



## AVITA Medical Reports Fourth Quarter Fiscal 2019 Financial Results and Company Update

July 30, 2019

- Total revenue of A\$17.0 million for fiscal year 2019 (FY19), an increase of 50% year-over-year
- S. product sales of A\$6.2 million for FY19
- S. product sales of A\$2.9 million for fourth quarter, an increase of 32% compared to FY third quarter sales

**Valencia, Calif., USA, and Melbourne, Australia, 31 July 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 30 June 2019, the fourth quarter of its fiscal 2019.

Provided below is an update regarding the substantial accomplishments achieved during the quarter and full fiscal year.

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

Avita began fulfilling orders within three weeks of the September 20, 2018 FDA approval in a pre-launch phase prior to the full nationwide launch which commenced in January 2019. The fourth quarter represents the second quarter of active promotion of the product. Product sales and other revenues for the fourth quarter and fiscal year ended 30 June 2019 were as follows (unaudited):

	Three Months Ended		Year Ended	
(In thousands of AUD)	30 June		30 June	
	2019	2018	2019	2018
U.S. product sales	A\$2,867	A\$ -	A\$6,215	A\$ -
International product sales	591	354	1,490	1,199
Total product sales	3,458	354	7,705	1,199
Other revenue (including BARDA)	1,781	4,766	9,321	10,173
Total revenue	A\$5,239	A\$5,120	A\$17,026	A\$11,372

### Fourth Quarter Highlights

- A\$2.9 million U.S. sales of the RECELL System, 32% sequential quarterly growth and 100% growth year-over-year
- S. commercial achievements to date
  - 41 of 134 U.S. burn centers have ordered RECELL
  - 136 of 300 burn surgeons at 59 of the 134 U.S. burn centers have been trained and have performed a RECELL procedure
  - RECELL has a 100% success rate for hospital purchasing approval (U.S. Value Analysis Committee or "VAC")
- Clinical and cost-savings advantages of using the RECELL System for the treatment of severe

- burns in broad range of patient populations and burn types highlighted during 10 presentations at the American Burn Association (ABA) 51st Annual Meeting 2-5 April 2019, in Las Vegas,
- Published health economic model in *Advances in Therapy* demonstrating [reduced cost and decreased hospital stay with the RECELL System](#). Utilizing this model, health economic data projects that use of the RECELL System to treat in-patient burns could save a major U.S. burn center up to U\$28 million annually, approximately 14 to 17% of their overall costs, compared to treatment with the standard of care.<sup>i</sup>
  - A\$0.6 million international product sales for fourth quarter (FY19), 100% sequential quarterly growth. On 12 June 2019, the notified body responsible for EU certificates closed all open administrative and procedural non-conformities previously announced on 4 March 2019, and fully reinstated AVITA's EU certificates allowing the resumption of sales throughout the
  - Presentations and publications on RECELL System studies highlighted the potential use of the RECELL System in regenerative dermatology and wound healing:
    - Preliminary data for treatment of vitiligo and facial acne scars presented at World Congress of Dermatology 10-15 June 2019 in Milan, Italy
    - Feasibility study results presented at 11th annual meeting of the Japanese Society of Limb Salvage & Podiatric Medicine 28-29 June 2019 in Kobe, Japan, demonstrated that use of the RECELL System reduced size of wounds caused by diabetic foot ulcers in all participants
    - Publication in the *Journal of Dermatological Treatment* of favorable results, particularly in pediatric patients, from a retrospective study of before-and-after comparisons exploring the use of the RECELL System in the treatment of patients with stable vitiligo<sup>ii</sup>

#### Full Year Highlights

- A\$17.0 million total revenue, 50% growth year-over-year. (RECELL was launched in the U.S. in the second half of the fiscal year 2019)
- Received U.S. Food and Drug Administration (FDA) Approval of the RECELL System in September 2018 for treatment of acute thermal burns
  - Attained reimbursement coding guidelines (from ABA), issued within one week of FDA approval
  - First commercial order received within three weeks of FDA approval
  - S. field force completely in place within 8 weeks of FDA approval
  - S. commercial launch in January 2019
- Expansion of manufacturing capabilities to support U.S. launch of the RECELL System
- Executed collaboration agreement with COSMOTEC, an M3 Group company, and application to market the RECELL System in Japan was submitted for review
- Commenced enrollment in the U.S. Pediatric Donor Site Study
- Presented and published RECELL System data:
  - 50+ RECELL System presentations at more than 15 medical conferences
  - Pivotal trial results demonstrating safety and effectiveness of the RECELL System in the treatment of second-<sup>iii</sup> and third-degree burns<sup>iv</sup> published and presented at ABA Annual meeting

"We view AVITA's financial performance for the year as a tremendous success, driven largely by the strong uptake of the RECELL System by U.S. burn centers that have been quick to adopt this innovative technology," said Dr. Michael Perry, AVITA Medical's Chief Executive Officer. "This positive growth momentum will continue in the next year with the anticipated expansion into the Japanese market and advancement of our clinical pipeline in additional high-value indications."

#### Recent Developments

On 19 July 2019, AVITA submitted a confidential draft registration statement on Form 20-F under the Securities Exchange Act of 1934 to the Securities and Exchange Commission relating to the proposed registration in the United States of its class of American Depositary Shares (ADS) representing ordinary shares of the Company. This disclosure does not constitute an offer to sell, or the solicitation of an offer to buy, any securities of the Company.

In connection with the registration of such class of securities, the Company intends to apply for listing on NASDAQ. Should such listing be approved, our ADS would trade on NASDAQ and would no longer trade on the over-the-counter market. There is no guarantee that the Company's efforts will be successful and the Company may abandon its efforts to register this class of shares and the NASDAQ application at any time at its sole discretion.

## Pipeline Update

In fiscal 2020, AVITA anticipates pivotal trials commencing to establish the safety and effectiveness of the RECELL System for early intervention treatment of pediatric scald wounds and for trauma/soft tissue repair. In fiscal 2021, AVITA expects to commence a pivotal study of the RECELL System for the treatment of vitiligo and anticipates, in collaboration with COSMOTEC, an M3 Group company, securing marketing approval and reimbursement of the RECELL System in Japan.

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.

## Fourth 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 fourth quarter of fiscal 2019, the quarter ended 30 June 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 implementation of further clinical development of the RECELL System.

During the quarter ended 30 June 2019, total cash receipts were A\$5,040, an increase of A\$192 or 4% compared to the prior quarter ended 31 March 2019. Cash receipts from customers for the quarter ended 30 June 2019 were A\$3,514, an increase of A\$1,001 or 40% compared to the prior quarter due to the second quarter of commencement of the U.S. national market launch of the RECELL System. Cash received from BARDA during the current quarter totaled A\$1,526, a decrease of A\$198 or 11% 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 the RECELL System as well as compassionate use and continued access programs. Through 30 June 2019, cumulative payments of A\$25.9 million have been received under the BARDA contract.

Overall payments for operating expenses increased in line with expectations during the fourth quarter of fiscal 2019 as a result of increased initiatives. During the quarter ended 30 June 2019, payments related to sales and marketing, staffing, administrative and corporate costs for the current quarter totaled A\$13,265 a A\$3,687 or 38% increase compared to the quarter ended 31 March 2019. During the quarter ended 30 June

2019, payments related to product manufacturing and operating costs totaled A\$1,036, a A\$117 or 13% increase compared to the quarter ended 31 March 2019. The increase was directly related to the increase in sales during the current quarter. During the quarter ended 30 June 2019, payments for research and development costs totaled A\$1,429, a A\$504 or 54% increase compared to the quarter ended 31 March 2019. This increase was the result of the expansion of research and development 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, 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 30 June 2019 was A\$10,430, a A\$3,949 or 61% increase compared to the quarter ended 31 March 2019. The current quarter increase in net cash used in operating activities resulted from the increase in payments for operating expenses, partially offset by cash receipts.

During the quarter ended 30 June 2019, net proceeds provided by employee stock options exercised, was A\$453. Cash and cash equivalents held at 30 June 2019 was A\$29,155.

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 8,000 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.*

### FOR FURTHER INFORMATION:

#### U.S. Media

##### Sam Brown, Inc.

Christy Curran

Phone +1 615 414 8668

[christycurran@sambrown.com](mailto:christycurran@sambrown.com)

#### O.U.S Media

##### Monsoon Communications

Sarah Kemter

Phone +61 (0)3 9620 3333

Mobile +61 (0)407 162 530

[sarahk@monsoon.com.au](mailto:sarahk@monsoon.com.au)

#### Investors:

##### Westwicke Partners

Caroline Corner

Phone +1 415 202 5678

[caroline.corner@westwicke.com](mailto:caroline.corner@westwicke.com)

##### AVITA Medical Ltd

Timothy Rooney

Chief Administrative Officer

and Interim Chief Financial Officer Phone +1 661 367 9161

[trooney@avitamedical.com](mailto:trooney@avitamedical.com)

i Kowal S, Kruger E, Bilir P, Holmes JH, Hickerson W, Foster K, Nystrom S, Sparks J, Iyer N, Bush K, Quick A. Cost-Effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States. *Advances in therapy*. 2019. 36: 1715-1729. <https://doi.org/10.1007/s12325-019-00961-2>

ii Liu B, Chen HH, Liu ZH, Liang JF, Xue RJ, Chen PJ, Li CX, Liang XD, Deng J, Ye RX, Zhang XB. The clinical efficacy of treatment using the autologous non-cultured epidermal cell suspension technique for stable vitiligo in 41 patients. *Journal of Dermatological Treatment*. 2019. (accepted). <https://doi.org/10.1080/09546634.2019.1619657>

iii Holmes IV JH, Molnar JA, Carter JE, Hwang J, Cairns BA, King BT, Smith DJ, Cruse CW, Foster KN, Peck MD, Sood R. A comparative study of the ReCell® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. *Journal of Burn Care & Research*. 2018. 39(5): 694-702. <https://doi.org/10.1093/jbcr/iry029>

iv Holmes IV JH, Molnar JA, Shupp JW, Hickerson WL, King BT, Foster KN, Cairns BA, Carter JE. Demonstration of the safety and effectiveness of the RECELL® System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. *Burns*. 2019. 45(4): 772-782. <https://doi.org/10.1016/j.burns.2018.11.002>