ReNerve

ASX Announcement

19 October 2026

Positive 12-month preclinical data for NervAlign® Nerve Guide Matrix

Key Highlights

- 12-month preclinical sheep data show strong nerve regeneration and return of nerve function across a 4cm gap, a critical sized defect gap*, using NervAlign Nerve Guide Matrix
- All animals treated showed similar walking ability to animals treated with an autologous nerve graft and untreated animals
- The animals also recovered well, moved freely and recovered quickly post-surgery
- Nerve testing demonstrated return of both sensory and motor nerve signals in the NervAlign and autologous graft groups, with similar results observed between the groups
- Preliminary tissue analysis identified blood vessel and nerve fibre regrowth throughout the NervAlign implants and into the nerve beyond the repair site
- Further animals are scheduled for assessment in November 2026, further results to follow

ReNerve Limited (ASX:RNV) ("ReNerve" or the "Company"), an Australian medical device company focused on peripheral nerve repair, is pleased to report positive interim 12-month results from its ongoing preclinical study of the NervAlign® Nerve Guide Matrix ("NGM").

The study is evaluating a 4cm section of the NGM implanted in a sheep peripheral nerve model, compared with an autologous nerve graft control. Nerve defects longer than 3cm are generally considered critical and published literature notes that marketed nerve conduits have demonstrated reliable regeneration only over shorter gaps of up to approximately 3cm. Whether reconstruction of defects of 4cm or more is possible has been identified as a key question in the field.* The positive data generated in this study at the 4cm gap length therefore highlight the utility and value of the ReNerve NGM in a clinically challenging setting. The use of a large animal model is also relevant to human application, as rodent models have been criticised as poorly suited to translational nerve research because of differences in scale.* The study included six implants in total, with three NGM implants (N=3) and three autologous nerve grafts (N=3). The NGM implants replicate a typical nerve replacement.

Autologous nerve grafting, where a patient's own nerve is used to repair a damaged nerve, is a commonly used surgical approach for repairing larger nerve gaps. The study is assessing whether NGM can support nerve regeneration across a 4cm gap without requiring a donor nerve.

All animals recovered well following surgery and were walking freely within hours. At 12 months, animals treated with NGM showed similar gait to animals treated with an autologous nerve graft and animals that had not undergone the nerve intervention.

Nerve conduction testing at 12 months detected both sensory and motor nerve signals in animals treated with NGM, demonstrating that nerve signals were able to travel across the repaired area. Similar nerve conduction results were observed in animals treated with autologous nerve grafts. Because of the small number of animals reported to date, formal statistical assessment is not yet possible.

Preliminary histological assessment found regrown vascularisation and axonal structures in sections taken along the length of the implants and into the distal nerve segment. More detailed staining and analysis is in progress, and the Company will report further findings as that work is completed.

In one NGM animal, a minimal area of inflammation was observed within the implant at 12 months, although axonal regrowth was present throughout the length of that implant. Earlier ReNerve data have shown that some inflammation can be seen at around three months and has cleared by around ten months, which may be part of the normal remodelling process. The inflammatory cell accumulation in this single 12-month implant is so far unexplained, however could be part of the natural nerve regeneration. The Company is investigating it as part of the ongoing histological analysis.

Next steps

Additional animals are scheduled to be explanted in late November 2026. The Company will complete the detailed histological analysis, including investigation of the inflammatory finding, and expects to provide a further update once the data from the additional animals and the full analysis are available.

Dr Julian Chick, CEO of ReNerve, said: "These 12-month results are very encouraging because we have seen nerve fibres regrow across the full 4cm NGM implant, together with the return of sensory and motor nerve signals, as well a restoration of leg function back to 'normal'. The results observed to date are like those in the autologous nerve graft group, which is an important benchmark for our technology and shows the NGM has the potential to offer a true alternative to autologous nerve grafts.

"We are continuing the detailed analysis, including investigation of the inflammation observed in one implant, and look forward to reporting results from the remaining animals."

These results are preclinical data and complement existing 3-, 6-and 10-month data as well as additional bench testing and safety profiling of the NGM. Preclinical results are not necessarily predictive of outcomes in humans. The NervAlign® Nerve Guide Matrix is in development and is not approved for sale in any jurisdiction. ReNerve continues to consult with the regulatory authorities on its path forward to regulatory marketing approval.

* - https://pmc.ncbi.nlm.nih.gov/articles/PMC6538587/ - Kornfeld T, Vogt PM, Radtke C. Nerve grafting for peripheral nerve injuries with extended defect sizes. [Journal, year]. PMID: 30547373; PMCID: PMC6538587.

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

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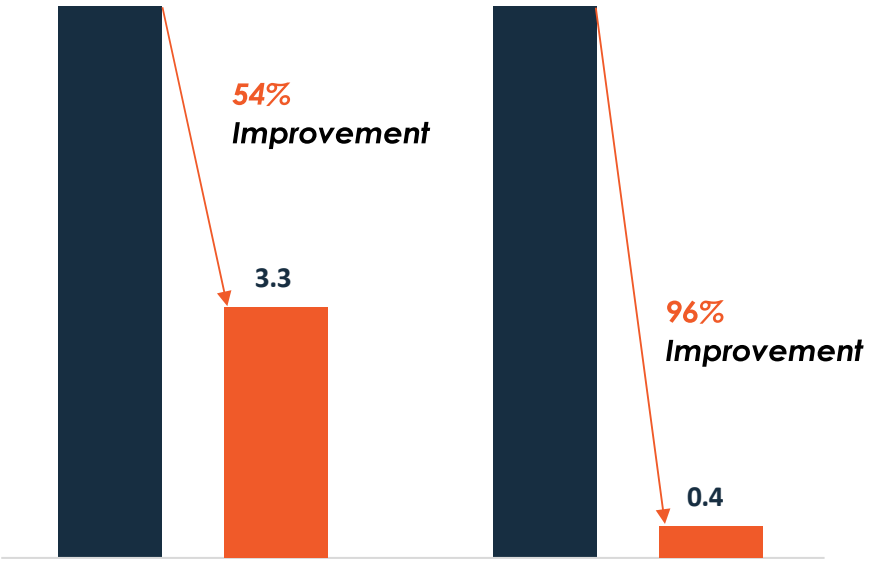
About ReNerve Limited (ASX:RNV)

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. 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)