



## AVITA Medical Third Quarter Fiscal 2019 Quarterly Cash Flow Report and Company Update

April 30, 2019

### Recent Highlights

- Strong U.S. product sales of A\$2.2 million for third quarter of Fiscal 2019 were double second quarter sales
- Ten presentations highlighting RECELL® System additional clinical and economic benefits featured at American Burn Association (ABA) 51st Annual Meeting
- Japan collaboration agreement with COSMOTEC
- Application to market RECELL System filed in Japan
- Equity placements completed for a total of A\$15.5 million in proceeds

**Valencia, Calif., USA, and Melbourne, Australia, 30 April 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 March 2019, the third quarter of its fiscal 2019. Provided below is an update regarding the substantial accomplishments achieved during the quarter, including the ramp up of RECELL® System sales during the first three months of promotion of the product.

### U.S. Commercial Sales of RECELL System

Active sales and marketing of the RECELL System in the U.S. for the treatment of acute thermal burns commenced with the January 2019 national market launch, therefore the third quarter of fiscal 2019 represents the first three months of promotion for the product. Product sales and other revenues for the quarter and nine months ended 31 March 2019 were as follows (unaudited):

	Three Months Ended		Nine Months Ended	
(In thousands of AUD)	<u>31 March</u>		<u>31 March</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
U.S. product sales	A\$2,179	A\$ -	A\$ 3,281	A\$ -
International product sales	<u>189</u>	<u>238</u>	<u>900</u>	<u>845</u>
Total product sales	2,368	238	4,181	845
Other revenue (including BARDA)	<u>2,335</u>	<u>1,492</u>	<u>7,344</u>	<u>5,349</u>
Total revenue	A\$ <u>4,703</u>	A\$ <u>1,730</u>	A\$ <u>11,525</u>	A\$ <u>6,194</u>

"We are well ahead of our expectations for the U.S. launch of the RECELL System and are delighted that sales doubled during this quarter compared to the prior quarter," said Dr. Mike Perry, Chief Executive Officer. "The third quarter represents the first three months of our market launch, and we have been very pleased with the quick uptake of the RECELL System by burn centers that have been the first movers in adopting the product. To date, 26 of the 134 burn centers within the U.S. have placed orders for the RECELL System."

"As we move beyond the early adopters, our collective experience tells us that many of the remaining burn centers will follow a more standard process for adopting the RECELL System, including an initial evaluation of the product and advancement through their hospital's Value Analysis Committee (VAC), before making the formal decision to purchase for regular use. This process can often take six months or more to complete," said Erin Liberto, Chief Commercial Officer. "The recent ABA meeting added greatly to the awareness and credibility of the RECELL System within the burn community, and we look forward to converting this excitement into product evaluations and the Value Analysis Committee approvals required for adoption by additional U.S. burn centers."

### RECELL System Featured in Ten Presentations at ABA Conference

Burn center professionals made ten presentations describing the RECELL System at the American Burn Association (ABA) 51st Annual Meeting held in Las Vegas April 2-5, 2019. Key results presented at the ABA meeting included the following:

- **Pediatric Treatment Outcomes:** Pediatric patients with mixed and full-thickness burns treated with the combination of Spray-On Skin™ Cells prepared using the RECELL System and widely meshed autografts experienced excellent healing

outcomes, with 98% of wounds healed four weeks after treatment. The presentation was selected as a “Best of the Best Abstract” out of more than 500 abstract submissions to the ABA

- **RECELL Projected to Reduce Cost of Treating Severe Burns:** Health economic data projects that use of the RECELL System to treat patients with severe burns could save up to USD \$28 million annually compared to treatment with the standard of care at the Arizona Burn Center, part of the Maricopa Integrated Health System (MIHS), a major public teaching hospital and safety net system of care based in
- **Long-Term Review by Co-Inventor:** Professor Fiona Wood, AM, Burns Service of Western Australia, Fiona Stanley and Perth Children's Hospitals, described her experience treating more than 3,500 patients with burns and other cutaneous injuries, including a reduction in the number of surgical procedures, earlier intervention, and reduction in time to healing and length of
- **Donor Site Treatment Outcomes:** Preliminary results demonstrated that donor sites treated with the Spray-On Skin Cells prepared using the RECELL System could be reharvested in as little as seven days after treatment. The presentation was awarded best in category at the ABA
- **Treatment of Extensive Burns:** Patients with extensive burns, greater than 50% total body surface area (TBSA), treated with Spray-On Skin Cells in combination with widely meshed autografts healed as quickly as patients with smaller burn injuries provided the same treatment combination, despite the far greater clinical challenges associated with treatment for burns over 50%
- **Publication Recognition:** The 2018 publication of the RECELL System pivotal trial in second-degree burns in the *Journal of Burn Care & Research* was recognized during the “The Year in Review: The Top Journal Publications” session of the ABA

Patients from the pediatric, donor site and large TBSA presentations were treated under Investigational Device Exemption (IDE) programs which allowed the use of the RECELL System to treat patients in advance of the September 2018 market approval in the U.S. The pediatric, treatment of donor sites, and extensive burns presentations include classes of patients that fall outside of the currently approved U.S. product labeling. 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.

Funding and technical support for the development of the RECELL System is 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 funded under the BARDA contract include 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.

### Japan Collaboration and Application for Approval

In February AVITA Medical entered into a collaboration with COSMOTEC, an M3 Group company, to market and distribute the RECELL System for the treatment of burns and other wounds in Japan. In addition, COSMOTEC filed on 25 February 2019 a Japan's Pharmaceuticals and Medical Devices Act (“JPMDA”) application for approval to market the RECELL System in Japan. The JPMDA has accepted the application and review is expected to take nine months to a year.

COSMOTEC has extensive experience marketing medical devices and other products into hospitals and surgical suites throughout Japan, including specialties requiring a high level of training such as cardiovascular treatment, making them an ideal partner for AVITA Medical. COSMOTEC is wholly owned by the M3 Group, a major healthcare company with great physician access in Japan and other markets. The filing of the JPMDA application is a major milestone, and AVITA Medical looks forward to making the RECELL System available to patients in Japan.

### Third 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 third quarter of fiscal 2019, the quarter ended 31 March 2019, is attached. Operations for the quarter were focused primarily on the U.S. national market launch of the RECELL System for the treatment of acute thermal burns, and the preparation and conduct of further clinical development of the RECELL System.

During the quarter ended 31 March 2019, total cash receipts were A\$4,848, an increase of A\$2,015 or 71% compared to the prior quarter ended 31 December 2018. Cash receipts from customers for the quarter ended 31 March 2019 were A\$2,513, an increase of A\$1,655 or 193% compared to the prior quarter due to the commencement of the U.S. national market launch of the RECELL System. Cash received from BARDA during the current quarter totalled A\$1,724, a decrease of A\$251 or 13% compared to the prior quarter. The decrease was the result of wind-down of certain activities associated with supporting the U.S. FDA approval of RECELL System as well as Compassionate Use and Continued Access programs. Through 31 March 2019, cumulative payments of A\$24.36 million have been received under the BARDA contract.

As the result of the U.S. national market launch of the RECELL System and related initiatives, overall payments for operating expenses increased during the third quarter of fiscal 2019. During the quarter ended 31 March 2019, payments related to sales and marketing, staffing, administrative and corporate costs for the current quarter totalled A\$9,578, a A\$611 or 7% increase compared to the quarter ended 31 December 2018. The increase was in a large part due to the November 2018 hiring of the U.S. sales force for commercialization of the RECELL System, a team that was in place for the entire quarter ended 31 March 2019. During the quarter ended 31 March 2019, payments related to product manufacturing and operating costs totalled A\$919, a

A\$565 or 160% increase compared to the quarter ended 31 December 2018. The increase was directly related to the increase in sales during the current quarter. These increases were partially offset by payments for research and development, which during the current quarter totalled A\$925, a A\$644 or 41% decrease compared to the quarter ended 31 December 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 March 2019 was A\$6,481, a A\$102 or 2% decrease compared to the quarter ended 31 December 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 31 March 2019, net proceeds provided by Tranche 2 of an institutional placement of shares to U.S., Australian and international institutional and sophisticated investors, and under a Share Purchase Plan, was A\$15,536. Cash and cash equivalents held at 31 March 2019 was A\$38,902.

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™ (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 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, AVITA Medical's products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, acute wounds, scars and vitiligo. The RECELL System is TGA-registered in Australia and CFDA-cleared in China.

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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