

## AROA BIOSURGERY HALF YEARLY REPORT H1 FY24

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### Financial Highlights

- H1 FY24 product sales grew 8% to **NZ\$31.2 million** compared to H1 FY23. **Anticipated H2 FY24 product revenue of ~NZ\$41-\$44 million, representing a ~30-40% increase on H1 FY24.**
- **80% increase** in high-margin Myriad™ H1 FY24 sales (compared to H1 FY23) to **NZ\$10.2 million**, reflecting the building momentum of AROA's direct field sales team. Myriad continues to lead growth across the portfolio, accounting for **33% of H1 FY24 total product sales** (up from 19% in H1 FY23) and reflecting **67% of AROA's direct sales mix** in Q2 FY24.<sup>1</sup>
- **37% increase in TELA Bio's sales** of OviTex™ and OviTex PRS during H1 FY24 compared to H1 FY23. However, H1 FY24 product revenue from TELA Bio of **NZ\$14.9 million** was 13% lower than H1 FY23, reflecting a focus on lowering inventory levels and improving inventory management as logistics mature.
- H1 FY24 normalised<sup>2</sup> EBITDA loss of NZ\$2.7 million predominantly a result of sales to TELA Bio reflecting the transitional impact of inventory management, with an **anticipated H2 FY24 normalised EBITDA profit of ~NZ\$4-5 million.**
- Total reported H1 FY24 revenue inclusive of project fees grew 9% to **NZ\$31.9 million.**
- Product gross margin of **84%**, constant with H1 FY23.
- Strong cash balance of **NZ\$34.0 million** as at 30 September 2023 and the Company is debt-free.
- Full-year FY24 guidance updated to a reported basis, to **NZ\$73-76 million** total revenue, **NZ\$72-75 million** product revenue (a 19-24% increase on FY23), **85%** product gross margin and a normalised EBITDA profit of **NZ\$1-2 million.**<sup>3</sup>

### Operational Highlights

- Targeted investment into AROA's US commercial operations continuing to deliver results and lay the groundwork for increasing profitability beyond FY24. Myriad active accounts<sup>4</sup> grew to 187 at the end of H1 FY24, up from 166 at the end of FY23. Results also reflect deeper penetration within existing accounts.
- In August, AROA submitted a US FDA 510(k) application for Myriad Flow™, a new Myriad product that could be commercialised in combination with the previously US FDA-cleared components of the Enivo™ system.
- To date, five participants in the Enivo pilot clinical study (n=10) have completed treatment and follow-up care, with no clinically relevant seroma or complications reported.
- Seven peer-reviewed clinical studies published in H1 FY24, including a retrospective case

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<sup>1</sup> % of product revenue excluding sales to TELA Bio, Inc ('TELA Bio').

<sup>2</sup> 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.

<sup>3</sup> This guidance reflects an updated expected NZ\$/US\$ exchange rate of 0.62 for H2 FY24 and is subject to TELA Bio delivering on its CY23 revenue guidance of US\$57-60 million (reflecting 38-45% growth over CY22).

<sup>4</sup> Represents accounts to which sales were made in the applicable period.



- series<sup>5</sup> (n=10) published in leading plastic surgery journal, *ePlasty* indicating that complex traumatic wounds may heal faster, with less complications and require fewer applications, when treated with Myriad than current standard of care.
- Article by interprofessional working group convened by AROA on surgical reconstruction of stage 3 and 4 pressure injuries selected as a finalist for 'Best Advance in Original Research' at the 2023 Advances in Skin Wound Care awards (jointly sponsored by the American Professional Wound Care Association and highly regarded peer-reviewed *Advances in Skin & Wound Care* journal).
  - Enrolments into AROA's Myriad Augmented Soft Tissue Regeneration Registry ('MASTRR') continued tracking well during H1 FY24, with 225 participants out of a target of 300 and 9 out of 10 sites recruited. 42 participants (n=120) enrolled across eight study sites for the Symphony™ randomised clinical trial commenced in June.
  - Seasoned Life Sciences and pharmaceutical executive, Scott Sherriff, joined AROA's leadership team as Chief Operating Officer from July.
  - Continued investment into expanding AROA's tissue manufacturing capacity, including taking delivery of an additional freeze dryer to at least double freeze-drying capacity.
  - Focus on expanding AROA's profile across investment communities reflected in an active investor relations schedule during H1 FY24, including presentations at institutional conferences and broker network meetings, and hosting two well-attended investor meetings.
  - AROA will host an investor webinar today at 10 a.m. AEDT to discuss these results. [Click here](#) to register to attend.

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Soft tissue regeneration company Aroa Biosurgery Limited (ASX: ARX, 'AROA' or the 'Company') is pleased to announce its results for the first half of the 2024 financial year, which ended on 30 September 2023.

### Management Commentary

Top-line growth was led by sales of the Myriad™ product family which grew by 80% on H1 FY23 to NZ\$10.1 million. Myriad accounted for 33% of H1 FY24 total product sales (up from 19% in H1 FY23) and 67% of AROA's direct sales mix<sup>6</sup> in Q2 FY24 (up from 46%, 50% and 56% in Q1 FY23, Q2 FY23 and Q1 FY24 respectively).

This continued growth reflects the Company's targeted investment into its US commercial operations which continues to deliver results. AROA ended the half year with 187 Myriad active accounts<sup>7</sup> (up from 166 at the end of FY23) and key wins with the prestigious Cleveland Clinic, Case Western and Ohio State University. We are pleased to report that the team's focused efforts also delivered deeper penetration within existing accounts.

The H1 FY24 results also reflect the field sales team's accelerating productivity, with ten field sales representatives at an average run rate of at least US\$750,000 per annum and over half (23) at an average run rate of at least US\$250,000 (up from ten field sales representatives at an average run rate of at least US\$500,000 at the end of FY23).

Founder and Chief Executive Officer, Brian Ward said "I am pleased with the team's efforts in what we

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<sup>5</sup> 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. The full study is available [here](#).

<sup>6</sup> I.e. excluding sales to TELA Bio, Inc.

<sup>7</sup> Represents accounts to which sales were made in the applicable period.

expected to be a transitional year of relatively modest overall revenue growth.

Myriad had to lead our growth and our people delivered. The strong AROA direct performance validates the strategic importance of Myriad and building momentum of our US commercial operations.

We expect revenue to increase by ~30-40% in the second half, with continued strong Myriad performance bolstered by an anticipated re-alignment in demand from TELA Bio. That revenue uplift will significantly improve our bottom-line.

TELA Bio recently delivered its 11th consecutive quarter of at least 35% year-on-year growth.<sup>8</sup> Their operations continue to mature, and they have focused on lowering inventory levels and improving inventory management. These improvements will benefit AROA going forward by smoothing demand and bringing both parties' sales into closer alignment.

We are confident that AROA is well-placed to deliver compelling top-line growth and increasing profitability beyond FY24. With a history of strong growth across the portfolio, increasing productivity, momentum in our US commercial operations, expected H2 FY24 normalised EBITDA profit of ~NZ\$4-\$5 million, net cash outflows from operation expected to move towards breakeven in the second half, and a healthy cash balance of NZ\$34 million, we have the fundamentals for success in place".

### Normalised Profit or Loss<sup>1</sup>

	Reported H1 FY24 NZ\$000	Reported H1 FY23 NZ\$000	Reported YoY %	CC <sup>2</sup> H1 FY24 NZ\$000	CC <sup>2</sup> H1 FY23 NZ\$000	CC <sup>2</sup> YoY %
Product sales	31,186	28,845	8	29,188	27,365	7
Other revenue	685	492	39	634	467	36
<b>Total revenue</b>	<b>31,871</b>	<b>29,337</b>	<b>9</b>	<b>29,822</b>	<b>27,832</b>	<b>7</b>
<b>Gross profit</b>	<b>26,808</b>	<b>24,621</b>	<b>9</b>	<b>24,758</b>	<b>23,116</b>	<b>7</b>
<b>Product gross margin %</b>	<b>84%</b>	<b>84%</b>	<b>0 bps</b>	<b>83%</b>	<b>83%</b>	<b>0 bps</b>
Other income	970	753	29	970	753	29
Normalised selling and administrative expenses <sup>3</sup>	(27,482)	(19,904)	38	(26,183)	(19,188)	36
Normalised research and development <sup>3</sup>	(5,102)	(5,995)	(15)	(5,102)	(5,415)	(15)
<b>Total normalised operating expenses</b>	<b>(32,584)</b>	<b>(25,899)</b>	<b>26</b>	<b>(31,285)</b>	<b>(25,183)</b>	<b>34</b>
<b>Normalised EBIT</b>	<b>(4,806)</b>	<b>(525)</b>	<b>(815)</b>	<b>(5,557)</b>	<b>(1,314)</b>	<b>(510)</b>
<i>Add back: Depreciation &amp; amortisation</i>	2,139	1,844	16	2,139	1,844	16
<b>Normalised EBITDA</b>	<b>(2,667)</b>	<b>1,319</b>	<b>N/A</b>	<b>(3,418)</b>	<b>530</b>	<b>N/A</b>
Normalised net finance income / (expenses) <sup>3</sup>	703	1,290	(46)	727	322	(126)
<b>Normalised profit / (loss) before income tax</b>	<b>(4,103)</b>	<b>765</b>	<b>N/A</b>	<b>(4,830)</b>	<b>(992)</b>	<b>(387)</b>

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. The Group has removed the impact of non-cash share-based payments expense and unrealised foreign currency gains or losses 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 0.65 has been used in the constant currency analysis.
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' on page 5 of AROA's Interim Consolidated Financial Statements (30 September 2023).

<sup>8</sup> TELA Bio press release dated 9 November.



### Product sales

Product sales of NZ\$31.2 million for the half-year were up 8%, compared to H1 FY23 (NZ\$28.8 million). On a constant currency basis, product sales for the half year were up 7%, compared to H1 FY23. Myriad sales of NZ\$10.2 million (NZ\$9.5 million on a constant currency basis) were up 80% (75% on a constant currency basis), compared to H1 FY23. 37% increase in TELA Bio's sales of OviTex™ and OviTex PRS during H1 FY24 compared to H1 FY23. However, H1 FY24 product revenue from TELA Bio of NZ\$14.9 million was 13% lower than H1 FY23, reflecting a focus on lowering inventory levels and improving inventory management as logistics mature. Endoform™ sales remained constant, compared to H1 FY23, with Symphony sales contributing a modest amount to the balance of sales for H1 FY24.

### Other revenue

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

### Product gross margin %

Product gross margin % of 84% (83% on a constant currency basis) for the half year was constant, compared to H1 FY23, primarily due to the lower recovery of indirect manufacturing overheads from OviTex and OviTex PRS sales offsetting the incremental gross margins realised from Myriad sales.

### Normalised operating expenses

Selling and administrative expenses of NZ\$27.5 million for the half-year were up 38%, compared to H1 FY23 (NZ\$19.9 million). On a constant currency basis, selling and administrative expenses were up 36%, primarily reflecting increases to sales team headcount, increases in variable sales compensation and increased clinical development activities.

Research and development expenses for the half-year of NZ\$5.1 million were down 15%, compared to H1 FY23, primarily reflecting the capitalisation of NZ\$0.6 million in research in development costs during H1 FY24 (H1 FY23 NZ\$nil).

### Normalised EBITDA

AROA made a normalised EBITDA loss of NZ\$2.7 million for H1 FY24, predominantly a result of lower TELA Bio sales reflecting the transitional impact of inventory management.

### Cash Flows

Cash receipts from sales revenue was NZ\$29.5 million for H1 FY24, compared to NZ\$24.5 million in H1 FY23, reflecting the increase in sales and improvements in customer collections. Net cash outflow from operating activities was NZ\$7.3 million for H1 FY24 compared to a net cash outflow from operating activities of NZ\$4.6 million in H1 FY23.

Purchases of property, plant and equipment were NZ\$2.1 million for H1 FY24 compared to NZ\$2.2 million in H1 FY23, reflecting the investment in new plant and equipment to expand the Group's manufacturing capacity.

Net cash outflow from financing activities were NZ\$0.6 million for H1 FY24, compared to a net cash inflow from financing activities of NZ\$0.3 million for H1 FY23.

The Group remains debt-free with cash on hand and term deposits of NZ\$34.0 million, providing adequate cash reserves as the Group advances towards positive net cash inflows.

### Financial Outlook

Full-year FY24 guidance is updated to a reported basis, to NZ\$73-76 million in total revenue, NZ\$72-



75 million in product revenue (a 19-24% increase on FY23) and an 85% product gross margin. The Company anticipates H2 FY24 product revenue of ~NZ\$41-\$44 million as Myriad continues to perform strongly and TELA Bio demand re-aligns to service its growth trajectory. The Company expects H2 FY24 normalised EBITDA profit of ~NZ\$4-5 million and FY24 full-year normalised EBITDA profit of NZ\$1-2 million.

Guidance reflects an updated expected NZ\$/US\$ exchange rate of 0.62 for H2 FY24 and is subject to TELA Bio delivering on its CY23 revenue guidance of US\$57-60 million (reflecting 38-45% growth over CY22).<sup>9</sup>

The Company's previous full-year guidance, first communicated on 31 May 2023, was in the same amounts presented on a constant currency basis (using a NZ\$/US\$ exchange rate of 0.65), and was based on TELA Bio's previous CY23 revenue guidance of US\$60-65 million.

### Enivo™

As previously communicated, we have decided to invest into bringing AROA's innovative second technology platform, Enivo, to market as quickly as possible. Enivo reflects significant commercial potential; in addition to an estimated total addressable market ('TAM') of over US\$1 billion,<sup>10</sup> the technology represents a unique opportunity to address a currently unmet market need, leverage synergies with the existing AROA ECM™ portfolio to deliver a step change in outcomes and continue to improve our field sales team's productivity.

In August, the Company submitted a US FDA 510(k) application for Myriad Flow™, a new Myriad product that could be commercialised in combination with the components of the Enivo system cleared by the US FDA in April 2023. The application is currently under review, with an update expected in early CY24.

Following positive pre-clinical results published in October 2022, AROA commenced a New Zealand-based pilot clinical study (n=10) during the half year to assess the efficacy of the Enivo technology. As at the date of this report, five participants have undergone their surgical procedure, with the Enivo device being placed intra-operatively. No clinically relevant seroma or complications have been reported for the participants who completed their treatment and follow-up care.

### Clinical Validation

AROA continued to bolster the clinical evidence for its products, with seven peer-reviewed studies<sup>11</sup>

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<sup>9</sup> TELA Bio press release dated 9 November.

<sup>10</sup> Management estimates.

<sup>11</sup> 1. Melnychuk, I., I. Servetnyk and N. Kosnik (2023). "Extracellular Matrix-Based Collagen Dressings for Scalp Repair Following Mohs Micrographic Surgery." *Cutis* 111(5): E33-E35; 2. Bohn, G. A. (2023). "Key concepts in healing venous leg ulcers." *Wounds* 35(Suppl 5): S1-S6; 3. Sharma, A., D. Sharma, and F. Zhao. 2023. 'Updates on Recent Clinical Assessment of Commercial Chronic Wound Care Products', *Advanced Healthcare Materials*, Jun 12: e2300556; 4. Bosque, B. A., S. G. Dowling, B. C. H. May, R. Kaufman, I. Zilberman, N. Zolfaghari, H. Que, J. Longobardi, J. Skurka, J. E. Geiger and M. M. Melin (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Lower-Extremity Soft-Tissue Defects: A Retrospective Multi-Center Case Series." *J Am Podiatr Med Assoc* 113(3): 22-081; 5. Hsu, A., K. Schlidt, C. R. D'Adamo, B. A. Bosque, S. G. Dowling and J. H. Wolf (2023). "Surgical management of perianal fistula using an ovine forestomach matrix implant." *Techniques in Coloproctology*. 27(9):769-774; 6. Fragoso, N. M., R. Masson, T. J. Gillenwater, V. Y. Shi and J. L. Hsiao (2023). "Emerging Treatments and the Clinical Trial Landscape for Hidradenitis Suppurativa—Part II: Procedural and Wound Care Therapies." *Dermatology and Therapy* 13(8): 1699-1720; 7. Cormican, M. T., N. J. Creel, B. A. Bosque, S. G. Dowling, P. P. Rideout and W. M. Vassy (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series." *ePlasty* 23: e66.



published during H1 FY24. This included a retrospective case series<sup>12</sup> describing the clinical effectiveness of Myriad Matrix™ and Myriad Morcells™ in complex traumatic wound reconstruction. The study was published in the September issue of leading plastic surgery journal, *ePlasty*, and involved 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, and no complications reported. This indicates that traumatic wounds may heal faster, with less complications and require fewer applications when treated with Myriad than current standard of care. As previously signalled, with an estimated US TAM of US\$300 million,<sup>13</sup> we see a real opportunity for Myriad to be a market leader in trauma procedures and are focusing our sales and clinical efforts accordingly (five of the study sites enrolled into MASTRR are specialised trauma centers).

An article by an interprofessional working group convened by AROA on surgical reconstruction of stage 3 and 4 pressure injuries, was also selected as a finalist for 'Best Advance in Original Research' at the 2023 Advances in Skin Wound Care awards. The article<sup>14</sup> proposes a surgical algorithm for stage 3 and 4 pressure injury reconstruction with adjunctive use of negative pressure wound therapy and bioscaffolds such as Myriad Matrix. It was published in the highly regarded peer-reviewed journal, *Advances in Skin & Wound Care* journal, which jointly sponsored the 2023 Advances in Skin Wound Care awards with the American Professional Wound Care Association.

AROA's MASTRR and Symphony™ clinical studies progressed well in H1 FY24. MASTRR is AROA's largest prospective study to date, evaluating Myriad Matrix and Myriad Morcells (including short and long-term healing outcomes) in a wide range of surgical specialties and procedures. Nine (of a target of 10) study sites and 225 (of a target of 300) patients were enrolled into MASTRR by the end of H1 FY24. We have enrolled 42 participants (n=120) across eight study sites for the Symphony randomised clinical trial, an 18-month study assessing the efficacy of Symphony in treating diabetic foot ulcers.

### Other updates

Seasoned Life Sciences and pharmaceutical executive, Scott Sherriff, joined AROA's leadership team as Chief Operating Officer from July. Scott has previously held roles at global pharmaceutical companies Bayer Pharma Ag and Novartis and was most recently Chief Commercial Officer at New Zealand headquartered life sciences company, Douglas Pharmaceuticals.

AROA continued investing into expanding its tissue manufacturing capacity during H1 FY24 and has taken delivery of an additional freeze dryer to at least double its freeze-drying capacity.

Taking a holistic approach to growing shareholder returns, the Company is also focused on expanding its profile across investment communities. AROA maintained an active investor relations schedule, with presentations by Brian Ward (CEO) or James Agnew (CFO) at institutional conferences and broker network meetings. These included the 2023 Macquarie Australia Conference, the Wilsons Drug & Device Conference in Noosa (AU) and 2023 Bioshares Biotech Summit in Hobart (AU). AROA is currently covered by Morgans, Wilsons, Bell Potter, Jarden and Cannacord Genuity.<sup>15</sup> AROA also

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<sup>12</sup> 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. The full study is available [here](#).

<sup>13</sup> Management estimates.

<sup>14</sup> Awad, S. S., J. D. Stern, C. T. Milne, S. G. Dowling, R. Sotomayor, E. A. Ayello, L. J. Feo Aguirre, B. Z. Khalaf, L. J. Gould, M. N. Desvigne and A. E. Chaffin (2023). "Surgical Reconstruction of Stage 3 and 4 Pressure Injuries: A Literature Review and Proposed Algorithm from an Interprofessional Working Group." *Advances in Skin & Wound Care* 36(5): 249-258. The article is available [here](#).

<sup>15</sup> Unless expressly specified otherwise, AROA does not endorse the content of broker reports.



hosted two well-attended investor meetings during H1 FY24, including in Sydney (AU) on 1 June with a presentation by Dr. Samir Awad, a key opinion leader and Professor of Surgery, and Vice Chair for Surgical Quality and Safety at the Baylor College of Medicine (US).

### Half Year Results Webinar

The Company will hold a webinar with CEO Brian Ward and CFO James Agnew today, **Tuesday November 28, 2022, at 10 a.m. AEDT**, 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\\_tnwln5YqQ2iBS3unAmNzJA](https://us02web.zoom.us/webinar/register/WN_tnwln5YqQ2iBS3unAmNzJA)

Questions can be submitted prior to the webinar to [investor@aroabio.com](mailto:investor@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.**

### Contacts

#### **Investor Relations**

[investor@aroabio.com](mailto:investor@aroabio.com)

+64 21 744 915

#### **Media**

[sarah.tora@aroabio.com](mailto:sarah.tora@aroabio.com)

+64 21 531 043

#### **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.

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.aroa.com](http://www.aroa.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 morcellised version of Myriad Matrix that easily conforms to optimize contact with irregular wound beds. Myriad Morcells Fine is a morselized conformable ECM graft that can be used either by itself or synergistically with Myriad Matrix.

#### **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.