ReNerve

ASX Announcement

21 September 2026

ReNerve completes first surgical cases in Hong Kong and Malaysia as Asia-Pacific commercialisation accelerates

Key Highlights

- **First NervAlign® Nerve Cuff cases completed in Hong Kong** following the Company's expanded regulatory approval in the region and the appointment of its exclusive distributor
- **First surgical case completed in Malaysia**, converting the Company's January 2026 market registration into commercial use in a market of 35 million people
- Milestones follow ReNerve's **record FY26 sales of $510,357, up 88% on the prior year**, and its strongest-ever quarter of $211,000 in the June 2026 quarter
- **US momentum continues** – Distribution network now at 25 partners, purchasing approvals secured across US Department of Defense and Veterans Affairs healthcare systems, and growing uptake of the Empliq® human tissue range alongside NervAlign®
- ReNerve now has commercial activity across seven jurisdictions – USA, NZ, Hong Kong, Thailand, Malaysia, Indonesia and the Philippines

ReNerve Limited (ASX: RNV, "ReNerve" or "the Company"), an Australian medical device company developing innovative products for peripheral nerve injury (PNI) repair, is pleased to announce the completion of the first surgical cases using its NervAlign® Nerve Cuff in both Hong Kong and Malaysia, marking the transition from regulatory approval to commercial use in two of the Company's key Asia-Pacific growth markets.

First cases in Hong Kong

The cases represent the first commercial use of NervAlign® in the territory and follow key commercial and regulatory milestones announced earlier this year:

- **Expanded product approval** across Hong Kong, Macau and the Greater Bay Area, broadening the range of ReNerve products cleared for use in the region[1]; and
- The **appointment of STC as exclusive distributor** under a three-year agreement covering a combined addressable population of approximately 88 million people, with initial stocking orders shipped in June 2026[1].

STC, a leading Hong Kong-headquartered medical device distributor with established hospital and surgeon relationships across the region, has commenced surgeon education and product in-servicing at major hospitals, with further cases scheduled over the rest of the year. ReNerve is providing clinical and technical

[1] https://www.bayarea.gov.hk/en/about/overview.html

support, training and regulatory liaison under the agreement. STC and ReNerve has also had a strong presence at a number of local industry events and conferences.

First case in Malaysia

The Company's first Malaysian case was performed at Thomson Hospital in Kuala Lumpur. ReNerve received market registration in Malaysia for the NervAlign® Nerve Cuff in January 2026, an important market within ReNerve's regional strategy, having several hospital groups operating across multiple South-East Asian countries and using hospitals in Malaysia to provide services to patients in the region.

"Completing our first cases in Hong Kong and Malaysia within months of securing approval and appointing distributors is exactly the kind of execution we set out to deliver. Regulatory approval is only the starting line – what matters is surgeons choosing to use NervAlign® in the operating theatre, and that is now happening in both markets.

"The Greater Bay Area alone represents an addressable population of approximately 88 million people, and STC has moved quickly to get product into hospitals and onto surgeons' preference lists. In Malaysia, our team has hit the ground running and the pipeline of scheduled cases gives us real confidence about the coming quarters.

"Importantly, this regional expansion is being built on top of a US business that is growing strongly. With 25 distribution partners, access to the DoD and VA systems, and Empliq® now contributing alongside NervAlign®, we have multiple channels supporting our growth. FY26 was our strongest year yet and remain focused on executing our commercial strategy in FY27." **Said CEO Dr Julian Chick.**

Continued growth in the United States

The Asia-Pacific milestones come as ReNerve's core US business continues to expand. During FY26 the Company:

- Grew its US distribution network to **25 partners**;
- Secured purchasing approvals across the **US Department of Defense and Veterans Affairs** healthcare systems[5];
- Launched the **Empliq® human tissue product range**, which is now making a meaningful contribution to revenue and leveraging the Company's existing NervAlign® distribution relationships[6]; and
- Appointed **J4 Biologics as a second manufacturing partner** for Empliq® to support scalability and supply-chain resilience[4].

These initiatives supported FY26 sales revenue of $510,357, up 88% on FY25 ($272,000), including a record June 2026 quarter of $211,000, representing 50% growth on the March 2026 quarter[4,5]. Sales momentum has continued into FY27, with the Company recording even stronger sales in the current quarter. ReNerve will report on this in more detail in the next Appendix 4C quarterly report.

Next steps

ReNerve intends to provide further updates when cases and sales volumes become material and as the Company advances commercial entry into Indonesia, the Philippines and India, where the NervAlign® Nerve Cuff has also received marketing approval.

In parallel, the Company continues to advance the NervAlign® Nerve Guide Matrix through Stage 3 of its four-stage development program, with completion currently targeted by the end of calendar 2026, and the NervAlign® Nerve Conduit through commercial scale-up ahead of market launch. In addition 12 month preclinical study data will be released in the coming weeks as the company continues to investigate the benefits of the NervAlign® Nerve Guide Matrix in nerve repair and replacement.

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

For further information and enquiries, please contact:

Dr Julian Chick
CEO & Managing Director
ReNerve Ltd
+61 (03) 9482 3940
info@renerve.com.au

Matthew Wright
Investor & Media Relations
NWR Communications
+61 (0) 451 896 420
matt@nwrcommunications.com.au

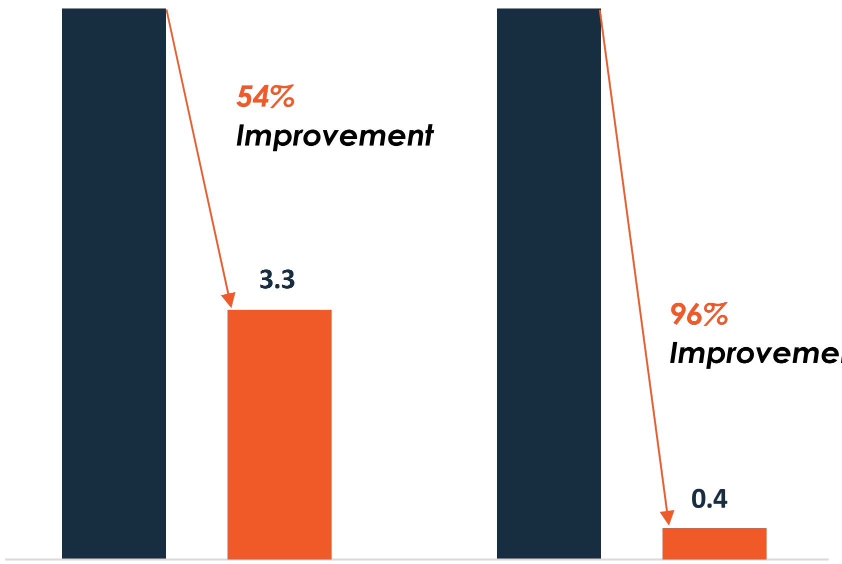
About ReNerve Limited (ASX:RNV)

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.[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)