



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

January 30, 2019

### Recent Highlights

- Pre-launch U.S. product sales of A\$1.1 million in second quarter
- Successful preparation for U.S. national market launch in January 2019
- 26 abstracts highlighting RECELL® System clinical and economic benefits accepted for presentation at multiple burn conferences, including the American Burn Association (ABA) 51st Annual Meeting
- A\$41.7 million equity financing provide resources for U.S. launch and pipeline expansion

**Valencia, Calif., USA, and Melbourne, Australia, 31 January 2019** — 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 31 December 2018. Provided below is an update regarding the substantial accomplishments achieved during the second fiscal quarter, including the first U.S. commercial sales of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of acute thermal burns.

### First U.S. Commercial Sales of RECELL System and U.S. National Market Launch

During the quarter ended 31 December 2018, the Company's primary commercial focus was preparing for the January 2019 U.S. national market launch of the RECELL System. Key commercial achievements during the quarter included recruiting, hiring and training a highly experienced sales team of 20 professionals, the receipt of American Burn Association (ABA) issued reimbursement coding guidelines within one week of U.S. Food and Drug Administration (FDA) approval, and commercial product availability within two weeks of approval.

In advance of the January 2019 U.S. national market launch and without any direct promotional effort, the clinical and economic benefits of the RECELL System generated strong interest from burn centers and greater than expected sales orders. Product sales and other revenues for the quarter and six months ended 31 December 2018 were as follows (unaudited and provided in advance of completion of Company's Mid- Year Report to be filed in Appendix 4D):

(In thousands of AUD)	Three Months Ended		Six Months Ended	
	<u>31 December</u>		<u>31 December</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
U.S. Product Sales	\$1,102	\$ -	\$1,102	\$ -
International Product Sales	<u>343</u>	<u>318</u>	<u>711</u>	<u>608</u>
Total Product Sales	1,445	318	1,813	608
BARDA Revenue	<u>2,456</u>	<u>2,040</u>	<u>5,009</u>	<u>3,857</u>
Total Revenue	<u>\$3,901</u>	<u>\$2,358</u>	<u>\$6,822</u>	<u>\$4,465</u>

"We are excited that in advance of our U.S. national market launch in January 2019 the patient benefits and cost savings associated with the RECELL System resulted in strong commercial sales during the first three months after FDA approval," said Dr. Mike Perry, Chief Executive Officer. "We look forward to reporting our progress through 2019 as we begin to see the results of the U.S. national launch and the deployment of our full sales team of 20 professionals."

### RECELL System Clinical Results Featured in 26 Presentations at Early 2019 Burn Conferences

26 abstracts highlighting the clinical and cost savings benefits of the RECELL® Autologous Cell Harvesting Device (RECELL® System) have been selected for presentation at four burn conferences in early 2019. Nine of the presentations will be made at the largest burn conference, the American Burn Association (ABA) 51st Annual Meeting to be held in Las Vegas April 2-5, 2019, including a Top-Five Abstract presentation in plenary session. These abstracts build upon and greatly advance the pivotal clinical trial results and health economic data presented at last year's ABA meeting and will highlight the positive clinical outcomes that burn surgeons have observed in a broad range of patients and burn types.

In January 2019 eight presentations were made at the North American Burn Society 37th Annual Conference held in Park City, and one presentation was made at the LA-ACS/SAL Annual Meeting in New Orleans, further supporting the clinical and economic benefits of the RECELL System. In

addition to the strong interest from major burn conferences, results from the Company's second pivotal clinical trial of the RECELL System full-thickness burns were published in *Burns*, a major peer-reviewed journal. The clinical results reflected in the 26 abstracts and the *Burns* publication further expand the body of scientific materials demonstrating that the RECELL System is a major innovation in the treatment of burn patients.

Funding and technical support 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 included in the above abstracts and publication which were funded under the BARDA contract include the two randomized, controlled pivotal clinical trials, the Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients.

## **Second 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 second quarter of fiscal 2019, the quarter ended 31 December 2018, is attached. Operations for the quarter were focused primarily on preparation for the U.S. national market launch of the RECELL System which occurred in January 2019, the commencement of product shipments in the U.S. after the September 2019 FDA approval of the RECELL System for the treatment of burns, limited commercial sales efforts in selected markets in which the RECELL System is approved for sale, and the preparation and conduct of further clinical development of the RECELL System.

During the quarter ended 31 December 2018, total cash receipts were \$2,833, a decrease of \$1,643 or 37% compared to the prior quarter ended 30 September 2018. Cash receipts from customers for the quarter ended 31 December 2018 were \$858, an increase of \$511 or 147% compared to the prior quarter due to the commencement of U.S. product sales. Cash received from BARDA during the current quarter totalled \$1,975,

a decrease of \$1,643 or 40% compared to the prior quarter. The decrease was the result of a one-time rate adjustment that was received during the quarter ended 30 September 2018. Through 31 December 2018, cumulative payments of \$22.64 million have been received under the BARDA contract.

As the result of investments in commercial, manufacturing, and system capabilities for the U.S. market launch of the RECELL System and related initiatives, overall payments for operating expenses increased during the second quarter of fiscal 2019. During the quarter ended 31 December 2018, payments related to sales and marketing, staffing, administrative and corporate costs for the current quarter totalled \$8,967, a \$2,158 or 32% increase compared to the quarter ended 30 September 2018. The increase was primarily due to the hiring of the U.S. sales force for the RECELL System and related activities. This increase is partially offset by payments for research and development, manufacturing and operating costs which during the current quarter totalled

\$1,923, a \$628 or 25% decrease compared to the quarter ended 30 September 2018. The decrease was the result of the wind-down of certain activities associated with supporting the U.S. FDA approval of the RECELL System as well as the Compassionate Use and Continued Access programs. As a result of the national launch of the RECELL System in the U.S. in January 2019, and the expansion of research and development, payments for operating expenses will increase in future quarters. These expense payments will be partially offset by receipts from customers and receipts under the BARDA contract.

Total net cash used in operating activities during the quarter ended 31 December 2018 was \$6,583, a \$2,763 or 72% increase compared to the quarter ended 30 September 2018. The current quarter decrease in net cash used in operating activities resulted from the decrease in total cash receipts combined with the increase in payments for operating expenses, partially offset by the \$1,421 research and development tax credit received.

During the quarter ended 31 December 2018, net proceeds provided by Tranche 1 of an institutional placement of shares to U.S., Australian and international institutional and sophisticated investors was \$22,268. Cash and cash equivalents held at 31 December 2018 was \$30,342. Including the net proceeds of \$13,829 and \$1,765 received in January 2019 from Tranche 2 of the institutional placement and from a share purchase plan, respectively, the pro forma cash and cash equivalents balance at 31 December 2018 was \$45,936.

Future cash requirement will be dependent upon the success of AVITA Medical's efforts to commercialize the RECELL System, 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 current cash resources, and potentially the issuance of shares and 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™ (REST™), 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 is used to prepare 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 (<https://recellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets outside of Europe, our products are 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, CFDA-cleared in China, and received CE-mark approval in Europe.

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.*

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