

## CEO Shareholder Letter and Quarterly Report

Dear Shareholder,

At the conclusion of another quarter, I would like to update you on the work undertaken and completed during the last three months. Certainly, the pace has been furious at our Valencia office near Los Angeles, where the team made significant progress toward submitting our Premarket Approval (PMA) dossier to the US Food and Drug Administration (FDA). Expectations are running quite high about the outcome of the clinical data for the trial, which will be at heart of the dossier. The completed data set is now with independent statisticians, and as soon as we receive the complete results, we will be reporting back to you with topline outcomes.

As we await the completion of the clinical data analyses, the team has been assembling a host of other information required by the FDA. There is a reason why an FDA approval, more so for a Class 3 medical device such as ReCell® – a breakthrough device that has no predicate -- is regarded by many as the gold standard for regulatory approval. The level of scrutiny is very high, and we must provide evaluations on a whole host of areas, such as product stability, sterility, validation of our cell suspension, and a validated supply chain. These projects are all in progress, and will be concluded in short order as we work to meet our stated ambitious timeframes for PMA submission. In parallel, this work brings us closer to achieving other key milestones such as the first procurement from the US Biomedical Advanced Research and Development Authority (BARDA), which is valued at USD\$8m.

### US Market Evaluation Reveals Positive Prospects

In Boston in March, we had a strong presence at the annual meeting of the American Burns Association. This is the biggest event on the calendar of the US burns community, and more than 1,000 surgeons, researchers and sector players attended the four-day event. Team Avita was there in force with a clear mission: to find out more about how our unique approach is being received by the US burns community. It was a real chance to engage with those who had already used the ReCell® device, under a clinical trial setting either as part of our PMA approval process, or through the FDA's Compassionate Use Program. These programs have allowed many US burns surgeons to access the device during our pre-authorization phase, and so of course, we were very anxious to hear about their experiences to date. It

was great to hear some very positive reports on patient outcomes from this eminent group. In the US, the device has mostly been used on larger burns, treated with our formulation that gives 1920cm<sup>2</sup> of wound coverage per device. Several of the US surgeons were able to relay their experiences of how the 1920cm<sup>2</sup> device saved lives. They also saw much better healing, reduced use of donor sites for accompanying skin grafts, and vastly shorter lengths of stay in intensive care. They are eagerly awaiting the results of our clinical trial, and one surgeon said he believes the introduction of ReCell® to the US will be “a revolution in the standard of care for burns patients, which will totally change the landscape.”

Additionally, under a more formal structure we commissioned an independent marketing group, who approached physicians variously engaged in trauma, burns and plastic surgery. When presented with the proposition of utilizing ReCell® in their respective settings; 64% said they believed the product was well-differentiated compared with other burns treatment; 52% said they believed the approach would be an extremely valuable addition to their current burns treatment; and 52% said they would be extremely likely to use our product. This is all very encouraging, and we believe these findings reflect a mounting expectation about ReCell®’s prospects for the US, where many burns surgeons are very excited about getting hold of the product. Evidence of this can be seen in the increased numbers of applications under Compassionate Use, which the FDA in the last quarter expanded to enable us to treat up to 68 patients in 18 US Burn centers. Importantly, projects such as these, especially when added to ongoing work being conducted in health economics, pricing models and the implementation of robust training plans should give you a sense of the thoroughness of our approach towards the US market.

### **Financial and Market Update**

During the third quarter, overall receipts from customers were \$403K, which represents a 61% increase of \$248K as compared to the previous quarter. The increase in revenue is largely due to the transition of our sales model from distributor to direct in some markets, and we have seen a healthy increase in device usage in the UK and Germany. Our approach is focused on getting traction in key high volume accounts, and the early signs are very promising.

We are recruiting clinical specialists to support our distributor in China, Sinopharm with its strategy to increase our standing in the leading burns centers of the main Chinese cities. The focus for burns and reconstructive work is within both public and military hospitals, and we are engaged with private clinics mainly for repigmentation and other elective offerings.

South Africa is another market of interest due to the high incidence of burns there, and hence, a large addressable patient population. There are about 14 registered public sector burns clinics in South Africa, and in these, some 10 surgeons have now evaluated ReCell®, and the feedback has been very positive. We are also exploring with our distributor how we can operate in the private sector, as many cases are presented to private clinics.

Receipts from BARDA totaled \$1.87M in the third quarter as reimbursements continue under our USD\$61.9M contract with BARDA, a \$220K (13.4%) increase compared to the previous quarter. We also received a \$972K tax credit from the Australian Tax Office, as a rebate to support our Research and Development Strategy.

Research and clinical costs paid in the third quarter increased by \$800K as compared to the previous quarter as we approach FDA PMA submission. This was partially offset by a decline of \$255K in operating costs paid in the third quarter as compared to the previous quarter. Total net cash outflows in the third quarter were \$1.86M, an improvement over the last quarter by 17.6% (\$2.26M) and over the same period in the previous year by 36.5% (\$2.94M), and are in-line with Company expectations for both the quarter and YTD. Total cash and cash equivalents held by Avita at the end of March 2017 were \$6.34M.

So Avita keeps on building, as we progress towards FDA approval and achieving BARDA's first stockpile order. Team Avita will keep executing on these strategic goals, which we are confident will be great value drivers for the Company, and its supporters.

Yours faithfully

**ADAM KELLIHER**  
**Chief Executive Officer**

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## **ABOUT AVITA MEDICAL LIMITED**

Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the patients' own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.

ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell® is an investigational device limited by federal law to investigational and compassionate use.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. ReCell® is designed for the treatment of burns and

plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCell™ is tailored for aesthetic applications including the restoration of pigmentation.

To learn more, visit [www.avitamedical.com](http://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.*

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#### FOR FURTHER INFORMATION:

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## 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")**

31 March 2017

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	403	839
1.1a Receipts from BARDA	1,865	4,854
1.2 Payments for		
(a) research and development	(1,184)	(2,566)
(b) product manufacturing and operating costs	(436)	(1,476)
(c) advertising and marketing	(465)	(1,179)
(d) leased assets	(97)	(240)
(e) staff costs	(1,956)	(5,334)
(f) administration and corporate costs	(1,110)	(2,820)
1.3 Dividends received (see note 3)		
1.4 Interest received	29	108
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	972	972
1.8 Other (provide details if material)	16	191
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,963)</b>	<b>(6,651)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(60)	(141)
(b) businesses (see item 10)		
(c) investments		

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(d) intellectual property		
(e) other non-current assets		
2.2 Proceeds from disposal of:		
(a) property, plant and equipment		
(b) businesses (see item 10)		
(c) investments		628
(d) intellectual property		
(e) other non-current assets		
2.3 Cash flows from loans to other entities		5
2.4 Dividends received (see note 3)		
2.5 Other (provide details if material)		
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(60)</b>	<b>492</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares		9,015
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		(606)
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)		
<b>3.10 Net cash from / (used in) financing activities</b>		<b>8,409</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	8,389	4,172
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,963)	(6,651)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(60)	492
4.4 Net cash from / (used in) financing activities (item 3.10 above)		8,409

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held	(22)	(78)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>6,344</b>	<b>6,344</b>

<b>5. Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1 Bank balances	208	743
5.2 Call deposits	6,136	7,646
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,344</b>	<b>8,389</b>

**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

(112)

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 Directors fees (95k), Clinical Advisory Board fees (10k) and Bioscience Consultancy (7k)

**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. <b>Financing facilities available</b> <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.		

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9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	515
9.2 Product manufacturing and operating costs	825
9.3 Advertising and marketing	306
9.4 Leased assets	153
9.5 Staff costs	2,035
9.6 Administration and corporate costs	598
9.7 Other (provide details if material)	
<b>9.8 Total estimated cash outflows</b>	<b>4,432</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	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.

**Gabriel Chiappini**  
Company Secretary  
28 April 2017

### **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.