



AVITA Medical Reports Second Quarter Fiscal 2020 Financial Results and Company Update

January 30, 2020

U.S. RECELL® System product sales of A\$4.66M for fiscal second quarter

Valencia, Calif., USA, and Melbourne, Australia, 31 January 2020 — AVITA Medical Limited (ASX: AVH, NASDAQ: RCEL), a regenerative medicine company with a technology platform positioned to address unmet medical needs in therapeutic skin restoration, reported financial results for the fiscal second quarter ended 31 December 2019 today in its Appendix 4C - Quarterly Cash Flow Report filed with the Australian Securities Exchange (ASX).

U.S. Commercial Sales of RECELL® System for Quarter and Half-Year Ended 31 December 2019

Product sales and other revenues for the second quarter and six months ended 31 December 2019 were as follows (unaudited):

(Thousand Australian \$'s)	Three Months Ended		Six Months Ended	
	<u>31 December</u>		<u>31 December</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
U.S. product sales	A\$4,661	A\$1,102	A\$ 9,274	A\$1,102
International product sales	<u>234</u>	<u>343</u>	<u>410</u>	<u>711</u>
Total product sales	4,895	1,445	9,684	1,813
Other income (including BARDA)	<u>705</u>	<u>2,509</u>	<u>3,846</u>	<u>5,113</u>
Total revenue	<u>A\$5,600</u>	<u>A\$3,954</u>	<u>A\$13,530</u>	<u>A\$6,926</u>

"We are extremely pleased with the expanding use of the RECELL System in a large number of U.S. burn centers and in a broadening array of burn types. We have very high interest in the RECELL System with more than 160 trained burn physicians and 63 accredited burn institutions either having navigated through the Value Analysis Committee (VAC) approval process or obtaining ad hoc approval to purchase the RECELL System. In addition, we see ongoing strong support and usage of the RECELL System, including in the last two months of 2019 where we witnessed our highest procedural volumes since FDA approval. Physician feedback continues to be highly positive and we are well-placed to broaden usage as physicians gain broader clinical experience and begin to migrate from large total body surface area (TBSA) full thickness burns to smaller TBSA burns and partial thickness burns. We believe that broader TBSA utilization within our existing customer base, together with the addition of new RECELL customers, provides ample opportunity for us to drive revenue increases in 2020. By leveraging our success within our initial market of 14,000 eligible in-patient burn patients, we are now eager to approach the larger opportunities within burns (i.e. smaller burns), soft tissue reconstruction, vitiligo and genetic errors," said Dr. Mike Perry, AVITA Medical's Chief Executive Officer.

2019 in Review

United States In-Patient Burns

31 December 2019 marked the first full calendar year (CY) of sales since the U.S. commercial launch of the RECELL System in early January. During the first half of CY2019, our commercial and clinical support team made concerted efforts to build awareness and to promote the donor-sparing, point-of-care and related clinical benefits of the RECELL System among an initial cohort of the 132 burn centers (i.e. the in-patient setting) that treat approximately 40,000 burn patients each year.

The core of these early efforts involved educating and training many of the 300 certified burn surgeons, proctoring bench and in vivo use of the RECELL System, and ultimately seeking hospital approval to purchase the RECELL System through the respective VAC at each burn center.

With RECELL being the first product in more than 20 years granted Premarket Approval (PMA) by the U.S. Food and Drug Administration (FDA) to treat severe thermal burns, we were able to quickly secure orders in 39 of the 132 U.S. burn centers (and train 136 burn surgeons) by 30 June 2019. Consistent with our two randomized clinical studies and our PMA, early utilization of the RECELL System by the first adopters mainly focused on the less common full thickness or "big burns"; that is, the larger and deeper (full thickness) TBSA burns bracket within the approximately 14,000 of the 40,000 patients treated within the in-patient setting.

In the quarter ended 30 September 2019, we added a further 13 institutions (as well as increasing to 157 trained burn surgeons) and saw our top line revenue consequently benefit from the addition of these new customers, including some larger stocking orders from key customers during that period. With the initial core customer base established within this window, our commercial efforts in Q3 CY2019 shifted to building consistent RECELL utilization by ensuring strong clinical outcomes within those early users of the RECELL System. Creating a strong commercial support presence in

centers, paired with excellent RECELL clinical experience was a key focus during the first quarter of fiscal year (FY) 2020 (Q3 CY2019) because the in-patient burn treatment setting is characterized by physician preference and inherent variability in month-to-month patient accrual (i.e. burns are random, or “accident-induced,” and therefore lack a consistent referral path).

The closing three months of 2019 (FQ2 FY2020 / Q4 CY2019) resulted in growing and consistent utilization of the RECELL System across our customer base, including some of the highest procedural rates with the RECELL System since PMA (and 15 to 20% higher than FQ1 FY 2020 / Q3 CY 2019). Furthermore, we were able to add eight new customers late in the quarter and train an additional nine burn surgeons. This brought our 2019 total to 63 ordering customers and 166 trained burn surgeons. Due to our commercial team’s efforts in educating both physicians and burn centers, we have reaped to date 100% success in navigating the VAC approval process and have established a base of “super users,” or physicians using the RECELL System across a broad array of burn sizes and depths, and patient types. In this regard, our top 20 customers are relatively concentrated and delivered approximately 60% of revenue in each of the last two quarters of CY2019. Because of this, we see the opportunity in 2020 to similarly more broadly penetrate our other RECELL customers, as well as to expand our footprint into new burn centers.

In pursuit of wider utilization of the RECELL System, we intend to add 25 new sites in CY2020 and will leverage our current commercial infrastructure to do so. The rate of in-patient burn admissions is inherently variable, but we feel very confident of incremental revenue growth across the entirety of CY2020 as we

continue to focus on our “go deep” strategy of (1) broader TBSA burn utilization (i.e. broadening RECELL use from large, full thickness, TBSA wounds, or “big burns,” to the much higher incidence of smaller or partial thickness burns) consistent with usage patterns demonstrated by our most experienced users; and (2) educating and training other burn surgeons within our customer base. We see a total addressable burn market for the RECELL System of U.S. \$200 million in in-patient burns.

A summary of CY2019 commercial highlights is set out below

Quarter Ended

31 March 30 June 30 Sept 31 Dec

(United States \$'s)

U.S. RECELL Sales \$1,577,341 \$2,036,270 \$3,183,030 \$3,178,160 \$9,974,801

Cumulative. U.S. RECELL Sales \$1,577,341 \$3,613,611 \$6,796,641 \$9,974,801

New Accounts	9	21	13	8
<u>Cumulative Accounts</u>	<u>18 39 52 60</u>			
Physicians Trained	32	39	21	9
Cumulative Physicians	97	136	157	166

Other Developments

While we are making multiple strides across the burn landscape and expanding our addressable markets within those applications, we see many potential synergies across other areas of skin regeneration, and we are moving forward exploring new indications and approvals.

The nearest term opportunity we are advancing is in trauma and soft tissue injuries where, similar to the burn market, surgeons graft skin to repair defects from accidents (e.g. road rash, lacerations, gun shots, etc). The grafting process in these situations is surgically quite similar and, importantly, performed by many of the same physicians as they often complete surgical rotations both in trauma and in burns (thereby potentially allowing portability of the RECELL System across multiple different types of injuries). We expect, and we are already seeing in clinical practice, that surgeons comfortable with using the RECELL System in burns would become experienced and ready adopters of RECELL in the trauma setting. In addition, we are presently pursuing reimbursement for the out-patient setting which we are optimistic to see progress with later this year.

In September 2019, we secured an investigational device exemption (IDE) to pursue FDA approval for soft tissue reconstruction (i.e. trauma injuries). This study will assess the safety and efficacy of the RECELL System in a minimum of 65 trauma patients, and we expect to commence enrollment within FQ3 FY2020 (Q1 CY2020). We see an addressable trauma market for the RECELL System of U.S. \$550 million.

Likewise, we are also seeking FDA approval for a “pediatric scald” label. We have IDEs in-hand for two pediatric studies and are pursuing this with BARDA support and financial assistance. We are working closely with BARDA to obtain agreement to commence these studies and are targeting enrollment in mid-2020. For pediatric scalds we see a total addressable market of U.S. \$250 million.

Looking ahead to another area of skin regeneration, we see readily addressable markets in skin defects, which are caused from other disorders, including conditions such as vitiligo where patients present with areas of skin absent of pigmentation (color). Within the burn setting, we’ve already demonstrated that the RECELL System can deliver Spray-On-Skin cells including melanocytes. Further, we have treated more than 1,000 vitiligo patients in China and have seven published scientific papers, which provides a high degree of confidence that we can help patients with stable vitiligo. In late December 2019, we received FDA IDE approval for a feasibility study with 10 vitiligo patients to primarily determine the optimal concentration of the cell suspension prepared using the RECELL System. This single site study is expected to commence enrollment in FQ3 FY2020 (Q1 CY2020). We predict an addressable market for the use of the RECELL System in vitiligo of U.S. \$600 million.

We also see large opportunities for the RECELL System as a delivery platform to help address cellular and genetic disorders. We believe that the RECELL System can support, and enable, multiple therapies that seek to treat disorders of the skin. To this end, we entered into a sponsored research

agreement with the Gates Center for Regenerative Medicine at the University of Colorado in November 2019. This relationship is focused on proof-of-concept and development of a spray-on treatment of genetically modified cells for patients with the genetic skin disease epidermolysis bullosa (EB), with potential applicability to other genetic skin disorders. There are more than 50 genetic disorders of the skin and we believe this opportunity is potentially significantly larger than the aggregate of the other opportunities mentioned above.

Outside of the U.S., we continue to supply our existing users while maintaining our plan to devote limited commercial resources to the select geographical regions in which the RECELL System is already approved for sale. We will continue to make investments where there is a business opportunity, such as in our announced collaboration agreement with COSMOTEC, an M3 Group company, to market

and distribute the RECELL System for the treatment of burns and other wounds in Japan. On 25 February 2019, COSMOTEC filed a Japan's Pharmaceuticals and Medical Devices Act ("JPMDA") application for approval to market the RECELL System in Japan. The JPMDA application has been accepted, and the review is ongoing.

Podium and Papers

CY2019 was also a busy year for scientific publications and presentations, notably including the following:

- RECELL System clinical data demonstrating cost savings and efficacy presented by physicians at four regional U.S. burn conferences and by Fiona Wood at the Congress of the Asian Pacific Society for Scar Medicine with the Japan Scar Workshop 2-3 November 2019 in Tokyo, Japan
- Data published in *Aesthetic Plastic Surgery* by the Department of Plastic Surgery at Peking Union Medical College Hospital exploring the use of the RECELL System combination with dermabrasion to treat facial acne scars
- Feasibility study results presented at the 11th annual meeting of the Japanese Society of Limb Salvage & Podiatric Medicine 28-29 June 2019 in Kobe, Japan, demonstrating that use of the RECELL System reduced the size of wounds caused by diabetic foot ulcers in all participants
- Preliminary data of RECELL for the treatment of vitiligo and facial acne scars presented at World Congress of Dermatology 10-15 June 2019 in Milan, Italy
- Clinical and cost-savings advantages of using the RECELL System for the treatment of severe burns in a 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, Nevada
- 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
- Exhibited at the American Burn Association National Burn Reconstruction Conference 16-18 October 2019 in Chicago
- 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

Second Quarter Fiscal 2020 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 2020, the quarter ended 31 December 2019, is attached. Operations for the quarter were focused primarily on the U.S. national adoption 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 31 December 2019, total cash receipts were A\$7,689, an increase of A\$2,452 or 47% compared to the prior quarter ended 30 September 2019. Cash receipts from customers for the quarter ended 31 December 2019 were A\$4,920, an increase of A\$841 or 21% compared to the prior quarter due to increased sales on a year-to-date basis. Cash received from BARDA during the current quarter totalled A\$2,769, an increase of A\$1,611 or 139% compared to the prior quarter. The increase was the result of a one-time rate adjustment that was received during the quarter ended 31 December 2019. Through 31 December 2019, cumulative payments of A\$31.8 million have been received under the BARDA contract.

Overall payments for operating expenses increased in line with expectations during the second quarter as a result of increased initiatives. During the quarter ended 31 December 2019, payments related to sales and marketing, staffing, administrative and corporate costs for the current quarter totalled A\$10,578, a A\$1,043 or 11% increase compared to the quarter ended 30 September 2019 primarily due to higher legal and staffing costs. During the quarter ended 31 December 2019, payments related to product manufacturing and operating costs totalled A\$1,974, a A\$630 or 47%

increase compared to the quarter ended 30 September 2019. During the quarter ended 31 December 2019, payments for research and development costs totalled A\$1,333, a A\$33 or 3% increase compared to the quarter ended 30 September 2019. As a result of the ongoing commercialization of the RECELL System in the U.S. along with other planned initiatives set forth by the Company, payments for operating expenses are expected to increase during 2020. These expense payments are expected to 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 2019 was A\$6,335, a A\$702 or 10% decrease compared to the quarter ended 30 September 2019 driven primarily by timing of planned initiatives. Cash and cash equivalents held at 31 December 2019 was A\$124,658.

Authorised for release by the Chief Executive Officer of Avita Medical Limited.

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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, 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 and received CE-mark approval in Europe.

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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