

Avita Medical First Quarter Fiscal 2019 Quarterly Cash Flow Report and Company Update

Recent Highlights

- *FDA approval of RECELL[®] System for the treatment of acute thermal burns in adults*
- *Commencement of U.S. commercial sales and shipments*
- *Clinical results demonstrate patient benefits and cost savings in multiple conference presentations*
- *Expansion of commercial and manufacturing capabilities to support U.S. launch of RECELL System*

Valencia, Calif., USA, and Melbourne, Australia, 31 October 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, announced that it filed today with the ASX its Appendix 4C - Quarterly Cash Flow Report for the quarter ended 30 September 2018. Provided below is an update on the substantial accomplishments achieved during the first fiscal quarter, including the September 2018 approval by the U.S. Food and Drug Administration (FDA) of the RECELL[®] System for the treatment of patients with acute thermal burns.

FDA Approval to Market RECELL System in the U.S. and First Commercial Shipments

On 20 September 2018, the FDA approved the RECELL System for the treatment of acute thermal burns in patients 18 years and older. The FDA approval allows the Company to commence marketing the RECELL System in the U.S., the largest market in the world for the treatment of burns.

“The importance of our approval cannot be overstated, not only for AVITA Medical but for the burn community. The RECELL System was the first Premarket Approval (PMA) application for the treatment of burns approved by the FDA in over 20 years,” said Dr. Michael Perry, Chief Executive Officer. “We believe that the approval will allow us to significantly advance the standard of care for the treatment of severe burns and greatly improve outcomes for patients.”

Less than a month after FDA approval the Company received the first commercial sales orders from multiple U.S. burn centers for the RECELL System and commenced commercial shipment of the product. The national commercial launch of the RECELL System is not scheduled to occur until after the completion of hiring and training of the Company’s field sales force, which is currently underway. Of the 134 burn centers in the U.S., 24 already have experience using the RECELL System through participation in clinical trials and the Compassionate Use and Continued Access programs. Notably, these 24 burn centers are estimated to treat more than 30 percent of the U.S. burn patients annually. A number of the larger burn centers experienced with the RECELL System have commenced incorporating the product into their practices in advance of AVITA Medical’s market launch.

RECELL System Clinical Results Prominently Featured in Conference Presentations

During the first quarter of fiscal 2019 the body of clinical data supporting the RECELL System combined with support from key opinion leaders resulted in the presentation of clinical results at multiple scientific

conferences. These presentations continue the substantial exposure the RECELL System has received at burn and other scientific conferences throughout 2018 and have greatly increased the awareness and credibility of the product among burn care professionals. Recent conference presentations include:

- **U.S. Defense Department Military Health System Research Symposium** (August 2018): Results from the two U.S. pivotal clinical trials supporting the FDA approval were presented at this premier U.S. military conference. The results demonstrated that treatment of acute burn wounds with the RECELL System used substantially less donor skin than required with conventional split-thickness autografts to achieve closure of burn wounds, meeting the primary endpoints of both trials.
- **46th Annual Eastern Great Lakes Burn Conference** (September 2018) and **Midwest Region Burn Conference** (October 2018): The results of two U.S. pivotal clinical trials were presented demonstrating the effectiveness and clinical benefits of the RECELL System. In addition, medical symposiums were conducted by key opinion leaders at each conference as the first step in training U.S. physicians within these regions who had not previously treated patients with the RECELL System.

Commercial and Manufacturing Preparations for Planned U.S. Launch of the RECELL System

Among the major investments made by AVITA during the quarter were substantial efforts to prepare for the U.S. market launch. These initiatives included the commencement of the recruitment of a field sales team experienced in regenerative medicine and in the treatment of burns, completion and assimilation of extensive direct market research, establishment of pricing and reimbursement strategies and support infrastructure, and going live with our customer service team within a business day of FDA approval.

During the quarter the Company also commenced and successfully completed multiple production runs for the RECELL System within its newly acquired manufacturing facility in Ventura, California. Effective July 1, 2018, AVITA Medical acquired the facility from a Fortune 500 manufacturer that had previously assembled the RECELL System on a contract basis. The manufacturing runs were performed after AVITA Medical's takeover of the facility and represent the first production activities undertaken by the Company's own manufacturing and quality control personnel. This operational milestone enabled the Company to fulfill the sales orders that were received shortly after FDA approval, as well as clinical trial and internal sales requirements.

Funding for the development of the RECELL System 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. Programs discussed above which were funded under the BARDA contract include the two randomized, controlled clinical trials, the Compassionate Use and Continued Access programs, the PMA and related activities, development of the health economic model demonstrating the cost savings associated with the RECELL System and two randomized, controlled clinical trials which will evaluate the RECELL System in the pediatric population. Also included in the Contract is future procurement of the RECELL System by BARDA under a vendor-managed inventory system to bolster preparedness by providing availability for use in a national disaster.

First Quarter Fiscal 2019 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 September 2018 is attached. Operations for the quarter were focused primarily on preparation for the U.S. launch of the RECELL System, limited commercial sales efforts in selected markets in which the RECELL System is approved for sale, and preparation for the further clinical development of the RECELL System. Commercial sales of the RECELL System in the U.S. had not commenced as of 30 September 2018.

During the quarter ended 30 September 2018, total cash receipts were \$4,476, an increase of \$2,265 or 102% over the prior quarter ended 30 June 2018. Total cash receipts for the quarter ended 30 September 2018 were comprised of receipts from customers of \$347 and cash received from BARDA totalling \$4,129. Through 30 September 2018, cumulative payments of \$20.66 million have been received under the BARDA contract.

As the result of investments in commercial, manufacturing, leadership and system capabilities for the U.S. launch of the RECELL System and related product and corporate initiatives, payments related to operating expenses increased during the first quarter of fiscal 2019. During the quarter ended 30 September 2018, payments for research and development, manufacturing and operating costs totalled \$2,551, a \$1,176 or 86% increase compared to the quarter ended 30 June 2018. Total payments related to commercial, staffing, administrative and corporate costs for the current quarter totalled \$6,809, a \$147 or 2% increase compared to the quarter ended 30 June 2018. As AVITA Medical undertakes the launch of the RECELL System 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 and receipts from customers.

Total net cash used in operating activities during the quarter ended 30 September 2018 was \$3,820, a \$1,184 or 24% decrease compared to the quarter ended 30 June 2018. The current quarter decrease in net cash used in operating activities resulted from the increase in total cash receipts partially offset by the increase in payments for operating expenses.

During the quarter ended 30 September 2018, net proceeds provided by an institutional placement of shares to international and Australian institutional and sophisticated investors was \$3,041. Cash and cash equivalents held at 30 September 2018 was \$14,122.

Future cash requirement will be dependent upon the success of AVITA Medical's efforts to commercialize the RECELL System, particularly in 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 current cash resources, 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. The medical devices work by preparing a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™), an autologous suspension comprised of the patient's skin cells necessary

to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Medical's first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA in September 2018). The RECELL System is indicated for use in the treatment of acute thermal burns in patients 18 years and older. The RECELL System produces Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 7,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device for a full description of important safety information including contraindications, warnings and precautions.

In international markets outside of Europe, our portfolio is marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL System 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. The RECELL Autologous Cell Harvesting 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," "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

ABN

28 058 466 523

Quarter ended ("current quarter")

30 September 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	347	347
1.1a Receipts from government contract (BARDA)	4,129	4,129
1.2 Payments for		
(a) research and development	(1,526)	(1,526)
(b) product manufacturing and operating costs	(1,025)	(1,025)
(c) advertising and marketing	(1,933)	(1,933)
(d) leased assets	(152)	(152)
(e) staff costs	(3,513)	(3,513)
(f) administration and corporate costs	(1,211)	(1,211)
1.3 Dividends received		
1.4 Interest received	44	44
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	1,020	1,020
1.8 Other (provide details if material)		
1.9 Net cash used in operating activities	(3,820)	(3,820)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(340)	(340)
(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 used in investing activities	(340)	(340)
3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	3,250	3,250
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	(209)	(209)
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 financing activities	3,041	3,041

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net increase in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	14,825	14,825
4.2	Net cash used in operating activities (item 1.9 above)	(3,820)	(3,820)
4.3	Net cash from used in investing activities (item 2.6 above)	(340)	(340)
4.4	Net cash from financing activities (item 3.10 above)	3,041	3,041
4.5	Effect of movement in exchange rates on cash held	416	416
4.6	Cash and cash equivalents at end of quarter	14,122	14,122

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	14,122	14,825
5.2 Call deposits	-	-
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)	14,122	14,825

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	(256)
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 (164k), Directors fees (64k), Clinical Advisory Board fees (11k), and Bioscience Consultancy (17k)	

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 transactions included in items 7.1 and 7.2	

8. Financing facilities available <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. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	1,300
9.2 Product manufacturing and operating costs	500
9.3 Advertising and marketing	1,200
9.4 Leased assets	125
9.5 Staff costs	4,100
9.6 Administration and corporate costs	750
9.7 Other (provide details if material)	
9.8 Total estimated cash outflows*	7,975

* Pertains to outflows only, inflows from customer receipts and government contracts, which totalled \$4,476 for the quarter ended 30 September 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 October 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.