

ASX Announcement

15 April 2026

ReNerve's Nerve Guide Matrix Enters Stage 3 of Commercial Development

ReNerve Limited (ASX, "ReNerve" or "the Company"), an Australian biotechnology company developing innovative products for peripheral nerve injury ("PNI") repair, is pleased to announce that its NervAlign Nerve Guide Matrix has entered stage 3 of the 4-stage scaled commercial production process in preparation for FDA submission.

Stage 3 is the verification process of development and is anticipated to generate product that will be used in the commencement of formal preclinical testing, production of the related packaging and manufacturing of the final product. Stage 3 is expected to be completed by the end of calendar 2026.

"This is a very important stage forward in moving the Nerve Guide Matrix to FDA submission and into the market. This will be a significant product for ReNerve, with testing in large animal models highlighting its suitability for the replacement of damaged nerves, and we expect this will provide surgeons with an alternative to donor nerves, which have limitations." said **Dr Julian Chick, CEO of ReNerve.**

The Nerve Guide Matrix is in commercial development with a GMP production facility in preparation for its formal marketing submission to the FDA.

Stage 4 will be the final production and testing of the Nerve Guide Matrix batches. ReNerve has been holding ongoing meetings with the FDA throughout the commercial development process, and testing will be undertaken in consideration of feedback provided by the FDA.

ReNerve is developing the NervAlign Nerve Matrix for the repair and replacement of injured and damaged nerves. The global market for nerve repair is estimated to be around USD\$2Bn. The NervAlign Nerve Guide Matrix complements the rest of the ReNerve NervAlign product portfolio.

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This announcement has been approved for release by the Company's Board of Directors.

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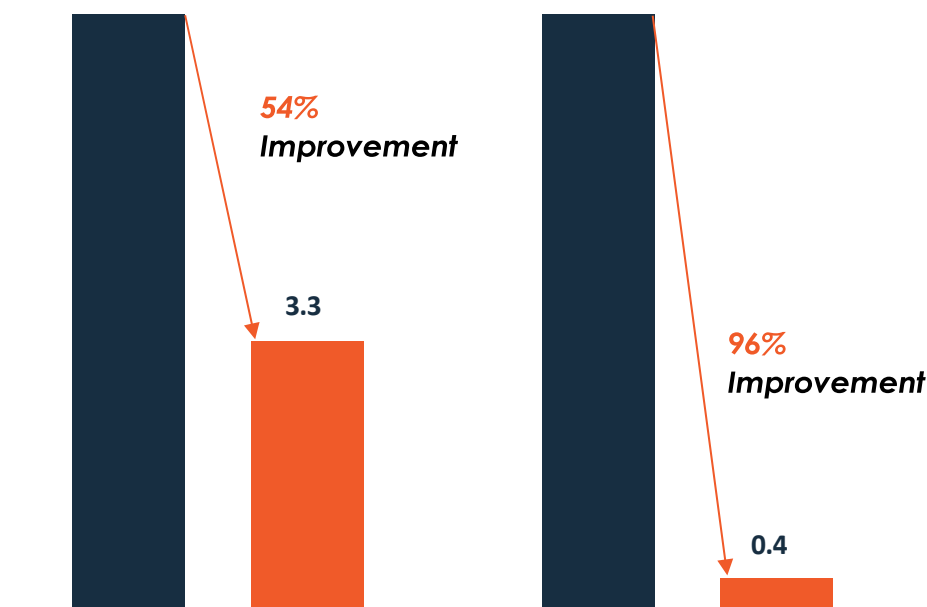
About ReNerve Limited (ASX:RNV)

ReNerve Limited (ASX:RNV) is transforming nerve repair and improving lives through breakthrough medical technology. Founded by a neurosurgeon and medtech researchers, ReNerve is a rapidly growing medical device company that has revolutionised peripheral nerve surgery with its innovative, ready-to-use solutions for peripheral nerve injuries (PNI). Our scientifically backed products are delivering measurably better outcomes for patients worldwide.

Proven Clinical Success

ReNerve's first flagship product, the FDA-cleared **NervAlign® Nerve Cuff**, is already making a dramatic difference in surgical outcomes across the United States. A recently announced clinical study has demonstrated remarkable results, showing that patients treated with the NervAlign® Nerve Cuff experienced post-surgical pain scores dropping from 7.1 to just 0.4, compared to from 7.1 to 3.3 without the device being used – a statistically significant improvement that's changing lives.

Comparison of Patient Pre & Post Surgery Pain Score



Standard of Care vs NervAlign™ Nerve Cuff Protected Nerve Repairs

The comparison of pain scores between the two cohorts of patients

Comprehensive Product Portfolio

ReNerve is advancing a complete suite of nerve repair solutions and related surgical repairs:

On market

- **NervAlign® Nerve Cuff** – Our bioabsorbable protective wrap, naturally absorbed within six months of surgery.
- **Empliq™ Deep Dermal tissue product** -- A unique deep dermal product used in the repair of reconstructive and cosmetic surgical cases.
- **Empliq™ Amniotic tissue product ranges** -- Three amniotic tissue product ranges used to aid the healing of wounds.

In development

- **NervAlign® Nerve Conduit Range** – Next-generation nerve conduit leveraging advantages of eCOO technology in a material designed to facilitate nerve growth over short gaps between nerve ends.
- **NervAlign® Nerve Guide Matrix** – a customised and ready-to-use alternative to existing nerve grafts, for treatment of longer nerve gaps and more severe nerve injuries. It will eliminate the need for patients to undergo additional sural nerve harvesting.
- **NervAlign® Bionic Nerve** – Next-generation combination technology for the most challenging nerve repairs.

Market Leadership and Growth

With demonstrated market traction since the Company's 2022 product launch, ReNerve achieved 53% revenue growth in FY25, reaching \$271k in sales and YTD FY2026 sales revenues showing further significant increases across its portfolio. Our high-margin, scalable products are positioning us as the go-to solution for surgeons seeking superior patient outcomes in the rapidly expanding global nerve repair market, valued at US\$1.6 billion in 2024 and is projected to reach \$6.2 billion by 2031.¹

Vision and Values

We're not just developing medical devices – we're engineering hope. By creating the ideal healing environment for nerve repair and regeneration, ReNerve bridges critical gaps in healthcare while empowering the human body's natural healing process. Our cleaner, safer, and more effective solutions represent the future of peripheral nerve surgery.

¹ Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)