



# Investor

## Update

July 2012

***“Regenerative medicine is fundamentally changing the way we think about the treatment of a wide range of diseases, injuries and tissue defects. ReCell Spray-On-Skin, as one of the first regenerative therapeutic technologies available, provides a new and powerful tool for surgeons and is markedly resetting their expectation for patient outcomes.”***

***Dr. William Dolphin, Chief Executive Officer, Avita Medical***

28 July 2012

Dear Shareholder,

I am pleased to provide an update on Avita Medical for the Fiscal Year ended 30 June 2012.

Your Company continues to make excellent progress with strong and steady achievements against each of the key components of our long-term strategic plan:

- **Increase sales revenues in high-value markets;**

Total revenues increased by 13% for the 2012 fiscal year with 88% growth in revenues from our regenerative product, ReCell® Spray-On Skin™.

- **Implement continuous improvement models to operations;**

Modifications to the manufacturing process and increased operational efficiencies have yielded significant improvements in margins during FY12 with overall gross margins increasing from 72% in Q1 to 76% in Q4.

- **Obtain regulatory approvals in key markets;**

Avita received regulatory approvals for key markets including Russia and the Middle East and continues to progress the FDA clinical trials for regulatory clearance of ReCell in the US.

- **Strengthen product portfolio and expand intellectual property;**

Avita was granted a highly significant European patent of broad claims covering core aspects of the technology embodied in ReCell. Additionally, the Company was granted trademark protection for use of the term ‘Spray-On-Skin’ and three new patents were submitted in the US covering key features of the Company’s intellectual property related to its regenerative technology. With the transfer of previously licensed intellectual property from the McComb Foundation to Avita, the Company now has full ownership of all intellectual property pertaining to ReCell.

- **Increase market capitalization and share price**

Avita Medical’s share price on the ASX closed the year up 60%, rising from \$0.12 on 1 July 2011 to \$0.19 on 30 June 2012 with corresponding increase in market capitalisation from \$28 million to \$45 million during the year. Avita’s share price has significantly outperformed the US S&P500 and AUS All Ords during the 12 month period ending June 30, 2012.

The Company has 3 offices of operation: United States (Northridge, California) focussed on management of regulatory affairs, clinical trials worldwide and operations; United Kingdom (Cambridge) focussed on ReCell sales & marketing for the EMEA regions; and Australia (Perth, Western Australia) focussed on sales of respiratory products and market entry into Asia Pacific.

The practice of medicine is being fundamentally changed with the introduction of regenerative medicine and stem cell therapies. Avita Medical, as one of the very few companies that have successfully introduced a commercial regenerative product, is a leader in this emerging field. The core regenerative stem cell technology embodied in the Company’s ReCell Spray-On-Skin has application to a wide range of indications involving the treatment of burned, scarred, damaged, diseased or discoloured skin, thus encompassing the acute trauma, chronic wound, plastic surgery and aesthetic markets. ReCell is truly a transformational and disruptive product and technology.

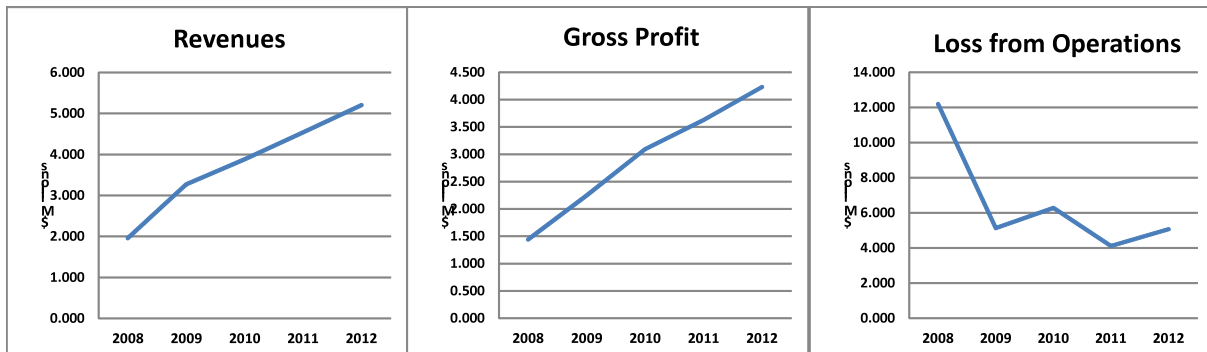
We are embarking on a new phase in the Company’s life. We will continue to solidify our position in our core European markets whilst expanding our geographic markets to include the Middle East, Russia and China. In addition to our geographic expansion we are implementing improvements to the ReCell product, expanding application of the core technology and commencing development of the next generation of regenerative products.



## Financial Results

### Key points:

- ReCell revenues up 88%
- Overall revenues up 13%
- Gross Profit up 17%



Total revenues for the fiscal year ending June 30, 2011 were \$5.2 million (unaudited, including sales, royalties, grants and interest), a 13% increase over FY11's revenues of \$4.5 million.

Revenues from the company's respiratory product line were \$2.2 million, down approximately 13% compared to FY11. This decrease was not unexpected and was primarily attributable to two factors: i) discontinuation of sales of the Funhaler paediatric spacer, and ii) cessation of royalty revenues from Philips Respironics with expiration of the licensing agreement during FY12. Revenues from the sale of the company's adult spacer, Breath-A-Tech, in Australia remain strong and represent a reliable, high-margin source of cash for the Company.



The major growth driver has been increased sales of Avita's flagship regenerative product, ReCell Spray-On Skin. Revenues from the sale of ReCell kits in FY12 were A\$1.1 compared to A\$0.56 million in FY11, an increase of 88% (compared to 61% growth FY 11 vs. FY10). ReCell sales represented approximately 33% of sales revenues during FY12 compared to approximately 16% in FY11. The majority of ReCell revenues came from sales in Europe, approximately 80% of which were generated for use in the treatment of burns. Total revenues attributable to ReCell, including grants, were \$1.9M.

The Company has in place a formal continuous-improvement process and a strong commitment to cost containment and improved efficiencies. Recent changes in manufacturing are yielding significant increases in margin which will be manifested in the coming quarters.

Gross profit increased by 17% for FY12: \$4.2 million, an increase of \$0.6 million over FY11. Overall gross margins were 73% for the year, beginning at 71% in Q1 and, increasing to 76% in Q4.

The Company is entering into an expansion stage with increased efforts being directed toward R&D, sales & marketing and clinical research. As such, there has been and will continue to be a concomitant increase in operating costs (up 13% vs. FY11). The Company had FY12 operating losses of \$5.0 million.

Expenditure on R&D increased by 306% over FY11 with major efforts directed at the development of the next generation ReCell product and expanded fields of use.

Management is pleased with the strong growth in ReCell sales and is confident this growth trend will continue; revenues from regenerative products will continue to grow and contribute an ever-increasing proportion of total sales revenues.

## Sales and Marketing

### Key Points:

- **Distribution agreements for China Russia and Turkey; Joint Ventures in Middle East, Italy, in place**
- **Inaugural ReCell Skin Regeneration Symposium attended by 120 surgeons**
- **Positive clinical outcomes reported by surgeons in China**

Avita's continued strategy of 'deep versus broad', i.e., focussing on a few high-value markets and within those markets on a limited number of key surgeons and clinical sites, is yielding positive results.

**EMEA.** The Company has a limited direct sales force serving France, Germany and the United Kingdom - 'core' markets for the Company. The strategy has been to closely engage a select group of highly regarded surgeons of international stature thereby developing a team of Expert Users and Key Opinion Leaders (KOLs) to establish best practises in the use of ReCell, demonstrate the substantial benefits of ReCell in the treatment of a wide range of indications, and present their results with ReCell as publications in peer-reviewed journals and presentations at national and international congresses.

In March 2012 Avita sponsored the first annual Skin Regeneration Symposium in Rome, Italy. The event was attended by over 120 clinicians and physicians from 13 countries throughout Europe and the Middle East. Three panel presentations, led by a multi-disciplinary group of 24 invited ReCell experts from across the globe (Australia, China, France, Germany, Italy, Jordan, the United Kingdom and the United States) covered application of ReCell in the areas of burn treatment, plastic and aesthetic applications (including the treatment of scars, vitiligo, and facial rejuvenation) and hard-to-heal wounds (including treatment of venous and diabetic foot ulcers and other chronic/challenging wounds). The symposium led to a vibrant exchange of information, with strong implications for the advancement of the use of ReCell across the Middle East and Europe.

Over the next several months Avita intends to add additional sales representatives in Germany and the UK. Joints ventures in the Middle East and Italy are progressing well and recently added distributors in Russia and Turkey are anticipated to commence sales & marketing efforts in September 2012.

**China** Following ReCell's SFDA approval, Avita continues to progress its entry into the very large Chinese market and recently signed with a Chinese distributor. In recent months Avita has participated in congresses and hosted ReCell workshops in major Chinese cities. Activities have included scientific and clinical presentations and panel discussions lead by prominent surgeons from prestigious Chinese hospitals. Surgeons presented excellent clinical outcomes achieved with ReCell in procedures performed in a variety of fields including burns, plastic and reconstructive surgery.

A critical initiative underway is the obtainment of an official Pricing Code, equivalent to a Diagnosis Related Group (DRG) code used for reimbursement in much of the world and necessary for the commencement of commercial sales of ReCell in China; this requires small-scale clinical evaluation studies designed to demonstrate and substantiate the value of ReCell based on a limited number of procedures at major hospitals within key provinces. Over 100 ReCell procedures have been performed to date by Chinese surgeons for indications spanning burns, scar revision, dyspigmentation, aesthetic procedures and Vitiligo at leading Chinese hospitals. Data obtained in these evaluation studies will be used in to obtain endorsement by senior hospital administrators and support the submission of pricing applications in the respective provinces.

We are committed to increasing our sales and marketing efforts. The Company will continue to expand its presence in Europe and will be increasing its direct sales force in the core markets, participating in regional and international congresses, sponsoring targeted clinical marketing studies and supporting our direct sales representatives and distributors in advertising and marketing.



Panelists at the Skin Regeneration Symposium in Rome, Italy discuss a paediatric burn case. Panelists (left to right): Mr. Bruce Philp, Broomfield Hospital, UK; Mrs Joanne Atkins, Chelsea and Westminster Hospital, UK; Mr Jeremy Rawlins, Pinderfields Hospital, UK; Prof Fiona Wood, Royal Perth Hospital, Australia; Dr Rajiv Sood, Wishard Memorial Hospital, USA.

## Regulatory Affairs/Clinical Trials

### Key Points:

- **Approximately 75% of US FDA Burn Trial subjects recruited**
- **Commenced US Department of Defense funded 20 patient pilot study for scar revision**
- **Results from pilot wound study extremely positive**

The US FDA burn trial is progressing with 7 investigational sites in the US actively enrolling patients; the company anticipates adding an additional Canadian site (ethics approval process underway) within the next two months. The study, partially funded by the US Department of Defense AFIRM Program (Armed Forces Institution for Regenerative Medicine), is comparing the performance of ReCell against split-thickness grafts, the current standard of care. The study requires enrolment of a minimum of 90 patients of which approximately ¾ have been enrolled to date. The protocol as required by the FDA, is complex and enrolment criterion strict, hence enrolment has been slower than hoped; we are confident recruitment will accelerate in the coming months. US FDA regulations prohibit release of results until the completion of the study; however, participating surgeons have been enthusiastic about the results to date.

Avita has commenced enrolment of an FDA pilot study for the use of ReCell in the treatment of hypertrophic dyspigmented scars: i.e., raised and/or discoloured scars, a critical first step in its efforts to gain US FDA regulatory approval for entry into the very large US cosmetic market. The study, funded by the US Department of Defense, permits the Company to treat 20 patients with pre-existing scars comparing healing rates and aesthetic enhancement achieved with ReCell against the current standard of care in scar remodelling. The Company anticipates completion of enrolment by the end of the calendar year. Data obtained from the pilot study will be used to design a larger, statistically powered pivotal clinical investigation which will be submitted to the FDA as part of the approval process for use of ReCell in the treatment of scars.

During the past several months Avita has been conducting open-label studies on the effectiveness of ReCell in the treatment of chronic ulcers including venous leg ulcers (VLU) and diabetic foot ulcers (DFU) at centres in Italy, Germany and the UK. With approximately 60 patients treated to date, the results in the treatment of persistent, hard-to-heal ulcers open for 12 weeks to 7 years and unresponsive to standard treatment have been extremely encouraging. During the next quarter the company will be commencing a multi-centre randomised control study comparing ReCell to the current standard of care for the treatment of VLUs and DFUs. Lower limb ulcers are a major healthcare burden, afflicting roughly 1.5% of the general population and greater than 3% of the population over 70 years of age in OECD countries. Management believes the chronic wound market represents a very large and significant opportunity for Avita.

Additionally, Avita is conducting several small-scale in-market studies on a variety of indications, including treatment of burns, acne scarring, scar revision, vitiligo and rejuvenation procedures (e.g., wrinkle removal), representing a subset of potential applications for ReCell, at leading centres throughout Europe. Results of these studies will be presented at scientific medical conferences and published in peer-reviewed medical journals. As an example of the success of these efforts, 7 papers on the use of ReCell in the treatment of burn patients have been accepted for presentation at the upcoming International Society for Burn Injuries (ISBI) congress to be held in Scotland this September 2012.



## Outlook

### Key Points:

- **Avita is making excellent progress and achieving key objectives across the business**
- **ReCell markets, acceptance and uptake are expanding**
- **Well positioned to become a leader in regenerative medicine**

Avita Medical continues to make excellent progress in all aspects of its business, successfully achieving key targets and goals set out in the Company's strategic plan. ReCell is increasingly being adopted by surgeons across a range of clinical indications and is becoming integral to the treatment of acute and chronic wounds, plastic and reconstructive surgeries and a variety of aesthetics procedures. The healing capacity of ReCell's unique activated

autologous cell suspension is changing clinician's thinking about wound care and scar management and is creating new opportunities for the treatment of dermal defects.

Avita is entering into a new phase in the company's evolution. We are expanding our geographic reach, addressing new fields of use for our flagship ReCell product and advancing the development of the next generation of regenerative products. With the increasingly positive market reception and acceptance of ReCell, we are highly optimistic about our prospects for establishing Avita as a market leader in the emerging field of regenerative medicine.

Despite current global economic conditions and uncertainties - creating an environment in which governments, hospitals and clinicians have become increasingly conservative in their adoption of highly innovative and disruptive new technologies such as ReCell - Avita has achieved another year of record growth.

Management has again set ambitious targets for the upcoming year. We are confident that we will meet and exceed those goals and that the fiscal year 2013 will be another year of major growth for the Company.

On behalf of the Avita Medical Board of Directors I thank our shareholders and employees for your loyalty, support and dedication. I am honoured to have you with us in this fascinating and exciting endeavour and look forward to providing updates on the progress of Avita in the coming months.

Please feel free to contact me with any questions or for additional information.

Yours faithfully



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