Avita Medical Announces Financial Results for Fourth Quarter Fiscal 2016

Q4 Financial Highlights

- Total cash inflows of $1.1m for the quarter and $4.4m for the year
- Cash receipts from BARDA totalled $2.1m for the year
- Net operating cash outflows of $2.6m for the quarter and $10.2m for the year
- Total ReCell® revenue for the full 2016 fiscal year increased 2% over the previous year
- Device utilization increased 135%, 70%, and 44% for Germany, UK, and France, respectively
- Awarded extension deal from BARDA which provides an additional $USD7.96 million for the support of its US product launch and commercialization
- Cash of $4.17m at the end of the quarter with an additional $9m raised the first week of July

Northridge, CA, USA, Perth, Australia and Cambridge, United Kingdom, 29 July 2016 – 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 business update for the fourth quarter of fiscal 2016 which concluded on June 30, 2016.

In recent months, Avita has been very active on various fronts: financial, business operations, clinical and regulatory. The company has continued to execute its strategy by strengthening its balance sheet, expanding its leadership team, and growing its distribution network. It also progressed its clinical development program, and further engaged with the medical community for the use of its regenerative medicine technology. The sale of its respiratory business in February of this year has allowed the Company to give its complete focus to building recurrent sales of its regenerative family of devices.

Avita announced during the quarter that its BARDA contract had been increased with an extra ~US$8 million of non-dilutive financing. This takes the contract total to US$61.9 million, of which US$24.9 is fully committed by the US federal disaster preparedness agency, with the balance to be provided should various options be exercised. The extra $8 million of funds will be deployed to directly support the Company's build-out of its US operations in support of the FDA PMA submission towards approval in advance of a launch in the lucrative US market. Avita is in close contact with BARDA to fulfil the terms of their mutual contract, and the Company regards the extended funding as a strong validation of its strategy and progress in the US. The Company also raised AUD$9 million, pre costs, in a Rights Issue, which will provide further financing for its commercial objectives in the US and global markets.

The company reported total cash inflows of $1.1m for the quarter and $4.4m for the year. Net operating cash outflows reached $2.6m for the quarter and $10.2m for the full financial year, in-line with expectations. Receipts from customers for the year equalled $2.2m vs last fiscal year of $2.6m; the drop off due to the divestiture of the respiratory product line in early February, leaving nearly five months

void of revenues from the discontinued operations. The impact of this was offset by cash received from BARDA, which started coming through in Q3, and totalled $2.1m for the year. The Company reported that device utilization was on the increase in its key European markets, being up 135%, 70% and 44% in Germany, the UK and France respectively. However, as Avita has moved from a direct sales to a distributor sales model in these markets, this has entailed a reduced margin, resulting in total Regenerative revenues over the fiscal year increasing by a modest 2%.

“Increasing the usage of our devices is the fundamental first step in our commercialization programme,” said Avita CEO Adam Kelliher. “We know that once medical professionals experience the first-hand clinical and health-economic benefits from using the device, and see the transformative outcomes in their patients, they will buy recurrently. So we are putting great efforts to create this virtuous cycle. The increased device usage shows that we are on the right track and we will keep working on this steady build. “

To support this fundamental activity, Avita has made several strategic hires, including the appointment of Troy Barring to the role of COO, a position he assumed from Tim Rooney, who will now be focused solely on his role as CFO. To further improve its commercialization efforts, Avita added a new VP of sales and marketing, Ross Saunders. These two hires were specified by their prior experience in developing markets which require specialist training; this continues the trend of adding human capital that is adept at building the infrastructure required to properly launch the Company’s commercialization strategy. The addition of these two industry veterans will be valuable as the Company rolls out the strategy with an emphasis on regional deployment of educational and clinical resources to develop Centres of Excellence to drive recurrent product usage and position Avita for long-term success.

The Company has recognised that a key reason why previous sales strategies in various territories have achieved limited traction is due to the lack of in-market training and support. To achieve stronger recurrent sales, the focus now is to ensure each key market has a Preceptorship Programme, a Centre of Excellence as a reference centre for Peer to Peer support and sufficient clinical and health economic data to support reimbursement activities. In addition, we will add clinical support resources for thorough training of sales representatives, in-servicing of each new customer, and maintaining close contact with a growing group of Key Opinion Leaders. This emphasis is expected to lead to a more rapid product acceptance and building a pattern of repeat sales. This activity in the US will be directly supported by BARDA, which is funding an education strategy to ensure leading burns surgeons are adept at Avita’s approach. BARDA is also funding a premier health economics agency to investigate how Avita’s devices may save money by reducing patient’s length of stay and saving on other costs typically associated with the current standard of care.

As part of its focus on Asian markets, the Company conducted a series of conferences in China, in which experts from Europe and Australia addressed some 300 Chinese clinicians on the benefits of using ReCell® for the skin condition, Vitiligo. Avita’s distributor in China, Sinopharm, pushed ahead with its activity plan focused on Beijing, Shanghai, Guangzhou, and Xian, with the appointment of regional sub-distributors, and the commencement of clinical evaluations in leading hospitals. Avita signed on a Malaysian distributor and appointed distributors in Japan and South Korea who made progress towards regulatory approval. Distributors are allowing the Company to quickly put additional feet on the ground in the target markets, freeing the Avita team to focus its investment on building user experience and developing Key Opinion Leaders.

The Company’s clinical programme continued apace, with the enrolment of the first patient in a study of ReGenerCell™, exploring how the device may treat Diabetic Foot Ulcers (DFUs). This UK-based study takes the Company into a treatment area of massive significance, given the growing global incidence of diabetes. Elsewhere, the Company entered into the final safety observation period of its multi-centre FDA approval study for burns, now that the enrolment and treatment periods have been completed.

Once fully collated, the data will be submitted under the PMA approval pathway, and the Company reports that it is on track for approval in the second half of calendar 2017.

Avita provided supporting data for its technology in presentations at various industry conferences, and in peer-reviewed journals. At the American Burn Association's (ABA) 48th Annual Meeting, results from a UK study confirmed that ReCell® effectively reduces the occurrence of long-term scarring and itching symptoms associated with paediatric burn treatment, compared to various treatment modalities. In addition, a randomised clinical trial from Germany published in the peer-reviewed journal, *Burns*, demonstrated that the combination of medical needling with a suspension of epithelial cells provided by ReNovaCell™ can restore pigment on burn scars. At the Charing Cross Symposium in London, leading UK vascular surgeons who are experienced users of the medical device presented findings showing that early intervention with ReGenerCell™ can kick-start the closure of hard-to-heal Venous Leg Ulcers, and save public health bodies significant money. The journal *Regenerative Medicine* published a wrap-up of the various studies and data presented at the Company's Skin Regeneration Symposium, held in April in Cambridge, UK. The data showed consistent positive outcomes in the three key treatment areas of Avita's focus: burns, chronic wounds and aesthetics.

"My team have worked hard to position the company for long-term growth, and our activities over the fiscal fourth quarter demonstrate our plans are now building in momentum," Kelliher commented. "During the quarter, we further validated our technology and our clinical efforts, and it has been great to see how our approach is getting increased recognition amongst doctors in a range of markets.

"Both the recent supplemental contract with BARDA, worth USD$8 million, and the support from our shareholder base in the recent rights issue completed in Australia, which brought in AUD$9 million, put us in a strong position to push ahead with our commercialization plans," the Avita CEO said. "We would like to thank all of our supporters as we commence a new financial year."

The Company said all of its activities were aimed at delivering shareholder value, and that there were various clinical and commercial milestones to be achieved throughout the 2017 financial year that it believed would be further catalysts of value.

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 enrolment completion anticipated by the end of 2015. To learn more, visit www.avitamedical.com.

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FOR FURTHER INFORMATION

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Rule 4.7B

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 2016

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	167	2,219
1.2	Royalties and other income	927	2,070
1.3	Interest and other items of a similar nature received	22	110
1.4	Payments for (a) administration	(407)	(1,789)
	(b) marketing & sales	(926)	(3,957)
	(c) research & clinical	(815)	(3,451)
	(d) operations	(555)	(2,017)
	(e) corporate	(999)	(4,024)
1.5	Dividends received	2	2
1.6	Interest and other costs of finance paid	-	-
1.7	Income taxes (paid)/received	-	654
	Net operating cash flows	**(2,584)**	**(10,183)**

+ 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)	**(2,584)**	**(10,183)**
	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	(29)	(48)
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)	-	2,030
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
	(e) other non-current assets	-	-
1.11	Loans to other entities	(7)	(7)
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)	-	-
	Net investing cash flows	**(36)**	**1,975**
1.14	**Total operating and investing cash flows**	**(2,620)**	**(8,208)**
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	-	10,026
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	(2)	(613)
	Net financing cash flows	**(2)**	**9,413**
	Net increase (decrease) in cash held	**(2,622)**	**1,205**
1.21	Cash at beginning of quarter/year to date	6,794	2,967
1.22	Exchange rate adjustments to item 1.20	-	-
1.23	**Cash at end of quarter**	**4,172**	**4,172**

+ 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	109
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

$454k shares in Medical Developments International Limited (MVP) allotted under terms from sale of respiratory business

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	2,473	199
4.2	Deposits at call	1,699	6,595
4.3	Bank overdraft	-	-
4.4	Deposits securing guarantees	-	-
	Total: cash at end of quarter (item 1.22)	**4,172**	**6,794**

Acquisitions and disposals of business entities

		Acquisitions *(Item 1.9(a))*	Disposals *(Item 1.10(a))*
5.1	Name of entity	Nil	Assets of Visiomed Group Pty Limited Respiratory business
5.2	Place of incorporation or registration		WA Australia
5.3	Consideration for acquisition or disposal		$2.47m
5.4	Total net assets		$259k
5.5	Nature of business		Respiratory devices (asthma)

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 January 2016

Print name: Gabriel Chiappini

+ See chapter 19 for defined terms.

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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