

## AVITA Medical Fourth Quarter 2018 Quarterly Cash Flow Report and Company Update

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### Recent Highlights

- *Published pivotal clinical trial results in second-degree burns in Journal of Burn Care & Research*
- *Acquired manufacturing facility to support planned U.S. launch of RECELL® Device*
- *Expanded management team to facilitate U.S. commercial launch*
- *Completed institutional placement of A\$16.0 million*
- *RECELL Device clinical results demonstrate patient benefits and cost savings in multiple conference presentations*

**Valencia, California, USA, and Melbourne, Australia, 31 July 2018** — AVITA Medical (ASX: AVH, OTCQX: AVMX), a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications, announced that it filed today with the ASX its Appendix 4C - Quarterly Cash Flow Report for the quarter ended 30 June 2018. The Company is also providing below an update on the substantial progress made during the fourth fiscal quarter including preparations for the planned launch, pending approval, of the RECELL® Device in the United States for the treatment of severe burns.

### RECELL Device Clinical Results Prominently Featured in Conference Presentations and Publication

During the quarter the extensive body of clinical results for the RECELL Device, including the data from two controlled pivotal trials, were presented at multiple major scientific conferences and were published for the first time in a peer-reviewed burn journal. Presentations of clinical results demonstrating the patient benefits and cost-effectiveness of the RECELL Device included:

- **Journal of Burn Care & Research** (June 2018): Results from a pivotal clinical trial demonstrating the benefits of the RECELL Device in the treatment of deep partial-thickness (second-degree) burns were published for the first time in a major peer-reviewed journal. In the randomized, controlled clinical trial, burn sites treated with the RECELL Device required 97.5 percent less donor skin than burn sites treated with the standard of care, resulting in a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved donor scar outcomes.
- **2nd Changhai Academic Week for Burns Treatment** (June 2018, Shanghai): Results from two U.S. pivotal clinical trials and the U.S. Compassionate Use program demonstrating the benefits of the RECELL Device were presented at this international conference.
- **International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 23rd Annual International Meeting** (May 2018, Baltimore): A health economic model was presented and demonstrated that use of the RECELL Device could reduce the cost of treatment by 44 percent or greater for patients with large burns. In addition, the budget impact component of the model

concluded that in a burn center with 200 patients, the use of the RECELL Device would reduce annual total treatment costs by USD \$13.0 million.

- **American Burn Association (ABA) 50th Annual Meeting** (April 2018, Chicago): Researchers from major burn centers throughout the U.S. made six presentations of clinical results including the two pivotal trials supporting the Company's U.S. Premarket Approval (PMA) application and a study showing cosmetic outcomes in facial burn patients.

Currently the RECELL Device is not approved for sale in the U.S. and is limited by Federal Law to investigational use.

The RECELL Device is designed to enable medical professionals to produce, at the point-of-care, a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) using a small sample of the patient's own skin. The autologous suspension contains cells necessary to regenerate epidermis and provides a new way to achieve permanent closure in burns and other wounds while reducing the amount of skin harvested at the time of surgery. Reduction in donor-site skin requirements has important benefits from both clinical and health economic perspectives. A U.S. PMA application for the treatment of burn injuries is currently under review by the U.S. Food and Drug Administration (FDA). AVITA Medical expects completion of the FDA review of the PMA during the third quarter of calendar 2018, followed by U.S. approval and market launch.

#### **Manufacturing and Commercial Preparations for Planned U.S. Launch of RECELL Device**

Effective July 1, 2018 AVITA Medical acquired a manufacturing facility to support the planned U.S. launch of the RECELL Device in the treatment of burns. The facility was previously operated by a Fortune 500 contract manufacturer that assembled the RECELL Device for AVITA Medical. The 2,200 square meter (23,000 square foot) manufacturing plant is located in Ventura, California. Manufacturing and warehouse equipment within the facility was transferred to AVITA Medical at no cost and AVITA Medical retained key employees from the contract manufacturer. As part of the takeover of the facility, AVITA Medical entered into a five-year lease agreement with three one-year options to renew.

The opportunity to acquire the facility arose due to the contract manufacturer's decision to consolidate its facilities. Having direct control over the manufacturing of the RECELL Device is designed to ensure that AVITA Medical has the capacity to meet commercial demand, including the planned U.S. launch and BARDA procurement, and provide AVITA Medical further control over its production processes and timelines. Acquiring this facility that has a track record of producing the RECELL Device is intended to allow AVITA Medical to realize the benefits of in-house production while maintaining the continuity of proven manufacturing and quality processes and systems.

During the quarter AVITA Medical continued to build out its marketing and sales team, and expanded its management team in the commercial, legal and medical affairs functions, in preparation of the planned U.S. launch of the RECELL Device. Joining AVITA Medical were Donna Shiroma, General Counsel, Terry Bromley, Vice President, Commercial Operations, and Debbie Garner, Vice President, Global Marketing. The Company also announced the promotion of Katie Bush, PhD, to Vice President, Medical Affairs.

These leaders and their respective teams join AVITA Medical at a transformative time as the Company takes the steps to prepare for a successful planned launch of the RECELL Device in the U.S. The Company is pleased to have such a strong group of professionals join us and look forward to benefiting from their experience in the commercialization of products in the regenerative medicine and skin care spaces.

Funding for the clinical trials described above, as well as the health economic model, was provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

#### **Fourth Quarter Fiscal 2018 Financial Results (Unaudited)**

(All amounts are in thousands of AUD except where noted)

A copy of the Appendix 4C - Quarterly Cash Flow Report for the quarter ended 30 June 2018 is attached. Operations for the quarter were focused primarily on preparation for the planned U.S. launch of the RECELL Device, limited commercial sales efforts in selected markets in which the RECELL Device is approved for sale, and preparation for the further clinical development of the RECELL Device.

During the quarter ended 30 June 2018, total cash receipts were \$3,023, an increase of \$783 or 35% over the prior quarter. Total cash receipts for the quarter ended 30 June 2018 were comprised of receipts from customers of \$402 and cash received from BARDA totaled \$2,621. Through 30 June 2018, cumulative payments of \$16.535 million have been received under the BARDA contract.

As the result of investments in commercial, manufacturing, leadership and system capabilities in preparation for the planned U.S. launch of the RECELL Device and related product and corporate initiatives, payments related to operating expenses increased during the quarter ended 30 June 2018. During the quarter ended 30 June 2018, payments for research and development, manufacturing and operating costs totaled \$1,375, a \$378 or 28% increase compared to the prior quarter. Total payments related to commercial, staffing, administrative and corporate costs for the current quarter totaled \$6,662, a \$1,834 or 38% increase compared to the prior quarter. Total net cash used in operating activities during the quarter ended 30 June 2018 was \$5,004, a \$1,486 or 42% increase compared to the prior quarter. As AVITA Medical continues its preparations for the planned launch of the RECELL Device in the U.S. and expands research and development, payments for operating expenses will increase in future quarters. These expense payments will be partially offset by receipts under the BARDA contract.

During the quarter ended 30 June 2018, net proceeds provided by an institutional placement of shares to international and Australian institutional and sophisticated investors was \$11.940 million. Cash and cash equivalents held at 30 June 2018 was \$14.825 million. The institutional placement included a second tranche totaling \$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on 23 July 2018, and the net proceeds of \$3.041 million were received by AVITA Medical 26 July 2018.

Future cash requirement will be dependent upon the success of AVITA Medical's efforts to commercialize the RECELL Device, particularly in the U.S., and the timing and magnitude of clinical and other research and development programs the Company elects to undertake to expand its product pipeline. Until such time that the Company generates sufficient cash flow from operations, it expects to fund its future cash requirements through a combination of the issuance of shares and potentially debt financing.

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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 patient's 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, RECELL is not approved for sale and is 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

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

Avita Medical Limited
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**ABN**

28 058 466 523
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**Quarter ended ("current quarter")**

30 June 2018
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Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	402	1,811
1.1a Receipts from government contract (BARDA)	2,621	7,773
1.2 Payments for		
(a) research and development	(900)	(3,630)
(b) product manufacturing and operating costs	(475)	(1,823)
(c) advertising and marketing	(1,395)	(3,309)
(d) leased assets	(125)	(460)
(e) staff costs	(3,998)	(11,732)
(f) administration and corporate costs	(1,144)	(5,084)
1.3 Dividends received (see note 3)		
1.4 Interest received	10	66
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)		3
<b>1.9 Net cash used in operating activities</b>	<b>(5,004)</b>	<b>(16,385)</b>

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(157)	(499)
(b) businesses (see item 10)		
(c) investments		
(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 used in investing activities</b>	<b>(157)</b>	<b>(499)</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	12,774	29,810
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	(834)	(1,883)
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 financing activities</b>	<b>11,940</b>	<b>27,927</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>4.</b>	<b>Net increase in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	8,026	3,790
4.2	Net cash used in operating activities (item 1.9 above)	(5,004)	(16,385)
4.3	Net cash from used in investing activities (item 2.6 above)	(157)	(499)
4.4	Net cash from financing activities (item 3.10 above)	11,940	27,927
4.5	Effect of movement in exchange rates on cash held	20	(8)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>14,825</b>	<b>14,825</b>

<b>5. 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	14,825	8,026
5.2 Call deposits	-	-
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>14,825</b>	<b>8,026</b>

<b>6. Payments to directors of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1 Aggregate amount of payments to these parties included in item 1.2	(252)
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	
6.1 Executive Director remuneration (161k), Directors fees (63k), Clinical Advisory Board fees (11k), and Bioscience Consultancy (17k)	

<b>7. Payments to related entities of the entity and their associates</b>	<b>Current quarter \$A'000</b>
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>8. Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.		

<b>9. Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1 Research and development	900
9.2 Product manufacturing and operating costs	475
9.3 Advertising and marketing	1,400
9.4 Leased assets	125
9.5 Staff costs	4,000
9.6 Administration and corporate costs	1,150
9.7 Other (provide details if material)	
<b>9.8 Total estimated cash outflows*</b>	<b>8,050</b>

\* Pertains to outflows only, inflows from customer receipts and government contracts, which totalled \$3,023 for the quarter ended 30 June 2018, are not included.

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	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.

*Dale Sander*

**Dale Sander**

**Chief Financial Officer**

**31 July 2018**

### 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.