

## Avita Medical Quarterly Activities Report

March Quarter 2014

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### HIGHLIGHTS

- ReCell revenues improved 38% compared to the March 2013 quarter
  - Total year to date revenues at A\$2 million
  - Sales & marketing resources restructuring in UK near completion
  - FDA IDE approved for Compassionate Use of ReCell
  - ReCell with ambient-stored enzyme launched in UK and Europe
  - Cash balance at 31 March 2014 at A\$5.0 million, with no debt
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### FINANCE AND SALES

Avita Medical Limited ("Avita" or "the Company") continued to make considerable progress throughout the quarter with sales improvements in some regions. Revenues from ReCell® Spray-On Skin® are showing consistent growth compared to corresponding financial periods.

For the March 2014 quarter, ReCell revenues improved 38% compared to the March 2013 quarter and by 21% year to date compared to the nine months ending 31 March 2013. ReCell revenues also improved 30% compared to the preceding quarter ending 31 December 2013.

The twelve-month growth demonstrates the improvement in market and industry awareness of ReCell and the increasing understanding of the technology's benefits, not only in Europe but also across Australia, China and Turkey.

Avita Medical's Australian operations achieved a very strong quarter with ReCell sales up 73% compared to the March quarter 2013 and year to date sales now up 25% on last year. The vast improvement has been buoyed by an increased marketing and sales focus on Australia as an emerging, high volume customer of ReCell.

Sales in the UK were impacted by a financial deficit experienced by the United Kingdom's National Health Service (NHS) foundation trusts, the first such deficit since 2006. Avita Medical also undertook a restructure of its marketing function in the UK in the quarter, with four new staff joining the team in late April. The team restructuring, combined with the NHS purchasing slowdown, caused UK quarter sales of ReCell to fall 68% on the same quarter last year and 11% under last year's revenue for the same nine month period. NHS recovery plans for affected hospitals are now in place, and further, Avita Medical is satisfied that with a revised, targeted marketing strategy and completion of recruitment of new sales and marketing team members, sales will recover in the United Kingdom in future quarters.

In China and Turkey, Avita Medical's distributors placed repeat orders, as envisaged in the Company's December 2013 quarterly activities report.

Year to date sales in France and Germany continue to grow despite the limited sales and marketing resources applied to those markets. France revenues recovered from the previous quarter and were up 70% on the same quarter last year and are now 1% ahead of the previous year to date period, while Germany slowed 3% compared to the same quarter last year but remains 9% ahead of last year's year to date revenues.

Unit sales in the Company's Italian joint-venture have continued to be disappointing and trail last year by 57%. The business model and strategy in Italy will continue to be evaluated in the June quarter.

Revenue from Avita Medical's respiratory product line (Breath-A-Tech and Funhaler) was 6% below the same nine month period to March last year.

Total revenue for the quarter was \$635k (accrual basis), a 1% increase compared to the same quarter ending 31 March 2013.

Cash receipts from customers for the quarter were \$543k, down from last quarter due largely to the seasonality in the respiratory product line. Losses due to net operating cash flows for the quarter were \$1.77 million, an 8% improvement over the corresponding March 2013 quarter. The cash balance at 31 March 2014 was A\$5.0 million with no debt.

## **REIMBURSEMENT**

In the UK, the National Institute For Health And Care Excellence (NICE) issued a medical technology consultation document stating that the ReCell® Spray-On Skin® system is a "promising technology with potential to improve healing in acute burns, especially for patients with burns that need skin grafting" but requires further evidence to support the case for its routine adoption in the NHS. NICE has provisionally recommended that further research be submitted as evidence.

NICE's role is to improve outcomes for people using the NHS and other public health and social care services in the UK.

The ReCell consultation document is not NICE's final guidance on the ReCell® Spray-On Skin® system as it is seeking further comments from the public and the company by 19 May 2014. Avita will be submitting further evidence to address the guidance issued by NICE. A second NICE Medical Technologies Advisory Committee meeting will be held on 17 July 2014 to consider the additional information and final guidance from NICE is anticipated in September 2014.

## **CLINICAL TRIALS**

### **Chronic Wounds**

Cardiff University Hospital of Wales and Bradford Royal Infirmary, both in the UK, have joined Avita's multi-centre randomised control trial of ReCell for the treatment of venous leg ulcers, bringing the total number of participating sites to five. Enrolment is anticipated to be completed during the first quarter of 2015. Additional sites are also being prepared for participation as a contingency.

### **Plastics/Aesthetics/Dyspigmentation**

An abstract submitted by Dr. Matthias Aust on the use of ReCell in the treatment of hypopigmented scars has been accepted by the 14<sup>th</sup> Spring Academy of the Association of the German Aesthetic Plastic Surgeons (Vereinigung der Deutschen Ästhetisch-Plastischen Chirurgen, VDÄPC 2014). The presentation, on 10 May in Frankfurt, will highlight interim results from an ongoing pilot controlled study.

### **Burns**

Avita Medical is pleased to have gained approval from the United States Food and Drug Administration of an Investigational Device Exemption (IDE) for compassionate use of ReCell. The approval allows Avita Medical to clinically evaluate ReCell in up to 12 patients who have insufficient healthy skin to harvest for the skin grafts needed to conventionally treat their life-threatening wounds from burn, trauma, or congenital skin defects. The cases in this IDE will be exemplary demonstrations of ReCell treatment for larger and more serious defects than currently being studied in the United States. This clinical work also supports the company's effort toward re-direction of the positioning of ReCell in burns to benefit patients through reduction in the requirement for skin grafting.

### **MARKETING**

Following the appointment of EU Sales and Marketing Director Lesley Whitlock earlier this year, a complete restructure of the team has been undertaken and four new members have been recruited and are officially joining Avita Medical in the last week of April. A recruitment program is also underway in Australia to expand the commercialisation and marketing effort outside of Western Australia. With the addition of these new sales and marketing resources during the June quarter, the sales and marketing team will be focused on delivering the sales tactical plan and marketing strategy, building customer relations and achieving sales momentum.

Essential to marketing the ReCell technology is the importance of providing a highly integrative product. To meet end-users needs, Avita Medical has developed a new version of ReCell for the United Kingdom and Europe market that no longer requires refrigeration. This greatly improves the commercial and practical benefits to clinicians.

The new version of ReCell has been approved for use and is now available in the United Kingdom and Europe. Avita Medical is also submitting an application to the Therapeutic Goods Administration (TGA) in Australia for use of the new version of ReCell in Australia. The timeframe required for regulatory review and approval will be advised.

### **CORPORATE**

A shortlist of candidates for the position of Avita Medical Chairman has been finalised. The Company will make an announcement once the selection process is completed and the terms of engagement have been finalised.



**ASX | News Release**  
**24 April 2014**

Proposals from three dedicated Biotech/Life Sciences executive recruitment companies have been received to conduct a recruitment process for a permanent CEO. A formal process to review external and internal candidates will now commence. The process will be managed by the Nominations committee with input from the new Chair on his/her formal appointment.

#### **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® 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.

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#### **FOR FURTHER INFORMATION:**

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# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

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

Name of entity
Avita Medical Limited

ABN
28 058 466 523

Quarter ended ("current quarter")
31 March 2014

### 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	543	2,224
1.2 Royalties and other income	92	387
1.3 Interest and other items of a similar nature received	35	163
1.4 Payments for (a) administration	(295)	(1,073)
(b) marketing & sales	(795)	(2,385)
(c) research & clinical	(325)	(2,293)
(d) operations	(429)	(1,053)
(e) corporate	(596)	(1,688)
1.5 Dividends received	-	-
1.6 Interest and other costs of finance paid	-	-
1.7 Income taxes (paid)/received	-	129
<b>Net operating cash flows</b>	<b>(1,770)</b>	<b>(5,589)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter A\$000's	Year to date A\$000's
1.8 Net operating cash flows (carried forward)	(1,770)	(5,589)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) Net cash acquired on acquisition( item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	(12)	(55)
(e) other non-current assets	-	-
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	5
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	(12)	(50)
<b>1.14 Total operating and investing cash flows</b>	(1,782)	(5,639)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	-	-
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Other	-	-
1.18 Repayment of borrowings	-	-
1.19 Dividends paid	-	-
1.20 Share issue expenses	-	-
<b>Net financing cash flows</b>	-	-
<b>Net increase (decrease) in cash held</b>	(1,782)	(5,639)
1.21 Cash at beginning of quarter/year to date	6,760	10,617
1.22 Exchange rate adjustments to item 1.20	-	-
<b>1.23 Cash at end of quarter</b>	<b>4,978</b>	<b>4,978</b>

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+ 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	77
1.25	Aggregate amount of loans to the parties included in item 1.11	-

1.26 Explanation necessary for an understanding of the transactions

**Non-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 in businesses in which the reporting entity has an interest

Nil

**Financing 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	-	-

+ 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	860	895
4.2	Deposits at call	4,118	5,865
4.3	Bank overdraft	-	-
4.4	Deposits securing guarantees	-	-
<b>Total: cash at end of quarter (item 1.22)</b>		<b>4,978</b>	<b>6,760</b>

## Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	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  
24 April 2014



## 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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