

## AROA BIOSURGERY JUNE 2021 4C – COMMENTARY

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### HIGHLIGHTS

- US medical procedure numbers continue to reflect a positive trend supporting improved sales momentum. AROA maintains its published product sales guidance of \$30-33 million (up 39-53% on FY21) and gross margin above 70%.
  - Net cash outflow from operations was NZ\$2.7 million for the June quarter, in line with management expectations.
  - Cash on hand of NZ\$31.4 million at 30 June 2021.
  - New Myriad Morcells™ product line extension launched at Society for Advanced Wound Care conference 10-14 May 2021.
  - Large retrospective Endoform™ real-world study in diabetic foot ulcers concluded and submitted, with publication expected in September quarter.
  - AROA's dead space management system targeting an unmet need with an estimated US\$2.5 billion market was previewed with investors and three further patents filed relating to key aspects of this technology.
  - Manufacturing construction progressing to plan to expand capacity from NZ\$35 million to NZ\$100 million in annual sales.
  - Annual General Meeting scheduled for 1pm (NZST), 11am (AEST) on Tuesday 20 July 2021.
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Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'AROA' or the 'Company') is pleased to provide an update on its activities for the quarter ended 30 June 2021.

### Financial commentary

AROA maintains product sales guidance of NZ\$30-33 million (up 39-53% on FY21) and gross margin above 70%. EBITDA will continue to be negative as previously forecast. Guidance is subject to no resurgence of COVID-19 in the US, TELA Bio delivering strong growth (based on its revenue guidance of 48-65% growth in CY21 compared to CY20) and continued improvement in US medical procedure numbers. It also assumes an average NZD/USD exchange rate of US\$0.72.

Cash receipts for Q1 FY22 were NZ\$5.3 million, reflecting sustained sales activities over the course of the June quarter. This reflects lumpy product shipments and timing of payments, but is in line with management expectations.

Net cash outflow from operations was NZ\$2.7 million for the June quarter, ending the quarter with cash on hand of NZ\$31.4 million. In line with management's expectations, this reflects payments which typically fall within this quarter, including employee bonuses for achievement of the Company's FY21 performance goals and year end compliance costs.

In accordance with ASX Listing Rule 4.7C.3, AROA advises that an aggregate amount of NZ\$102,000 was paid during the quarter to AROA's five Non-Executive Directors in payment of their director fees.

Appendix A provides a summary of actual expenditure, compared to the estimated use of funds set out in AROA's IPO Prospectus, in accordance with ASX Listing Rule 4.7C. Cash expenditure is consistent with the use of funds set out in that Prospectus.

### Myriad Morcells launched at SAWC Spring

Following US FDA 510(k) clearance for Myriad Morcells in April 2021, AROA launched Myriad Morcells at the Symposium for Advanced Wound Care Conference ('SAWC') Spring. SAWC is the pre-eminent US wound event providing education, advanced state-of-the-art clinical reviews, and emerging research findings.

Myriad Morcells, is a powder format of Myriad Matrix™ that easily conforms to optimize contact with irregular wound beds and delivers a bolus of biologically important extracellular matrix proteins known to 'kick start' healing. Myriad Morcells will be used alone in some cases and combined with Myriad Matrix in other cases. Both products take advantage of the AROA ECM™ bioscaffold technology, including important secondary molecules and residual vascular channels to support new tissue growth, which may lead to faster healing, recovery and hospital discharge. Earlier pre-clinical studies have shown that the AROA ECM technology



includes over 150 different components known to aid wound repair, blood vessel formation and attract stems cells. Myriad Morcells is now being evaluated in hospitals across the United States ('US').

### Positive Outlook from TELA Bio

TELA Bio, AROA's US commercial partner for hernia and breast reconstruction products (selling OviTex™ and OviTex PRS™), is maintaining its total revenue guidance of US\$27.0 million to US\$30.0 million. This guidance reflects growth of 48% to 65% over the prior year period. With launch inventory levels now consumed, AROA expects ongoing shipments to TELA Bio to correspond with increasing hospital demand. AROA receives 27% of TELA Bio's net product sales.

The BRAVO study, which is evaluating the clinical performance of OviTex Reinforced Tissue Matrix for the treatment of ventral hernia, reported the full patient cohort of 76 patients at 12 months. Only two patients had a recurrence, both adjacent to the original repair, with the OviTex repairs remaining intact. 51 patients reached the 24-month follow-up, with no patients experiencing a recurrence.

To build on the success of the BRAVO study, TELA Bio has initiated the BRAVO II study to examine the efficacy and durability of the OviTex LPR for robotic hernia repair in up to 100 patients. OviTex LPR is specifically designed for use in robotic hernia repair. The incidence of postoperative surgical site occurrences, wound-related events, and other complications will be evaluated at 90 days, 12 months, and 24 months.

### "Endoform RWD" DFU Study

In July, AROA concluded the "Endoform RWD study", a large retrospective real-world data study comparing the healing outcomes in diabetic foot ulcers ('DFU's) treated with either Endoform (ovine forestomach matrix, 'OFM') or collagen/oxidized regenerated cellulose ('ORC'). Each study arm includes over 1000 patients and represents the first large retrospective real world data analysis comparing OFM and collagen/ORC.

Up to one-third of the half billion people with diabetes worldwide will develop a DFU over the course of their lifetime<sup>1</sup>. Current estimates demonstrate one in six patients with a DFU will undergo an amputation, making DFUs the leading cause of non-traumatic amputations in the US<sup>2</sup>. Additionally, there are significant financial burdens incurred by DFUs. A 2012 retrospective study of 7099 DFUs reported a mean cost to achieve closure of \$3927 per DFUs<sup>3</sup>. The DFU related cost and burden to the US health care system has been estimated at \$9-13 billion<sup>4,5</sup>.

The clinical study has been submitted for peer reviewed publication and AROA expects to announce the outcomes within the September quarter.

### Dead Space Management System Preview & Patent Filings

AROA previewed its new dead space management platform technology in presentations during the quarter. The new system is designed to close tissue cavities at a surgical site created by surgical dissection or tissue removal. It is comprised of a specially designed AROA ECM implant that is coupled to an external single-use negative pressure pump. When the product is deployed, the tissue surfaces are drawn together, held in place and tissue fluids are carried by the vacuum to an external fluid collection bag.

AROA intends to develop and launch a new class of products utilising this new platform technology. These new products will address an unmet need in a number of surgical specialties, including general and plastic surgery. The first product based on this technology is expected to be commercialized in CY23 for linear cavities, with a subsequent product being commercialized in 2025

<sup>1</sup> Armstrong, D.G., et al., *Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer*. J Foot Ankle Res, 2020. **13**(1): p. 16.

<sup>2</sup> Boulton, A.J.M., et al., *Diagnosis and Management of Diabetic Foot Complications*, in *Diagnosis and Management of Diabetic Foot Complications*. 2018: Arlington (VA).

<sup>3</sup> Fife, C.E. and M.J. Carter, *Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry*. Wounds, 2012. **24**(1): p. 10-7.

<sup>4</sup> Rice, J.B., et al., *Burden of diabetic foot ulcers for medicare and private insurers*. Diabetes Care, 2014. **37**(3): p. 651-8.

<sup>5</sup> Barshes, N.R., et al., *The system of care for the diabetic foot: objectives, outcomes, and opportunities*. Diabet Foot Ankle, 2013. **4**.



for large surface area cavities. Management estimates that the market opportunity for this new class of products is more than US\$2.5 billion.

AROA has recently filed three new patents relating to key aspects of this technology. These patents build on three previous patents filed for this platform technology since 2018.

## Manufacturing Expansion

Construction of AROA's second manufacturing facility is proceeding to plan and is expected to be completed by the end of the calendar year. The Company is well placed to meet increased demand in the coming year, and by March 2022 will have manufacturing capacity to support NZ\$100 million in annual sales.

## Investor Relations

AROA's Investor Day on 5 July 2021 provided an opportunity for the Company to provide more background on key aspects of the business and introduce the leadership team. The event was well attended by Australian and New Zealand institutional funds.

Replays of the presentations can be requested from Simon Hinsley (shinsley@aroabio.com) by 30 July 2021.

## Annual General Meeting

The annual general meeting of shareholders of AROA is scheduled for 1pm (NZST), 11am (AEST) on Tuesday 20 July 2021. Shareholders may attend in person at the Company's registered office at 64 Richard Pearse Drive, Mangere, Auckland, New Zealand or online at: [https://us02web.zoom.us/webinar/register/WN\\_-Fgj3mBbQUStV9gBGtRWg](https://us02web.zoom.us/webinar/register/WN_-Fgj3mBbQUStV9gBGtRWg)

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**Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.**

### About Aroa Biosurgery:

Aroa Biosurgery is a soft-tissue regeneration company committed to 'unlocking regenerative healing for everybody'. We develop, manufacture, sell and distribute medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Our products are developed from a proprietary AROA ECM™ technology platform, a novel extracellular matrix biomaterial derived from ovine (sheep) forestomach. Clinically proven with peer reviewed publications, AROA's products have been used in more than four million procedures to date, with distribution into our key market of the US via our direct sales force and our partner TELA Bio. Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX:ARX). [www.aroabio.com](http://www.aroabio.com)

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## APPENDIX A

In accordance with ASX Listing Rule 4.7C, Aroa provides the following use of funds information:

Use of funds	Prospectus Estimate NZ\$m	Actual Funds Used NZ\$m	Actual as a % of Estimate	Note
Investment in sales and marketing	\$5.0	\$3.5	70%	1
Investment in additional manufacturing capacity, investment in new products, plant and equipment and other general corporate capital expenditure	\$5.0	\$2.0	40%	2
Working capital, other operating costs	\$5.0	\$3.1	62%	3
Repayment of borrowings	\$13.1	\$0.0	0%	4
Offer costs	\$3.8	\$3.9	103%	5
<b>Total</b>	<b>\$31.9</b>	<b>\$12.5</b>	<b>39%</b>	

Notes:

1. Continued rollout of new sales and marketing initiatives including management of over 20 direct sales personnel hired in Q4 FY21.
2. Includes preliminary costs of manufacturing expansion in H2 FY21.
3. Net operating cash outflows since July 2020, excluding cash outflows relating to the investment in sales & marketing.
4. Maturing on 31<sup>st</sup> March 2022. Remains unchanged from the prior quarter.
5. Includes cash outflows prior to IPO. Remains unchanged from the prior quarter.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Aroa Biosurgery Limited

**ABN**

ARBN 638 867 473

**Quarter ended ("current quarter")**

30 June 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$NZ'000</b>	<b>Year to date (3 months) \$NZ'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	5,268	5,268
1.2 Payments for		
(a) research and development	(191)	(191)
(b) product manufacturing and operating costs	(994)	(994)
(c) advertising and marketing	(1,378)	(1,378)
(d) leased assets	(4)	(4)
(e) staff costs	(4,906)	(4,906)
(f) administration and corporate costs	(1,182)	(1,182)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	625	625
1.8 Other (rent received)	39	39
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,722)</b>	<b>(2,722)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(910)	(910)
(d) investments	-	-
(e) intellectual property	(37)	(37)

Consolidated statement of cash flows	Current quarter \$NZ'000	Year to date (3 months) \$NZ'000
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(947)</b>	<b>(947)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	33	33
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	76	76
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
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 (lease liability payments)	(240)	(240)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(131)</b>	<b>(131)</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	35,381	35,381
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,722)	(2,722)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(947)	(947)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$NZ'000</b>	<b>Year to date (3 months) \$NZ'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(131)	(131)
4.5	Effect of movement in exchange rates on cash held	(208)	(208)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>31,373</b>	<b>31,373</b>

<b>5.</b>	<b>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 \$NZ'000</b>	<b>Previous quarter \$NZ'000</b>
5.1	Bank balances	11,373	15,381
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term deposits less than 90 days)	20,000	20,000
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>31,373</b>	<b>35,381</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$NZ'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	102
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$NZ'000</b>	<b>Amount drawn at quarter end \$NZ'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	11,430	10,248
7.2 Credit standby arrangements	485	360
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>11,915</b>	<b>10,608</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>1,307</b>
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
Includes the following: <ol style="list-style-type: none"> <li>1. an unsecured loan of NZ\$10.3m from Hollister Incorporated at 6.25% p.a. with a maturity date of 31 March 2022; and</li> <li>2. a secured facility of NZ\$1.2m with the Bank of New Zealand at 4.93% p.a., which remained undrawn as at 30 June 2021.</li> </ol>		

<b>8. Estimated cash available for future operating activities</b>	<b>\$NZ'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,722)
8.2 Cash and cash equivalents at quarter end (item 4.6)	<b>31,373</b>
8.3 Unused finance facilities available at quarter end (item 7.5)	1,307
8.4 Total available funding (item 8.2 + item 8.3)	32,680
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>12.0</b>
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

## 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.

Date: 15 July 2021.....

Authorised by: By the board.....  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.