



AROA BIOSURGERY SECURES FDA CLEARANCE FOR NEW PRODUCT, MYRIAD MORCELLS™ OFFERING HIGHLY CONFORMABLE TISSUE REGENERATION IN WOUND BEDS

HIGHLIGHTS

- U.S. FDA 510(k) clearance received for a new Aroa Biosurgery product named Myriad Morcells™, a morcellized (powder) format of Myriad Matrix™ that easily conforms to optimize contact with irregular wound beds.
- The morcellized format increases AROA ECM™ surface area to maximize delivery of important ECM proteins.
- This clearance further builds on the applications and commercial potential for the Myriad™ portfolio following recent studies showing positive clinical outcomes for Myriad Matrix™'s use in surgical treatment of hidradenitis suppurativa, complex wounds and exposed vital structures.

Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'Aroa' or the 'Company') has gained U.S. FDA 510(k) clearance for Myriad Morcells™, a morcellized (powder) format of Myriad Matrix™ that easily conforms to optimize contact with irregular wound beds.

Aroa's Vice President of Research and Clinical Development, Dr Barnaby May said Myriad Morcells™ delivers a bolus of biologically important ECM proteins known to 'kick start' healing in a format that conforms to the intricacies of a wound.

"When using Myriad™ products for dermal reconstruction, Myriad Morcells™ can be used concomitantly with Myriad Matrix™ to accelerate granulation tissue formation. The combination of Myriad Morcells™ with Myriad Matrix™ helps provide rapid and sustained delivery of biological components important during tissue regeneration as well as a porous scaffold for cell infiltration," Dr May said.

The new product, which is not indicated for implantation, is provided in a convenient tray for hydration, mixing, and pouring.

Myriad Matrix™ is a highly perforated, multi-layered extracellular matrix (ECM) graft engineered to have a high volume and surface area with interstitial spaces that are easily and rapidly accessible to cells. It takes advantage of the Aroa ECM™ bioscaffold technology, including important secondary molecules and residual vascular channels to support new tissue growth. Myriad Matrix™ enables rapid vascularization and helps build new tissue, which may lead to faster healing, recovery and hospital discharge.

Earlier pre-clinical studies have shown that the Aroa ECM™ technology includes over 150 different components known to aid wound repair, blood vessel formation and attract stem cells.

Aroa received FDA 510(k) clearance for Myriad Matrix™ in June 2017, which led to first sales in early 2020 with a total estimated market size for the product globally of US\$350 million. In late July 2020 it was approved for commercial use in the European Union by European notified body DEKRA Certification B.V.

"We are pleased with the progress we are making to grow the applications for the Myriad™ portfolio. This clearance for Myriad Morcells™ follows closely on studies showing positive clinical outcomes from the use of Myriad Matrix™ on exposed vital structures, in surgical treatment of serious cases of the inflammatory skin condition hidradenitis suppurativa and in reconstruction of complex non-healing wounds," said Aroa Founder and CEO Brian Ward.

Aroa has six commercial product families approved for sale in the US based on its ECM technology, which has been used in more than four million procedures targeting chronic wounds, hernia, soft tissue and breast reconstruction. Aroa has regulatory clearance in more than 44 countries.

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

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About Aroa Biosurgery:

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. Clinically proven with peer reviewed publications, Aroa's products have been used in more than four 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/

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