

ASX Announcement

10 August 2026

ReNerve Secures Marketing Approval for NervAlign® Nerve Cuff in India

Key Highlights

- NervAlign® Nerve Cuff receives registration **approval from India's Central Drugs Standard Control Organization (CDSCO)**.
- ReNerve's first product approval in the significant and growing Indian market – **a major milestone**.
- **Clears the way for** ReNerve and its Indian commercialisation partner, NetCentrix Ventures, to progress **the commercial rollout of the NervAlign® Nerve Cuff across India**.
- As the world's most populous nation — with over 1.45 billion people — India represents one of the largest market opportunities in ReNerve's global commercialisation strategy.
- The Indian nerve repair and regeneration **market is valued at approximately USD \$700 million in 2025¹**, underpinned by its population and having one of the world's highest burdens of road-trauma².

ReNerve Limited (ASX:RNV, "ReNerve" or "the Company"), an Australian biotechnology company developing innovative products for peripheral nerve injury ("PNI") repair, is pleased to announce that it has received marketing approval for its NervAlign® Nerve Cuff in the major market of India.

This approval, granted by India's Central Drugs Standard Control Organisation (CDSCO), clears the way for commercial supply of the NervAlign® Nerve Cuff in India and delivers the first key objective of ReNerve's partnership with its Indian commercialisation partner, NetCentrix Ventures. To date ReNerve and Netcentrix have been working within India to identify customers as the hospital approval processes.

"Securing marketing approval in India is a landmark milestone for ReNerve. India is the world's most populous country and one of the largest and fastest-growing healthcare markets globally, and the clinical need for effective peripheral nerve repair, driven by significant number of trauma cases, is enormous," said Dr Julian Chick, CEO of ReNerve.

"Together with our partner NetCentrix Ventures, we can now work to make the NervAlign® Nerve Cuff available to Indian surgeons and their patients. This approval is further validation of the strength of our clinical data and the clear benefit the product delivers."

ReNerve entered its agreement with NetCentrix Ventures — a commercialisation specialist in the Indian healthcare market — in April 2025 to pursue regulatory approval and commercialisation of the NervAlign® Nerve Cuff in India. NetCentrix provides ReNerve with local regulatory expertise and established distribution

¹ Grand View Research report 2026 -2030

² Indian nerve repair market size based on third-party market research; see ReNerve Limited, ASX announcement 'ReNerve Expands Global Footprint with Strategic Partnership in India', 10 April 2025 and the Market to Market 2025 nerve repair and regeneration report.



networks, and holds a Memorandum of Understanding with BRIC-RGCB, an institution of the Biotechnology Research and Innovation Council under the Government of India's Department of Biotechnology. With approval now secured, the two companies will progress a coordinated commercialisation strategy tailored to the Indian healthcare ecosystem².

India's demographic and clinical profile points to substantial and growing demand for peripheral nerve repair solutions:

- **Population scale** – India is the world's most populous country, home to over 1.45 billion people — a very large and rapidly expanding addressable patient population³.
- **Trauma burden** – Road trauma is a leading source of peripheral nerve injury. India records the highest number of road-traffic deaths of any country in the world — more than 150,000 fatalities each year — with far larger numbers of serious injuries. Two-wheelers account for a substantial share of casualties, making road trauma a major cause of traumatic peripheral nerve damage and severe limb injury⁴.

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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.

² ReNerve Limited, ASX announcement 'ReNerve Expands Global Footprint with Strategic Partnership in India', 10 April 2025.

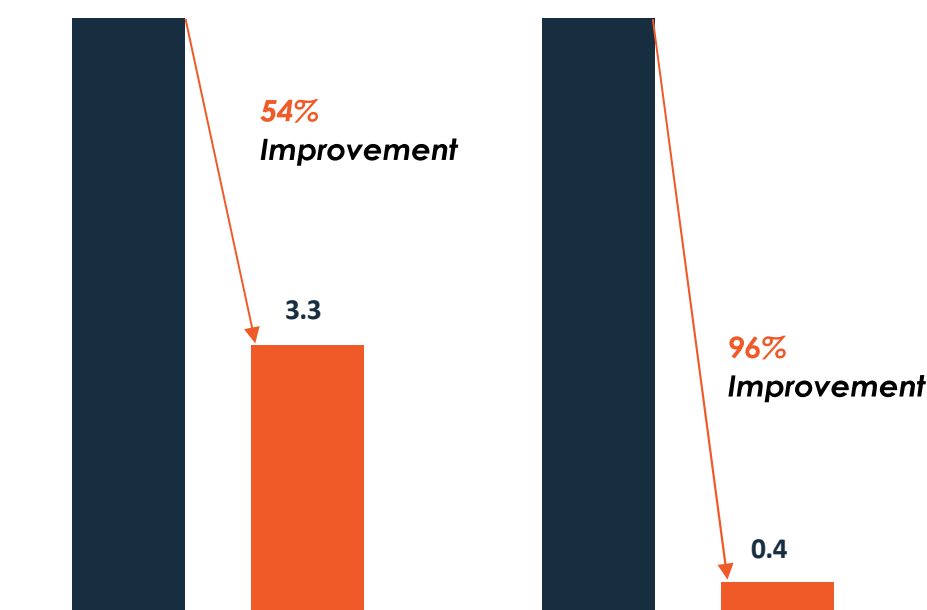
³ World Bank, World Development Indicators, 2024 (India population approximately 1.45 billion).

⁴ Government of India, National Crime Records Bureau and Ministry of Road Transport & Highways, road accident statistics.

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 2031⁶.

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.

⁶ Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)