



AVITA Medical Half-Year Financial Report for Fiscal 2020

February 18, 2020

Valencia, Calif., USA, and Melbourne, Australia, 19 February 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, announced that it filed today with the Australian Securities Exchange (ASX) its Appendix 4D – Half-Year Report for the six month period ended 31 December 2019.

Revenues of RECELL® System for First Six Month Period Ended 31 December 2019

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

Six Months Ended

(In thousands of Australian Dollars) 31 December

	<u>2019</u>	<u>2018</u>
U.S. product sales	A\$ 9,274	A\$1,102
International product sales	<u>410</u>	<u>711</u>
Total product sales	9,684	1,813
Other income (including BARDA)	<u>3,846</u>	<u>5,113</u>
Total revenue	A\$ <u>13,530</u>	A\$ <u>6,926</u>

"We continue to be pleased with early RECELL System utilization as we progress our "go deep" strategy within the in-patient burn setting. We are focused on driving incremental growth within existing accounts, together with broadening our commercial footprint via the addition of 25 burns centers throughout calendar 2020. Early 2020 sales performance has highlighted the commitment of burn specialists to the RECELL System, particularly among our group of super users," said Dr. Mike Perry, AVITA Medical's Chief Executive Officer. "With our strong balance sheet, buoyed by our successful financing in November, we are also exploring opportunities to advance our existing clinical programs as well as potentially commencing additional late-stage studies where we believe we have achieved a significant level of de-risking via our substantive body of clinical evidence and peer-reviewed publications. As an example, we will be working with the FDA to explore the possibility of using an adaptive pivotal study design for vitiligo in place of, or adjunctive to, the currently approved IDE in this indication. We plan to provide updates on these opportunities over the next few months."

U.S. RECELL System Update

2020 is off to a pleasing start with consistent demand for the RECELL System, especially among our super users, and notwithstanding the 43rd Annual Boswick Burn & Wound Symposium being held in late January and our National Sales Meeting ("NSM") being held in early February. At our NSM, we spent a significant amount of time consulting with our burns surgeons, including our most experienced users, with a view to improving on best practices for use of the RECELL System. These activities included a specific focus around optimal usage and teaching methodology for the RECELL System, with a particular focus on the use of the RECELL System with smaller burns and as a standalone therapy.

These efforts, and our broader efforts to promote awareness of the RECELL System, will extend into the forthcoming Annual Meeting of the American Burn Association which will be held in Orlando, Florida, 17-20 March. At this meeting, there will be 8+ presentations highlighting RECELL focused on decreased length of stay, cost savings, use on small burns, and other potential uses.

Looking ahead, we will also be attending financial conferences to further educate investor and analyst audiences about RECELL and the potential of the platform. To this end, we will be attending the Cowen Annual Healthcare Conference in Boston, Massachusetts, 4 March. Our presentation will be webcast and a link to the audio track and the presentation will be available on our website, at <https://avitamedical.com/investors>.

Market Acceleration / Expansion Update

Our goal of expanding utilization of the RECELL System to 25 new burns centers during the 2020 calendar year (CY 2020) is well underway, with two new centers ordering as of the end of January. While the rate of in-patient burn admissions is inherently variable, we are confident that site expansion and our broader RECELL System usage will result in incremental revenue growth across the entirety of CY 2020. Consistent with this goal, we are keenly focused on our "go deep" strategy of (1) broadening our burn utilization from large, full thickness, wounds, or "big burns," to the much higher incidence of smaller or partial thickness burns which is consistent with usage patterns demonstrated by our most experienced burn specialists; and

(2) educating and training other burn surgeons within our customer base.

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. degloving, lacerations, gun shots, etc.). In 2019 September, we secured an investigational device exemption (IDE) to pursue FDA approval for soft tissue reconstruction (i.e. trauma) and we presently have three sites screening patients with our first patient expected

shortly. This study will assess the safety and effectiveness of the RECELL System in a minimum of 65 trauma patients. In addition, we are pursuing incremental reimbursement avenues within the out-patient setting as we believe this will be important to support adoption of the RECELL System.

Within the broader “burn market,” we are also seeking FDA approval for a pediatric scald indication. We have FDA investigational device exemptions for our two pediatric scalds studies and plan to commence these studies soon, with enrollment slated to start in mid-2020.

As previously disclosed, 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. While we remain committed to the 10-patient, single-site pilot study, we are presently considering adaptive trial designs that could lead to an acceleration of the commencement of a full pivotal

study for the RECELL System in vitiligo. Our depth of clinical experience with patients internationally makes us confident that such a strategy would address this unmet need, have a high likelihood of success, and could allow us to get our technology to patients more quickly and efficiently.

We are also continuing to explore large opportunities for the RECELL System as a delivery platform to help address cellular and genetic disorders. As previously disclosed, 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. It is early days in this program, but we are hopeful of first in-human studies commencing in the middle or second half of 2021. In parallel, we are well-advanced with discussions to secure a rejuvenation application for the RECELL System and hope to have further details available in the middle of this year.

Lastly, with our successful capital raising in November 2019, we have additional resources that may allow us to advance into a potential FDA registration study in an area where we have existing strong, and deep, clinical evidence. These opportunities are all presently under re-assessment, and we hope to provide more clarity, including details regarding the potential commencement of an additional registration study, on some of these opportunities over the coming months.

Further information on AVITA's current and future opportunities may be found in our recent operating review contained in the ASX Appendix 4C, dated 31 January 2020, together with the Company's revised corporate presentation which was lodged with the ASX today

Half-Year Fiscal 2020 Financial Results (Unaudited)

A copy of the Appendix 4D – Half-Year Report for the six months ended 31 December 2019 is attached. A summary of the financial results for the half year are as follows:

Six Months Ended

(In thousands of Australian Dollars) 31 December

	<u>2019</u>	<u>2018</u>
Sale of goods	\$ 9,684	\$ 1,813
Cost of sales	<u>(2,326)</u>	<u>(570)</u>
Gross profit	7,358	1,243
BARDA income	3,549	5,009
Other income	<u>297</u>	<u>104</u>
Total other income	3,846	5,113
Operating costs	<u>(32,185)</u>	<u>(21,935)</u>
Loss for the period	(20,981)	(15,579)
Foreign currency translation	<u>(2,775)</u>	<u>1,374</u>
Total other comprehensive loss	<u>(\$23,756)</u>	<u>(\$14,205)</u>

The increase in current-year sales occurred in the U.S. as a result of the commencement of the U.S. national market launch of the RECELL System in January 2019. Gross margin for the half-year ended 31 December

2019 was 76% compared to 69% for the same period in 2018, and the company expects gross margins to improve as sales ramp up within the U.S. market. BARDA income declined as a result of 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 the result of investments in commercial, manufacturing, and system capabilities to support the continued growth of the RECELL System in the U.S. market and related initiatives, operating costs and net loss for the half-year ended 31 December 2019 increased compared to the same period in the prior year.

During the six months ended 31 December 2019, the Company completed an institutional placement in which it issued 203,389,831 shares at a price of A\$0.059 per share and received gross proceeds of A\$120,000,000. The cash and cash equivalents balance at 31 December 2019 was

approximately \$124.7 million.

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

###

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:

U.S. Media

Sam Brown, Inc.

Christy Curran

Phone +1 615 414 8668

christycurran@sambrown.com

O.U.S Media

Monsoon Communications

Rudi Michelson

Phone +61 (0)3 9620 3333

Mobile +61 (0)411 402 737

rudim@monsoon.com.au

Investors:

Westwicke Partners

Caroline Corner

Phone +1 415 202 5678

caroline.corner@westwicke.com

AVITA Medical Ltd

David McIntyre

Chief Financial Officer Phone +1 661 367 9178

dmcintyre@avitamedical.com