

# AROA BIOSURGERY DECEMBER 2022 4C - COMMENTARY

#### **Financial Highlights**

- Strong cash receipts from customers of NZ\$17.1 million during the quarter.
- Net cash inflow from operations of NZ\$0.2 million for the guarter.
- Net cash outflow from investing activities was NZ\$2.0 million for the quarter, reflecting AROA's investment into additional manufacturing plant & equipment capacity.
- AROA ended the quarter with a strong cash balance of NZ\$48.3 million as at 31 December 2022
- FY23 product revenue guidance **maintained at NZ\$60-62 million**<sup>1</sup> (up 36-41% on a constant currency basis<sup>2</sup> on FY22).
- FY23 total revenue guidance maintained at NZ\$62-64 million¹ (up 39-43% on FY22 on a constant currency basis).
- FY23 product gross margin guidance maintained at 84%.<sup>1</sup>
- FY23 normalised EBITDA expected to be approximately breakeven.<sup>1</sup>

#### **Operational Highlights**

- Focus on building the US Sales team continues, with 5 new hires during the quarter and 123 active Myriad™ accounts.
- A peer reviewed study published in February 2023 indicates that AROA's Endoform™ Natural
   High Flow is compatible with Negative Pressure Wound Therapy.<sup>3</sup>
- In November, AROA submitted an application for regulatory clearance for the first product in the Enivo™ range to the US Food & Drug Administration.
- 48 new patients were enrolled in the Myriad MASTRR study during the quarter.
- In January 2023, AROA was awarded a contract with leading Canadian group purchasing organisation, HealthPRO. The contract will provide HealthPRO's over 1,300 members with access to Endoform™ Natural and Endoform™ Antimicrobial from 1 June 2023.
- Received regulatory approval for Myriad Matrix™ in Brazil in December.
- No damage to AROA facilities as a result of the recent severe rainfall and flash flooding in Auckland, New Zealand.
- Presented at The Jarden Future Leaders Conference, The Great Wilsons Drug and Device Conference and also conducted a New Zealand roadshow.
- AROA will host an investor webinar today at 11:00 AEST to discuss the results. Register here.

<sup>&</sup>lt;sup>1</sup> Given the dynamic and evolving impact of COVID-19, guidance is subject to no material decline in US medical procedure numbers or sustained disruption to AROA's manufacturing or transportation activities and TELA Bio, Inc. delivering on its revenue guidance of US\$42-45 million in CY22. It also assumes an average exchange rate of US\$0.62/NZ\$1.00.

<sup>&</sup>lt;sup>2</sup> Constant currency (CC) removes the impact of exchange rate movements. This approach is used to assess the AROA Group's underlying comparative financial performance without any distortion from changes in foreign exchange rates, specifically the USD. The USD/NZD exchange rate of US\$0.62/NZ\$1.00 has been used in the constant currency analysis, representing approximately the average rate for H1 FY23 and the rate for FY23 financial guidance. All references in this announcement to 'constant currency' are as set out in this footnote.

<sup>&</sup>lt;sup>3</sup> Veale RWF, Kollmetz T, Taghavi N, Duston-Fursman CG, Beeson MT, Asefi D, Chittock HD, Vikranth AS, Dowling SG, Dempsey SG, Rose HJ, Mason ITT, May BCH. Influence of advanced wound matrices on observed vacuum pressure during simulated negative pressure wound therapy. J Mech Behav Biomed Mater. 2023 Feb;138:105620. AROA sponsored study.



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 31 December 2022.

# Financial commentary and outlook

Cash receipts received from customers for Q3 FY23 of NZ \$17.1 million, compared to NZ\$11.0 million in the prior quarter. This was primarily due to the timing of Q2 FY23 OviTex<sup>™4</sup> and OviTex PRS product revenues during the prior quarter and subsequent receipts during Q3 FY23. Cash receipts also included a one-off royalty payment from TELA Bio, Inc. for the final cumulative sales milestone in Europe.

Net cash inflows from operations for Q3 were NZ\$0.2 million, compared to net cash outflows of NZ\$4.3 million in Q2 FY23. This was primarily due to the stronger cash receipts during the quarter.

Net cash outflows from investing activities for Q3 were NZ\$2.0 million, primarily reflecting AROA's investment into additional manufacturing plant & equipment capacity.

AROA ended the quarter with a strong cash balance of NZ\$48.3 million.

AROA maintains its FY23 product revenue guidance of NZ\$60-62 million. This reflects a 36-41% increase on FY22 product revenue (on a constant currency basis).

Total revenue guidance for FY23, inclusive of project and license fees is NZ\$62-64 million, reflecting a 39-43% increase on FY22 total revenue (on a constant currency basis).

FY23 product gross margins are expected to be 84%. Normalised EBITDA is expected to be approximately breakeven.

Given the dynamic and evolving impact of COVID-19, guidance is subject to no material decline in US medical procedure numbers or sustained disruption to AROA's manufacturing or transportation activities and TELA Bio, Inc. delivering on its revenue guidance of US\$42-45 million in CY22.<sup>5</sup> It also assumes an average US\$/NZ\$ exchange rate of US\$0.62/NZ\$1.00.

In accordance with ASX Listing Rule 4.7C.3, AROA advises that an aggregate amount of NZ\$131,000 was paid during the quarter to the Company's six Non-Executive Directors for directors' 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 and remains unchanged from the prior quarter.

#### **US** sales

AROA's focus on building its US sales team continued, with 5 new hires, ending the quarter with 40 direct US sales representatives and 8 inside sales representatives. The US sales team delivered 123 Myriad active<sup>6</sup> accounts at the end of Q3 FY23, with 8 representatives at a current average run rate of

<sup>&</sup>lt;sup>4</sup> TELA Bio and OviTex are trademarks of TELA Bio, Inc.

<sup>&</sup>lt;sup>5</sup> TELA Bio, Inc. press release dated 9 November 2022.

<sup>&</sup>lt;sup>6</sup> Represents accounts to which sales were made in the applicable quarter.



over US\$500,000 per annum.

AROA's sales and clinical teams attended and presented in-person, alongside Key Opinion Leaders, at 17 key industry conferences, including the US Orthopaedic Trauma Association's 38<sup>th</sup> Annual Meeting, Royal Australasian College of Surgeons, and WoundCon Fall 2022 (US).

## Clinical evidence

AROA continues to grow its clinical evidence for AROA ECM™ with publications in peer-reviewed journals.

In the February 2023 issue of "The Journal of the Mechanical Behavior of Biomedical Materials", AROA published a study, titled "Influence of advanced wound matrices on observed vacuum pressure during simulated negative pressure wound therapy".

The first of its kind study investigated changes in the observed vacuum pressure when collagen matrices were used with Negative Wound Pressure Therapy ('NPWT').

The study showed that some collagen-based matrices can significantly<sup>7</sup> reduce the vacuum pressure, which may lessen the therapeutic effectiveness of NPWT. Matrices that are thoughtfully designed for use with NPWT can mitigate this risk. For example, the study showed that AROA's Endoform Natural - High Flow devices were compatible with NPWT and were unobstructive to the delivered vacuum pressure, thus providing the potential for better healing outcomes.

The full study is available to read here.

# Myriad MASTRR study enrolments

Progress on AROA's Myriad Augmented Soft Tissue Regeneration Registry ('MASTRR') study continues tracking well. The study is the Company's largest prospective study to date and is evaluating AROA's Myriad Matrix and Myriad Morcells™ products in a wide range of surgical specialties and procedures in up to 10 sites.

The study is targeting 300 patients over a three-year period, and will assess several factors, including time to complete healing, percentage rate of surgical complications and time to 100% granulation of the graft. A total of 138 patients have been enrolled in the study to date with 48 joining during the quarter.

#### Enivo

In November 2022, AROA submitted an application for regulatory clearance for the first product in the Enivo range to the US Food & Drug Administration. The application is currently being reviewed, with an update expected early in CY23. The Company estimates the total addressable market for Enivo in the United States to be in excess of US\$1 billion.

# Intellectual Property update

AROA's patent portfolio currently includes 19 registered patents, 35 pending patent applications and 9 filed patent applications across 10 patent families. 6 of these patent families relate to developments for our new Enivo platform technology.

<sup>&</sup>lt;sup>7</sup> Reduction of observed vacuum pressure of up to 50%.



### Award of HealthPRO contract - Canada

In January 2023, AROA was awarded a contract with leading Canadian group purchasing organisation, HealthPRO.<sup>8</sup> HealthPRO's membership reflects coverage across all Canadian provinces other than Quebec. This is the first opportunity AROA has had to be on contract with a Canadian GPO since our products entered the Canadian market.

The contract will enable HealthPRO's over 1,300 members to access AROA's Endoform Natural and Endoform Antimicrobial products from 1 June 2023. The contract will be for an initial six (6) year term, with the option of a two-year extension at HealthPRO's election.

# Regulatory approvals

AROA received regulatory approval for Myriad Matrix in Brazil in December 2022, adding to the existing Endoform offering.

# Auckland flooding

On Friday 27 January, severe rainfall caused flash flooding in several areas of Auckland, New Zealand including disruption to operations at Auckland Airport.

No damage to AROA facilities occurred due to the rainfall. An area wide power outage on Friday night had a brief and minimal impact on one of AROA's facilities, with all facilities now operating as normal.

#### Investor relations

AROA continues to engage with the investment community regularly. In November, CEO Brian Ward and CFO James Agnew presented at The Jarden Future Leaders Conference and The Great Wilson Drug and Device Conference. In December, AROA undertook a New Zealand roadshow, with in person and virtual meetings held in Auckland and Wellington.

#### Quarterly webinar

The Company will hold a webinar with CEO Brian Ward and CFO James Agnew today, on Tuesday 31 January at 11.00 am AEDT to discuss the December Quarterly Results which will be released pre-market the same day.

Investors can register for the webinar via the following link: <a href="https://us02web.zoom.us/webinar/register/WN">https://us02web.zoom.us/webinar/register/WN</a> KNLEalMhS0StKx5grvdYXQ

Questions can be submitted prior to the webinar to <a href="mailto:shinsley@aroabio.com">mailto:shinsley@aroabio.com</a> or live via the Q&A function on Zoom.

<ENDS> Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward,

<sup>&</sup>lt;sup>8</sup> HealthPRO Procurement Services Inc. ('HealthPRO').



#### **Contacts**

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#### **About AROA™**

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. Over 5.8 million AROA products have been used globally in a range of procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELA Bio, Inc. Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX: ARX). www.aroabio.com

#### **About Myriad™**

Myriad Matrix<sup>™</sup> is an extracellular matrix graft, composed of AROA ECM and designed for soft tissue reconstruction and complex wounds. Myriad Morcells<sup>™</sup> is a powder format of Myriad Matrix that easily conforms to optimize contact with irregular wound beds.

#### About Endoform™

Endoform™ products are unique extracellular matrix products, composed of AROA ECM, for the management of acute and chronic wounds.

#### **About Symphony™**

Symphony is a new product which has been developed off the strength of AROA ECM. It is applied as a graft and is surgically fixed at the margins. It is designed to support healing during the proliferative phase to reduce time to wound closure, particularly in patients whose healing is severely impaired or compromised due to disease.

#### **About Enivo™**

This is a new tissue apposition system which AROA is developing, 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.

#### **About OviTex™ and OviTex PRS**

OviTex and OviTex PRS are reinforced bioscaffolds manufactured by AROA. The products are based on AROA ECM technology, co-developed with our partner, TELA Bio, Inc. (US) and sold by

# ASX ANNOUNCEMENT/MEDIA RELEASE 31 January 2023



TELA Bio in the United States and Europe. TELA Bio is licensed to sell OviTex for abdominal wall reconstruction and hernia repair. Since the first hernia product was launched in 2016, the portfolio has expanded to include hernia products for minimally invasive surgery (robotic) and the launch of OviTex PRS (licensed to TELA Bio for breast reconstruction).



#### APPENDIX A

In accordance with ASX Listing Rule 4.7C, AROA provides the following use of funds information, which remains unchanged from the prior quarter:

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	\$5.0	100%	1
Investment in additional manufacturing capacity, investment in new products, plant and equipment and other general corporate capital expenditure	\$5.0	\$5.0	100%	2
Working capital, other operating costs	\$5.0	\$5.0	100%	3
Repayment of borrowings	\$13.1	\$11.1	85%	4
Offer costs	\$3.8	\$3.9	103%	5
Total	\$31.9	\$30.0	94%	

#### Notes:

- 1. Funds fully utilised for investment in new sales and marketing initiatives including the costs of over 20 direct sales personnel hired in Q4 FY21.
- 2. Funds fully utilised for investment in additional manufacturing capacity. capital expenditure for new products, plant and equipment and other general capital expenditure.
- 3. Funds fully utilised from net operating cash outflows since July 2020, excluding cash outflows relating to the investment in sales & marketing.
- 4. Full repayment of borrowings made during Q2 FY22. The variance between actual and estimate reflects the interest cost savings for early repayment and the favourable foreign exchange rate at the time of payment compared to the time of estimate.
- 5. Includes cash outflows prior to IPO.

# **Appendix 4C**

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

# Name of entity

Aroa Biosurgery Limited

ABN

Quarter ended ("current quarter")

ARBN 638 867 473

31 December 2022

Con	solidated statement of cash flows	Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	17,081	42,019
1.2	Payments for		
	(a) research and development	(742)	(1,834)
	(b) product manufacturing and operating costs	(1,681)	(5,727)
	(c) advertising and marketing	(3,424)	(7,657)
	(d) leased assets	(5)	(12)
	(e) staff costs	(9,189)	(25,811)
	(f) administration and corporate costs	(1,990)	(5,660)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	272	480
1.5	Interest and other costs of finance paid	-	1
1.6	Income taxes paid	(172)	(374)
1.7	Government grants and tax incentives	-	161
1.8	Other (rent received)	-	34
1.9	Net cash from / (used in) operating activities	150	(4,380)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1,952)	(4,171)
	(d) investments	-	-
	(e) intellectual property	(34)	(165)

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$NZ'000	Year to date (9 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)	-	-
2.6	Net cash from / (used in) investing activities	(1,986)	(4,336)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	121	166
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	18	174
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)	(261)	(762)
3.10	Net cash from / (used in) financing activities	(122)	(422)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	50,120	56,165
4.2	Net cash from / (used in) operating activities (item 1.9 above)	150	(4,380)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,986)	(4,336)

Con	solidated statement of cash flows	Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(122)	(422)
4.5	Effect of movement in exchange rates on cash held	138	1,273
4.6	Cash and cash equivalents at end of period	48,300	48,300

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 \$NZ'000	Previous quarter \$NZ'000
5.1	Bank balances	10,166	11,986
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term deposits less than 90 days)	38,134	38,134
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	48,300	50,120

6.	Payments to related parties of the entity and their associates	Current quarter \$NZ'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	131
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includation for, such payments.	de a description of, and an

7.	Financing facilities  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.	Total facility amount at quarter end \$NZ'000	Amount drawn at quarter end \$NZ'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	549	223
7.3	Other (please specify)	-	-
7.4	Total financing facilities	549	223
7.5	Unused financing facilities available at qu	uarter end	326
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: N/A		

8.	Estimated cash available for future operating activities	\$NZ'000
8.1	Net cash from / (used in) operating activities (item 1.9)	150
8.2	Cash and cash equivalents at quarter end (item 4.6)	48,300
8.3	Unused finance facilities available at quarter end (item 7.5)	326
8.4	Total available funding (item 8.2 + item 8.3)	48,626
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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**

- 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:	31 January 2023
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.
- 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".
- 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.