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

April 28, 2020

Valencia, Calif., USA, and Melbourne, Australia, 29 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, reported financial results for the fiscal third quarter ended 31 March 2020 (Q3) 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 Ended 31 March 2020

Product sales and other revenues for the third quarter and nine months ended 31 March 2020 were as follows (unaudited):

(Thousand Australian $'s)	Three Months Ended 31 March		Nine Months Ended 31 March	
	2020	**2019**	**2020**	**2019**
U.S. product sales	A$5,809	A$2,206	A$15,083	A$3,308
International product sales	148	189	558	900
Total product sales	5,957	2,395	15,641	4,208
Other income (including BARDA)	2,108	2,427	5,954	7,540
Total revenue	**A$8,065**	**A$4,822**	**A$21,595**	**A$11,748**

"Our strong fiscal third quarter results demonstrate continued growing adoption trends within both our existing and new RECELL System customers," said Dr. Mike Perry, AVITA Medical's Chief Executive Officer. "In the current COVID-19 environment, we are deploying various strategies, including supply redundancies and digital training, to drive usage and continue serving burn surgeons and their patients. While severe burn treatments are not elective procedures, there has been a pause in enrollment in some of our clinical trials due to COVID-19; however, we are advancing our pipeline and are currently developing the protocol and FDA Investigational Device Application for the RECELL vitiligo pivotal study. In addition, we are continuing to make progress toward redomiciling the Company to the United States to better align the Company's corporate structure with our U.S. business operations."

Corporate Update

Our commercial efforts in Q3 progressed well with quarterly growth exceeding 20% across both procedural volume and U.S. RECELL System revenue. Q3 represents our strongest quarter since launching in the United

States in January last year reflecting strong customer uptake, even with the COVID-19 pandemic beginning toward the end of the quarter. In the quarter ended 31 March 2020, we also added nine new customers and certified an additional 21 surgeons, bringing our total to 69 customers and 205 certified burn surgeons, together with progressing our ongoing clinical investigations with first patient enrollment in our soft tissue and pediatric partial thickness studies. All of these factors collectively demonstrate ongoing high interest in the RECELL System, together with consistent usage and acceptance across our growing customer base.

We have seen consistent growth since the launch of the RECELL System and we have, so far, been somewhat insulated from the COVID-19 challenges to-date given the treatment of burns patients is generally not elective nor deferrable. While we didn't see any impact to the rate of burn incidence or RECELL System utilization during the quarter, it continues to be difficult to predict the breadth of potential impacts over the coming months due to the current COVID-19 macroenvironment. These considerations operate in addition to the overarching burn environment which is inherently "lumpy" and difficult to forecast.

Set out below is additional information which builds on our two earlier news releases on our progress and COVID-19 implications:

- Our field force, as with all our employees, continue to operate largely on a work-from-home basis with severely limited travel. These measures have been implemented in accordance with relevant government requirements and, more importantly, to protect the safety and welfare of our employees. We continue to monitor the environment but, at this juncture, do not expect a relaxation or reduction of the restrictions until June at the earliest, and potentially

- The Company is well-positioned from a supply and distribution perspective and does not envisage any disruption or delays to the availability of the RECELL System. In addition, the Company has established two offsite storage points which house RECELL System inventory in case of disruption at the Company's manufacturing facility in Ventura,
- With nationwide COVID-19 restrictions, our field force has very limited face-to-face access with our existing and potential new customers and our current commercialization efforts continue to be largely driven in a remote format. These activities may be summarized as follows:
    - Extensive digital and telephonic outreach in a variety of
        - Webinars, teach-ins, digital proctoring, remote "in-service" interactions, remote wet labs are some
    - Live digital and audio case support continues as
    - Live case support by our field force in a very limited number of
    - Identification of certain unique cases that demonstrate the clear benefits of the RECELL System, such as the "faces" presentation which may be accessed at https://www.avitamedical.com/about-recell-us.
    - We also continue to conduct remote teach-ins and regional Advisory Board forums, to enable shared RECELL System experience and to broaden physician awareness around the unique benefits of the RECELL System (including one this past weekend).
- We reached further corporate milestones during the quarter by initiating two (2) pivotal studies with treatment of the first patient in our soft tissue reconstruction study, and in our pediatric partial-thickness (scald)

- We were disappointed with the understandable cancellation of the 52nd annual American Burn Association (ABA) Meeting in March; however, data abstracts from the meeting are summarized at https://www.avitamedical.com/uploads/pdf/ABA-Data-Press-Release-04022020.pdf.

3Q Review & 2020 Perspective

As we look back at Q3, this quarter represents one of our best performances since launch and included revenue and procedural volume growth exceeding 20%. Q3 also marked the first quarter for the RECELL System to be utilized in more than 400 procedures marking continued strong endorsement of the unique benefits that the RECELL System offers.

A summary of our quarterly commercial highlights is set out below:

(United States $'s)	**Quarter Ended**				
	31 March 2019	**30 June 2019**	**30 Sept 2019**	**31 Dec 2019**	**31 March 2020**
US RECELL Sales	$1,577,341	$2,036,270	$3,183,030	$3,178,160	$3,861,530
Cumulative. U.S. RECELL Sales	$1,577,341	$3,613,611	$6,796,641	$9,974,801	$13,836,331
New Accounts	9	21	13	8	9
Cumulative Accounts	18	39	52	60	69
Physicians Certified	32	39	21	27	21
Cumulative Physicians	97	136	157	184	205

As we look back at a very successful quarter and think about the path ahead, it is clear that our customers are now operating under challenging conditions, and this is creating a broad spectrum of commercial behavior which varies greatly and is driven by heterogeneic considerations such as:

- Localized COVID-19 conditions (i.e. whether the hospital is located within or near to a COVID-19 “hotspot”).
- The breadth of the infrastructure within a relevant hospital, and its inherent ability to cope with COVID-19 patient admission surges with, or without, impacting the treatment of burn patients in that
- The availability of proximate hospital facilities with burn treatment capabilities that enable burn patients to be re-distributed to preserve COVID-19 response
- Institutional specific policies that limit the number of ICU beds available to treat burn

Given the above, we are experiencing a wide degree of commercial variability across the United States, which is representative of the inconsistent and regionalized nature of COVID-19 outbreaks. In regions where we see highly restrictive operating conditions or constrained burn treatment resources, our ability to be effective in those locations is impacted by the number of our customers in those regions and, more importantly, the associated degree of RECELL System experience (i.e. our outcomes are impacted by regional COVID-19 considerations and whether the affected hospital is, for example, a “super user”).

Independent of the above and despite burn procedures being non elective, our experience tends to indicate

that the incidence of burns will not be immune from the lower levels of economic activity (e.g. manufacturing, retail, etc.) and reduced travel and road activity that are presently occurring in the United States due to the COVID-19 pandemic. Similar to the experience with the declining number of car accidents and heart attacks, our best guess is that the number of burns patients could decline during the COVID-19 overhang and that decline could potentially occur in the range of 0 to 20%.

Despite these unprecedented operating conditions, our commercial team continues to be highly active with our customers as circumstances permit. However, the lack of face-to-face time with our customers and the fact that hospital resourcing is generally focused around COVID-19 means that new account accrual and the opportunity for our field force to assist newer accounts to develop broader burns treatment experience (i.e. migrating from bigger to smaller burns, and using the RECELL System without autografting) is presently impaired.

Other Developments and Updates

As broadly reported across the United States, the COVID-19 pandemic has required hospitals and clinical research institutions to prioritize their resources, efforts and facilities to expand, and reserve, capacity for the treatment of COVID-19 patients. The direct implication of this is that clinical investigational studies are not generally being actively pursued and, in consequence, enrollment in our existing clinical studies (i.e. our soft tissue reconstruction pivotal, pediatric partial-thickness pivotal study and our vitiligo feasibility study) is largely paused pending further developments with COVID-19. We are hopeful that the present re- prioritization of resources away from clinical studies will lessen in the short term to allow a restart of our studies. We will provide updates here as appropriate.

Vitiligo

Over the last few months, we have been exploring the possibility of advancing a pivotal study that would evaluate the safety and effectiveness of the RECELL System in the treatment of stable vitiligo patients.

These efforts have incorporated a range of discussions with industry experts and key opinion leaders for the purpose of determining essential elements of a potential clinical protocol including, among other things, primary endpoints, study population, and the treatment protocol.

The above efforts are now approaching completion and we are presently in the process of compiling an Investigational Device Exemption (“IDE”) application for the vitiligo pivotal study which we plan to submit to the U.S. Food & Drug Administration (“FDA”) before the end of June. The current proposal remains formative but is expected to incorporate the following elements:

- Eligible patients with stable vitiligo as confirmed by no new lesions in the last twelve (12)
- The treatment arms would include skin cell suspensions with multiple
- Patients will act as their own control by providing two (2) areas of
- Primary endpoint at twenty-four (24) weeks will likely speak to the extent of re-pigmentation as determined by a blinded evaluator, with a patient rated satisfaction score as a secondary

The Company believes the vitiligo market represents a large, attractive market, and one for which there is no approved therapy for patients. Vitiligo is an autoimmune deficiency which creates enormous quality of

life implications for patients and is comparable to the stigma experienced by patients suffering from psoriasis, acne or rosacea. Subject to receiving FDA approval for the IDE, the Company is hopeful of being ready to initiate this pivotal study in the second half of 2020 (subject to COVID-19 developments). If the pivotal study thereafter successfully meets its endpoints, the Company will leverage its existing premarket approval (“PMA”) to submit a PMA supplement to the FDA (as opposed to being required to submit a full PMA) thereby seeking to add a new indication for use (i.e. patients with stable vitiligo) to our existing acute thermal burns indication.

Independent of the above efforts, the Company already has an IDE for a vitiligo pilot study and recently entered into a research collaboration with the University of Massachusetts. As previously disclosed, this pilot study (n=10) will also include patients who have vitiligo lesions that have been stable

for at least one year. This study will provide incremental learnings and data, operating in parallel with the Company's new efforts to bring forward a pivotal study with the FDA as discussed above.

Pediatric Studies

In early March 2020, we announced the initiation of a pivotal trial for the treatment of pediatric scald injuries with enrollment of the first patient at the Arizona Burn Center at Valleywise Medical Health Center in Phoenix, AZ. This study seeks to demonstrate that treatment with the RECELL System of partial-thickness burn injuries within 72-hours can safely and effectively increase the incidence of healing at day 10 when compared to a standard wound dressing. This study is ongoing, but enrollment is paused given the COVID- 19 pandemic.

Additionally, the Company has a second pediatric study which is commonly referred to as the "pediatric donor study". This is a randomized clinical study to compare the healing of a donor site in pediatric patients treated with the RECELL System versus conventional care (i.e. standard dressings only). This study was conceived more than three (3) years ago and prior to the PMA, and the growing commercial adoption, of the RECELL System in the United States. Given the premarket approval of the RECELL System and the resultant strong early adoption, the Company believes that there is little clinical utility, and little practical benefit, in continuing this study (including no ability for this study to expand our existing approved burn indication). For these reasons, the Company is actively pursuing terminating this study (but continuing with the pediatric partial thickness study mentioned above).

Data Publication

A study titled "A pilot multi-centre prospective randomized controlled trial of RECELL for the treatment of venous leg ulcers," by Paul D. Hayes, Keith G. Harding, Susan M. Johnson, Charles McCollum, Luc Teot, Kevin Mercer, and David Russell published online in the *International Wound Journal* in February and will also publish in the June print edition of the journal.[1]

Intention to Redomicile to the United States of America

On 20 April 2020, we announced our intention to redomicile from Australia to the United States. Under the proposed redomiciliation, AVITA Therapeutics, Inc.[2] ("AVITA US") will become our new parent company.

1 Hayes, PD, Harding, KG, Johnson, SM, et al. A pilot multi-centre prospective randomised controlled trial of RECELL for the treatment of venous leg ulcers. *Int Wound J*. 2020; 17: 742– 752. https://doi.org/10.1111/iwj.13293

2 AVITA Therapeutics, Inc. is a newly incorporated Delaware company that we control (and which has been solely

While the group will have a new parent company as a result of the redomiciliation, underlying operations, business and assets of the group will remain completely unchanged.

Since 2018, the Company has had no physical business presence, and only one (1) employee, in Australia. In addition, our immediate commercial focus is on unlocking the U.S. market, where we currently source virtually all of our revenue. Against this background, the beneficial owners of a majority of our shares are now located outside Australia, with ~50% of shares being beneficially owned by investors in the United States alone.

The redomiciliation proposal therefore provides the Company with the opportunity to align our corporate structure with our business and beneficial ownership, and has the added benefit of providing a familiar investment offering (versus our existing American Depositary Shares) to investors in the United States, which is the world's largest capital market in terms of market capitalization and trading volume.

Importantly, the proposal allows us to substantially reduce our financial reporting and compliance burden and save costs, while not impacting the quantity of financial information provided to investors or disrupting trading on either the ASX or NASDAQ.

The proposal, which will be implemented pursuant to a scheme of arrangement under Australian law, is subject to approval by shareholders (at a shareholders' meeting currently tentatively scheduled for 15 June 2020) and orders of the Federal Court of Australia as well as regulatory review by various government bodies, including the Australian Securities and Investments Commission and the Foreign Investment Review Board. The Company is anticipating that it will be in a position to send to shareholders in mid-May 2020 a Scheme Booklet that will contain a detailed explanation of the redomiciliation proposal, including the advantages, disadvantages and risks of the proposal, together with an Independent Expert's report that will set out whether, in the expert's opinion, the proposal is in the best interests of shareholders as a whole.

We have received a number of enquiries since the proposal was announced on 20 April 2020 and, as such, for ease of reference we set out below some key features of the redomiciliation proposal. ***It is however important that shareholders appreciate that the below is a brief and high level overview of some key aspects of the proposal (if implemented), and the Board of Directors strongly encourages shareholders to review the Scheme Booklet in detail when they receive it and to take part in the shareholders' meeting. Further, shareholders should consult their financial, legal, taxation or other independent and qualified professional adviser if they have any questions in relation to the proposal***.

· Appendix A provides a simple illustrative example of how the redomiciliation will affect eligible shareholdings.

- Electronic ***trading will continue on both the ASX and NASDAQ***; that is, shareholders will continue to be able to trade on the ASX and NASDAQ in a similar fashion to how they have always traded (except that trading will now be in securities of AVITA Therapeutics, Inc. rather than AVITA Medical Limited).
- Trading is expected to continue to use the same ticker codes; the ASX will continue to use "AVH" and NASDAQ will continue to use "RCEL".

· Eligible shareholders[3] will have the same proportionate value and ownership on completion of

established for the purposes of redomiciliation).

3 Shareholders in countries outside of Australia, the United States, Hong Kong, New Zealand, the United, Kingdom, France, Norway, Switzerland, the United Arab Emirates and Singapore, together with shareholders with less than

the redomiciliation as they held before the redomiciliation (subject to adjustments for fractional interests). In other words, underlying ownership and proportionate value for eligible shareholders will remain unchanged by the proposal.

- Under the proposal, eligible shareholders will swap their existing interests in the Company for:
  - Common stock in AVITA US, if shareholders currently hold American Depositary Shares ("ADSs") in the Company (which are presently traded on NASDAQ).
    - Holders of ADSs will receive one (1) share of common stock in AVITA US for every 5 ADSs (which represent 100 ordinary shares) held by
    - As noted above, it is expected that AVITA US common stock will trade on NASDAQ under ticker code "RCEL".
  - CHESS Depositary Interests4 ("CDIs") in AVITA US, if shareholders currently hold ordinary shares in the Company (which are presently traded on the ASX).
    - Ordinary shareholders will receive 5 CDIs in AVITA US for every 100 ordinary shares in the Company held by
    - *Five (5) CDI's traded on the ASX will represent one (1) share of common stock on NASDAQ US*.
    - As noted above, AVITA US CDI's will trade on the ASX under ticker code "AVH".
  - The proposal will have the effect of consolidating the number of securities that the group has on issue (i.e. the same effect as a share consolidation or a reverse split as it is more commonly known) by reducing the number of shares the group will have outstanding from the existing level of approximately 2.1
  - The Company is presently well-capitalized and is not undertaking the redomiciliation for the purposes of enabling a new listing of the group in a new capital market or delisting the group from the
  - If the redomiciliation proposal is approved by shareholders and all of the relevant conditions5 that the proposal is subject to are satisfied or waived, then shareholders will not be required to do anything further as the above process will be facilitated automatically by the Company and its Australian and U.S. transfer agents (Computershare).

Third 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 third quarter of fiscal 2020, the quarter ended 31 March 2020, 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.

100 shares, will not be eligible to participate and will have the common stock or CDI entitlement to which they would otherwise have been entitled "cashed out" on their behalf and the net cash proceeds remitted to them.

4 Foreign companies are only permitted to trade on the ASX via CDIs. An example of another company trading CDIs on the ASX is Resmed, Inc., which uses ticker code "RMD" (while its primary listing is on the NYSE, also under ticker code "RMD").

5 The conditions precedent and requisite approvals will be set out in detail in the Scheme Booklet which is currently expected to be made available to shareholders in mid-May 2020.

During the quarter ended 31 March 2020, total cash receipts were A$5,743, a decrease of A$1,946 or 25% compared to the prior quarter ended 31 December 2019. Cash receipts from customers for the quarter ended 31 March 2020 were A$5,254, an increase of A$334 or 7% compared to the prior quarter due to increased sales. Cash received from BARDA during the current quarter totalled A$489 a decrease of A$2,280 or 82% compared to the prior quarter. The decrease was the result of a one-time rate adjustment that was received during the prior quarter ended 31 December 2019. Through 31 March 2020, cumulative payments of A$31.2 million have been received under the BARDA contract.

Overall payments for operating expenses increased in line with expectations during the third quarter of fiscal 2020. During the quarter ended 31 March 2020, payments related to sales and marketing, staffing, administrative and corporate costs totalled A$14,287, a A$3,709 or 35% increase compared to the quarter ended 31 December 2019 due to increased initiatives and staffing costs. During the quarter ended 31 March 2020, payments related to product manufacturing and operating costs totalled A$1,678, a A$296 or 15% decrease compared to the quarter ended 31 December 2019. During the quarter ended 31 March 2020, payments for research and development costs totalled A$1,918, a A$585 or 44% increase compared to the quarter ended 31 December 2019 driven by the increased initiatives. 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 March 2020 was A$11,866, a A$5,531 or 87% increase compared to the quarter ended 31 December 2019 driven primarily by increased legal and professional costs associated with the planned redomiciliation, together with annual employee incentives.

Cash and cash equivalents held at 31 March 2020 was A$129,935 compared to A$124,658 in the prior quarter, an increase of A$5,277 or 4%. The increase was attributable to the effect of movement in exchange rate on cash held, partially offset by operating expenses.

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

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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

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 RES® REGENERATIVE EPIDERMAL SUSPENSION, 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; risks associated with commercial, supply chain or other business interruptions or downturns associated with national, state or international health emergencies (e.g. pandemics), 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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