

ASX Announcement

14 October 2026

ReNerve receives positive FDA feedback on NervAlign® Nerve Guide Matrix regulatory pathway

Key Highlights

- **ReNerve receives positive feedback** from the US Food and Drug Administration (FDA) following a pre-submission meeting for its NervAlign® Nerve Guide Matrix (NGM)
- **FDA feedback** supports ReNerve's proposed preclinical evaluation model and provides further guidance on the control groups required
- **FDA also outlines** biochemical and biophysical testing expectations to support a future regulatory submission as agreed path forward
- **Feedback** will inform the Company's final testing plan and regulatory submission package
- **Manufacturing of NGM** continues with ReNerve's contract manufacturing organisation (CMO)

ReNerve Limited (ASX: RNV, "ReNerve" or "the Company"), an Australian medical device company focused on peripheral nerve repair, is pleased to announce that it held a positive pre-submission meeting with the US Food and Drug Administration (FDA) on 30 September 2026 for its NervAlign® Nerve Guide Matrix (NGM) program.

The pre-submission meeting, supported in writing, gave ReNerve the opportunity to discuss its regulatory plan for the NGM with the FDA and to seek feedback before making a formal submission and provide the company with the clear path forward for FDA submission ahead of marketing approval clearance.

The Company's discussions with the FDA were positive and confirmed ReNerve's submission strategy, while also providing important feedback from the regulator. The FDA agreed that the model ReNerve has chosen for its preclinical evaluation is appropriate and provided additional guidance on the control groups it expects. The FDA also set out clear expectations for the biochemical and biophysical data needed to support clearance.

ReNerve is reviewing the feedback in detail and will use it to finalise its testing plan and the data package for the NGM. The Company is continuing production with its CMO and will update the market on progress including the timing of planned submission.

Dr Julian Chick, CEO of ReNerve, said: "This is an important step forward for our NervAlign Nerve Guide Matrix program, providing greater clarity on the FDA's expectations as we progress towards a regulatory submission.



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"The feedback is particularly encouraging given the positive results we have from our ongoing preclinical study. We now have a clearer understanding of the additional testing and data required, allowing us to focus our development activities on progressing NGM towards the US market."

ENDS -

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

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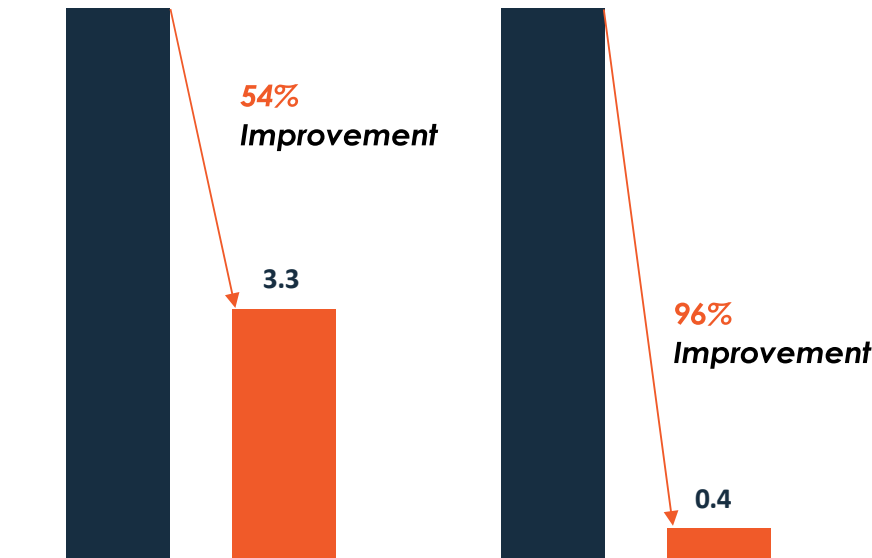
About ReNerve Limited (ASX:RNV)

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. 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)