ReNerve

ASX Announcement
26 February 2026

ReNerve releases 31 December 2025 Half Year Results

Highlights:

- **Accelerating Sales Growth:** In the half-year, sales increased by 60.2% in H1 FY26 compared to the corresponding period in FY25, reflecting growing adoption of the NervAlign® Nerve Cuff in the United States and increasing surgeon utilisation.
- **Portfolio Expansion:** Successfully launched the Empliq™ human tissue product range, achieving first sales of the Empliq™ dermal and amniotic tissue products, broadening ReNerve's commercial offering and strengthening use of its distribution channels.
- **Expanded Hospital Network Access:** NervAlign® Nerve Cuff secured purchasing approvals across the US Department of Defence (DoD) and Veterans Affairs (VA) healthcare systems, providing access to more than ~1,800 military hospitals, clinics, medical centres and outpatient facilities.
- **International Regulatory Expansion:** Secured regulatory approvals for the NervAlign® Nerve Cuff in Malaysia and Hong Kong post-period and progressed regulatory and market entry planning across additional Asia-Pacific and European jurisdictions.
- **Clinical Study Progress:** Continued recruitment in the NervAlign® Nerve Cuff clinical study following statistically significant interim results, with completion of recruitment expected around mid CY2026.
- **Product Pipeline Advancement:** Achieved key development milestones for the NervAlign® Nerve Conduit, with production hardware and manufacturing processes finalised and first production batches expected in 1H CY2026. Volume prototype production of the NervAlign® Nerve Guide Matrix was also completed, supporting planned clinical trials in CY2027.
- **Closing cash of $4.18M,** excludes additional $0.6m from the capital raising completed in November 2025**.**

ReNerve Limited (ASX, "**ReNerve**" or "the **Company**), an Australian biotechnology company developing innovative products for peripheral nerve injury ("PNI") repair, today announced its half-year financial results for the six months ended 31 December 2025 (1HFY26). The Company has continued to broaden its geographic reach and distribution capability, further expand its product portfolio and build on its sales momentum throughout the period.

Financial Performance

ReNerve delivered strong revenue growth in the half-year, with sales increasing 60.2% compared to the prior corresponding period to $163,719, reflecting continued commercial momentum. The loss widened to $2.7m (H1 FY25: $1.8m) driven by higher employment and commercialisation costs and increased R&D activity to support the expanding product portfolio. The Company also strengthened its balance sheet through a $3.2m capital raise, supporting broader commercial growth initiatives.

Operational Review

ReNerve achieves first sales of amniotic tissue range

ReNerve achieved its first commercial sale of its Empliq™ amniotic tissue products, marking another step in the Company's transition from a pure R&D business into commercial activities.

The Empliq™ range, which includes three minimally processed amniotic tissue products, was recently showcased at the American Society for Surgery of the Hand (ASSH) annual meeting in Vancouver. The products are designed to support faster post-surgical recovery by using endogenous growth factors and cytokines to aid wound healing.

The Empliq™ products are complementary to ReNerve's NervAlign® range and can be used in wound management associated with peripheral nerve repair, as well as in broader applications including diabetic ulcers. With regulatory clearance in the major US market and alignment with ReNerve's existing sales and distribution channels, the Empliq™ range is positioned to support ongoing revenue growth.

The Empliq™ launch follows ReNerve's strategic partnership with Berkeley Biologics LLC, announced in June 2025, which supports the Company's expansion into deep dermal and amniotic tissue-based products. ReNerve is also progressing its eCOO-based nerve conduit products and proprietary nerve guide matrix for the treatment of more severe nerve injuries, targeting large and growing global markets in peripheral nerve repair and dermal and amniotic tissue products.

NervAlign® approved for use in US Department of Defense (DoD) & Veterans Affairs (VA) healthcare systems

In November, NervAlign® Nerve Cuff was approved for use across the US Department of Defense (DoD) and Veterans Affairs (VA) healthcare systems following a successful federal tender process, establishing an ongoing product supply agreement and granting ReNerve preferred supplier status across both networks.

This approval allows the NervAlign® Nerve Cuff to be purchased and stocked across DoD hospitals worldwide and VA hospitals throughout the United States, creating a long-term pathway for consistent product adoption and expanded clinical reach.

The approval provides access to the DoD's 51 military hospitals and 424 clinics, as well as the VA's 170 medical centres and more than 1,193 outpatient facilities, providing ready access to the technology for the approximately 9.5 million patients across both healthcare systems who may benefit from its use.

Under this agreement, ReNerve will supply the NervAlign® Nerve Cuff on an ongoing basis, positioning the Company to pursue sustained use and stocking opportunities across both systems.

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

ReNerve has already received an initial purchase order and a subsequent repeat order from federal medical facilities, enabling immediate deployment of the NervAlign® system into select DoD and VA facilities, with a broader rollout planned for 2026, supported by the ongoing federal supply agreement.

New international regulatory approvals

Following the end of the half, ReNerve announced regulatory approvals in each of Malaysia and Hong Kong for the NervAlign® Nerve Cuff.

The nerve repair market across Asia-Pacific is estimated to be worth around USD$100 million in 2026[1].

These new approvals are in addition to ReNerve's marketing of NervAlign® Nerve Cuff in the US, Bahrain, New Zealand and Thailand, whilst pursuing approvals in more than 10 further countries.

These new approvals also provide ReNerve with further validation of the effectiveness of Nerve Cuff to support initiating the approval processes in additional geographies including Europe.

Clinical study evaluating NervAlign® Nerve Cuff expanded

During the half, ReNerve announced 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), expanded the cohort into a definitive trial phase.

This study is 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 postoperative 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.

Corporate Updates

Appointment of Non-Executive Chair as part of Board Renewal process

In December, the Company appointed Maja McGuire and Dr Paul Savage as Non-Executive Directors, with Ms McGuire also appointed Chair, strengthening the Board as the Company continues to expand its commercial and development activities.

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

Mrs McGuire is an experienced corporate executive and company director, having worked with ASX public listed companies as a non-executive chair/director, general counsel and in top tier legal private practice. Mrs McGuire has led strategy and corporate development across both small and large cap organisations, focused on growing and delivering shareholder value, with a background spanning the medical device, life sciences and resources sectors. Mrs McGuire holds law and business qualifications from The University of Western Australia and has lived and worked in both Australia and North America. In addition to ReNerve, she currently serves on the boards of LTR Pharma Ltd (ASX:LTP), TechGen Metals Ltd (ASX:TG1), Indiana Resources Ltd (ASX:IDA) and Kuniko Ltd (ASX:KNI).

Dr Savage brings 35 years of experience with CSIRO, including senior leadership roles in science, manufacturing and technology commercialisation, with a background in biomedical science, medicinal chemistry, drug discovery, biotherapeutics and medical devices. His experience includes building research capability, managing R&D risk and leading innovation initiatives across the life sciences and advanced manufacturing sectors.

The appointments form part of ReNerve's Board renewal process announced at the Annual General Meeting (AGM) in November, which is aligned with the Company's transition from an early-stage research business to a commercial medical device company. As part of this process, Stephen Cooper and Dr Michael Panaccio resigned as Directors.

Fundraising Activities

$3.2 million capital raising

During the period, ReNerve completed a $3.2 million capital raising through a two-tranche placement of 26,666,667 new shares at $0.12 per share, providing funding to accelerate sales, marketing and product expansion. The offer price represented a 22.6% discount to the last closing price and a 28.2% discount to the 15-day VWAP.

The placement comprised a $2.6 million unconditional tranche issued under existing placement capacity and a $0.6 million conditional tranche approved at an Extraordinary General Meeting (EGM) held on 5 January 2026. The placement was supported by new and existing institutional and sophisticated investors.

Each new share was issued with a one-for-one free attaching option with an exercise price of $0.18 and a two-year maturity, also approved at the EGM.

Funds raised will be used to accelerate sales and marketing of the NervAlign® Nerve Cuff and Empliq™ ranges, support the development and launch of new products including the nerve conduit and nerve guide matrix, strengthen the sales team, and provide working capital.

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

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

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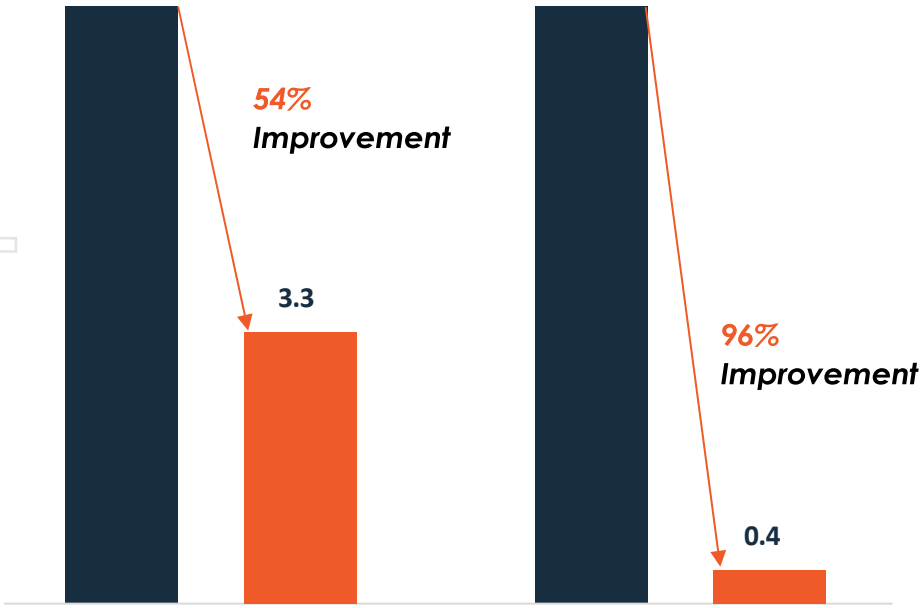
About ReNerve Limited (ASX:RNV)

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

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

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.[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)

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