

Avita Medical Provides Business Update and Announces Financial Results for First Quarter Ending 30 September 2014

Northridge, CA and Cambridge, United Kingdom, 31 October 2014 — Avita Medical Ltd. (ASX: AVH), 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 quarter which concluded on 30 September 2014.

First Quarter Highlights

- FDA grants key modification for ReCell® burn trial enabling more broad use and improved enrolment rates
- High capacity ReCell Device introduced at the 17th Congress of the International Society for Burn Injuries
- Regenerative product line expansion planned for Q2
- Total ReCell® Spray-on Skin® sales increase 25% compared to Q1 2013/14
- Total ReCell® Spray-on Skin® sales increase 57% compared to last quarter
- Spending reduced by 31% compared to Q1 2013/14
- R&D tax refund for \$1.4million expected during Q2

“I am especially pleased with progress achieved this past quarter with the commercialisation of ReCell® Spray-on Skin® in international markets, and the continued development of this platform technology for a wide range of skin defects. Clearly, a major accomplishment during the quarter was the FDA approving our request to expand the use of ReCell® broadening the eligibility criteria for participants in the acute burn trial,” commented Tim Rooney, Interim Chief Executive Officer of Avita Medical.

Business and Financial Update

This past quarter, the Company received FDA approval to modify the eligibility criteria and the modality of use of its lead product, ReCell® Spray-on Skin®, for the treatment of acute burns. The first of the two eligibility modifications granted the expansion of the study’s age range. Initially, the study limited the age range to 18-65 years, however, the FDA allowed the Company to adjust the age range to 5 years and older. This adjustment should allow the Company to forgo the time and cost of an additional paediatric trial to approve the use of ReCell in a paediatric patient population. The second eligibility modification broadens from treatment of deep partial-thickness injuries to any depth of injury for which skin grafting is necessary. The study formerly positioned treatment using ReCell alone against treatment using standard mesh grafting alone, exclusively for deep partial-thickness injuries. This approach has been modified such that the new comparison is between standard grafts with and without adjunct use of ReCell rather than as a replacement for skin grafts. The Company feels this approach provides for a softer point of entry into the clinical market, and that these study data therefore have commercial impact world-wide. Further, the FDA modification has now raised the TBSA injured to 50%, allowing treatment for patients who are in even greater need. The work is progressing as planned toward securing the necessary local ethics approvals and contracts for commencement of enrolment at the beginning of 2015. Contract Research Organization (CRO) services have been retained with Advanced Clinical, LLC (www.advancedclinical.com).

Enrolment in Avita’s pilot RCT (randomised controlled trial) in difficult-to-heal venous leg ulcer treatment continues to be on track for completion during the 1st quarter of the 2015 calendar year.

Doncaster and Bassetlaw Hospital in Doncaster (UK) have joined the study to complete our planned roster of sites.

While the U.S. trial is focused on acute burn treatment, ReCell's single-use, autologous cell harvesting technology is applicable for a wide variety of burns, plastic, reconstructive and cosmetic procedures. As the company's operational goal for the last fiscal year was to position itself for major, long-term commercial traction leveraging ReCell as its platform technology, the boost in global ReCell sales is evidence that it was the right strategic decision as the product had a 25% increase in sales compared to the same quarter last year. ReCell also enjoyed a 57% jump in sales from last quarter.

In addition to highlighting ReCell as the Company's platform technology, the respiratory product line consisting of Breath-A-Tech and Funhaler, remain integral to the business. Breath-A-Tech, a medication spacer for adults and children of all ages, and Funhaler, a small volume medication spacer that makes it easier for children to take their aerosol asthma medication, continue to serve as revenue generating assets. While respiratory sales dropped by 7% as compared to the first quarter of last year, sales increased by 11% from the last quarter. Overall sales for the quarter are on par with sales from the same quarter last year, and total sales are up 21% from last quarter.

Overall net operating cash flow was improved by 31% as compared to the first quarter last year, and 1% compared to last quarter. The cash balance at 30 September 2014 was A\$2.35 million. The Company is also expecting a A\$1.4M research and development tax refund from the Australian government within the 31 December 2014 quarter.

Additionally, Avita was pleased to participate in the prestigious International Society of Burn Injuries' (ISBI) 17th Biennial Congress held Oct 12-16 in Sydney, Australia. The Company's robust presence centered on the multiple applications of the ReCell[®] Spray-on Skin[®] system in the treatment of acute burn injuries and burn scar, and included keynote addresses, faculty panel representation, five accepted free-paper presentations, and a company booth in the exhibition hall. The introduction of a new version of ReCell designed to treat six times the area of the current version of ReCell garnered positive attention due the associated marked enhancement to the product's value proposition. The new product release is pending regulatory approvals. Participation in conferences such as ISBI, provides the Company the opportunity to continue to raise awareness around the clinical impact and commercial role ReCell can play in the burn injury space.

Regulatory filings have also been submitted for the two new members of the regenerative product family: ReGenerCell[™] for the treatment of chronic wounds; and ReNovaCell[™] for aesthetic applications. Product announcements will be forthcoming.

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 United States, 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	Quarter ended ("current quarter")
28 058 466 523	30 September 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	834	834
1.2 Royalties and other income	6	6
1.3 Interest and other items of a similar nature received	14	14
1.4 Payments for (a) administration	(295)	(295)
(b) marketing & sales	(631)	(631)
(c) research & clinical	(398)	(398)
(d) operations	(372)	(372)
(e) corporate	(526)	(526)
1.5 Dividends received	-	-
1.6 Interest and other costs of finance paid	-	-
1.7 Income taxes (paid)/received	72	72
Net operating cash flows	(1,296)	(1,296)

+ 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)	(1,296)	(1,296)
Cash flows related to investing activities		
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	(7)	(7)
(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)	-	-
Net investing cash flows	(7)	(7)
1.14 Total operating and investing cash flows	(1,303)	(1,303)
Cash flows related to financing activities		
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	-	-
Net financing cash flows	-	-
Net increase (decrease) in cash held	(1,303)	(1,303)
1.21 Cash at beginning of quarter/year to date	3,648	3,648
1.22 Exchange rate adjustments to item 1.20	-	-
1.23 Cash at end of quarter	2,345	2,345

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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	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

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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	-	-

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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	771	765
4.2 Deposits at call	1,574	2,883
4.3 Bank overdraft	-	-
4.4 Deposits securing guarantees	-	-
Total: cash at end of quarter (item 1.22)	2,345	3,648

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
31 October 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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