

AROA BIOSURGERY SEPTEMBER 2023 4C – COMMENTARY

Financial Highlights

- Strong cash receipts from customers for the quarter of NZ\$14.8 million.
- In line with expectations, net cash outflows from operations reduced by NZ\$1.6 million from the previous quarter to NZ\$3.2 million. Net cash outflow from investing activities was NZ\$1.2 million for the quarter, reflecting further investment into additional manufacturing plant & equipment capacity.
- Strong cash balance of NZ\$34.0 million as at 30 September 2023, with net cash outflow from operations expected to move towards breakeven for the balance of FY24.
- FY24 product revenue guidance **maintained at NZ\$72-75 million** (25-30% increase on FY23 on a constant currency basis¹), product gross margin guidance **maintained at 85%** and normalised² EBITDA profit guidance **maintained at NZ\$1-2 million**.³
- H1 FY24 results to be released on 28th November 2023.

Operational Highlights

- AROA ended the quarter with ten field sales representatives at a current average run rate of at least US\$750,000 per annum (up from eight and five respectively in the previous two quarters) and over half of the field sales team at an average run rate at least US\$250,000 per annum.
- Myriad™ sales continued to grow, reflecting 67% of AROA's direct sales mix⁴ in the quarter compared to 50% in Q2 FY23.
- In August, AROA submitted a US FDA 510(k) submission for Myriad Flow™, a new Myriad product that could be used in combination with AROA's Enivo™ system.
- Peer-reviewed study published in industry leading journal during the quarter.
- 42 patients out of a target of 120 are now enrolled in the multi-center Symphony™ randomised control trial assessing the efficacy of Symphony in treating diabetic foot ulcers.
- Two additional participants were enrolled into the Enivo pilot clinical study taking the total treated to 3 of the planned 10 patients.
- Enrolments into MASTRR continue tracking well, with a total of 225 patients as at September 30, 2023 (increased by 41), with 9 study sites confirmed (increased by 5 sites).
- In September, following its annual audit by DEKRA, AROA was re-certified for compliance to ISO 13485 and for the Medical Device Single Audit Program.
- In July, CEO Brian Ward presented at the Macquarie Australia Conference. Brian Ward and James Agnew (CFO) also presented at the Wilsons Drug & Device Conference and the 2023 Morgans Conference, both in October.
- AROA was a finalist in the American Chamber of Commerce in New Zealand -DHL Express Success & Innovation Awards.
- AROA will host a webinar to discuss these results today at 9 a.m. AEST. [Click here to register.](#)

¹ Constant currency removes the impact of exchange rate movements. This approach is used to assess the AROA group's ('Group') underlying comparative financial performance without any distortion from changes in foreign exchange rates, specifically the USD. The NZ\$/US\$ exchange rate of 0.65 has been used in the constant currency analysis. All references in this announcement to 'constant currency' or 'CC' are as set out in this footnote.

² Normalised EBITDA is non-conforming financial information, as defined by the NZ Financial Markets Authority, and has been provided to assist users of financial information to better understand and assess the Group's comparative financial performance without any distortion from the one-off transactions. The impact of non-cash share-based payments expense and unrealised foreign currency gains or losses has also been removed from the Profit or Loss. This approach is used by Management and the Board to assess the Group's comparative financial performance. All references to normalized EBITDA in this announcement are as set out in this footnote.

³ This guidance is subject to there being no material decline in US medical procedure numbers or sustained disruption to AROA's manufacturing or transportation activities and TELA Bio delivering on its CY23 revenue guidance of US\$60-65 million. It also assumes an average NZ\$/US\$ exchange rate of 0.65 (compared to the average exchange rate of 0.62 in FY23).

⁴ I.e. excluding sales to TELA Bio, Inc.

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 September 2023.

Financial commentary and outlook

Q2 FY24 cash receipts from customers remained strong at NZ \$14.8 million, compared to NZ\$15.2 million in the prior quarter.

Net cash outflows from operations for the quarter were NZ\$3.2 million, compared to net cash outflows of NZ\$4.8 million in the previous quarter. In line with expectations, this reflects a decrease in the planned operating loss for the quarter. Net cash outflows from investing activities for Q2 FY24 were NZ\$1.2 million, primarily reflecting AROA's investment into additional manufacturing plant & equipment capacity.

AROA ended the quarter with a strong cash balance of NZ\$34.0 million, with net cash outflows from operations expected to move towards breakeven for the balance of FY24.

The Company intends to release its financial results for H1 FY24 on Tuesday, 28th November 2023.

AROA maintains its FY24 product revenue, product gross margin and normalized EBITDA profit guidance of NZ\$72-75 million, 85% and NZ\$1-2 million respectively.³

In accordance with ASX Listing Rule 4.7C.3, AROA advises that an aggregate amount of NZ\$215,000 was paid during the quarter to the Company's six non-executive directors for directors' fees.

US sales

AROA's US commercial operations continued to deliver, with increasing average run rates across the field sales team. The Company ended the quarter with ten field sales representatives at an average run rate of at least US\$750,000 per annum (up from eight and five respectively in the previous two quarters) and over half its field sales representatives achieved an average run rate of at least US\$250,000.

AROA also continued to grow its Myriad active accounts,⁵ with a total of 187 at the end of the quarter (up from 166 at the end of FY23). The Company ended the quarter with 42 field sales representatives and eight inside sales representatives.

The Company's sales and clinical teams attended and presented in-person, alongside key opinion leaders, at 12 major industry conferences around the world, including Wild on Wounds (US) and The American Association for the Surgery of Trauma 82nd Annual Meeting.

CEO Brian Ward says: "Our high-margin Myriad product family continues to be a key driver for growth and sales momentum is building. We are very encouraged by its clinical performance in a wide range of procedures both in day-to-day surgical use, and the MASTRR study. Myriad sales continue to grow, increasing to 67% of AROA's direct sales mix⁴ in Q2 compared to 50% in Q2 FY23. We are especially pleased to see that this growth is coming through increasing penetration within existing accounts."

⁵ Represents accounts to which sales were made in the applicable quarter.



"Looking forward, we see a real opportunity for Myriad to be a market leader in trauma surgery with recent clinical studies validating the efficacy of Myriad Matrix™ and Myriad Morcells™ in trauma procedures, which has a total addressable market of US\$300 million."

US FDA 510(k) submission for Myriad Flow

In August, the Company submitted a 510(k) application to the US Food & Drug Administration for Myriad Flow, a new product based on the AROA ECM™ platform technology and with features that could be used in combination with AROA's Enivo system. The application is currently under review, with an update expected in early CY24.

Clinical evidence

Clinical evidence supporting the efficacy of AROA ECM products continues to grow, with a peer-reviewed study published during the quarter.

The study titled "*Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series*"⁶ was published in the September issue of leading plastic surgery journal, *ePlasty*. It involved a retrospective case series describing the clinical effectiveness of Myriad Matrix and Myriad Morcells in complex traumatic wound reconstruction, and was conducted across ten patients at a single US Level 1 trauma center between January 2021 and February 2023.

The study found the average time to soft tissue coverage and fill was 23.4±9.2 days, with a median product application of 1.0. No complications were reported from the study cohort.

This adds to increasing evidence demonstrating that AROA ECM products can be used to facilitate the formation of well vascularized soft tissue in patients with traumatic injuries. The full study is available online, [here](#).

Symphony clinical study

Enrolments are tracking well for AROA's Symphony randomised clinical trial with 42 participants enrolled across eight sites. The 18-month multi-center study will assess the efficacy of Symphony in treating diabetic foot ulcers and is targeting 120 participants.

Enivo clinical study

Patient enrolments in the Enivo pilot clinical study continue to track well, with three patients now enrolled. The New Zealand-based study is targeting ten participants undergoing a simple unilateral mastectomy and will assess the efficacy of the Enivo system.

MASTRR enrolment

During the quarter, 41 patients were enrolled in AROA's Myriad Augmented Soft Tissue Regeneration Registry ('MASTRR') taking total enrolments to 225.

⁶ Cormican, M T, Creel, N J, Bosque, B A, Dowling S G, Rideout P P and Vassy WM (2023). "*Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series*". *ePlasty*, September 2023.



With five additional study sites added during the quarter, AROA now has nine enrolled study sites out of a total target of ten sites. Of the nine enrolled study sites, five are specialised trauma centers.

The information obtained from MASTRR will be used to evaluate AROA's Myriad Matrix and Myriad Morcells products, including short and long-term healing outcomes and any observed post-surgical complications across a wide variety of procedures.

DEKRA audit and ISO 13485/ MDSAP re-certification

In September AROA underwent its annual audit by global certification organisation, DEKRA, and was re-certified for compliance to ISO 13485, the internationally recognised standard for medical device quality management. The re-certification is for a further period of 3 years.

The Company was also re-certified for a period of 3 years, for the Medical Device Single Audit Program (MDSAP) providing compliance certification for the country specific regulatory requirements for the US, Canada, Brazil, and Australia.

Investor Relations

AROA continues to proactively engage in investor relations activities, including a presentation by Brian Ward, CEO at the 2023 Macquarie Australia Conference in July and the Wilsons Drug & Device Conference in October. James Agnew, CFO also recently presented at the 2023 Morgans Conference in Noosa, Australia.

AMCHAM New Zealand – DHL Express Success & Innovation Awards

In August, AROA was named as a finalist in the American Chamber of Commerce in New Zealand DHL Express Success & Innovation Awards, in the category 'High Growth Exporter of the Year to the USA'.

Quarterly webinar

The Company will hold a webinar with CEO Brian Ward and CFO James Agnew today, Tuesday 31 October at 9 a.m. AEST to discuss the September Quarterly Results.

Investors can register for the webinar via the following link:

https://us02web.zoom.us/webinar/register/WN_-ihrH9Z3RHO434ZftGTQQw

Questions can be submitted prior to the webinar to investor@aroabio.com or live, via the Q&A function on Zoom.

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

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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 6 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™ is an extracellular matrix graft, composed of AROA ECM and designed for soft tissue reconstruction and complex wounds. Myriad Morcells™ 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 Platform 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

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 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 September 2023

Consolidated statement of cash flows	Current quarter \$NZ'000	Year to date (6 months) \$NZ'000
1. Cash flows from operating activities		
1.1 Receipts from customers	14,803	29,955
1.2 Payments for		
(a) research and development	(435)	(902)
(b) product manufacturing and operating costs	(1,618)	(4,989)
(c) advertising and marketing	(2,868)	(6,409)
(d) leased assets	(1)	(9)
(e) staff costs	(11,120)	(22,123)
(f) administration and corporate costs	(2,262)	(4,325)
1.3 Dividends received (see note 3)	1	1
1.4 Interest received	478	1019
1.5 Interest and other costs of finance paid	(10)	(10)
1.6 Income taxes paid	(134)	(274)
1.7 Government grants and tax incentives	-	84
1.8 Other (rent received)	-	-
1.9 Net cash from / (used in) operating activities	(3,166)	(7,982)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1,099)	(2,108)
(d) investments	-	-
(e) intellectual property	(151)	(448)

Consolidated statement of cash flows	Current quarter \$NZ'000	Year to date (6 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	(1,250)	(2,556)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3	18
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	41	41
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)	(309)	(614)
3.10 Net cash from / (used in) financing activities	(265)	(555)

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	38,526	44,722
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,166)	(7,982)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(1,250)	(2,556)

Consolidated statement of cash flows		Current quarter \$NZ'000	Year to date (6 months) \$NZ'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(265)	(555)
4.5	Effect of movement in exchange rates on cash held	110	326
4.6	Cash and cash equivalents at end of period	33,955	33,955

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	3,955	3,392
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term deposits less than 90 days)	30,000	35,134
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	33,955	38,526

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	215
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7. Financing facilities	Total facility amount at quarter end \$NZ'000	Amount drawn at quarter end \$NZ'000
<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	-	-
7.2 Credit standby arrangements	970	415
7.3 Other (please specify)	-	-
7.4 Total financing facilities	970	415
7.5 Unused financing facilities available at quarter end		555
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)	(3,166)
8.2 Cash and cash equivalents at quarter end (item 4.6)	33,955
8.3 Unused finance facilities available at quarter end (item 7.5)	555
8.4 Total available funding (item 8.2 + item 8.3)	34,510
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	11
<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	
<i>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.</i>	

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: 31 October 2023

Authorised 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.