

# **Avita Medical Quarterly Activities Report**

June Quarter 2014

Avita Medical Limited ("Avita" or "the Company") is pleased to provide a business update to accompany the attached Appendix 4C Quarterly Cash Flow report for the period ended 30 June 2014.

#### **HIGHLIGHTS**

- Incoming Chairman commences role 1 July 2014
- Sales & marketing resources restructured to drive strategy
- Repositioning strategy of indication-specific product portfolio
- Positive trial results in two different pigmentation trials
- Reinvestment in respiratory product line
- R&D tax refund of approx. \$1.4 million expected by 31 December 2014
- Cost management provides improved cashflow result
- Annual ReCell revenues increased by 5% compared to last year
- Total revenues including other income for the year at A\$3.3 million
- Cash balance at 30 June 2014 at A\$3.6 million

### **OVERVIEW**

Avita Medical Ltd ("Avita" or "the Company") is a global medical technology company that develops and distributes highly innovative products in Regenerative and Respiratory Medicine.

For the quarter ending 30 June 2014, Avita Medical focussed on progressing the receipt of additional regulatory approvals and commercial uptake of its flagship ReCell® Spray-On Skin® technology, directing most of its efforts to the larger commercial opportunities of chronic wounds and aesthetic segments, while also working intently to regain momentum in the smaller burns segment.

Post quarter, a decision has been made by the company to increase investment in the company's respiratory product line, to enhance cashflow as it builds ReCell clinical and commercial acceptance and sales.

A strong focus on cost management and budgetary discipline enabled Avita Medical to record a 26% improvement in net operating cash outflow over the previous quarter, despite the anticipated reduction in revenues associated with reduced sales of the Company's ReCell and respiratory products.

As forecasted, sales were impacted by last quarter's strategic revamping of the company's UK ReCell sales team and marketing activities that continued into the quarter, as well as limited investment in respiratory product sales.

Avita Medical expects the changes to the Company's ReCell marketing strategy and team, and renewed investment in respiratory product marketing, will begin to translate into increased revenues towards the end of the September quarter as marketing activities are converted into product sales.

Avita Medical's regenerative and tissue-engineered products provide revolutionary solutions utilising the patient's own skin and the regenerative capability of the human body to treat a wide range of wounds, scars and skin defects. ReCell® Spray-On Skin® is a stand-alone, rapid cell harvesting device that enables surgeons to treat these skin defects using the patient's own cells.

Additionally, the company commercialises innovative medical technologies for improved medication delivery and adherence in patients suffering from chronic respiratory diseases. Key respiratory products include Breath-A-Tech®, the leading spacer for adolescents and adults in Australia, and the Funhaler®, an incentive asthma spacer designed specifically for the paediatric market.



The Company's marketing plan is now targeting two particular large commercial segments of unmet need, and therefore sales opportunities, in chronic lower limb wounds (venous leg ulcers and diabetic foot ulcers) and aesthetics (including repigmentation).

The company is also very pleased to report that AusIndustry has certified the successful application of overseas finding under the R&D Tax Incentive and Avita expects to receive an R&D tax refund of approximately \$1.4 million prior to 31 December 2014.

#### **FINANCE AND SALES**

Strong fiscal management helped Avita Medical to reduce losses due to net operating cash flows in the June quarter to \$1.31 million, a 26% improvement compared to the March 2014 quarter.

The focus on fiscal management is expected to provide ongoing financial benefits for the company.

Total revenue for the quarter was \$678k, a 19% decrease compared to the same quarter ending 30 June 2013, caused by a 13% drop in respiratory sales and 33% anticipated drop in sales of ReCell® Spray-On Skin® compared to last quarter due primarily to the strategic reorganisation of the UK sales and marketing structure.

Cash receipts from customers for the quarter were \$708k, up 30% from last quarter due to the seasonality in the respiratory product line.

The company ended the June quarter with a cash balance of \$3.6 million. As reported earlier, the company expects to receive an R&D tax refund of approximately \$1.4 million prior to the end of the calendar year.

### ReCell

Despite the short-term disruption of revenue associated with the EU sales & marketing restructuring that impacted fourth quarter sales, annual revenues from ReCell® Spray-On Skin® for the financial year ended June 30 were 5% higher than the previous financial year. At the end of the March 2014 quarter, year to date revenues were 38% higher than prior corresponding period, however due to the previously advised restructuring of the sales & marketing team and ongoing financial issues at the UK National Health Service, ReCell revenues for the June 2014 quarter slipped by 33% compared to the June 2013 quarter (total \$0.22 million). The Avita board and management are confident the short term impact created by the major overhaul of the marketing strategy and team will yield outstanding long term benefits for the Company.

ReCell kits were sold by Avita to the following markets during the 2014 fiscal year: United Kingdom, France, Germany, Italy, Turkey, Australia, New Zealand, China, Malaysia, and Singapore.

### **Respiratory products**

Total financial year revenue from the Company's respiratory product line (Breath-A-Tech and Funhaler) was 8% below last year.

After careful evaluation of the strategic options available to the company, management has decided that shareholders' interests are best served by reinvigorating the company's respiratory product line with renewed focus and investment. The company is now actively engaging new resources and initiatives to build upon its market leadership after a protracted period of reduced investment.

The cash flows provided by this product line have always been a very robust asset to the company and management is confident that the increased cash flows provided by refocusing on the respiratory line



will provide a material return on the additional investment required and ultimately generate enhanced returns to shareholders.

#### **MARKETING**

Significant effort was invested during the quarter in the continued restructuring of UK sales and marketing team and to begin implementing the new marketing strategy, focussing largely on chronic lower limb wounds and aesthetics (including repigmentation). Management is enthusiastic that the restructuring is now completed and that the new team has entered the market and initiated execution of the commercialization strategy.

Chronic lower limb wounds are a very large opportunity for ReCell. The cost of diabetic related disease to the UK NHS is GBP10 billion. In the UK there are half a million amputations a year which comprises 0.7% of the overall NHS spend, providing considerable sales potential for ReCell to aid recalcitrant wounds.

The marketing focus in specific clinical areas will be on market education through development of improved messaging and branding, and through development of cost analyses and health economic tools for presentations to key stakeholder groups and incorporation into their business plans in support of the use of ReCell. Together with development of complementary partnership initiatives with companies possessing relevant, existing sales channels, the net result is anticipated to be the generation of sustainable, recurring sales.

Also as a key component of the marketing strategy and the associated market research, the company progressed a significant amount of project work during the quarter towards reconfiguring the regenerative product portfolio. The ReCell technology will be further developed into three brand identities and configurations, to specifically address the varied requirements and opportunities found across the Chronic Wounds, Aesthetics, and Burns indications.

This effort differentiates the product for more focused indication-specific marketing and to facilitate separate potential partnering opportunities. Management looks forward to sharing further announcements and details as this program progresses and rolls out to the various markets.

#### **CLINICAL TRIALS**

Avita places the upmost importance and value on its clinical programs. The clinical data procured validates the technology and supports the ongoing marketing and commercial development. This ultimately leads to reimbursement and to increased awareness and uptake by clinicians.

#### **Chronic Wounds**

Avita is advancing clinical trials to continue the development of chronic wounds treatment using ReCell. The chronic wound market is estimated to be four times larger than the burns market opportunity Avita Medical initially concentrated on.

The addition of Cardiff University Hospital of Wales and Bradford Royal Infirmary to Avita's multi-centre randomized control trial of ReCell for the treatment of venous leg ulcers has had an immediate, positive impact on trial enrolments.

The number of enrolments passed the one-third mark of the 65 targeted enrolments during the quarter, with 28 enrolments now currently approved. The Company remains on track to achieve its previously stated enrolment completion target during the first quarter of CY2015.



### Plastics/Aesthetics/Dyspigmentation

The use of ReCell in the treatment of aesthetics has significant potential. The market is attractive given its size, growth and potential earnings.

In some of Avita's largest target markets, the company estimates more than 22 million aesthetics procedures are performed. The company will tap into this market by proving superior clinical results and ease of use compared to more invasive and less effective treatments.

Significant clinical progress was achieved in the quarter to demonstrate the effectiveness of ReCell in the aesthetics area.

A clinical study in Germany found ReCell provided clinically superior results for the treatment of hypopigmented scars. The ongoing study by German-based Associate Professor Dr Matthias Aust found that areas treated with ReCell combined with a scar treatment technique called medical needling showed statistically significant repigmentation, while the areas treated by medical needling without ReCell, did not.

The preliminary results were presented at the VDAEPC (Association of German Aesthetic Plastic Surgeons), where the presentation was awarded the conference's "Best of Europe" prize and as a result has been selected to be delivered as a German keynote lecture at the European Association of Societies of Aesthetic Plastic Surgery (EASAPS) in November 2014. Dr Aust also presented various aspects of his research at the UK Facial Aesthetic Conference and Exhibition (FACE) in June and is scheduled to present at the 7<sup>th</sup> World Congress on Pediatric Burns in September.

In a second, separate trial, ReCell was used successfully in place of costly permanent laboratory facilities, which require special licensure, in the treatment of patients with vitiligo or piebaldism. The study involved 10 patients who participated in a randomised, within-subject controlled pilot trial facilitated by the Netherlands Institute for Pigment Disorders.

#### **Burns**

Following Avita's successful application for approval from the United States Food and Drug Administration (USFDA) for an Investigational Device Exemption for the compassionate use of ReCell (where one patient has already been enrolled), Avita is currently in discussions with the USFDA to modify the US burns program. Avita is encouraged by recent progress in the continuing effort to resolve an ongoing issue with the strict criteria for patient participation which is impacting recruitment for the burns trial.

#### REIMBURSEMENT

Part of Avita Medical's marketing strategy is to secure reimbursement listing to improve the commercial attractiveness of ReCell for clinicians. Obtaining reimbursement is difficult in a cost-constrained international healthcare environment, however the benefits to Avita Medical, if successful, are considerable.

In the UK, a second National Institute for Health and Care Excellence (NICE) Medical Technologies Advisory Committee meeting planned for July was unexpectedly postponed. NICE notified the company that the meeting needed to be cancelled as the Committee would not be quorate due to unforeseen absences amongst the Committee members.

No date has been set for the rescheduled meeting, delaying Avita Medical's previously anticipated final guidance timeframe of September 2014.



#### **CORPORATE**

Lou Panaccio commenced as Chairman on July 1, 2014, replacing Ian Macpherson who fulfilled the role in an interim capacity since November 2013. Mr Macpherson remains on the Board in the role of Non-Executive Director.

Mr Panaccio, who also serves as a Non-Executive Director of ASX50 Company Sonic Healthcare Limited and Executive Chairman of Genera Biosystems Ltd., was appointed in May 2014 after an extensive search for a permanent Chairman.

Also on July 1, Non-Executive Director Dalton Gooding retired from the Company's board after providing 12 years of service.

Timothy Rooney is continuing in the role of Interim Chief Executive Officer, having successfully managed the Company for the six months post his initial appointment.

"As a management team we are proud of the work and progress that we have achieved this past quarter. The team has significantly reset the foundational work previously established and advanced Avita towards an exciting transition en route to the successful commercialisation of the ReCell technology. Simultaneously we are pleased to have advanced the work required to significantly progress our clinical programs and also establish a clear pathway towards growth of our respiratory product line," Mr Rooney said.

#### **ABOUT AVITA MEDICAL LIMITED**

Avita (<a href="http://www.avitamedical.com/">http://www.avitamedical.com/</a>) develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary non-cultured tissue collection and application technology provides innovative treatment solutions derived from a patient's own skin.

The Company's lead product, ReCell® Spray-On Skin®, 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 SFDA-cleared in China. ReCell is not available for sale in the United States; in the U.S. ReCell is an investigational device limited by federal law to investigational use. A Phase III FDA trial is in process.

Rule 4.7B

# **Appendix 4C**

# Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Avita Medical Limited

ABN
Quarter ended ("current quarter")
28 058 466 523

Quarter ended ("current quarter")

# Consolidated statement of cash flows

Cash	flows related to operating activities	Current quarter A\$000's	Year to date A\$000's
1.1	Receipts from customers	708	2,932
1.2	Royalties and other income	58	445
1.3	Interest and other items of a similar nature received	23	186
1.4	Payments for  (a) administration (b) marketing & sales (c) research & clinical (d) operations (e) corporate	(433) (534) (378) (344) (410)	(1,506) (2,919) (2,670) (1,397) (2,098)
1.5	Dividends received	-	-
1.6	Interest and other costs of finance paid	-	-
1.7	Income taxes (paid)/received	-	129
	Net operating cash flows	(1,310)	(6,898)

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<sup>+</sup> See chapter 19 for defined terms.

		Current quarter A\$000's	Year to date A\$000's
1.8	Net operating cash flows (carried forward)	(1,310)	(6,898)
	Cash flows related to investing activities		
1.9	Payment for acquisition of:		
	<ul><li>(a) Net cash acquired on acquisition (item 5)</li><li>(b) equity investments</li></ul>	-	-
	(c) intellectual property	-	- -
	(d) physical non-current assets	(20)	(76)
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	<ul><li>(d) physical non-current assets</li><li>(e) other non-current assets</li></ul>	-	5
	(c) other non-current assets	-	_
1.11	Loans to other entities	-	-
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)	-	
	Net investing cash flows	(20)	(71)
1.14	Total operating and investing cash flows	(1,330)	(6,969)
1.15	Cash flows related to financing activities Proceeds from issues of shares, options, etc.		
1.15	Proceeds from sale of forfeited shares	-	-
1.17	Other	_	_
1.18	Repayment of borrowings	-	-
1.19	Dividends paid	-	-
1.20	Share issue expenses	-	-
	Net financing cash flows	-	-
	Net increase (decrease) in cash held	(1,330)	(6,969)
1.21 1.22	Cash at beginning of quarter/year to date Exchange rate adjustments to item 1.20	4,978	10,617
1.23	Cash at end of quarter	3,648	3,648

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<sup>+</sup> See chapter 19 for defined terms.

# Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		Current quarter A\$000's	
1.24	Aggregate amount of payments to the parties included in item 1.2	89	
1.25	25 Aggregate amount of loans to the parties included in item 1.11		
1.26	Explanation necessary for an understanding of the transactions		
No	n-cash financing and investing activities		
2.1	Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows		
	Nil		
2.2 Details of outlays made by other entities to establish or increase their share the reporting entity has an interest		e in businesses in which	
	Nil		
Fir	nancing facilities available		

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

		Amount available A\$000's	Amount used A\$000's
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

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<sup>+</sup> See chapter 19 for defined terms.

### **Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter A\$000's	Previous quarter A\$000's
4.1	Cash on hand and at bank	765	860
4.2	Deposits at call	2,883	4,118
4.3	Bank overdraft	-	-
4.4	Deposits securing guarantees	1	-
	Total: cash at end of quarter (item 1.22)	3,648	4,978

# Acquisitions and disposals of business entities

		Acquisitions (Item $1.9(a)$ )	Disposals (Item 1.10(a))
5.1	Name of entity	Nil	Nil
5.2	Place of incorporation or registration		
5.3	Consideration for acquisition or disposal		
5.4	Total net assets		
5.5	Nature of business		

# **Compliance statement**

- 1 This statement has been prepared under accounting policies, which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Gabriel Chiappini Company Secretary 29 July 2014

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<sup>+</sup> See chapter 19 for defined terms.

#### **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, AASB 1026: Statement of Cash Flows apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 itemised disclosure relating to acquisitions
  - 9.4 itemised disclosure relating to disposals
  - 12.1(a) policy for classification of cash items
  - 12.3 disclosure of restrictions on use of cash
  - 13.1 comparative information
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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<sup>+</sup> See chapter 19 for defined terms.