



## Avita Medical Half-Year Financial Report for Fiscal 2019

February 27, 2019

**Valencia, Calif., USA, and Melbourne, Australia, 28 February 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, announced that it filed today with the ASX its Appendix 4D – Half-Year Report for the six months ended 31 December 2018.

### Revenues for First Six Months and Update on U.S. National Market Launch

AVITA Medical received U.S. Food and Drug Administration (FDA) approval of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of acute thermal burns in September 2018. As a result of the FDA approval, the Company's primary focus during the six months ended 31 December 2018 was preparing for the January 2019 U.S. national market launch of the RECELL System.

Prior to the January 2019 U.S. market launch and in advance of any direct promotional effort, the clinical and economic benefits of the RECELL System generated strong interest from burn centers and the Company recorded its first U.S. product sales. Product sales and other revenues for the six months ended 31 December 2018 were as follows:

Six Months Ended

(In thousands of AUD) 31 December

	<u>2018</u>	<u>2017</u>
U.S. product sales	\$1,102	\$ -
International product sales	<u>711</u>	<u>608</u>
Total product sales	1,813	608
BARDA revenue	<u>5,009</u>	<u>3,857</u>
Total revenue	<u>\$6,822</u>	<u>\$4,465</u>

The Company also provided an update on the early results from the U.S. national market launch of the RECELL System that commenced last month.

"As expected, most burn centers are following a fairly standard process for adopting a novel device which includes an initial evaluation of the product as well as advancement through their hospital's Value Analysis Committee (VAC) in order to receive formal approval to purchase for regular use. This process can often take six months or more to complete," said Erin Liberto, Chief Commercial Officer. "The emphasis of our field sales force right now is to further increase awareness and interest among burn surgeons and to train surgeons and their staff in the use of the RECELL System. Our team is also assisting burn centers with product evaluation and providing the health economic and other data required to successfully complete their VAC review. We are pleased that through today, 41 of the 134 burn centers in the U.S. have been trained and certified in the use of the RECELL System, and 19 of these centers have already purchased the product. This is amazing progress for this early stage of a product launch and is helped by the prior experience a number of centers gained due to their participation in clinical trials and the Compassionate

Use program, and the broader market awareness resulting from the large body of scientific meeting presentations and publications through the past year."

### Progress During First Six Months of Fiscal 2019 Set the Stage for Near-Term Milestones

A total of ten abstracts have now been accepted at the largest burn conference, the American Burn Association (ABA) 51st Annual Meeting to be held in Las Vegas April 2-5, 2019. The presentations of the RECELL System at the ABA conference will include a Top-Five Abstract presentation in plenary session covering the treatment of pediatric patients. Other presentations will include the clinical outcomes that burn surgeons have observed in a broad range of patients and burn types, including the use of the RECELL System in the treatment of donor sites, burns of the hand, and patients with large burn injuries.

The work undertaken by the Company's clinical and regulatory teams will also lead to two additional milestones during this quarter, the filing of approval to market the RECELL System in Japan, and the commencement of the second clinical trial in pediatric burn patients in the U.S. This second U.S. randomized, controlled pediatric trial will test the RECELL System in the treatment of partial thickness burns, a population and type of burn that is currently outside of the approved U.S. labeling for the product.

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.

#### Half-Year Fiscal 2019 Financial Results (Unaudited, in AUD)

A copy of the Appendix 4D – Half-Year Report for the six months ended 2019 is attached. A summary of the financial results for the half year are as follows:

Six Months Ended

(In thousands of AUD) 31 December

	<u>2018</u>	<u>2017</u>
Sale of goods	\$ 1,813	\$ 608
Cost of sales	<u>(570 )</u>	<u>(265 )</u>
Gross profit	1,243	343
BARDA revenue	5,009	3,857
Other income	104	37
Operating costs	<u>(21,935 )</u>	<u>(11,488 )</u>
Loss for the period	(15,579 )	(7,251 )
Foreign currency translation	<u>1,374</u>	<u>(55 )</u>
Total other comprehensive loss	<u>(\$14,205 )</u>	<u>(\$7,306 )</u>

The majority of the current-year increase in sales of goods occurred in the U.S. as a result of the September 2018 FDA approval. Gross margin for the half-year ended 31 December 2018 was 69% compared to 56% for the same period in 2017, and the Company expects gross margins to further increase as sales ramp up within the U.S. As in prior periods, the majority of other revenue consisted of funding from BARDA. As the result of investments in commercial, manufacturing, and system capabilities for the U.S. market launch of the RECELL System and related initiatives, operating costs and net loss for the half-year ended 31 December 2018 increased compared to the same period in the prior year and were in line with management expectations.

During the six months ended 31 December 2018, net proceeds provided by institutional placements of shares to U.S., Australian and international institutional and sophisticated investors was approximately \$25.4 million. The pro forma cash and cash equivalents balance at 31 December 2018, including the net proceeds of approximately \$13.8 million and \$1.8 million received in January 2019 from Tranche 2 of an institutional placement and from a share purchase plan, respectively, was approximately \$45.9 million.

"We appreciate the support provided by our shareholders, including those investors that participated in our placements of shares," said Dale Sander, Chief Financial Officer. "The cash on hand at 31 December 2018 is expected to allow full funding of the U.S. launch and commercial sales ramp up, as well as the product development programs currently underway or planned."

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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 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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