# AVITA Medical Provides Preliminary Top Line Results for the Third Quarter and COVID-19 Update

April 5, 2020

**Valencia, Calif., USA, and Melbourne, Australia, 6 April 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, today announced preliminary estimates of its top line results for the three months ended 31 March 2020, together with an operating update relating to the COVID-19 pandemic.

## Preliminary Estimates of Top Line Results for Three Month Period Ended 31 March 2020

On a preliminary estimate basis, AVITA Medical expects its results of operations for the three months ended 31 March 2020 to reflect:

- Total revenue of approximately A$6.0M, an increase of A$1.0M or 21% over the A$4.9M recognized during the previous
- S. RECELL Sales of approximately US$3.9M, an increase of US$0.7M or 22% over the US$3.2M recognized during the previous quarter.*
- Cash totaled A$129.9M, an increase of A$5.2M from the A$124.7M reported in the previous quarter, driven largely by the decline in value of the Australian dollar relative to the U.S.
- Commercial metrics:
    - Estimated procedural volumes increased by approximately 23% over the prior
    - New accounts added – 9.
    - Cumulative accounts with Value Analysis Committee (VAC) approval –

* This financial measure is not presented in accordance with International Financial Reporting Standards

(“IFRS”). Please see “Non-IFRS Financial Measures and Other Items” for more information.

The Australian Securities Exchange (ASX) Appendix 4C Quarterly Cash Flow Report (“4C Cash Flow Report”) is scheduled to be filed with ASX during the week commencing 27 April 2020.

“We are pleased with the continued growth trajectory of the RECELL System during the last quarter,” said Dr. Mike Perry, AVITA Medical’s Chief Executive Officer. “The onset of COVID-19 has created challenges for society in general, so it is pleasing to see that the unique benefits of the RECELL System, including reducing the length of stay for burn patients, are still being well received. While it is difficult to predict the medium- to long-term implications of the pandemic, we are committed to preserving the safety, health, and wellbeing of our employees, customers, and the burn patients we serve and are well capitalized to do so. We are operating in alignment with the guidelines of the World Health Organization, Centers for Disease Control, and local agencies, and our priority is to make sure the RECELL System is readily available for the treatment of burn patients. We expect the current environment will negatively impact the pace of enrollment of our investigational studies, and so we are continuing to adapt our practices and policies in line with daily developments.”

## Operating Update Related to the COVID-19 Pandemic

With governments launching unprecedented public-health and economic responses to the expanding COVID-19 pandemic, we provide the following overview of the operating measures that we have implemented in the communities in which we operate:

- Comprehensive work from home procedures, together with social distancing protocols, have been adopted across the majority of our
- Employees are largely utilizing company supplied digital and audio means to support the ongoing needs of the business.
- Manufacturing continues with relevant protective measures to ensure continuity of supply of the RECELL System for patients suffering from acute thermal
- Travel is limited to essential travel, meaning it is only permitted to the extent it is strictly required for patient safety or emergent case
- The broader business is tightly focused on existing activities pending the relaxation or cessation of movement and related social restrictions. In this context, the Company is managing expenses appropriately.

Developments in relation to COVID-19 are a day-by-day proposition that the Company monitors closely, and it will adapt its practices and policies in line with those changes. The Company provides the following information and guidance in relation to the potential impact of COVID-19 on its business:

- The Company is deeply committed to its employees and patients and is focused on ensuring that the RECELL System is continuously available, as
    - The Company believes it has enough supplies of raw material to support expected demand throughout the balance of this calendar year and has additional raw materials and access to service providers (i.e. sterilization) to support demand into
    - The Company does not presently expect any disruptions to its supply chain or distribution

    - To ensure continuity of supply, the Company has arranged for RECELL System inventory to be stored at various locations outside of our Ventura manufacturing

- Burn procedures are not elective and cannot be
    - Severe burn patients face serious health complications requiring immediate treatment and hospitalization, including within intensive care units (ICU's).
    - The incidence of burn procedures is "lumpy" and subject to multiple extrinsic and unpredictable conditions. The onset of COVID-19 has not changed that
    - Through the date of this report, there has been no substantial change in ordering habits of our hospitals.

- Healthcare institutions across the United States have implemented various restrictions, and together with our own COVID-19 protocols, we therefore have dramatically reduced face-to-face experience with our existing, new and potential customers. In the majority of territories, our clinical and commercial support employees are no longer providing live case support at the
    - Our commercial team is leveraging digital tools to sustain our business, preserve relationships, and support continued excellent results for burn

- Our RECELL System super users are more clinically experienced, and therefore more independent, than our newer users for whom we are deploying additional coaching, training, and
- Our field force continues to support cases and provide training virtually. For example, our case support staff are already successfully using online channels to provide virtual support for surgeons treating patients with the RECELL System (as needed).

- The Company will continue to target new account initiations throughout the course of 2020; however, the rate of progression is likely to be impaired by the current operating
    - With COVID-19 protocols in place and limited onsite hospital presence for our personnel, it is possible that new account acquisition and new user uptake may be delayed or more graduated than would otherwise be the
    - The cancellation of various professional meetings (e.g. the 2020 Annual American Burn Association Meeting in March) is disappointing and provides more limited access to existing and new customers than previously anticipated. The Company continues to pursue its communications and related strategies for abstracts, posters, and

- Investigational studies within the United States are largely being de-prioritized by hospitals and sponsors in order to not distract critical resources away from patients requiring COVID-19 treatment. While some of the Company's study sites continue to search for patients to enroll, the Company largely expects there to be a pause in enrollment and site roll-out until the COVID-19 pandemic

- The Company is well-capitalized and does not currently require additional

## Corporate Presentation

An updated corporate presentation will also be available on the Company's website later today.

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

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## Non-IFRS Financial Measures and Other Items

The foregoing information and estimates are preliminary in nature and are subject to revision as we prepare our 4C Cash Flow Report and other disclosures as of and for the three months ended 31 March 2020, including all disclosures required by ASX Listing Rules. Because we have not completed our normal quarterly closing and review procedures for the three months ended 31 March 2020, and subsequent events may occur that require material adjustments to these results, the final results and other disclosures for this period may differ materially from these estimates. These estimates should not be viewed as a substitute for the full disclosure of our 4C Cash Flow Report. These estimated results of operations should be read together with subsequent filings and announcements, including any subsequent press release announcing the Company's earnings for the quarter ended 31 March 2020.

*Non-IFRS Financial Measures and Other Items*

We use the following measures of financial performance which are not presented in accordance with IFRS:

- "U.S. RECELL Sales", which is the amount of revenue, denominated in United States dollars, we generate from our commercial efforts in relation to the sale of RECELL Systems within the United

States. Management believes that this measurement is useful for comparing period to period sales performance, and product acceptance, of the Company's lead product, the RECELL System, within the United States burn market.

U.S. RECELL Sales is a non-GAAP financial measure used by management in evaluating sales performance, and product acceptance, within the

United States and for the purposes of making strategic decisions. Management believes that the presentation of U.S. RECELL Sales provides useful information to investors regarding our revenue results because they assist both investors and management in analyzing and benchmarking the performance and value of our business. U.S. RECELL Sales provides indicators of product performance that are not affected by currency fluctuations. Accordingly, management believes that this measurement is useful for comparing general sales performance from period to period in the Company's largest market.

## 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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