



## INDIAN REGULATORY APPROVAL RECEIVED FOR THREE AROA PRODUCTS

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### HIGHLIGHTS

- The national regulatory authority of India, the Central Drugs Standard Control Organisation (CDSCO), approves Myriad™, Endoform® Natural and Endoform® Antimicrobial.
  - Significant market potential with large volume of acute and chronic wounds.
  - Distribution expected to commence in second half of the 2021 calendar year.
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Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'Aroa' or the 'Company') has gained regulatory approval to introduce three products to the Indian market based on its Aroa ECM platform. The three products, Myriad™, Endoform® Natural and Endoform® Antimicrobial, have been approved under the 'Medical Device Rules 2017' by the national regulatory authority of India, the Central Drugs Standard Control Organisation (CDSCO).

Aroa Biosurgery CEO Brian Ward says the regulatory approval is an exciting milestone for the company, given the scale of patient need in India.

"With more than 1.35 billion people, there is a high and continuing level of patient need in India. It is estimated that 20 million patients in India suffer from chronic wounds, with about 11 million suffering from diabetic ulcers. Introduction of the three products we now have approved for use will give a large number of people access to advanced wound care in a market where traditional wound care has been the primary treatment approach," Mr Ward says.

Estimates of the value of the advanced wound care market in India range from US\$225-485 million in 2020, with compounding growth between 5.5 and 8 percent per year.

Aroa is targeting distribution of its products in India in the second half of the 2021 calendar year. The company is currently in discussions to appoint an experienced Indian distributor to manage a network of sub-distributors across the subcontinent. Initial sales progress is expected to be impacted by the residual impact of COVID-19 as face-to-face meetings with health care providers and patients will be curtailed until the incidence of the virus is reduced.

Endoform® Natural and Endoform® Antimicrobial both provide a tissue matrix for treating chronic wounds (e.g. diabetic foot ulcers and venous leg ulcers) particularly during the inflammatory phase of healing. Myriad™ 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.

Aroa has five commercial products 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 and soft tissue. Aroa has regulatory market authorisation in more than 37 countries.

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

### **About Aroa Biosurgery:**

Aroa Biosurgery is a soft-tissue regeneration company that develops, manufactures, sells and distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Committed to 'unlocking regenerative healing for everybody', its products are developed from the Company's 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 its key market of the United States by Appulse and 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/](http://www.aroabio.com/)

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