



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

- U.S. RECELL® System product sales of A\$4.6M for fiscal first quarter, 60% growth quarter-over-quarter
- Over half of all U.S. burn centers and surgeons trained on RECELL System

Valencia, Calif., USA, and Melbourne, Australia, 31 October 2019 — AVITA Medical (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 first quarter ended 30 September 2019 today in its Appendix 4C - Quarterly Cash Flow Report filed with the ASX.

U.S. Commercial Sales of RECELL® System

The RECELL System has been actively promoted for nine months in the United States following approval by the U.S. Food and Drug Administration (FDA) on 20 September 2018, and the full nationwide commercial launch in January 2019. Product sales and other revenues for the first quarter ended 30 September 2019 were as follows (unaudited):

(In thousands of AUD)	Three Months Ended	
	<u>30 September</u>	
	<u>2019</u>	<u>2018</u>
U.S. product sales	A\$4,583	A\$ -
International product sales	<u>176</u>	<u>368</u>
Total product sales	4,759	368
Other revenue (including BARDA)	<u>3,141</u>	<u>2,604</u>
Total revenue	<u>A\$7,900</u>	<u>A\$2,972</u>

First Quarter Highlights

- A\$4.6 million U.S. sales of RECELL System, 60% growth quarter-over-quarter
- U.S. Commercial achievements since approval:
 - 56 of 132 U.S. burn centers have placed orders for the RECELL System
 - Over 50% of U.S. burn surgeons and burn centers are trained on the RECELL System
 - A\$10.8 million in U.S. sales
- Listed American Depositary Shares on the Nasdaq Capital Market under the ticker symbol “RCEL” with trading commencing 1 October
- AVITA Medical added to S&P/ASX300 index, which measures the performance of the largest 300 companies based on market capitalization on the Australian Securities Exchange
- Received U.S. FDA Investigational Device approval of pivotal study protocol to evaluate the RECELL System for soft tissue reconstruction, inclusive of traumatic wounds
- Publication of multiple studies in peer-reviewed medical journals investigating the potential use of the RECELL System for dermatological conditions:

- “The clinical efficacy of treatment using the autologous non-cultured epidermal cell suspension technique for stable vitiligo in 41 patients” by Bin Liu and Zhong-Hai Liu, Guangzhou New Centre Institute of Vitiligo, Guangzhou, PR China, and Hui-Heng Chen, Dongguan Eighth People’s Hospital & Dongguan Children’s Hospital, Dongguan, PR China, et al. published online in the *Journal of Dermatological Treatment*ⁱ
- “The use of noncultured regenerative epithelial suspension for improving skin color and scars: A report of eight cases and review of the literature” by Jie Ren, PhD, M.D., and Jianlan Liu, PhD, Department of Dermatology, Huashan Hospital, Fudan University, Shanghai, China, et al. published in the *Journal of Cosmetic Dermatology*ⁱⁱ
- “The clinical efficacy of RECELL autologous cell regeneration techniques combined with dermabrasion treatment in acne scars” by Qiao Chen, Nanze Yu, Zhifei Liu, et al. Department of Plastic Surgery, Peking Union Medical College Hospital Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China, published in *Aesthetic Plastic Surgery*ⁱⁱⁱ
- Health economics data demonstrating real-world cost savings and reduced length of hospital stay for burn patients treated at Metro Health Center in Cleveland, Ohio, with the RECELL System as compared to the National Burn Repository data set presented at the Eastern Great Lakes Regional Burn Conference 26-27 September 2019, in Pittsburgh, PA

“We are pleased with the substantial increase in quarterly sales and the robust uptake of the RECELL System by U.S. burn surgeons nine months into our commercial launch. Moreover, we are proud of the impact this innovative technology is having on the advancement of patient care,” said Dr. Mike Perry, AVITA Medical’s Chief Executive Officer. “With our recent Nasdaq listing of American Depositary Shares, we are providing broader access to investors and we look forward to maintaining our growth trajectory by sustaining a keen focus on U.S. commercial activities in tandem with growth of our development pipeline.”

Recent Developments

AVITA Medical exhibited at the American Burn Association National Burn Reconstruction Conference 16-18 October 2019, in Chicago, and RECELL System health economic and clinical data demonstrating costs savings and efficacy is being presented by physicians at four regional U.S. burn conferences this quarter. RECELL clinical data will also be presented at the Congress of the Asian Pacific Society for Scar Medicine with the Japan Scar Workshop 2-3 November 2019, in Tokyo.

Pipeline Update

In fiscal 2020, AVITA anticipates:

- Pivotal trials commencing to establish the safety and efficacy of the RECELL System for early intervention treatment of pediatric scald wounds and for soft tissue reconstruction and traumatic wounds
- Pilot studies with the RECELL System for the treatment of vitiligo with anticipation of advancing to pivotal clinical trials in fiscal 2021
- Securing marketing approval and reimbursement for the RECELL System in Japan in collaboration with COSMOTEC, an M3 Group company

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.

First 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 first quarter of fiscal 2020, the quarter ended 30 September 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 30 September 2019, total cash receipts were A\$5,237, an increase of A\$197 or 4% compared to the prior quarter ended 30 June 2019. Cash receipts from customers for the quarter ended 30 September 2019 were A\$4,079, an increase of A\$565 or 16% compared to the prior quarter due to increased sales in the U.S. Cash received from BARDA during the current quarter totalled A\$1,158, a decrease of A\$368 or 24% 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 September 2019, cumulative payments of A\$27.9 million have been received under the BARDA contract.

Overall payments for operating expenses decreased during the first quarter of fiscal 2020 as a result of the timing of planned initiatives set forth by the Company. During the quarter ended 30 September 2019, payments related to sales and marketing, staffing, administrative and corporate costs for the current quarter totalled A\$9,535, a A\$3,491 or 27% decrease compared to the quarter ended 30 June 2019 driven by the timing of planned initiatives. During the quarter ended 30 September 2019, payments related to product manufacturing and operating costs totalled A\$1,344, a A\$308 or 30% increase compared to the quarter ended 30 June 2019. The increase was directly related to the increase in sales during the current quarter. During the quarter ended 30 September 2019, payments for research and development costs totalled A\$1,300, a A\$129 or 9% decrease compared to the quarter ended 30 June 2019. The decrease was a result of the timing of research and development initiatives 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 are expected to increase in future quarters. 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 30 September 2019 was A\$7,037, a A\$3,393 or 33% decrease compared to the quarter ended 30 June 2019 driven primarily by timing of planned initiatives. Cash and cash equivalents held at 30 September 2019 was A\$22,656.

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, 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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ⁱ Bin Liu, Hui-Heng Chen, Zhong-Hai Liu, Jing-Feng Liang, Ru-Jun Xue, Ping-Jiao Chen, Chang-Xing Li, Xiao-Dong Liang, Jie Deng, Rui-Xian Ye, Xi-Bao Zhang & Jing-Yao Liang (2019) The clinical efficacy of treatment using the autologous non-cultured epidermal cell suspension technique for stable vitiligo in 41 patients, *Journal of Dermatological Treatment*, DOI: 10.1080/09546634.2019.1619657

ⁱⁱ Ren J, Liu J, Yu N, et al. The use of noncultured regenerative epithelial suspension for improving skin color and scars: A report of 8 cases and review of the literature. *J Cosmet Dermatol*. 2019;00:1–8. <https://doi.org/10.1111/jocd.13071>

ⁱⁱⁱ Chen, Q., Yu, N., Liu, Z. et al. *Aesth Plast Surg* (2019). <https://doi.org/10.1007/s00266-019-01481-8>

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Avita Medical Limited

ABN

28 058 466 523

Quarter ended ("current quarter")

30 September 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	4,079	4,079
1.1a Receipts from government contract (BARDA)	1,158	1,158
1.2 Payments for		
(a) research and development	(1,300)	(1,300)
(b) product manufacturing and operating costs	(1,344)	(1,344)
(c) advertising and marketing	(2,257)	(2,257)
(d) leased assets	(246)	(246)
(e) staff costs	(5,097)	(5,097)
(f) administration and corporate costs	(2,181)	(2,181)
1.3 Dividends received	-	-
1.4 Interest received	151	151
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash used in operating activities	(7,037)	(7,037)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(203)	(203)
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	(97)	(97)
(e) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) property, plant and equipment		
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
2.6 Net cash used in investing activities	(300)	(300)

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from financing activities	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net increase in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	28,983	28,983
4.2	Net cash used in operating activities (item 1.9 above)	(7,037)	(7,037)
4.3	Net cash from used in investing activities (item 2.6 above)	(300)	(300)
4.4	Net cash from financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	1,010	1,010
4.6	Cash and cash equivalents at end of quarter	22,656	22,656

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	22,656	28,983
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	22,656	28,983

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	(291)
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

6.1 Executive Director remuneration (170k), Directors fees (81k), Clinical Advisory Board fees (11k), and Bioscience Consultancy (29k).

7. Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1 Aggregate amount of payments to these parties included in item 1.2	
7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities		
8.2 Credit standby arrangements		
8.3 Other (please specify)		
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	1,600
9.2 Product manufacturing and operating costs	1,400
9.3 Advertising and marketing	2,400
9.4 Leased assets	250
9.5 Staff costs	5,200
9.6 Administration and corporate costs	2,100
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows*	12,950

* Pertains to outflows only, inflows from customer receipts and government contracts, which totalled \$5,237 for the quarter ended 30 September 2019 and are expected to increase in future quarters, are not included.

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Timothy Rooney

Timothy Rooney

Chief Administrative Officer and Interim Chief Financial Officer

31 October 2019

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.