

## Avita Medical Announces Financial Results and Provides Corporate Update for Fourth Quarter and Fiscal Year 2015

*Fiscal Fourth Quarter and 2015 Year-Over-Year Sales of ReCell® Increased 132% and 25%, respectively*

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**Northridge, CA and Cambridge, United Kingdom, July 29, 2015** — Avita Medical Ltd. (ASX: [AVH](#)), (OTCQX: [AVMXY](#)), a medical device company specializing in the treatment of wounds and skin defects, today announced its financial results and provided a corporate update for the fourth quarter and twelve months ended June 30, 2015.

Adam Kelliher, Avita's Chief Executive Officer, stated, "In the three months since I joined Avita, our team has made tremendous progress in the execution of our commercial growth and clinical development strategies. We further strengthened our ReCell IP portfolio in the fourth quarter, and continued to build awareness of the significant benefits of our regenerative technology platform. The success of these awareness-building efforts was reflected in our fourth quarter ReCell® sales, which increased 132% over the fourth quarter of fiscal 2014. We have a strong team in place executing a sound commercial strategy, and we believe the Company is well positioned to further penetrate our target markets, drive continued revenue growth and expand our business."

### Business and Clinical Development Highlights

- Fourth quarter total sales (for regenerative as well as legacy respiratory products) increased by 25% year-over-year and 51% versus the previous quarter
- Fourth quarter sales of ReCell® increased 132% year-over-year and 104% compared to the previous quarter
- Sales of ReCell® in strategic regions increased significantly during fiscal 2015: China +88%, Germany +81%, UK +28% and Australia/New Zealand + 13%
- Gained additional intellectual property protection with two newly issued U.S. patents that cover Avita's platform of regenerative products
- Successful results from randomized, controlled repigmentation study published in the *Journal of the American Academy of Dermatology*
- Nearly 50% of patients (14 of the targeted 30 subjects) are now enrolled in the U.S. FDA pivotal trial for acute burns
- Patients in the Venous Leg Ulcer randomized controlled pilot trial are now being followed-up, with results anticipated in the fourth quarter of CY 2015.

Avita demonstrated strong revenue growth during the fourth quarter and for the fiscal year 2015, as total revenue on a year-over-year basis increased by 25% for the quarter and approximately 3% for the full year. This was driven by strong ReCell® sales in several key strategic markets, including an increase in sales of 28% in the United Kingdom, 13% in Australia & New Zealand, 81% in Germany and 88% in China. Additionally, the Company reduced operating costs almost 2% for fiscal 2015 when compared to the previous fiscal year.

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During the quarter, Avita made significant progress in securing protection for its regenerative technology platform. Importantly, the U.S. Patent and Trademark Office (USPTO) issued a patent related to the methods of making and using a transplantable cellular suspension of living tissue suitable for grafting to a patient (patent 9,029,140; issued May 12, 2015), which is an integral part of the ReCell® technology. In addition, the USPTO issued a second patent providing broad protection of the autologous, non-cultured cell suspension prepared peri-operatively and directly applied to the patient epithelial cell suspension (patent 9,078,741; issued July 24, 2015), which covers ReCell®, ReGenerCell™, and ReNovaCell™.

The Company's proprietary regenerative technology platform was recently recognized by a peer-reviewed Journal. In July 2015, the *Journal of the American Academy of Dermatology* published results of a randomized, controlled study for ReCell®. The results demonstrated safety and efficacy in skin repigmentation for patients who have depigmented skin lesions caused by vitiligo and piebaldism. In the 30 lesion trial, lesions treated using ReCell® had 78% repigmentation versus 0% for lesions in the two control groups (CO<sub>2</sub> laser ablation and no treatment). The results were highly statistically significant (p-value =.001).

In addition, Avita provided humanitarian aid to the country of Taiwan by donating a number of free ReCell® devices and sent personnel experienced in burn treatment to provide support requested by Taiwanese authorities following a mass casualty event at a waterpark in which hundreds of people — many of them teenagers — were left seriously burned. With Avita's rapid response, the team was on hand and ready to support the medical personnel when significant skin graft operations got underway. Medical professionals used 50 donated devices, and orders have since been placed for 100 more.

Early in the fourth quarter, Avita participated, by invitation, in a key U.S. Government Symposium focused on Emergency Preparedness. Andrew Quick, Avita Medical's VP of Research and Technology, presented to influential delegates on how the ReCell® medical device could be a versatile and effective treatment for burns and skin wounds in a mass casualty event. Along with case studies in which Regenerative Epithelial Suspension™ (RES™) had reduced hospital time and delivered superior outcomes for scalds and massive burn injuries, he explained how the device can work in combination with skin grafts and other standard treatments, and that ReCell® is a simple and versatile way to deliver RES™.

Subsequently, the Biomedical Advanced Research and Development Authority, or BARDA, a U.S. federal agency assigned to ensure the United States is well prepared for public health emergencies, issued a formal public solicitation ([www.fbo.gov](http://www.fbo.gov)) indicating they are seeking to fund late-stage development and procurement of autograft-sparing products that can enhance the capacity to provide definitive care for thermal burn injuries. Last week on July 24<sup>th</sup>, the Company submitted a proposal to BARDA on how this need could potentially be met with ReCell®. BARDA utilizes a competitive bidding process and the awarding of, or timing for, a contract under this solicitation remains uncertain. If Avita were to receive an award, there are no certainties that the Company will be able to satisfy any of the conditions of such award, that the Company can begin to receive any proceeds from any such award within any specific period of time or that we can successfully negotiate a final contract resulting from the award. There may also be unexpected funding delays or the reduction and/or the elimination of BARDA funding under this solicitation. Regardless of the outcome, the Company intends to continue to pursue similar opportunities.

Most recently, an article published in the July/August 2015 issue of [Army Technology Magazine](#) reported on innovative regenerative strategies being evaluated by the Armed Forces Institute of Regenerative Medicine to heal complex wounds of military personnel injured in combat. ReCell® is one of two regenerative medicine technologies discussed within the article, in which Dr. Wendy Dean, Tissue Injury and Regenerative Medicine Program Management Office medical advisor at the U.S. Army Medical Materiel Development Activity, said, “The promise of both of these new technologies is that they could be the first substantial change in how burn and skin injuries are treated in the last half century. Sparing burn patients the pain of large donor sites, or offering surgeons a ready-made, permanent option for wound coverage could lead to a paradigm shift in skin injury treatment.” The article explained how Avita’s ReCell® device takes only 30 minutes to use a patient’s own cells to create a healing suspension, which can treat a skin wound 80 times larger than the skin sample taken, adding that “ReCell speeds the healing process, decreases the need to harvest skin from donor sites and improves the appearance of the burn scars.”

#### **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 U.S. 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 June 2015                      |

### Consolidated statement of cash flows

| Cash flows related to operating activities                | Current quarter<br>A\$000's | Year to date<br>A\$000's |
|---|-----------------------------|--------------------------|
| 1.1 Receipts from customers                               | 626                         | 2,597                    |
| 1.2 Royalties and other income                            | -                           | 6                        |
| 1.3 Interest and other items of a similar nature received | 19                          | 45                       |
| 1.4 Payments for  |                             |                          |
| (a) administration  | (644)                       | (1,572)                  |
| (b) marketing & sales                                     | (849)                       | (2,866)                  |
| (c) research & clinical                                   | (817)                       | (2,331)                  |
| (d) operations  | (467)                       | (1,509)                  |
| (e) corporate   | (224)                       | (2,132)                  |
| 1.5 Dividends received                                    | -                           | -                        |
| 1.6 Interest and other costs of finance paid              | -                           | -                        |
| 1.7 Income taxes (paid)/received                          | -                           | 1,517                    |
| <b>Net operating cash flows</b>                           | <b>(2,356)</b>              | <b>(6,245)</b>           |

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

|  | Current quarter<br>A\$000's | Year to date<br>A\$000's |
|--|-----------------------------|--------------------------|
| 1.8 Net operating cash flows (carried forward)       | <b>(2,356)</b>              | <b>(6,245)</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                      | (13)                        | (38)                     |
| (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>(13)</b>                 | <b>(38)</b>              |
| <b>1.14 Total operating and investing cash flows</b> | <b>(2,369)</b>              | <b>(6,283)</b>           |
| <b>Cash flows related to financing activities</b>    |                             |                          |
| 1.15 Proceeds from issues of shares, options, etc.   | 1,136                       | 6,178                    |
| 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                            | (157)                       | (575)                    |
| <b>Net financing cash flows</b>                      | <b>979</b>                  | <b>5,602</b>             |
| <b>Net increase (decrease) in cash held</b>          | <b>(1,390)</b>              | <b>(681)</b>             |
| 1.21 Cash at beginning of quarter/year to date       | 4,357                       | 3,648                    |
| 1.22 Exchange rate adjustments to item 1.20          | -                           | -                        |
| 1.23 <b>Cash at end of quarter</b>                   | <b>2,967</b>                | <b>2,967</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<br>A\$000's |
|------|--|-----------------------------|
| 1.24 | Aggregate amount of payments to the parties included in item 1.2 | 84                          |
| 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<br>A\$000's | Amount used<br>A\$000's |
|-----|-----------------------------|------------------------------|-------------------------|
| 3.1 | Loan facilities             | -                            | -                       |
| 3.2 | Credit standby arrangements | -                            | -                       |

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**Quarterly report for entities**  
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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<br>A\$000's | Previous quarter<br>A\$000's |
|---|------------------------------|-----------------------------|------------------------------|
| 4.1   | Cash on hand and at bank     | 248                         | 595                          |
| 4.2   | Deposits at call             | 2,719                       | 3,762                        |
| 4.3   | Bank overdraft               | -                           | -                            |
| 4.4   | Deposits securing guarantees | -                           | -                            |
| <b>Total: cash at end of quarter (item 1.22)</b>  |                              | <b>2,967</b>                | <b>4,357</b>                 |

**Acquisitions and disposals of business entities**

|     |   | Acquisitions<br>(Item 1.9(a)) | Disposals<br>(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: 29 July 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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