ReNerve

TRANSFORMING NERVE REPAIR THROUGH SCIENCE

Quarterly Investor Update

February 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.







ReNerve's Opportunity



TAM* (USD)	\$314m 2024 2030	2024 2030	\$635m 2024 2030	> \$400m 2023
	\$975m	\$3219m \$1015m	\$1991m	
FDA Status	Approved	Targeting Q4 CY25 filing	Targeting Q2 CY27 filing	Targeting Q3 CY28 filing
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
Application	 Trauma Breast reconstruction Orthopedics Oral & maxillofacial surgery 	 Trauma Breast reconstruction Orthopedics Foot and ankle 	 Trauma Breast reconstruction Orthopedics Hand & wrist 	 Trauma Craniotomy Spinal cord injury Spinal cord surgery
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
Product	 Used on damaged or transected nerves with no gaps or gap closure 	 Developed using same technology (scCOO2) as the nerve cuff 	 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















Global Nerve Repair Biomaterial Market





The Global Nerve Repair Biomaterials Market was valued at USD\$1.69Bn in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 17.8% from 2024 to 2031 to USD\$6.19Bn.*

Nerve surgeries occur in the United States (US) per annum, with no more than 24% of nerve surgeries restoring to 'as good as it was.*







Nerve Compression

Approximately 1-in-4 nerve repair cases receive surgery repair, with 30% failure/revision rates.*







ReNerve

Nervaign® Nerve

Quarterly Sales update

NERVE CUFF









Scies & Marketing

Sales Highlights



Sales for Q2 FY25 of A\$54K represented a +200% increase on sales for the PCP.



Preliminary unaudited revenue for 1H FY25 increase 176% on the PCP.



The calendar year on year sales increased around 100%.

Closed the quarter with \$6.4m in cash.



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



ReNerve Distribution

Key Hire

Eric has 25 years of medical technology sales experience, having previously worked at Skeletal Dynamics, Medartis, Smith & Nephew.

Eric is based in the Midwest of the U.S, significantly enhancing ReNerve's distribution & sales capabilities.





Smith&nephew





ReNerve

Nervaign[®] Nerve

Clinical trial update

NERVE CUFF









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

- 80% 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'.











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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 ulletand 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. ۲
- 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.



NervAlign[®] Nerve Cuff

Used to protect recently repaired nerves:

- can be secured by sutures, micro-clips, glue or, if appropriate, secured with no, or a single suture (anchor suture) in place;
- is designed to be pliable and easy to apply;
- is thin, being suitable for use in constricted tissue environments;
- is bioresorbable with 6 months
- protects nerves from negative inflammatory responses or scarring; and
- supports cell proliferation and nerve regeneration.







Research & Development Update

ReNerve is focused on progressing through the second stage

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.



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.







GROWING MARKET

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





BOARD & MANAGEMENT

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





Near Term Milestones – 2025







2H 2025

Near Term



Additional NervAlign[®] Nerve Cuff **Clinical Data**



Initial Clinical Cases for the **Nerve Conduit**



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ReNerve Questions

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