

## Avita Medical Announces Financial Results and Provides Corporate Update for First Quarter 2016

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**Northridge, CA and Cambridge, UK, 28 October 2015** — Avita Medical Ltd. (ASX:[AVH](#)) (OTCQX:[AVMXY](#)), a regenerative medicine company specializing in the treatment of wounds and skin defects, today announced its financial results and provided a corporate update for the first fiscal quarter of 2016 which concluded on 30 September 2015.

### Q1 and Recent Business and Clinical Development Highlights

#### *Business*

- ReCell® revenues for the quarter increased 52% year-over-year
- Total sales for the quarter increased 5.1% year-over-year and 1.6% on a sequential basis
- Awarded a contract with BARDA for up to USD\$53.9M
- Received CE Mark for ReGenerCell and ReNovaCell
- Entered into a research partnership with University of Huddersfield
- Received patent validation in 11 European Countries
- Secured AUD\$10 million in equity financing to support ongoing commercialization efforts and operational expenses

#### *Clinical*

- Achieved significant clinical trial progress for FDA U.S. Pivotal Trial for acute burn, enrolling 24 of the 30 targeted subjects
- Remain on track for results of Venous Leg Ulcer randomized controlled pilot trial in Q4 CY2015
- Publication of results from a series of cases using ReCell® showing clinically significant improvements in aesthetic outcomes in the *Journal of Cranio-Maxillo-Facial Surgery*
- First patient treated in investigator-initiated trauma wound trial at Walter Reed National Military Medical Center
- FDA-approval of expanded Compassionate Use Investigational Device Exemption (IDE) program for ReCell® to continue clinical evaluation on twice as many patients as originally permitted
- Presentation of three academic papers at the 16<sup>th</sup> European Burns Association Congress that further demonstrate ReCell®'s effectiveness

During the first fiscal quarter of 2016, Avita continued to increase sales, enhance its financial strength, and position the company for growth across global markets. Total group sales in the quarter were 5.1% higher than the same quarter last year. In particular, Avita achieved revenue growth of 52% for its ReCell® segment during the first quarter compared to the previous year, with strong showings in Germany and China, and new market expansion into Taiwan.

Importantly, Avita was recently awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA), a unit of the United States government responsible for federal disaster preparedness. This contract is worth up to USD\$53.9 million and further validates the Company's point-of-care technology to regenerate healthy skin damaged from burns and the importance of preparedness for mass casualty scenarios involving burn injuries. This is a five-year contract that includes procurement of ReCell® devices while also providing capital to support Avita's ongoing clinical efforts in the U.S. as it works toward FDA approval for commercialization.

In October, Avita closed an AUD\$10 million capital raise to support its ongoing growth efforts. This includes funds for operational expenses as well as providing support for the Company's execution of its large scale contract with BARDA. Funds from this financing will provide sufficient capital for the company for at least the next twelve months.

In addition, the Company announced publication of four academic papers in leading medical journals that further demonstrate ReCell®'s clinical effectiveness for triggering healing in burns, and helping with scar revision and repigmentation. Three of these papers were recently presented to peers in the wound-care space at the 16<sup>th</sup> European Burns Association Congress, of which the Congress proceedings appeared in a September supplement to the *Annals of Burns and Fire Disasters*. A report published in the *Journal of Cranio-Maxillo-Facial Surgery* represents one of the many real-world aesthetic applications of Avita's unique ReCell® technology. Results demonstrated that a secondary procedure including RES™ produced by ReCell® improved the pigment, volume, texture and elasticity of free flaps in the facial region in patients with repaired complex facial defects resulting from surgical removal of non-melanocytic skin cancers.

Regarding the FDA U.S. Pivotal Trial for acute burns, Avita has achieved significant clinical trial progress by enrolling 24 of the 30 targeted subjects and is on track to complete recruitment by the end of 2015.

Also on the clinical front, Avita recently announced commencement of enrolment at Walter Reed National Medical Center of an investigator-initiated trial to evaluate how ReCell® can be used to treat trauma wounds suffered by civilians and wounded military personnel. Avita will play an advisory supporting role in the study, which is funded through a US Department of Defense research program. Given that physicians are often limited in choice of donor sites for skin grafts when treating injuries associated with severe trauma, Avita believes there is a tangible need for an acceptable alternative to conventional skin autografting.

Adam Kelliher, Chief Executive Officer of Avita Medical, commented, "We entered the fiscal year with a renewed vigor led by a focused and dedicated management team with strong industry knowledge and a long-term vision for the Company. We are making tremendous strides to move the Company forward and bring our innovative, regenerative skin therapy to markets, and more importantly patients, that can truly benefit from our product. Through the increased sales over the last quarter, we believe that physician end-users are starting to recognize the true benefit that our technology can bring to patients in healing patients quickly with an aesthetic likeness to their natural skin. We look forward to continuing the momentum generated over this quarter and continuing to expand access to our ReCell® portfolio of products for the treatment of wounds, burns and skin defects."

#### **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 US trial is underway, with patient enrollment completion anticipated by the end of 2015. To learn more, visit [www.avitamedical.com](http://www.avitamedical.com).

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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	Quarter ended ("current quarter")
28 058 466 523	30 Sep 2015

### 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	1,028	1,028
1.2 Royalties and other income	-	-
1.3 Interest and other items of a similar nature received	5	5
1.4 Payments for		
(a) administration	(414)	(414)
(b) marketing & sales	(845)	(845)
(c) research & clinical	(778)	(778)
(d) operations	(523)	(523)
(e) corporate	(683)	(683)
1.5 Dividends received	-	-
1.6 Interest and other costs of finance paid	-	-
1.7 Income taxes (paid)/received	-	-
<b>Net operating cash flows</b>	<b>(2,210)</b>	<b>(2,210)</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>(2,210)</b>	<b>(2,210)</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	(3)	(3)
(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	-	-
(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>(3)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(2,213)</b>	<b>(2,213)</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	(123)	(123)
<b>Net financing cash flows</b>	<b>(123)</b>	<b>(123)</b>
<b>Net increase (decrease) in cash held</b>	<b>(2,336)</b>	<b>(2,336)</b>
1.21 Cash at beginning of quarter/year to date	2,967	2,967
1.22 Exchange rate adjustments to item 1.20	-	-
<b>1.23 Cash at end of quarter</b>	<b>631</b>	<b>631</b>

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**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	81
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	613	248
4.2 Deposits at call	18	2,719
4.3 Bank overdraft	-	-
4.4 Deposits securing guarantees	-	-
<b>Total: cash at end of quarter (item 1.22)</b>	<b>631</b>	<b>2,967</b>

**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.

Sign here:

Company Secretary

Date: 15 October 2015

Print name: Gabriel Chiappini

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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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