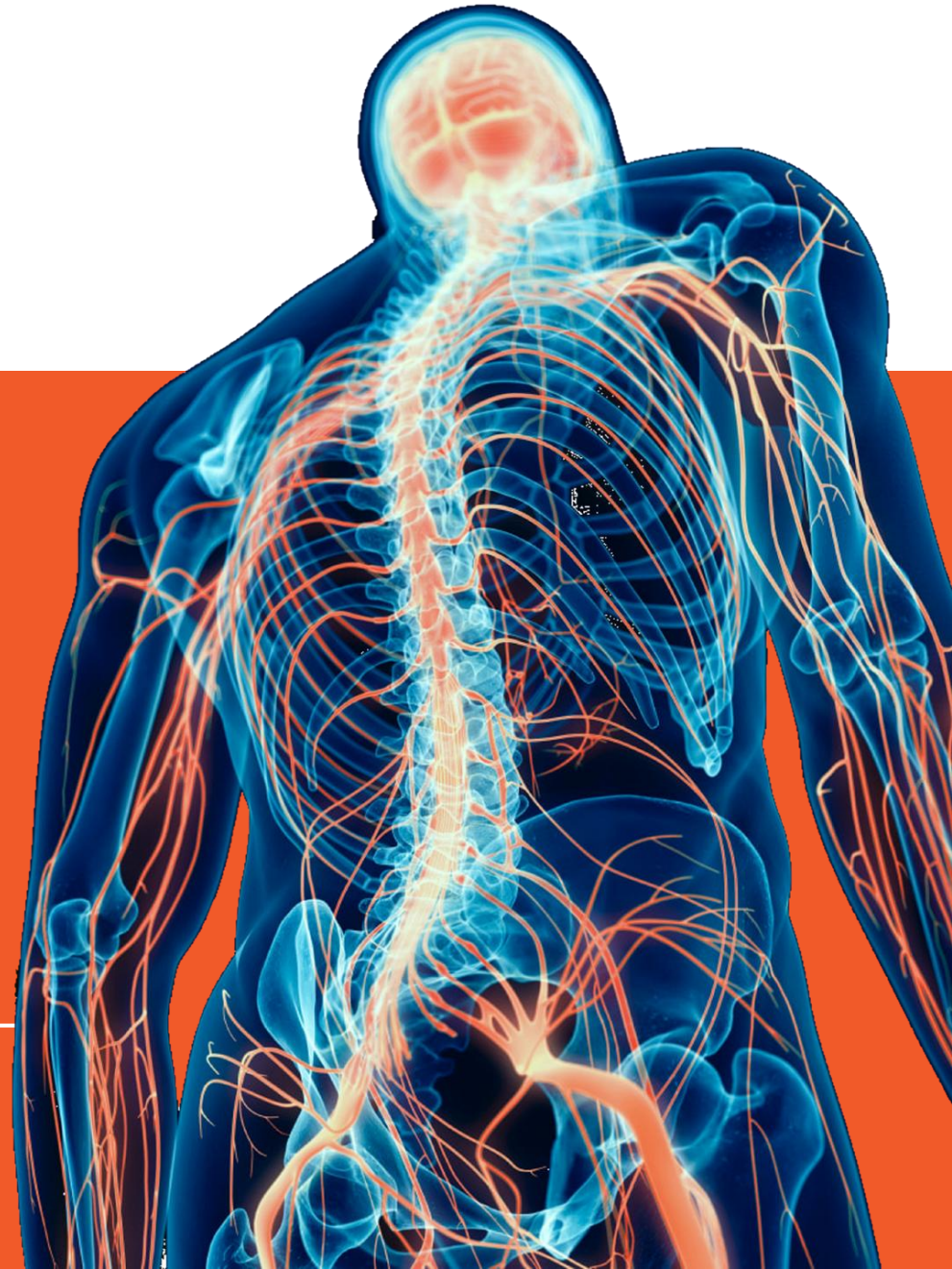
ReNerve

ASX:RNV

Transforming Nerve Repair Through Science



Quarterly investor update | May 2025

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ReNerve Ltd ABN 23 614 848 216

Executive Summary

Development of Novel Nerve Repair & Regeneration Products

ReNerve is focused on developing a portfolio of products for the nerve repair and regeneration markets, with clearly defined commercial demand.

Significant Product Portfolio

ReNerve currently has one product in market with a clear commercial pathway for FDA approval of 3+ products over the next 4 years.

Strong Sales & Distribution Presence

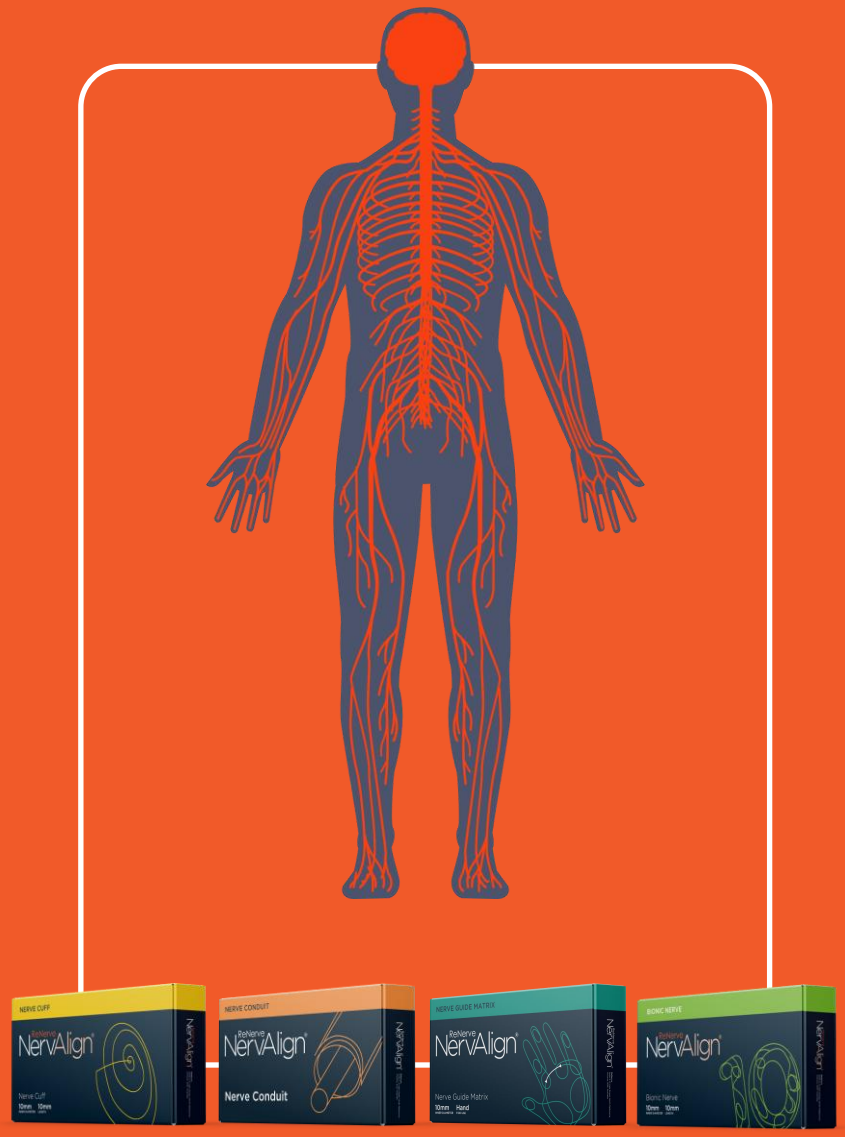
ReNerve have established logistics, warehouse and invoicing infrastructure with a strong focus on building a sales distribution network for all products.

Global Expansion & Commercialisation

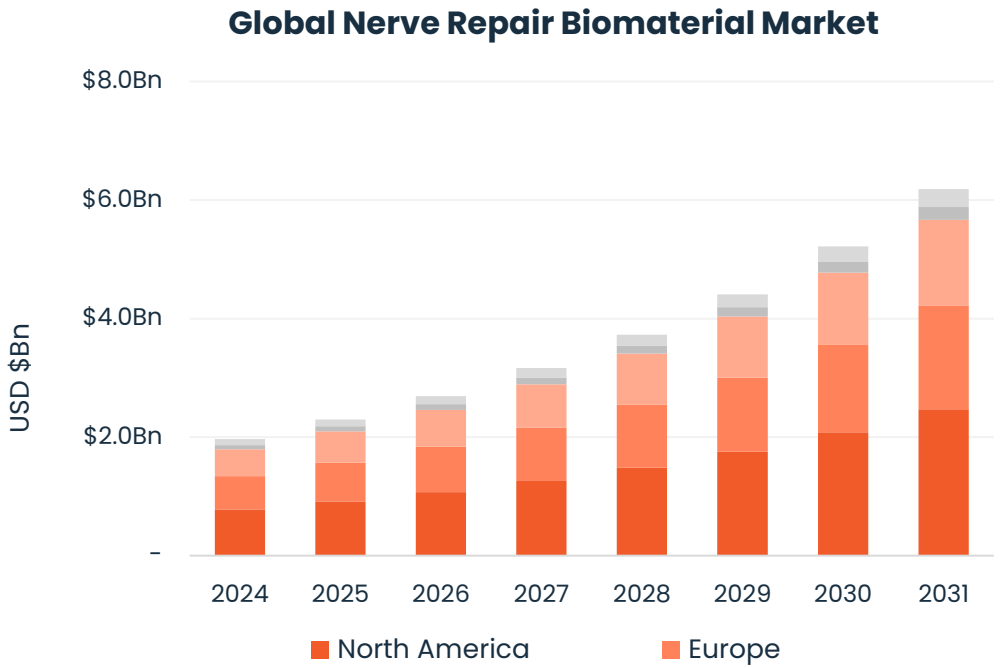
Successful ongoing expansion within the first year of listing into major surgical markets throughout Asia, The Middle East, and The Americas.

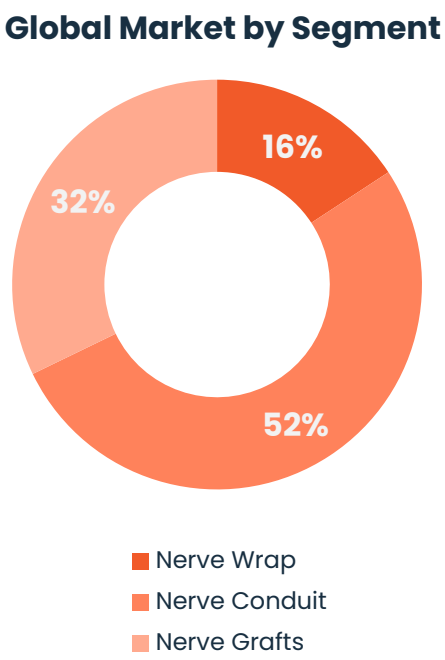
Clinical & Professional Validation

Improved patient outcomes for post-surgical measures of pain and surgery satisfaction, as well as proven ease of use for surgeons.



Global Nerve Repair Biomaterial Market





USD$1.69Bn

Three products already developed with an additional two currently under development.

~900k

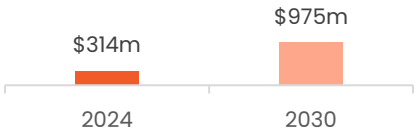
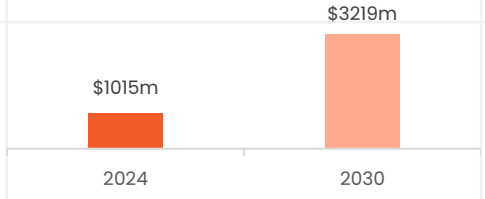
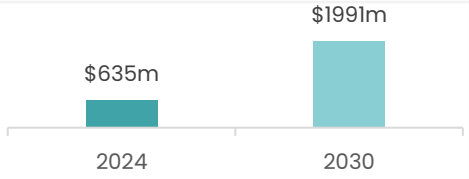
Three products already developed with an additional two currently under development.

Nerve Compression

Three products already developed with an additional two currently under development.

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

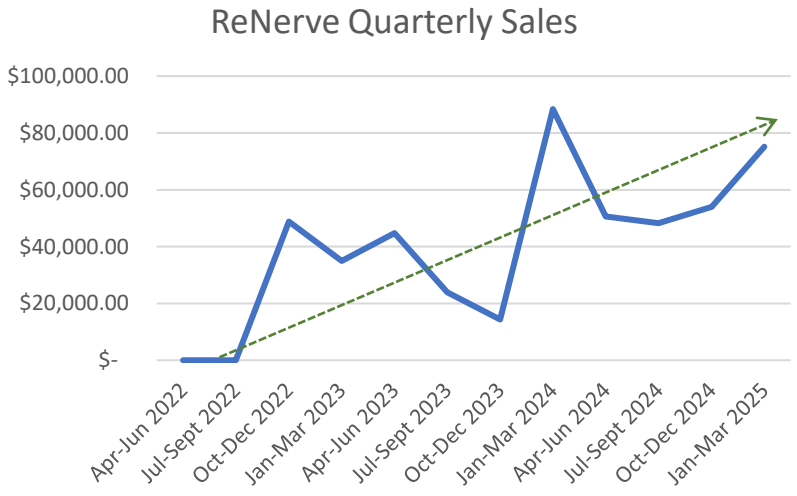
ReNerve's Opportunity

	ReNerve Nerve Cuff	ReNerve Nerve Conduit	ReNerve Nerve Guide Matrix	ReNerve Bionic Nerve
				
Product	• Used on damaged or transected nerves with no gaps or gap closure	• Improved Nerve Cuff developed from scCO2 tissue, offering better product profile	• An 'off-the-shelf', ready to use nerve graft replacement with internal guidance infrastructure	• An 'off-the-shelf', continuous nerve replacement, in a ready to use nerve structure
Procedure Use	• End to end suturing covered with a wrap/cuff • Protective cuff for grafts	• Protecting injured nerve repairs	• Replaces damaged nerve section instead of using donor or harvested tissue	• The Bionic Nerve is a nerve guide matrix with ionic polymers designed to replace injured and damaged nerves for lengths from 1cm to 20cm
Application	• Trauma • Breast reconstruction • Orthopaedics • Oral & maxillofacial surgery	• Trauma • Breast reconstruction • Orthopaedics • Foot and ankle	• Trauma • Breast reconstruction • Orthopaedics • Hand & wrist	• Trauma • Craniotomy • Spinal cord injury • Spinal cord surgery
Benefit	• Bio-absorbed removing need for additional surgery • Pliable and conforms	• Improved product profile to Nerve Cuff • Stronger patient reimbursement	• Can be cut to ideal length • Off-the-shelf, reducing logistics issues • Simple to use and cost effective	• Enable production of nerves of bespoke dimension
FDA Status	**Approved**	**Targeting Q4 CY25 filing**	**Targeting Q2 CY27 filing**	**Targeting Q3 CY28 filing**
TAM (USD)				

Company quarterly highlights

Sales Highlights

Sales for Q3 FY25 of A$75K represented a ~40% increase from the previous quarter.



ReNerve Global Expansion & Distribution

United States

Established sales presence in target states with a focus on key hospital systems in each region.

Hong Kong

Entered into partnership with Accession Medical Supplies Co in Hong Kong and **achieved first sale**

Latin America

Executed exclusive distribution agreement with Imbiomex in Mexico, targeting a USD$74 million nerve repair biomaterials market growing at 17% annually.

Southeast Asia

Secured commercial marketing approval in Thailand, enabling access to a population of 70+ million and the region's medical tourism market.

Middle East

Entered into exclusive partnership with Union Mediscience B.S.C in the Middle East.

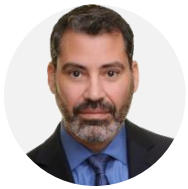
East Asia

Confirmed first hospital sales in Hong Kong, establishing clinical presence in a key Asian market.

Indian Subcontinent

Formed strategic partnership with NetCentrix Ventures to pursue regulatory approval in India's rapidly expanding nerve repair market (USD$115 million per annum, projected to reach USD$270+ million by 2030 at 18.5% CAGR).

Key Hire



ReNerve has appointed **Mr Eric Feliciano** as its VP of Sales & Marketing

Eric Feliciano, a seasoned medical technology sales expert, has worked with Skeletal Dynamics, Medartis, and Smith & Nephew. Based in the Midwest U.S., he enhances ReNerve's distribution and sales reach.

skeletal dynamics® medartis® smith&nephew

ReNerve

NervAlign®
Nerve Cuff

01

Key Features

Product

- The NervAlign® Nerve Cuff is an FDA cleared product used on damaged or transected nerves with no gaps or gap closure achieved by flexion.
- The product is used as a barrier between the repaired nerve and surrounding tissue.

Patient Benefit

- Bio-absorbed within 6-months.
- Produced using a non-toxic method.
- Terminally sterilised with no residual chemicals.
- Covered under procedural reimbursement rather than individual product reimbursement.
- Promotes vascular tissue formation on surrounding fascia tissue post-implant.

Surgeon Benefit

- Requires no change to surgical technique or procedures.
- Available in various sizes and thickness with ability to be trimmed to required shape.
- Is pliable and conforms.

Clinical Use

Patient Results

- Majority of cases to date have been focused on hand and wrist.
- Clinical cases have:
  - All reported positive outcomes; and
  - Shown better than expected outcomes for patients

Clinical Use

- Received positive feedback from surgeons stating it handles well, is pliable and conforms and has resulted in strong patient outcomes.
- ReNerve has started to explore podiatry, breast and urology as areas beyond hand and wrist.
- Has been used with attachment methods including sutures, glue, micro clips and ‘nothing’.

Clinical Study

- ReNerve has completed an initial clinical study to explore the benefits of using the NervAlign® Nerve Cuff in the repair of injured nerves.

- The data will be presented late March at the American College of Foot and Ankle Surgeons conference in Phoenix.

Clinical Study Design

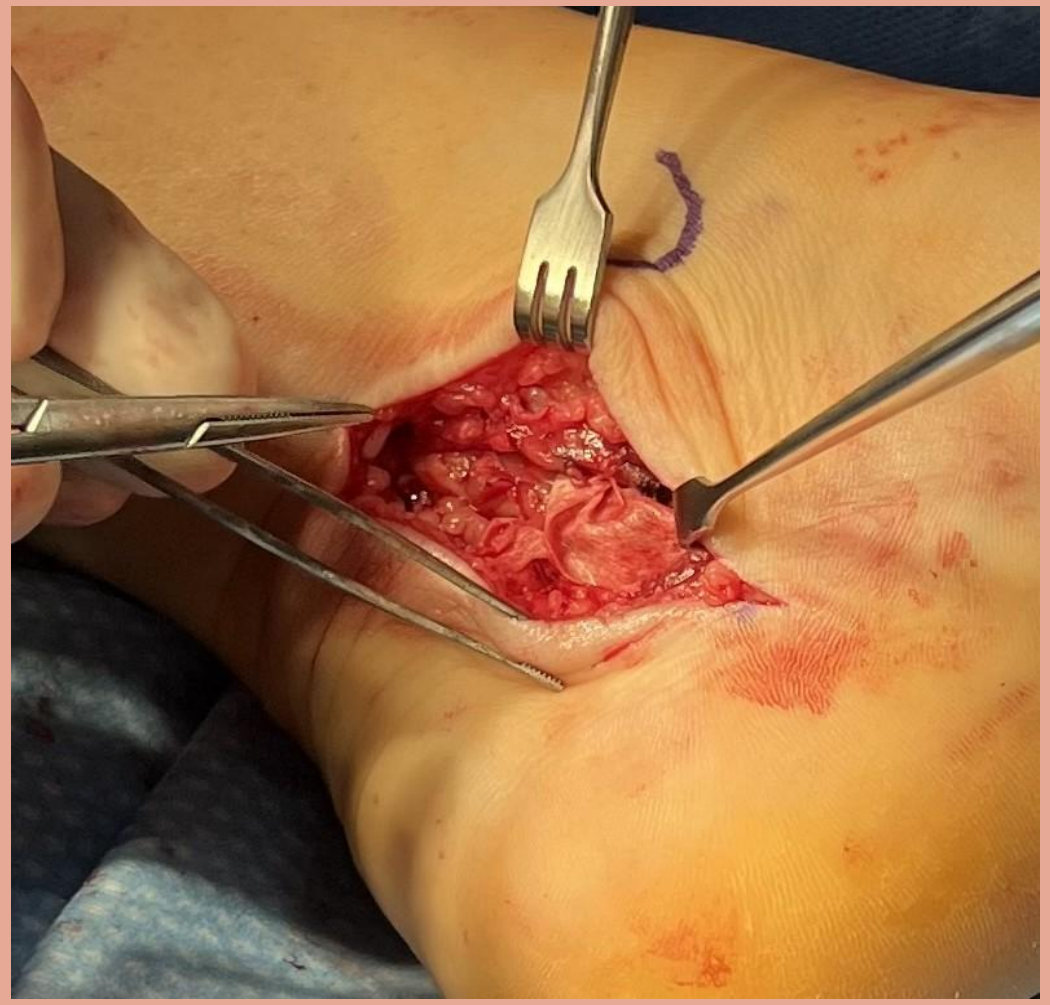
Two Cohorts

Two cohorts (blinded to ReNerve).

- One undergoing the 'standard of care' for neurectomies (nerve repairs).
- The second having the neurectomy repair wrapped with the NervAlign® Nerve Cuff.
- This includes repairs to both sensory and motor nerves.
- A range of nerve injuries included in the study.

Study Outcome to be Assessed

- Primarily looking at pain evaluations before and after surgery.
  - Pain is independently assessed.
- Statistical advantage of using the NervAlign® Nerve Cuff.



Clinical Validation

Clinical Study on the NervAlign® Nerve Cuff

At the American College of Foot and Ankle Surgeons Conference (27–30 March 2025), ReNerve presented a comparative clinical study showing statistically significant improvements in patient outcomes using the NervAlign® Nerve Cuff for peripheral nerve repair.

Study Design: Two patient cohorts

- Control Group: Standard neurectomy repair
- Test Group: Neurectomy repair with NervAlign® Nerve Cuff

Key Outcomes:

- Pain Reduction:
  - Control: 7.1 → 3.3
  - NervAlign™: 7.1 → 0.4
- Satisfaction & Recovery:
  - Higher satisfaction and improved recovery in the NervAlign™ group
  - Pain assessment conducted independently

NervAlign® Nerve Cuff significantly reduces post-operative pain and enhances patient satisfaction compared to standard surgical methods.

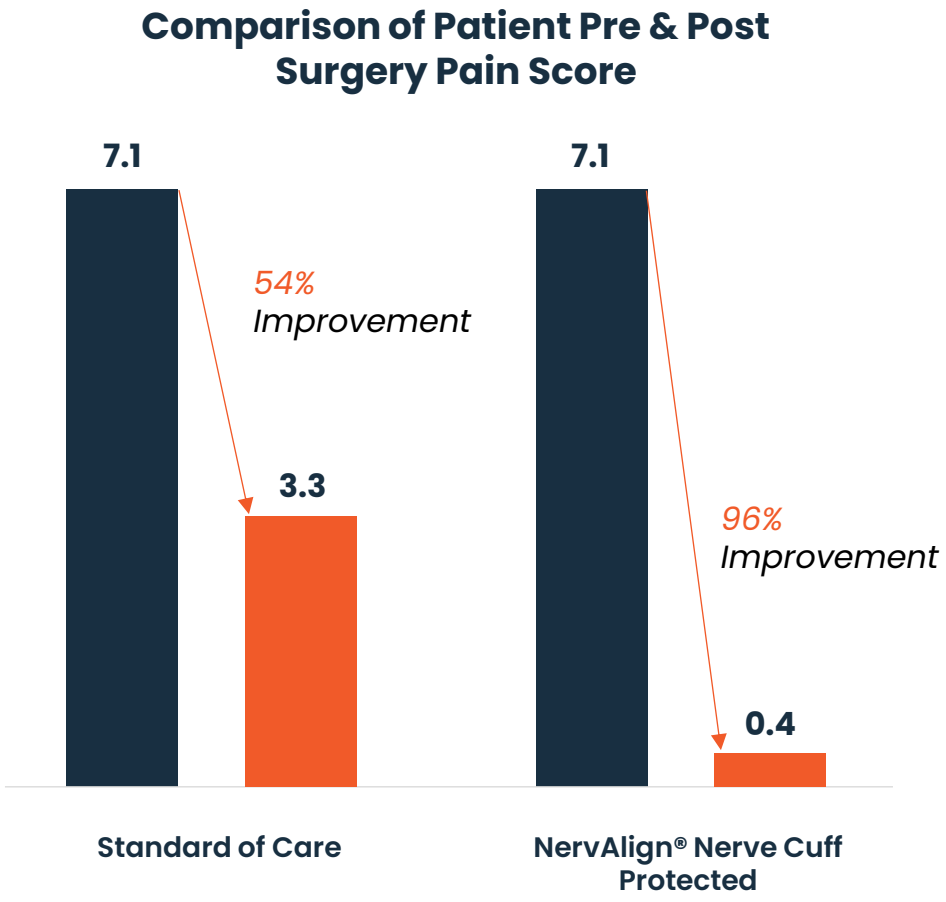
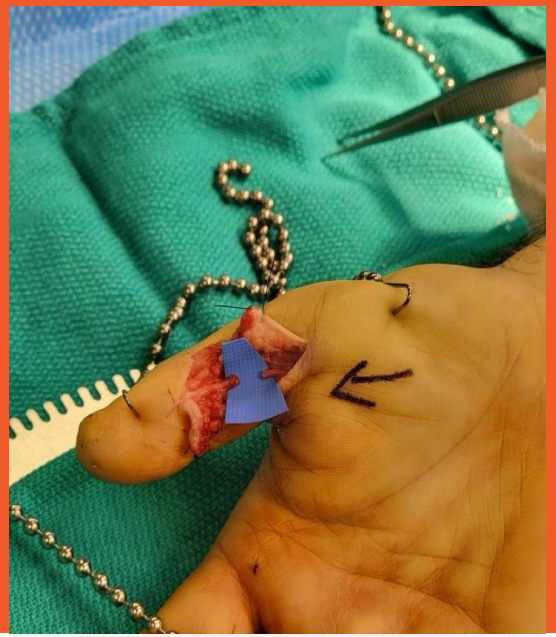


Figure 1. The comparison of pain scores between the two cohorts of patients

Efficacy of a Porcine Pericardium Nerve Wrap in Peripheral Nerve Surgery" March 2025 Namany et al. ACFAS 2025, (https://imis.acfas.org/ACFAS2025/ACFAS2025/Abstracts.aspx?hkey=5209f2e8-69fc-4935-8823-799c8f5c2922) Abstract Ref ID Sci-743

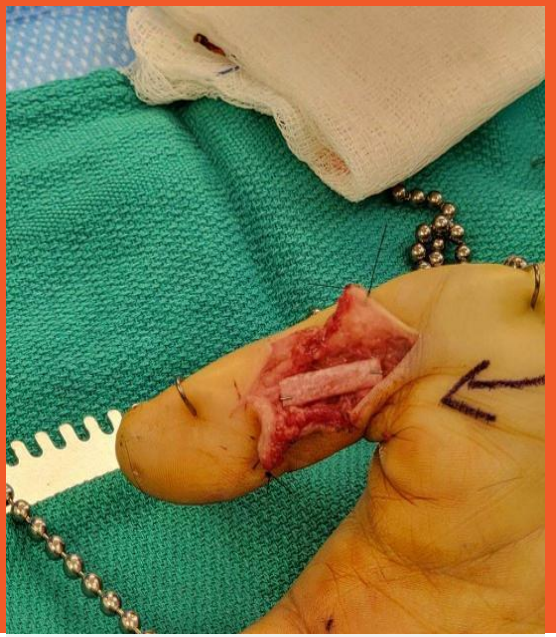
Clinical Use



Damaged nerve removed from the right thumb

Removed gap filled with a conduit

NervAlign®
Nerve Cuff used to protect the cuff conduit implant



Completed repair held in place with micro clips

ReNerve

NervAlign® Conduit

02

Key Features

- ReNerve is focused on developing a conduit from $scCO_2$ tissue from the Nerve Cuff.
- Project remains on track and working through commercial manufacturing
- ReNerve will be able to leverage existing data from the Nerve Cuff FDA application to accelerate FDA approval.
- Offers the followings benefits:
  - Expands the ReNerve product range and portfolio;
  - Better reimbursement for the conduit; and
  - Same outcome and better product profile as the Nerve Cuff.
- ReNerve are targeting a Q4 CY25 FDA filing.

ReNerve

NervAlign®
Nerve Guide Matrix (Graft)

03

Key Features & Guide Matrix

Product

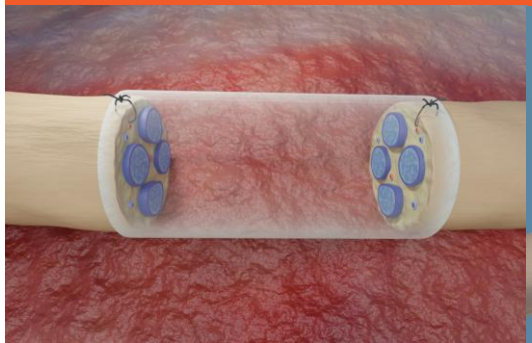
- The NervAlign® Neve Guide Matrix is an ‘off-the-shelf’, ready to use nerve graft replacement with internal guidance infrastructure.
- ReNerve is developing three product options:
  - Initial ‘wet’ prep nerve graft;
  - Dry version that's hydrated within 10 minutes; and
  - Longer lengths out to 7cms+.

Current Options

- Harvesting patients own nerves.
- Donor tissue graft.
- Conduits (for smaller repairs).

Benefit

- ReNerve Nerve Guide Matrix offers many benefits, including:
  - Doesn’t create secondary surgical site;
  - Stored at room temperature, removing storing issues;
  - Doesn’t go through Wallerian degradation;
  - Ease of use allows for immediate repairs;
  - Longer lengths enables surgical revisions;
  - More cost effective to existing options; and
  - Positive outcomes post-surgery.



Near Term Milestones – 2025

1H 2025

27 February 2025
Partnership Signed for Mexico Market

7 March 2025
R&D Tax Incentive Refund Received

11 March 2025
Thailand Approval & First Hong Kong Sale

28 March 2025
Clinical Study Results Presented

10 April 2025
Partnership for Indian Market Announced

29 April 2025
Q3 FY25 Results: Revenue Growth & Clinical Validation

2H 2025

NervAlign® Nerve Conduit into Market *(Q4 2025/Q1 2026)*

Initial Clinical Cases for the Nerve Conduit

Additional NervAlign® Nerve Cuff Clinical Data

Starting GMP manufacturing runs of the Nerve Guide Matrix

NervAlign® Nerve Cuff Approvals in New Countries & Territories

Near Term

Progression of the Nerve Guide Matrix to Stage 3 of Development

H2 2025 (Estimated) — India: Regulatory Approval Pathway Initiated

First clinical cases using the nerve guide matrix

NervAlign® Nerve Cuff filing for European approval

Investment Highlights

In Market Product

Nerve Cuff transitioned from R&D to commercial sales post FDA market clearance, achieving strong initial product margins.

Immediate Market Need

Product offering promotes nerve injury recovery and regrowth leading to faster patient recovery and better outcomes.

Growing Market

Nerve repair biomaterials market is forecasted to grow by >17% pa, estimated to be worth >**US$6.19Bn by 2031.**

Diverse Product Portfolio

Three products already developed with an additional two currently under development.

Growing Distribution

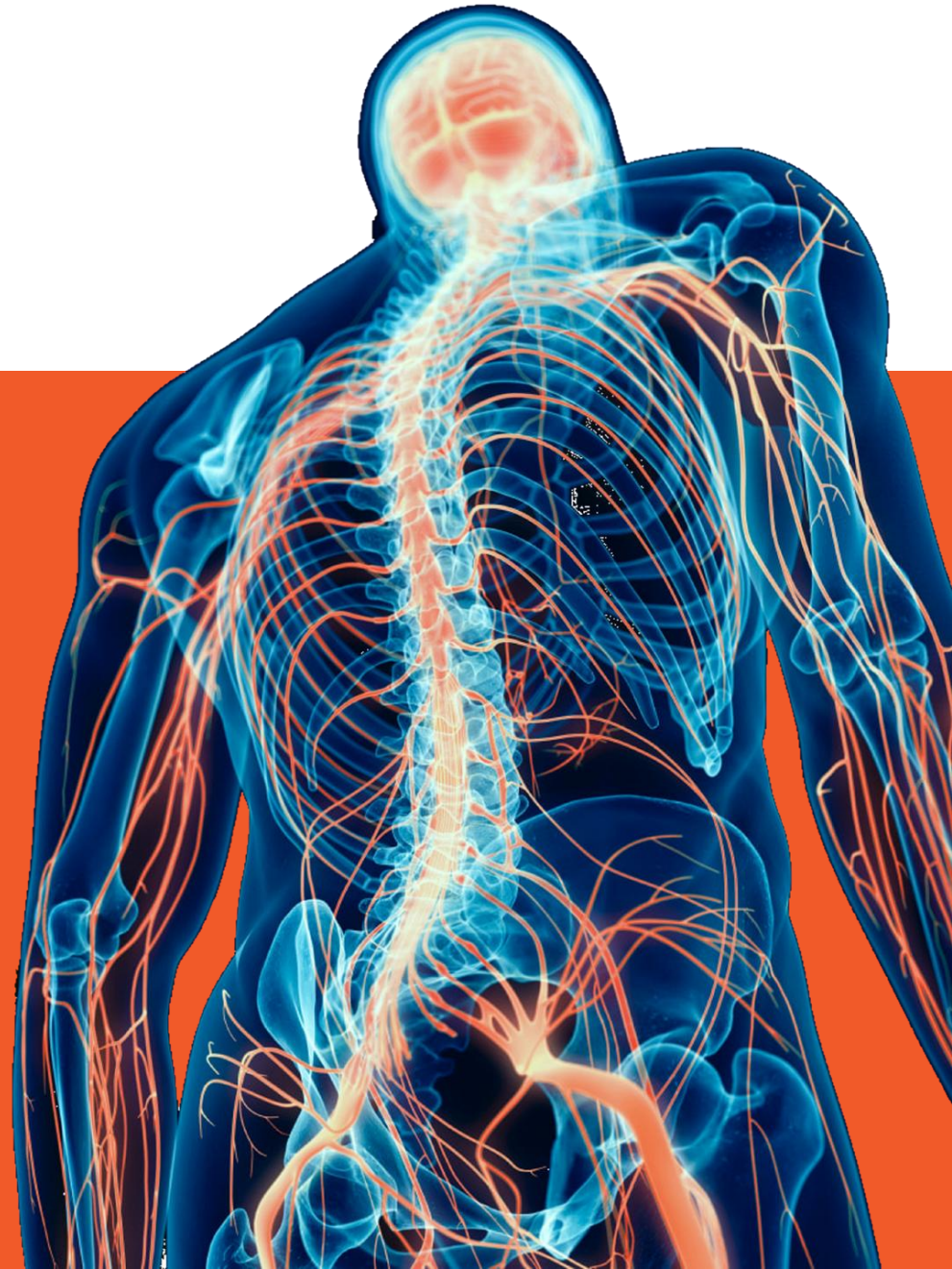
Continuing to build sales representation with a targeted-direct sales approach.

Board & Management

Highly accomplished executive team with a proven track record in the development & commercialisation of medical opportunities.

ReNerve

ASX:RNV



Contact

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Board & Management

STEPHEN COOPER
CHAIRMAN

Stephen was previously Managing Director at Grant Samuel, a leading Australian investment bank.

Stephen has over twenty-five years of experience in Investment Banking and has been responsible for numerous corporate advisory assignments including public company takeovers, mergers, business sales and acquisitions, schemes of arrangement, capital raisings and business valuations.

Stephen has previously served as Chairman of Avexa, an ASX-listed biotechnology company.

DR JULIAN CHICK
CEO & MANAGING DIRECTOR

Dr Julian Chick is an experienced healthcare executive with over 20 years' experience in senior management including in ASX listed companies Avexa and Admedus, and is currently Non-Executive Director at LTR Pharma (ASX:LTP).

Julian's previous roles include Chief Executive Officer, COO and Head of Business Development, as well as running early and late-stage R&D projects and launching medical devices into the global markets.

Julian has been involved in developing and obtaining FDA USA clearance for four tissue based medical devices. Julian, while COO at Admedus Ltd was involved in the R&D development, regulatory approval and launch of several tissue products in North America, Europe and Asia.

Julian has eight years' investment banker experience focused on healthcare and biotechnology. Julian has a PhD in Muscle Physiology.

DR MICHAEL PANACCIO
NON-EXECUTIVE DIRECTOR

Dr Michael Panaccio is one of the founders of Starfish Ventures, a venture capital firm that invests in early-stage technology companies and plays an active role in the management of its portfolio.

Michael has been a director of numerous technology businesses in Australia and the USA including SIRTeX Medical Ltd, Engana Pty Ltd (now part of Finisar Corporation), Energy Response (sold to EnerNoc Inc), ImpediMed Ltd, and Protagonist Therapeutics Inc.

Michael currently serves on the boards of Armaron Bio Ltd and Cylite Pty Ltd And ASX listed dorsaVi Ltd (ASX:DVL).

DR DAVID RHODES
EXECUTIVE DIRECTOR & CSO

Dr David Rhodes has more than 20 years' experience in healthcare and biotechnology industries, where he has held numerous senior management roles and developed technologies through to market approval.

David has been involved in obtaining several FDA USA and European marketing authorisation approvals for medical devices.

Previous roles include senior researcher at Amrad, Chief Scientific Officer of the medical devices company Admedus Ltd, COO of AdAlta Ltd and senior executive and Head of Drug Discovery and Senior Vice President Biology at Avexa Ltd.

David has successfully led multiple technology development programs attracting significant levels of funding from many State and Federal Government initiatives and research institute programs.

David has a PhD in Biochemistry.

DR ALEX ADAMIDES
CHIEF MEDICAL OFFICER

Dr Alex Adamides studied medicine at the University of Nottingham, UK, and completed his basic surgical training in Edinburgh before undertaking his neurosurgical training in Australia.

Dr Adamides became a fellow of the Royal Australasian College of Surgeons in 2012 and has since been a consultant neurosurgeon at the Royal Melbourne Hospital.

Dr Adamides is an honorary clinical senior lecturer at Melbourne University and a reviewer for the Journal of Clinical Neuroscience.

Working with ReNerve, Dr Adamides has developed pre-clinical models testing the safety and efficacy of surgical implants for the repair of peripheral nerves and dura.