ReNerve

ASX Announcement

5 November 2025

ReNerve Expands Clinical Study Evaluating NervAlign® Nerve Cuff in Peripheral Nerve Repair

- **Expansion of cohort for a definitive clinical trial to assess the efficacy of the NervAlign® Nerve Cuff**
- **Expansion builds on statistically significant interim data presented in March 2025**
- **Study to compare standard of care with and without the NervAlign® Nerve Cuff across multiple US centres**

ReNerve Limited (ASX, **"ReNerve"** or "the **Company**"), a leading Australian medical device innovator focused on solutions for peripheral nerve injury (PNI), is pleased to announce the expansion of the ongoing clinical study evaluating the NervAlign® Nerve Cuff. The study, which will investigate the Nerve Cuff's role in protecting nerves following neurolysis (nerve repair), will now expand the cohort into a definitive trial phase.

"This will be an important study for ReNerve as it extends the study cohort from the trial data presented by Dr Adams at the American College of Foot and Ankle Surgeons Annual Conference in March 2025. The trial data presented there emphasised the benefit of using the nerve cuff to protect the nerve post-surgery, with a Visual Analogue Score (VAS) of 7.1 pre-surgery reducing to 0.4 post-surgery for patients using the NervAlign® Nerve Cuff, compared to a 3.3 post-surgery VAS for patients not treated with the NervAlign® Nerve Cuff. The data showed clear patient benefit. However, bringing a much larger number of patients into this study will provide clinical evidence that demonstrates the efficacy of the NervAlign® Nerve Cuff across the wider range of commonly injured nerves," **said ReNerve CEO Dr Julian Chick**.

The NervAlign® Nerve Cuff is designed to provide a protective, biocompatible barrier around repaired nerves, potentially improving surgical outcomes and patient recovery. This study will be a definitive study exploring the overall benefit of using the Nerve Cuff to protect nerves.

The trial features two randomised parallel cohorts:

- **Control Group**: Patients receiving the current standard of care for nerve repair.
- **Intervention Group**: Patients receiving the standard of care with the addition of the NervAlign® Nerve Cuff applied to the repaired nerve.

Each cohort will enrol approximately 120 patients, with the primary endpoints focused on changes in pre and post-operative pain scores and functional recovery metrics. Secondary endpoints include assessments of patient quality of life and surgical site outcomes.

The study is currently being conducted across three centres in the United States, with ReNerve actively exploring the inclusion of additional sites to accelerate patient recruitment and broaden the geographic diversity of the study population. To date, approximately one-third of the total target enrolment has been achieved and ReNerve

anticipates completion of recruitment around midyear 2026. The study will also be used to support a European market approval filing for the NervAlign® Nerve Cuff. The ReNerve Nerve Cuff is the first of a portfolio of products ReNerve is developing for the repair and replacement of injured peripheral nerves. The company continues to progress its nerve conduit remains and nerve guide matrix to commercial validation manufacturing ahead of market entry.

Dr David Rhodes, Chief Scientific Officer at ReNerve, commented: *"We are eager to advance this important clinical program and further validate the potential of the NervAlign® Nerve Cuff to improve outcomes for patients undergoing nerve repair procedures. The expansion of this study reflects both the strength of our preliminary data and the growing interest from the surgical community in innovative solutions for peripheral nerve protection."*

ReNerve is committed to delivering transformative technologies that address unmet needs in nerve repair and regeneration. The results of this study will inform future regulatory and commercial strategies for the NervAlign Nerve Cuff in key global markets. The global market for peripheral nerve repair is estimated to be around USD$1.6 billion and growing at 17+%. The global dermal and amniotic tissue market is estimated to be worth around USD$2.7 billion in 2024 and growing at around 12% CAGR[1], with these products used in a range of applications.

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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.

[1] MarketWide Research – Dermal and Amniotic tissue market report 2025-2032, Published 2025

Comprehensive Product Portfolio

ReNerve is advancing a complete suite of nerve repair solutions:

- **NervAlign® Nerve Cuff** – Our bioabsorbable protective wrap, naturally absorbed within six months of surgery.
- **Deep Dermal tissue product** -- A unique deep dermal product used in the repair of reconstructive and cosmetic surgical cases.
- **Amniotic tissue product ranges --** Three amniotic tissue product ranges used to aid the healing of wounds.
- **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.[2]

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.

[2] Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)