

## Avita Medical Announces First Quarter 2018 Results

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### Recent Highlights

- *Submitted dossier to US FDA for Premarket Approval (PMA) for ReCell® for burns*
- *Executed contract option with BARDA valued at US\$24.3M, expanding trials into paediatric burns*
- *Broadened executive team in front of planned 2018 US product launch*
- *Granted US FDA approval for IDE supplement amending the Company's protocol for Continued Access*
- *New capital provides ability to focus on achieving near-term goals and objectives*

**Valencia, CA, USA, Perth, Australia and Cambridge, United Kingdom, 30 October 2017** — 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 first quarter of fiscal 2018, which concluded on 30 September 2017.

“I’m very pleased with our continued progress toward getting ReCell® into the hands of US surgeons,” said Dr. Michael Perry, Avita’s Chief Executive Officer. “With continued active support from the US Biomedical Advanced Research and Development Authority (BARDA), including the recent execution of a contract supporting two paediatric randomized trials as well as future commercial sustainability, approval of the next phase of our continued access protocol with the FDA, and of course the submission of our PMA dossier in September, we are continuing to move toward our goal of providing a clinically proven novel burn therapy to patients in the largest healthcare market in the world in 2018.”

In the first quarter, Avita submitted a Pre-Market Approval (PMA) application to the U.S. Food & Drug Administration (FDA) for its ReCell® Autologous Cell Harvesting Device for treatment of burn injuries. Management anticipates this approval in 2Q/3Q 2018.

Also in the quarter, management announced that the Company and BARDA have executed a contract option valued at approximately US\$24.3 million. This contract builds upon the company’s initial contract with BARDA from September 2015, and supports two randomized trials using ReCell® to treat paediatric burns. Recall that BARDA funded the successful US pivotal clinical trial and the contract includes other options in support of post market surveillance as well as the ability to provide the US government with up to 20,000 ReCell® devices for surge capacity.

Avita announced the appointment of Erin Liberto as Chief Commercial Officer during the quarter, in preparation for the anticipated US launch of ReCell®. Ms. Liberto last served as Vice President of Marketing at Allergan, and has led twelve successful product launches during her career.

In recent weeks, management announced two additional milestones. Firstly, the U.S. FDA approved an Investigational Device Exemption (IDE) supplement amending the Company’s protocol for Continued

Access of ReCell®, permitting participating physicians to discontinue the controlled comparison component, thereby facilitating enrolment as the Company approaches its anticipated U.S. commercial launch. Secondly, management announced a A\$16.9 million capital raise comprising of a private placement and a fully underwritten Rights Issue.

### **First Quarter 2018 Financial Results**

During the first quarter, overall receipts from customers were \$381K, an increase of 36% from Q1 2017 (\$281K) and a 9% increase over last quarter (Q4 2017).

Receipts from BARDA totalled \$1.83M in the first quarter as reimbursements were in line with the previous quarter's BARDA receipts of \$1.84M. Cumulative payments of \$10.5M (USD\$8.2M) have been received to date from BARDA under the full USD\$61.9M contract.

Total payments for operating activities in the first quarter were \$548K (11.6%) higher than the previous quarter (\$5.3M vs \$4.7M). There were reductions in spending across Admin/Corporate and Operations, and increases in Sales & Marketing, R&D, and staffing as more key personnel were added to support the build-up for US commercialisation. The staffing increase accounted for \$150K higher salaries and benefits in the quarter and \$50K in non-recurring recruitment expenses. Also, legal fees of \$125K related to Avita's capital raise were incurred during the quarter. Total net cash used in operating activities during the first quarter was \$3.1M and in-line with Company expectations.

Total cash and cash equivalents held by Avita at the end of September 2017 were \$726K. As announced on 11 October 2017, Avita is raising \$16.9M in new capital, comprised of a private placement of \$4.5M and a fully underwritten Rights Issue of \$12.4M. Avita completed the private placement portion of its capital raise and received net proceeds of \$4.28M on 16 October 2017. The Entitlement Offer closes on 2 November 2017.

### **ABOUT AVITA MEDICAL LIMITED**

Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the patients' own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.

ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, while a PMA for ReCell® is currently under review by the FDA, the product continues to be an investigational device limited by federal law to investigational use.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. ReCell® is designed for the treatment of burns and plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCell™ is tailored for aesthetic applications including the restoration of pigmentation. To learn more, visit [www.avitamedical.com](http://www.avitamedical.com).

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “intend,” “could,” “may,” “will,” “believe,” “estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “continue,” “outlook,” “guidance,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company’s control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.*

**FOR FURTHER INFORMATION:**

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

**Name of entity**

Avita Medical Limited

**ABN**

28 058 466 523

**Quarter ended ("current quarter")**

30 September 2017

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	381	381
1.1a Receipts from BARDA	1,830	1,830
1.2 Payments for		
(a) research and development	(912)	(912)
(b) product manufacturing and operating costs	(488)	(488)
(c) advertising and marketing	(583)	(583)
(d) leased assets	(141)	(141)
(e) staff costs	(2,132)	(2,132)
(f) administration and corporate costs	(1,025)	(1,025)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,069)</b>	<b>(3,069)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(21)	(21)
(b) businesses (see item 10)		
(c) investments		

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
(d) intellectual property		
(e) other non-current assets		
2.2 Proceeds from disposal of:		
(a) property, plant and equipment		
(b) businesses (see item 10)		
(c) investments		
(d) intellectual property		
(e) other non-current assets		
2.3 Cash flows from loans to other entities		
2.4 Dividends received (see note 3)		
2.5 Other (provide details if material)		
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(21)</b>	<b>(21)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares		
3.2 Proceeds from issue of convertible notes		
3.3 Proceeds from exercise of share options		
3.4 Transaction costs related to issues of shares, convertible notes or options		
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings		
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other (provide details if material)		
<b>3.10 Net cash from / (used in) financing activities</b>		

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	3,790	3,790
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,069)	(3,069)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(21)	(21)
4.4 Net cash from / (used in) financing activities (item 3.10 above)		

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held	26	26
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>726</b>	<b>726</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	726	3,790
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>726</b>	<b>3,790</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

<b>Current quarter \$A'000</b>
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(295)
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6.1 Executive Director remuneration (169k), Directors fees (96k), Clinical Advisory Board fees (10k) and Bioscience Consultancy (20k)
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**7. Payments to related entities of the entity and their associates**

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

<b>Current quarter \$A'000</b>
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8. <b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities		
8.2 Credit standby arrangements		
8.3 Other (please specify)		
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	600
9.2 Product manufacturing and operating costs	500
9.3 Advertising and marketing	500
9.4 Leased assets	150
9.5 Staff costs	1,800
9.6 Administration and corporate costs	1,000
9.7 Other (provide details if material)	
<b>9.8 Total estimated cash outflows*</b>	<b>4,550</b>

\* pertains to outflows only, inflows from customer receipts and government contracts are not included.

To augment the above cash outflow in the December 2017 quarter the company announced on 11 October 2017 that it is undertaking a capital raise of \$16.9m.

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

*Gabriel Chiappini*

**Gabriel Chiappini**  
**Company Secretary**  
**30 October 2017**

### **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 that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.