ASX ANNOUNCEMENT/MEDIA RELEASE
29 November 2022

AROA BIOSURGERY HALF YEARLY REPORT H1 FY23

Financial Highlights

- H1 FY23 Product sales were up 44% to **NZ$28.8 million** compared to H1 FY22 (NZ$20.1 million), and up 20% compared to H2 FY22 (NZ$24.0 million), on a constant currency basis.[1]
- Product gross margin % of **84%**, representing a 6% increase compared to H1 FY22, and a 5% increase compared to H2 FY22, on a constant currency basis.
- Total reported H1 FY23 revenue inclusive of project fees was **NZ$29.3 million.**
- H1 FY23 Myriad™ product revenue grew 242% on H1 FY22 and 147% on H2 FY22 (on a constant currency basis) to **NZ$5.6m million.**
- H1 FY23 normalised[2] EBITDA (unaudited) was positive.
- Upgraded FY23 guidance maintained at **NZ$62-64 million**.[3]
- Strong cash balance of NZ$50.1 million as at 30 September 2022 and the Company is debt free.

Operational Highlights

- The Company continues to gather clinical evidence, including publication of a pre-clinical study demonstrating the potential of AROA's new Enivo™ system, as well as ongoing recruitment of patients for the Myriad Augmented Soft Tissue Regeneration Registry.
- On 4th November, the Company submitted an application for regulatory approval to the US Food & Drug Administration ('FDA') for the first product in the Enivo range.
- The Company is planning a full launch of Symphony™ in April 2023 and expects to be well-positioned for pending reimbursement changes.
- Regulatory approval for Myriad Matrix™ in the Australian market was gained in September.
- Seasoned Medtech Executive and long-time entrepreneur Dr. Catherine Mohr joined AROA's Board on 1 November as a Non-Executive Director.
- Due to headcount growth, additional office space has been secured in Auckland, New Zealand.
- AROA will host an investor webinar today at 11:00 AEST to discuss these results. Click here to register to attend.

[1] 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.

[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 AROA Group's ("Group") comparative financial performance without any distortion from NZ GAAP accounting treatment specific to one-off fair value adjustments, one-off transaction costs associated with capital raisings. The impact of non-cash share-based payments expense and unrealised foreign currency gains or losses have 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 in this announcement to 'normalised EBITDA' are as set out in this footnote.

3 Given the dynamic and evolving impact of COVID-19, all forward-looking statements in relation to FY23 performance are 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, Inc. delivering on its revenue guidance of US$42-45 million in CY22. It assumes an average exchange rate of US$0.62/NZ$1.00.

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Soft tissue regeneration company Aroa Biosurgery Limited (ASX: ARX, 'AROA' or the 'Company') is pleased to announce its full results for the first half of the 2023 financial year, which ended on 30 September 2022.

Management Commentary

With fewer disruptions presented by COVID-19 in 2022, AROA entered FY23 with momentum, delivering a strong H1 result. To date, more than five and a half million AROA devices have been applied in treating patients globally.

Managing Director and CEO Brian Ward said:" "Overall, the business has produced a strong result, and with approximately NZ$50 million in cash, we are poised to enter H2 FY23 with confidence.

It's excellent to see such strong results across the Myriad portfolio, and as our sales force matures and product portfolio broadens, we expect to see momentum build even further.

We're pleased to advise that an application for regulatory approval has been submitted to the US Food & Drug Administration ('FDA') for the first product within the Enivo range, and we expect to be able to report back on this within the fiscal year.

It's important to acknowledge the significant contribution of our dedicated team of people at AROA. The collective effort of the team over the last six months has enabled us to deliver excellent performance in a complex, rapidly changing environment."

Financial Commentary

The Company has produced a strong H1 result. H1 FY23 product sales were up 44% on H1 FY22 on a constant currency basis, driven by outstanding sales growth in the Myriad product portfolio of 242% on H1 FY22 (on a constant currency basis).

As a result of the positive revenue performance and product gross margin result, the business was able to post a small positive normalised EBITDA, while still maintaining its strategy of increasing investment in sales, marketing, and research & development.

The Company ended the half year in a strong financial position with NZ$50.1 million and no debt.

Normalised Profit or Loss[1]

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	Reported H1 FY23 NZ$000	Reported H1 FY22 NZ$000	Reported YoY %	CC[2] H1 FY23 NZ$000	CC[2] H1 FY22 NZ$000	CC[2] YoY %
Product sales	28,845	17,661	63	28,845	20,087	44
Other revenue	492	191	158	492	217	127
Total revenue	**29,337**	**17,852**	64	**29,337**	**20,304**	44
Gross profit	**24,621**	**13,469**	83	**24,621**	**15,921**	55
Product gross margin %	**84%**	**75%**	9 bps	**84%**	**78%**	6 bps
Other income	753	94	704	753	94	704
Normalised selling and administrative expenses[3]	(19,904)	(12,647)	57	(19,904)	(13,699)	45
Research and development	(5,995)	(3,618)	66	(5,995)	(3,618)	66
Total normalised operating expenses	**(25,899)**	**(16,265)**	59	**(25,889)**	**(17,317)**	50
Normalised EBIT	**(525)**	**(2,702)**	81	**(525)**	**(1,302)**	60
Add back: Depreciation & amortisation	1,844	1,546	19	1,844	1,546	19
Normalised EBITDA	**1,319**	**(1,156)**	N/A	**1,319**	**244**	441
Normalised net finance income / (expenses) [3]	1,290	(1,193)	N/A	322	(869)	N/A
Normalised profit / (loss) before income tax	**765**	**(3,895)**	N/A	**(203)**	**(2,171)**	91

1. The normalised profit or loss is non-conforming financial information, as defined by the NZ Financial Markets Authority. It has been provided to assist users of financial information to better understand and assess the Group's comparative financial performance without any distortion from NZ GAAP accounting treatment specific to one-off transaction costs associated with financing activities (AROA's capital raising on the ASX in August 2021). The impact of non-cash share-based payments expense and unrealised foreign currency gains or losses have 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.
2. Constant currency ('CC') removes the impact of exchange rate movements. This approach is used to assess the 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.
3. These items have been normalised by the amounts outlined within the section headed 'Reconciliation of Normalised Profit or Loss to NZ GAAP Profit or Loss' below.

Product sales

Product sales of NZ$28.8 million for the half-year, were up 63% compared to H1 FY22 (NZ$17.7 million). On a constant currency basis, product sales for the half year were up 44% compared to H1 FY22 (NZ$20.1 million), and up 20% compared to H2 FY22 (NZ$24.0 million). Myriad was a key contributor to growth with H1 FY23 revenues of NZ$5.6 million, representing constant currency growth of 242% on H1 FY22 and 147% on H2 FY22. Endoform and Myriad sales contributed 22% and 19% respectively to total product sales in H1 FY23, with sales of OviTex™[4] and OviTex PRS contributing to the balance.

Other revenue

Other revenue represents project fees income, received for product development projects undertaken with TELA Bio, Inc.

Product gross margin %

Product gross margin % of 84% for the half-year was up 9% compared to H1 FY22 (75%), primarily due to the increase in higher margin product, manufacturing productivity improvements and favourable movements in the US$/NZ$ exchange rates. On a constant currency basis, product gross margin % increased by 6% compared to H1 FY22 (78%) and increased by 5% compared to H2 FY22 (79%).

[4] TELA Bio and OviTex are trademarks of TELA Bio, Inc.

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Normalised operating expenses

Selling and administrative expenses of NZ$19.9 million for the half-year represented a 57% increase compared to H1 FY22 (NZ$12.6 million). On a constant currency basis, selling and administrative expenses were up 45% compared to H1 FY22, reflecting the increased investment into the Company's US-based sales operations.

Research and development expenses for the half-year were NZ$6.0 million, a 66% increase compared to H1 FY22, reflecting the Company's increased investment in its tissue apposition platform (Enivo).

Cash Flows

Cash receipts from sales revenue was NZ$24.5 million for H1 FY23, compared to NZ$13.4 million in H1 FY22, primarily reflecting the strong growth in product sales revenue. Net cash outflow from operating activities was NZ$4.6 million for H1 FY23 compared to a net cash outflow from operating activities of NZ$5.7 million in H1 FY22.

Purchases of property, plant and equipment was NZ$2.2 million for H1 FY23 compared to NZ$2.0 million in H1 FY22, reflecting the investment in new plant and equipment to expand the Company's manufacturing facility.

Net cash outflow from financing activities was NZ$0.3 million for H1 FY23, compared to a net cash inflow from financing activities of NZ$37.9 million H1 FY22, reflecting the one-off net proceeds from the Company's capital raise in August 2021 of NZ$47.9 million, less full repayment of the debt outstanding to Hollister of NZ$9.5 million.

AROA ended H1 FY23 debt free with cash on hand and term deposits of NZ$50.1 million, providing adequate cash reserves to fund its planned further investment into its US commercial operations and for accelerating and broadening its research and development pipeline.

Financial Outlook

AROA maintains its FY23 guidance, which was upgraded on 25 October, reflecting improved FY23 performance expectations, including favourable foreign exchange movements. In conjunction with the guidance upgrade, the Company also revised the rate used in its constant currency analysis from US$0.70/NZ$1.00 to US$0.62/NZ$1.00 (being approximately the AROA group's average US$/NZ$ exchange rate for H1 FY23). On the revised constant currency basis, AROA's FY23 product revenue guidance is NZ$60-62 million (up from NZ$51-55 million).[5] 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. This reflects a 39-43% increase on FY22 total revenue (on a constant currency basis). FY23 product gross margins are expected to be 84% and normalised EBITDA 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$42-45 million in CY22.[6] An average US$/NZ$ exchange rate of US$0.62/NZ$1.00 is also assumed.

Enivo Regulatory approval submission

On 4th November 2022, the Company submitted an application for regulatory approval to the US Food & Drug Administration (FDA) for the first product in the Enivo range.

AROA expects to provide a progress update on the review process before the end of the current fiscal year. The FDA's average review time for similarly categorized medical devices (Product Code BTA) is 103 working days.

[5] At the exchange rate previously utilised by the Company, this represents a change from NZ$51-55 million to approximately NZ$53-55 million.
[6] TELA Bio, Inc. press release dated 9 November 2022.

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Symphony

The Centers for Medicare & Medicaid Services has postponed reimbursement changes for "skin substitutes" until CY 2024 to allow further time for stakeholder consultation. The Company will be proceeding with a full launch of Symphony in April 2023 and expects to be favorably positioned for subsequent reimbursement changes as they are implemented.

Clinical evidence

During H1 FY23, the Company continued to focus on building clinical evidence to support the efficacy of the product range.

In October 2022, a study was published in a leading peer-reviewed scientific journal, *ePlasty* (study available here), demonstrating the potential of AROA's new tissue apposition platform (Enivo) for promoting tissue apposition and reducing the formation of seromas[7] in surgical sites.

Use of Enivo resulted in near complete dead space closure at the conclusion of treatment (two weeks post-treatment), with a median seroma area of 2% and median seroma volume of 1.3 mL, compared to an area of 98% and volume of 188.5 mL for the Standard of Care treatment.

All participants in the Company's pilot Symphony™ study (n=10)[8] have completed their treatment and the encouraging results (currently being assessed) indicate the potential of Symphony's combination (AROA ECM™ and Hyaluronic acid) in healing complex wounds such as diabetic foot ulcers. The Company has commenced work on a 50-patient multi-centre prospective study and a 120-patient Randomised Control Trial to expand upon the clinical data for Symphony.

Progress on AROA's largest prospective study to date, evaluating AROA's Myriad Matrix and Myriad Morcells products in a wide range of surgical specialties and procedures, is tracking well with patient enrolment significantly ahead of target.[9] A total of 97 patients have been enrolled in the study to date from three sites, significantly ahead of the previous target of 75 by the end of the year.

TELA Bio, Inc. has also presented[10] additional positive data from its BRAVO I and ReBAR studies. The studies evaluate the use of the OviTex Reinforced Tissue Matrix and the data presented reflects a recurrence rate at 24-months of 2.6% and 1.9% respectively.

Regulatory Approval

The Company received Australian regulatory approval for Myriad Matrix in September 2022, the first AROA product to be approved for use in Australia.

New Independent Director

Seasoned medtech executive and inventor of the LapCap™, Dr Catherine Mohr joined AROA's Board on 1 November. Born in New Zealand and living in the US for many years, Dr. Mohr's background spans several key areas of expertise related to AROA's next stage of growth, including medtech product research and development, US FDA approvals, product commercialization and surgery technology innovation.

Operations

The Company has also signed a lease for additional office space in Auckland to accommodate its headcount growth.

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[7] Seromas form in the dead space that remains following the surgical separation and excision of soft tissue, where any damaged vessels can fill the resulting subcutaneous void with plasma and lymph fluid. They are a common post-surgical complication which can disrupt healing, increase pain, oedema (swelling) and result in poor cosmetic outcomes. They can also lead to more severe complications such as wound dehiscence, infection and necrosis of overlying tissue.
[8] Evaluating Symphony in the treatment of non-healing diabetic foot ulcers over a 12-week period.
[9] 97 patients to date compared to the end of year target of 75.
[10] At the 2022 American Hernia Society Meeting.

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Half Year Results Webinar

The Company will hold a webinar with CEO Brian Ward and CFO James Agnew today, **Tuesday November 29, 2022, at 11 am AEST,** to discuss the half year results.

Investors and interested parties can register to attend the webinar via the following link:

https://us02web.zoom.us/webinar/register/WN_1OvvlhH8TruQSaY0HEaHHw

Questions can be submitted prior to the webinar to shinsley@aroabio.com or during the webinar using the Q&A function on Zoom.

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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 every*body*'. 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.

AROA's products have been used in more than five and a half million procedures to date, with distribution into our key market of the United States 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

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 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.

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