

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

### **Recent Highlights**

- Six RECELL Device Presentations at 50th Annual Meeting of the American Burn Association
- Preparations for Planned 2018 U.S. Market launch of RECELL Device continue
- Expansion of U.S. Compassionate Use Program Approved by FDA
- Issuance of Additional U.S. Patent for RECELL Device
- Commencement of China Clinical Trial in Burns Funded by Government Agency

Valencia, Calif., USA, and Melbourne, Australia, 30 April 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMXY), 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 31 March 2018. The Company is also providing below an update on the substantial progress made during the third quarter, including preparations for the planned market launch of RECELL in the U.S. for the treatment of burns.

#### Six Presentations at ABA Meeting Raises Profile of RECELL in the Burn Community

We were proud to see prominent researchers from major burn centers throughout the U.S. make six presentations at the American Burn Association (ABA) 50th Annual Meeting in Chicago this month describing the clinical and cost-savings advantages of the RECELL® Device in the treatment of severe burns. Key highlights of the presentations included:

- The pivotal, controlled clinical trial of the RECELL Device in the treatment of second-degree burns
  demonstrated statistically significant reduction in donor skin requirements (97.5% reduction) and
  pain, increased patient satisfaction and improved donor scar outcomes, and the results were
  presented in the top five abstract session.
- The pivotal trial in third-degree burns met its co-primary endpoints and demonstrated statistically significant reduction in donor skin requirements.
- Externally validated health economic model demonstrated that use of the RECELL Device could reduce the cost of treatment by 44 percent or greater for patients with large burns.
- Results from a retrospective review of patients enrolled under Compassionate Use with seconddegree facial burns showed excellent cosmetic outcomes when treated with the RECELL Device.

The RECELL Device is an investigational medical device in the U.S. that 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.

#### Preparation for Planned U.S. Launch of RECELL

The two pivotal clinical trials described above were used to support AVITA Medical's U.S. PreMarket Approval (PMA) application for the treatment of burn injuries which is currently under review by the U.S. Food and Drug Administration (FDA). The Company expects completion of the FDA review of the PMA during the third quarter of calendar 2018, followed by U.S. approval and market launch.

In February 2018 the FDA approved a significant increase in the number of patients who may be treated in the U.S. with the RECELL Device under a FDA Compassionate Use Investigational Device Exemption (IDE) program. Under the expanded protocol, up to 88 patients with life-threatening injuries, including severe burns, may be treated with RECELL. This was the fifth expansion to the Compassionate Use protocol for RECELL approved by the FDA and expanded by 20 the number of patients who may be treated.

During the quarter the Company continued to build out is marketing and sales team in preparation of the planned U.S. launch of RECELL. In addition, the Company engaged third-party advisors to conduct direct market research and other analyses to help develop the pricing and market launch strategies for the U.S. The Company believes that the ability to achieve attractive pricing of RECELL in the U.S. and other markets will be assisted by the cost benefits of the treatment. A key output from the budget impact model presented at the ABA Meeting was the calculation of the annual budget impact of current management of burn treatment versus treatment with the RECELL Device for a burn center with 200 patients. The model determined that treatment with the RECELL Device would reduce annual total treatment costs from \$43.3 million to \$30.3 million, saving 30 percent or \$13.0 million. The health economic model has also been accepted for presentation at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 23rd Annual International Meeting on May 21, 2018 in Baltimore, Maryland.

In January 2018 the Company was issued an additional U.S. Patent covering the RECELL Device, U.S. Patent No. 9.867,692 titled "Cell suspension preparation technique and device." The present invention provides for methods and devices suitable for producing a transplantable cellular suspension of living tissue suitable for grafting to a patient.

The Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the US Department of Health and Human Services has provided funding under Contract No. HHSO100201500028C to support the development of RECELL by AVITA Medical, including clinical trials, the Compassionate Use program, and the health-economic model described above.

#### **International Expansion of RECELL Device**

In March 2018 a randomized, controlled clinical trial of RECELL commenced in China in the treatment of deep partial-thickness (second-degree) burns. The clinical trial entitled "Key Technique and Clinical Pathway for Burn Treatment" is being funded by the China National Health and Family Planning Commission. Our initiatives within China are consistent with our evolving strategy of using data from controlled clinical trials and health economic studies to ensure that RECELL is effectively promoted and priced in all major markets. AVITA Medical will support additional clinical trials in burn patients in Australia and the United Kingdom this year to further support promotion and reimbursement.

#### **Third Quarter Fiscal 2018 Financial Results**

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

A copy of the Appendix 4C - Quarterly Cash Flow Report for the quarter ended 31 March 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 RECELL is approved for sale, and preparation for the further clinical development of the RECELL Device.

During the quarter ended 31 March 2018, total cash receipts were \$2,240, an increase of \$130 or 6% over the prior quarter. Total cash receipts for the quarter ended 31 March 2018 were comprised of receipts from customers of \$448 and cash received from BARDA of \$1,792. Through 31 March 2018, cumulative payments of \$13.914 million have been received under the BARDA contract.

During the quarter ended 31 March 2018, payments for research and development, manufacturing and operating costs totalled \$997, a \$684 or 41% decrease compared to the prior quarter. The decrease in current-quarter payments resulted primarily from the completion of the PMA filing in 2017. Total payments related to commercial, staffing, administrative and corporate costs for the quarter ended 31 March 2018 totalled \$4,782, a decrease of \$442 or 8% compared to the prior quarter. The decrease compared to the prior quarter resulted from the reduction of costs in select geographic locations combined with the cyclical nature of certain payments, partially offset by increases related to preparations for the planned U.S. launch of RECELL. Total net cash used in operating activities during the quarter ended 31 March 2018 was \$3,518, a \$1,277 or 27% decrease compared to the prior quarter. As the Company continues its preparations for the planned launch of the RECELL Device in the U.S. and expands the clinical development of the RECELL Device, payments for operating expenses will increase in future quarters. These expense payments will be partially offset by receipts under the BARDA contract.

Cash and cash equivalents held at 31 March 2018 was \$8.026 million. 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 Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical'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™, an autologous suspension comprised of the patient's own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This autologous suspension is then sprayed onto the areas of the patient to be treated.

In the United States, the RECELL Device is an investigational device limited by federal law to investigational use. In September 2017, AVITA Medical submitted to the U.S. Food and Drug Administration (FDA) a PreMarket Approval (PMA) application for RECELL for the treatment of burn injuries.

In all countries outside of Europe, our portfolio is marketed under the RECELL Device brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. RECELL Device is TGA-registered in Australia, and CFDA-cleared in China.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. RECELL Device is designed for the treatment of burns and plastic reconstructive procedures; REGENERCELL™ Autologous Cell Harvesting Device has been formulated for chronic wounds including leg and foot ulcers; and RENOVACELL™ Autologous Cell Harvesting Device is tailored for aesthetic applications including the restoration of pigmentation.

To learn more, visit 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," "qoal," "target," "project," "continue," "outlook," "quidance," "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 forwardlooking 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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+Rule 4.7B

# **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		
ABN	ABN Quarter ended ("current quarter")		
28 058 466 523 31 March 2018			

Cons	colidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	448	1,409
1.1a	Receipts from government contract (BARDA)	1,792	5,152
1.2	Payments for		
	(a) research and development	(669)	(2,730)
	(b) product manufacturing and operating costs	(328)	(1,348)
	(c) advertising and marketing	(477)	(1,914)
	(d) leased assets	(79)	(336)
	(e) staff costs	(2,732)	(7,734)
	(f) administration and corporate costs	(1,494)	(3,940)
1.3	Dividends received (see note 3)		
1.4	Interest received	21	56
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)	0	3
1.9	Net cash from / (used in) operating activities	(3,518)	(11,382)

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<sup>+</sup> See chapter 19 for defined terms

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(274)	(342)
	(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)		
2.6	Net cash from / (used in) investing activities	(274)	(342)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	7	17,036
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		(1,048)
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)		
3.10	Net cash from / (used in) financing activities	7	15,988

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	11,777	3,790
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,518)	(11,382)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(274)	(342)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7	15,988
4.5	Effect of movement in exchange rates on cash held	34	(28)
4.6	Cash and cash equivalents at end of quarter	8,026	8,026

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	8,026	1,777
5.2	Call deposits	-	10,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	8,026	11,777

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	(611)
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 (491k), Directors fees (80k), Clinical Advisory Board fees (10k), and Bioscience Consultancy (30k)

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<sup>+</sup> See chapter 19 for defined terms

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
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 transactic items 7.1 and 7.2	ons included in

8.	Financing facilities available Add notes as necessary for an understanding of the position	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.		n entered into or are

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	1,500
9.2	Product manufacturing and operating costs	600
9.3	Advertising and marketing	1,000
9.4	Leased assets	200
9.5	Staff costs	4,300
9.6	Administration and corporate costs	1,400
9.7	Other (provide details if material)	
9.8	Total estimated cash outflows*	9,000

<sup>\*</sup> pertains to outflows only, inflows from customer receipts and government contracts 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		

<sup>+</sup> See chapter 19 for defined terms

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## **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 30 April 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.

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<sup>+</sup> See chapter 19 for defined terms