

## SYMPHONY™ RANDOMISED CONTROL TRIAL COMPLETE

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### Highlights

- AROA's Symphony randomised controlled trial (RCT) has been completed.
  - The study was a randomised, multi-centre trial comparing Symphony with standard of care in diabetic foot ulcers.
  - Preliminary findings indicate the trial met its primary endpoint, assessing whether more diabetic foot ulcers healed within 12 weeks with Symphony than with standard of care.
  - Publication of the study is expected to support both Symphony's clinical adoption in chronic, complex wounds and anticipated future US reimbursement requirements.
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Aroa Biosurgery Limited (ASX: ARX, "AROA" or the "Company") is pleased to announce that it has completed its randomised controlled trial (RCT) for Symphony and has received a preliminary study read-out.

Symphony is AROA's Cellular, Acellular and Matrix-like Product ('CAMP', or 'skin substitute') product that combines multiple layers of AROA ECM™ with high molecular weight hyaluronic acid. It is designed specifically for use in hard to heal wounds including diabetic foot ulcers and venous leg ulcers.

The Symphony RCT was designed to assess the safety and performance of Symphony in the treatment of chronic Wagner grade 1 and 2 non-healing diabetic foot ulcers (DFUs).

The study was a prospective, multi-centre, randomised trial comparing Symphony against Standard of Care (SOC), with treatment evaluated over a 12-week period. Patients were randomised to receive either Symphony or SOC dressings, weekly until wound healing, or up to 12 weeks.

The study design included recruitment of up to 150 patients across multiple US sites. The primary study endpoint assessed whether more DFUs healed within the 12-week period when treated with Symphony versus SOC treatment.

Preliminary findings indicate that the study achieved the primary endpoint. The Company believes these findings, once confirmed through final analysis and publication, will further support Symphony's clinical efficacy in the management of DFUs.

Publication of the full study results will also meet the rigorous clinical evidence thresholds that the Company expects are likely to be proposed in future reimbursement policy.

"This is a crucial step in building the clinical evidence base for Symphony and supporting clinical adoption in chronic, complex wounds," said AROA CEO Brian Ward. "Randomised controlled trials are regarded as the most robust form of clinical evidence, and these results clearly validate Symphony's clinical value. We are encouraged by the early study read-out and look forward to publication of the full study results in the coming months."

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

## **Contact**

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### **About AROA<sup>TM</sup>**

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<sup>TM</sup> technology platform, a novel extracellular matrix bioscaffold derived from ovine (sheep) forestomach.

Over 7 million AROA devices 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 TELABio, 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)