

## AVITA MEDICAL DECEMBER 2013 QUARTERLY ACTIVITIES

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### HIGHLIGHTS

- ReCell revenues increased by 35% compared to December 2012 quarter
  - Total sales revenues for the half-year at A\$1.37 million
  - Sales & marketing resources restructured to drive sales and revenue
  - Positive progress in clinical, sales and reimbursement in China
  - Cash balance at 31 December 2013 at A\$6.8 million, with no debt
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### FINANCE AND SALES

Avita Medical Limited's ("Avita" or "the Company") revenue from ReCell® Spray-On Skin® continues to show steady growth compared to previous financial periods. ReCell revenue for the December 2013 quarter increased by 35% compared to the December 2012 quarter, and by 11% for the financial year to date over the preceding first-half period ending 31 December 2012. ReCell revenue was also 12% higher than the September 2013 quarter.

The twelve month growth and continued quarter-on-quarter increase reflects the growing acceptance and market penetration of ReCell, particularly in the UK, where revenue was up 52% on the same quarter last year, and Australia, up 29% on the same quarter last year.

In terms of unit sales, year to date sales in the UK, Germany and Australia are now 34%, 17%, and 10% respectively ahead of last year's sales. This increase demonstrates Avita's enhanced focus towards growing the commercial acceptance of ReCell in its key markets.

Although the Company recognises the recent positive trend for uptake of ReCell, it expects the number of units sold in the March 2014 quarter to remain steady as the restructured marketing effort is implemented. Avita anticipates that the new initiatives will begin to be realised in sales uplift throughout the June 2014 quarter and beyond.

Unit sales in France and the Company's Italian joint venture have been disappointing, trailing last year half-on-half by 32% and 64% respectively. Avita's new sales leadership in the EU is forensically evaluating the strategies in both France and Italy to increase sales in future quarters.

Avita's Chinese market is progressing on three fronts: clinical, sales, and reimbursement. The immediate and mid-term market opportunities in China are in pigmentation and plastics. However, in parallel, the Company is laying the foundation in the burns market by developing key opinion leaders and

establishing reimbursement. The Company anticipates another stocking order from its distributor in the March 2014 quarter.

Revenue from the Company's respiratory product line (Breath-A-Tech and Funhaler) was effectively in line with the corresponding last half-year notwithstanding no further investment in the product line.

Total sales revenue for the half-year was \$1.37 million, a 1.3% increase compared to the corresponding year ending 31 December 2012.

Total cash inflows (including interest and other income) for the quarter were \$839,000. Cash receipts from customers for the quarter were \$645,000, down from last quarter due to the seasonality in the respiratory product line.

Losses due to net operating cash flows for the quarter were \$1.9 million, a 17% improvement against the corresponding December 2012 quarter due to a successful focus on reducing operating costs.

The cash balance at 31 December 2013 was \$6.8 million with no debt.

## **REIMBURSEMENT**

Reimbursement continues to be a critical focus for the Company and is integral to the commercial uptake of ReCell. Reimbursement requires data to demonstrate both clinical and cost effectiveness and relies on the endorsement and support of leading clinicians and hospitals.

UK: The National Institute for Health and Care Excellence (NICE) has accepted the Company's application for coding, published the Scoping Document for public comment, and has asked the External Assessment Centre to complete additional work. The Company anticipates a reimbursement decision in mid-2014.

Germany: Eight hospitals have submitted endorsement for reimbursement of ReCell in the treatment of burns and acute wounds, and 14 clinics have submitted for reimbursement for aesthetic and plastic procedures. The Company does not expect a decision prior to the close of the June 2014 quarter.

France: Avita is currently evaluating consultants to facilitate reimbursement efforts.

Italy: A diagnosis-related group (DRG) code is in place for burns procedures and currently working on establishing reimbursement for chronic wounds.

Turkey: An application has been submitted to the Social Security Institution (SGK) for reimbursement. ReCell has been classified with a code and included on the 'positive list'. Decision on final reimbursement is pending.

Australia: Previously, the sales focus was confined to two hospitals in Western Australia with limited resources directed towards the reimbursement effort. This has been reassessed under the new marketing strategy and the Company plans to have expanded sales and marketing reach across other regions and indications. The process from 'Initiation' to 'Listing' is extensive and Avita will be making a full reimbursement assessment and determining the most efficient pathway to generate revenue from the national growth potential.

New Zealand: Individual applications have been submitted to the New Zealand Accident Compensation Corporation (ACC). These submissions triggered the ACC to conduct a preliminary review for

reimbursement of ReCell in scar/pigmentation improvements. The ACC has now approved the use of ReCell for scar reconstruction in burns and trauma victims on a case-by-case basis.

China: A complex process involving differing requirements at the provincial and municipal levels. The Company is pleased to report that a key milestone was recently reached with price approval at the influential Peking Union Medical College Hospital (PUMCH) in Beijing which can now be used as a reference tool at other hospitals. Avita now has five hospitals that have approved purchasing submissions and seven other hospitals with submissions in preparation for review.

## **CLINICAL TRIALS**

### Chronic Wounds

Enrolment is progressing at three sites in a multi-centre, randomized European clinical trial evaluating the use of ReCell in the management of patients with venous leg ulcers. An additional two sites are planned during the March 2014 quarter to support targeted recruitment.

### Dyspigmentation

Participant follow-up in the Netherlands vitiligo study is complete, with manuscript submission for publication planned for the March 2014 quarter.

The US feasibility study of dyspigmented scar has concluded, and results are being analysed. Successful pilot outcomes in the Netherlands repigmentation study support the use of ReCell for turn-key live melanocyte transfer, without the need for special cell laboratory facilities. The feasibility of conducting a US confirmatory pivotal trial is being assessed.

### Burns

A Phase III (pivotal) United States Food and Drug Administration (FDA) study on the use of ReCell in the treatment of burn injuries is ongoing. While the current study has been frustratingly slow due to the complex protocol and strict inclusion criteria, recent successful compassionate use cases in the United States (FDA-approved to deviate from the current United States protocol), as well as trends in clinical use of ReCell outside the United States, point to a greater commercial opportunity for which additional United States studies are being considered.

### Aesthetics

To ensure appropriate focus and the availability of sufficient resources to deliver the desired results in burns, dyspigmentation and chronic wounds, a plan is being evaluated to focus on areas of the aesthetics market where ReCell uniquely offers re-pigmentation.

## **RESEARCH & DEVELOPMENT**

R&D expenditure was targeted toward short-term, incremental ReCell improvements to aid integration into clinical practice and increased market adoption. Two changes released last quarter reduce the number of steps required of clinicians, helping to increase product desirability. The focus on short-term, incremental improvements is planned to continue in an effort to improve uptake by incorporating features that ease integration into clinical practice and present a more compelling value proposition.

## **MARKETING**

During January 2014, Avita has moved to expand sales and marketing resources to drive its strategy. Australia is a market that the Company is seeking to increase its marketing efforts. To support this, the Company is developing an initiative to build ReCell in larger market opportunities outside of burns.

Avita's marketing and clinical plans have been assessed and restructuring has begun in areas nominated for improvement. Avita is confident that the appointment of a Sales & Marketing Director in UK/Europe and post implementation of the restructured sales & marketing strategy that we would expect to see accelerated sales results to flow into the June 2014 quarter.

As part of its revamped marketing strategy, Avita is repositioning ReCell in the market to utilise the brand's reputation, but shift away from general positioning towards a targeted, indication-specific positioning strategy. As a technology, ReCell has successfully appealed to a group of innovative, thought-leading clinicians. The market expansion effort the Company is now undertaking moves ReCell beyond the innovators to pursue the broader market of early adopters by leveraging key traits of the product best aligned with mainstream clinical practice. The product position is being redeveloped to make clear to prospective customers that adoption of ReCell in specific clinical cases will drive excellence in both patient outcomes and clinic revenues.

Resources are being directed toward careful and targeted market assessment to test the components of the new product positioning framework, so that decisions about ongoing clinical and product development can be made based on current data.

## **CORPORATE**

Managing Director & CEO Dr William Dolphin stepped down from his role and was replaced in an interim capacity by current Chief Operating Officer & Chief Financial Officer, Mr Timothy Rooney, until 30 June 2014. An internal and external search will be initiated to identify a permanent CEO prior to 30 June 2014.

At the Company's Annual General Meeting in Perth on Friday 22 November 2013, Mr Dalton Gooding, announced his intention to resign as Chairman of the Company after more than 10 years' service. The Board elected Mr Ian Macpherson as its interim Chairman and an executive recruitment firm has been engaged to identify a suitable candidate to be appointed as new Chairman.

## **ABOUT AVITA MEDICAL LTD**

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:**

**Contact:**

Avita Medical Ltd.

Ian Macpherson

Chairman

Phone: +61 (0) 8 9474 7738

Email: [imacpherson@avitamedical.com](mailto:imacpherson@avitamedical.com)

Avita Medical Ltd.

Tim Rooney

Chief Executive Officer/Chief Financial Officer

Phone: + 1 (818) 827-1695

Email: [trooney@avitamedical.com](mailto:trooney@avitamedical.com)

# 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	Quarter ended ("current quarter")
28 058 466 523	31 December 2013

### Consolidated statement of cash flows

	Current quarter A\$000's	Year to date A\$000's
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	645	1,681
1.2 Royalties and other income	139	295
1.3 Interest and other items of a similar nature received	55	128
1.4 Payments for		
(a) administration	(487)	(778)
(b) marketing & sales	(630)	(1,591)
(c) research & clinical	(758)	(1,967)
(d) operations	(295)	(624)
(e) corporate	(597)	(1,092)
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>(1,928)</b>	<b>(3,819)</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)	<b>(1,928)</b>	<b>(3,819)</b>
<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	(8)	(43)
(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	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>	<b>(3)</b>	<b>(38)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(1,931)</b>	<b>(3,857)</b>
<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>-</b>	<b>-</b>
<b>Net increase (decrease) in cash held</b>	<b>(1,931)</b>	<b>(3,857)</b>
1.21 Cash at beginning of quarter/year to date	8,691	10,617
1.22 Exchange rate adjustments to item 1.20	-	-
<b>1.23 Cash at end of quarter</b>	<b>6,760</b>	<b>6,760</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	316
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.

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

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**Reconciliation of cash**

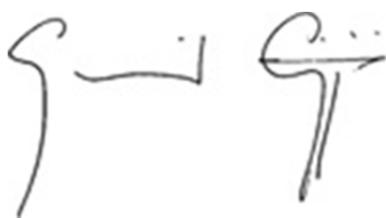
Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter A\$000's	Previous quarter A\$000's
4.1 Cash on hand and at bank	895	735
4.2 Deposits at call	5,865	7,956
4.3 Bank overdraft	-	-
4.4 Deposits securing guarantees	-	-
<b>Total: cash at end of quarter (item 1.22)</b>	<b>6,760</b>	<b>8,691</b>

**Acquisitions and disposals of business entities**

	Acquisitions <i>(Item 1.9(a))</i>	Disposals <i>(Item 1.10(a))</i>
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.



***Mr Gabriel Chiappini***  
 Company Secretary

Date: 31 January 2014

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## 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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