restore pigmentation and improve cosmesis of damaged skin.

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®, is used in the treatment of 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. In the United States, ReCell® is an investigational device limited by federal law to investigational use. A pivotal U.S. trial is underway, with patient enrolment completion anticipated by the end of 2015. To learn more, visit www.avitamedical.com.

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