ASX ANNOUNCEMENT
12 April 2023

AROA BIOSURGERY SECURES FIRST FDA CLEARANCE FOR ENIVO™ SYSTEM.

Highlights

- AROA has received U.S. FDA 510K clearance for its Enivo™ pump and catheter.
- U.S. FDA 510K clearance simplifies the process for initiating future clinical studies and early commercialization activities.
- AROA's management estimates the total addressable U.S. market for the Enivo™ Tissue Apposition Platform to be greater than $1B.

Aroa Biosurgery Limited (ASX: ARX, 'AROA or the 'Company') is pleased to announce that it has received U.S. Food and Drug Administration ('FDA') 510K clearance for its Enivo™ pump and catheter which are key components of the Company's new Enivo™ Tissue Apposition Platform.

The device applies negative pressure to a surgical site, helping to reduce fluid accumulation following surgery. It has been cleared for use in the removal of surgical and bodily fluids from a closed wound for hematoma and seroma prophylaxis following plastic surgery or other general surgeries where large flaps are formed.

Currently, surgeons use surgical drains, adhesives, and quilting sutures to manage dead-space and prevent fluid accumulation, but these techniques are unreliable.

AROA plans to pursue approval for the AROA ECM™ sleeve, the third component of this system, including a DeNovo application to support use and expand future claims.

AROA CEO Dr Brian Ward said that the clearance simplifies the process for initiating future clinical studies and early commercialization activities.

"Gaining FDA clearance is a key milestone in establishing our second technology platform. We expect to develop a portfolio of products based on this technology platform for a range of soft tissue reconstruction procedures.

This is the culmination of several years' development across a number of teams. The Enivo™ system complements our AROA ECM™ based products and we expect that these technology platforms will be synergistic when used concurrently."

The total addressable market for the Enivo™ Tissue Apposition Platform in the U.S. is estimated by AROA's management to be in excess of $1B.

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

About Aroa Biosurgery:
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™

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technology platform, a novel extracellular matrix biomaterial derived from ovine forestomach. AROA has four product families selling in the US based on its AROA ECM technology, targeting chronic wounds, hernia, soft tissue, and breast reconstruction. AROA's products have been used in more than 5.9 million procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELA Bio, Inc. AROA has regulatory approvals in more than 50 countries. Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX: ARX). http://www.aroabio.com

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