

For personal use only

# ReNerve

**TRANSFORMING NERVE REPAIR  
THROUGH SCIENCE**



Quarterly Investor Update

February 2025

# Important Notice & Disclaimer

**Nature of Document:** This presentation has been prepared and issued by ReNerve Ltd (Company) to provide general information about the Company. The information in this document is in summary form and should not be relied upon as a complete and accurate representation of any matters that a reader should consider in evaluating the Company. While management has taken every effort to ensure the accuracy of the material in this presentation, the Company have not verified the accuracy or completeness of the material contained in this presentation.

**Not an offer:** this presentation should not be distributed, transmitted, or viewed by any person in any jurisdiction where the distribution, transmission or viewing of this document would be unlawful under the securities or other laws of that or any other jurisdiction.

**Not financial product advice:** You should not act and should refrain from acting in reliance on this presentation. Nothing contained in this presentation constitutes investment, legal, tax or other advice. This presentation does not take into account the individual investment objectives, financial situation and particular needs of potential investors. Before making a decision to invest in the Company at any time, you should conduct, with the assistance of your broker or other financial or professional adviser, your own investigation in light of your particular investment needs, objectives and financial circumstances and perform your own analysis of the Company before making any investment decision.

**Forward looking statements:** This presentation contains forward-looking information about the Company and its operations. In certain cases, forward-looking information may be identified by such terms as "anticipates", "believes", "should", "could", "estimates", "target", "likely", "plan", "expects", "may", "intend", "shall", "will", or "would". These statements are based on information currently available to the Company and the Company provides no assurance that actual results will meet management's expectations. Forward-looking statements are subject to risk factors associated with the Company's business, many of which are beyond the control of the Company. It is believed that the expectations reflected in these statements are reasonable but they may be affected by a variety of variables and changes in underlying assumptions which could cause actual results or trends to differ materially from those expressed or implied in such statements. There can be no assurance that actual outcomes will not differ materially from these statements.

**Disclaimer:** No representation or warranty, express or implied, is made by the Company that the material contained in this presentation will be achieved or proved correct. Except for statutory liability which cannot be excluded, the Company, its directors, officers, and employees expressly disclaim any responsibility for the accuracy, fairness, sufficiency or completeness of the material contained in this presentation and excludes all liability whatsoever (including in negligence) for any loss or damage which may be suffered by any person as a consequence of any information in this presentation or any effort or omission therefrom. The Company will not update or keep current the information contained in this presentation or to correct any inaccuracy or omission which may become apparent, or to furnish any person with any further information. Any opinions expressed in the presentation are subject to change without notice.

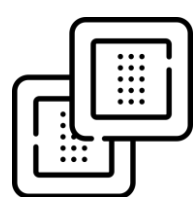
ReNerve Ltd ABN 23 614 848 216

# Executive Summary



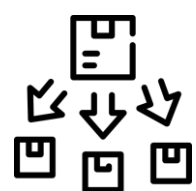
## Development of Novel Nerve Repair & Regeneration Products

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



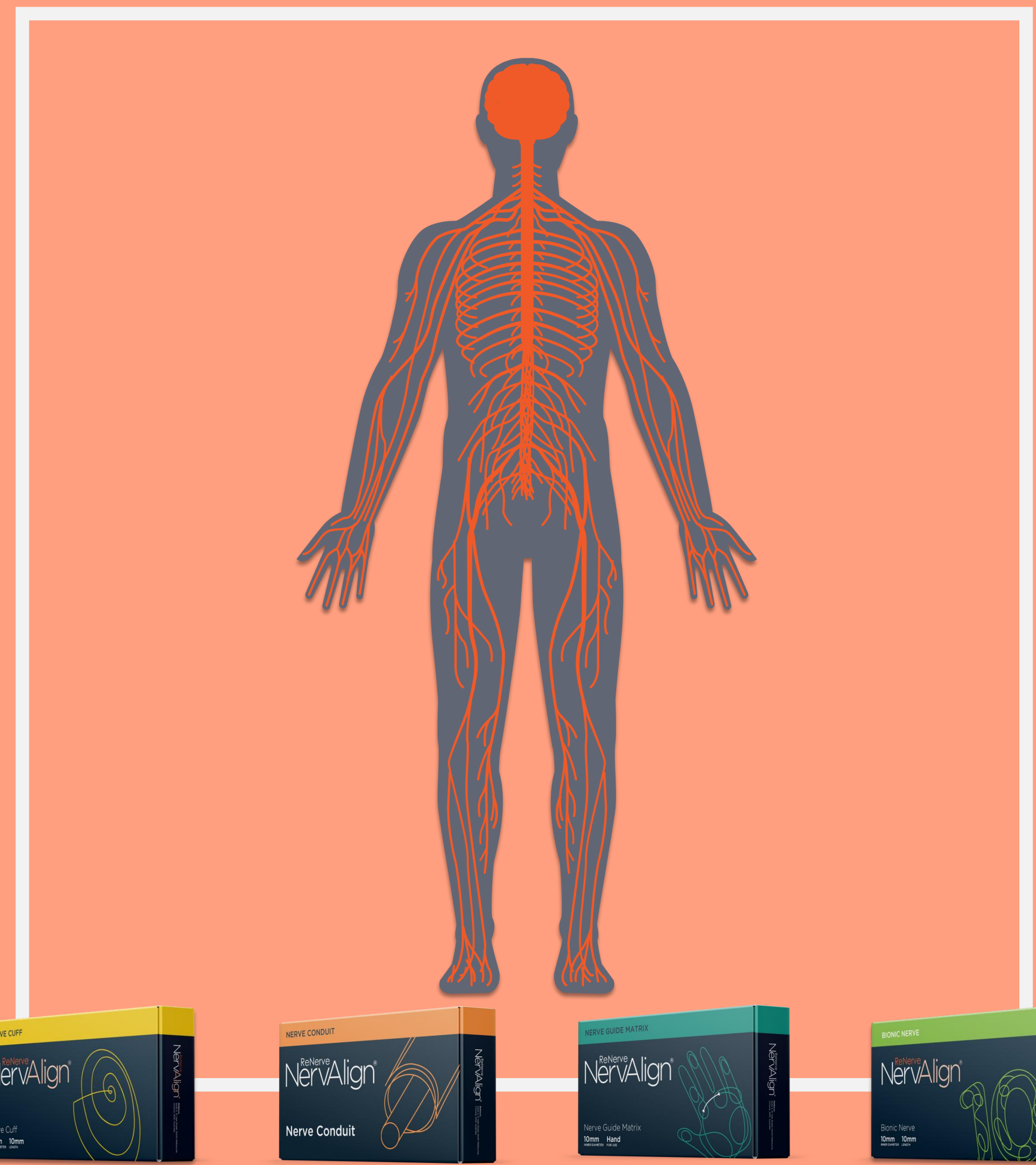
## Significant Product Portfolio

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.



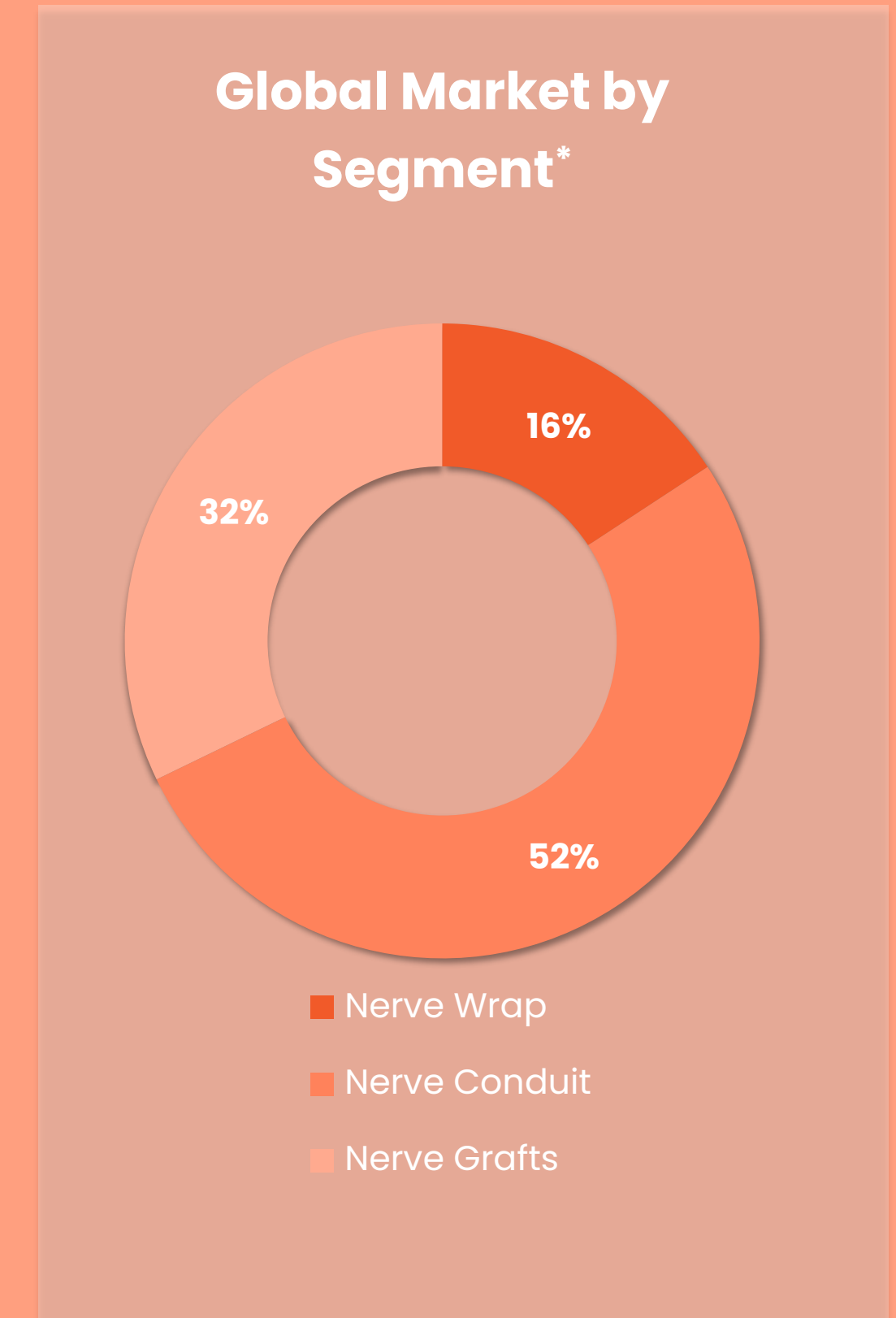
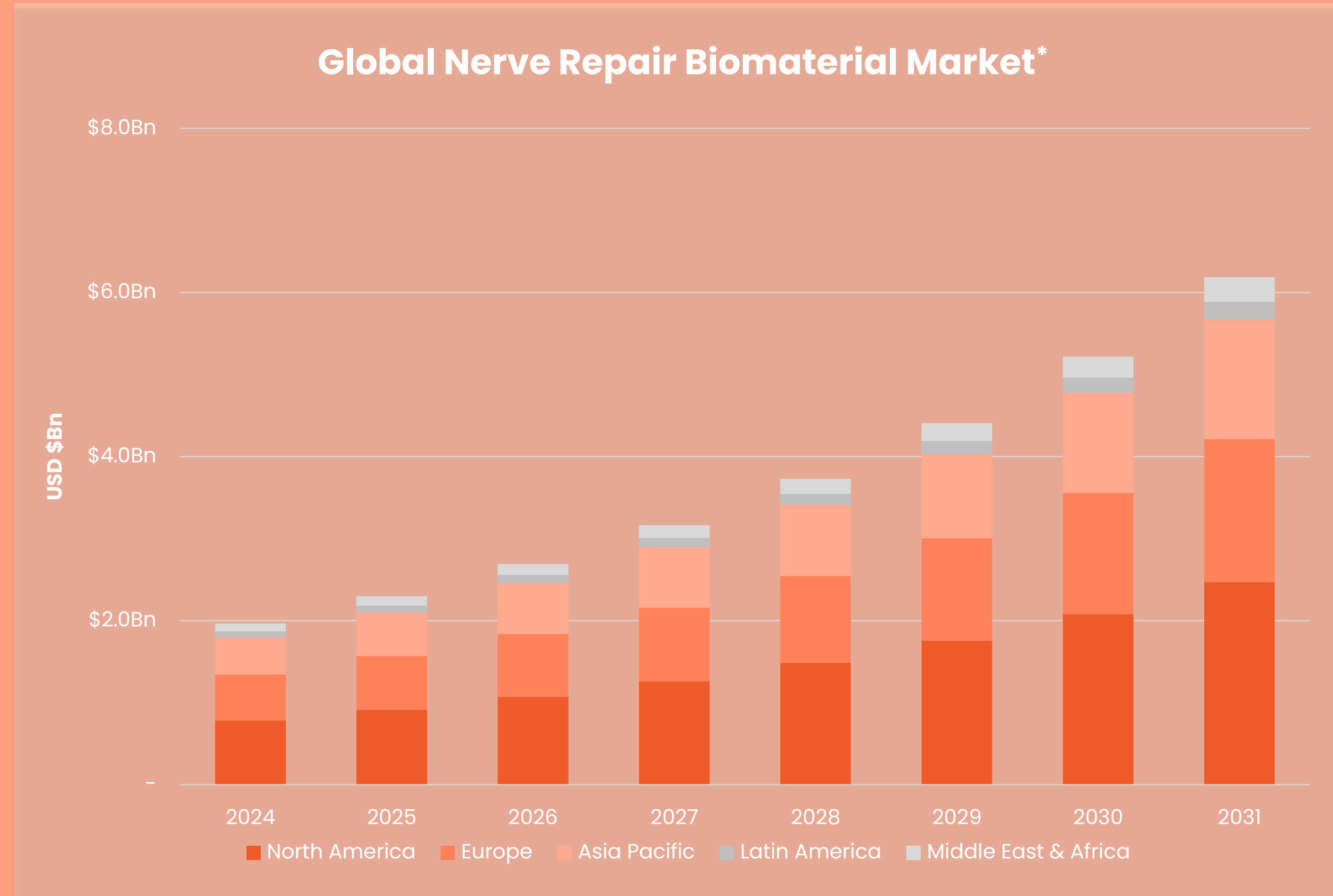
# ReNerve's Opportunity



|                      | ReNerve Nerve Cuff                                                                                                                                     | ReNerve Nerve Conduit                                                                                                                | ReNerve Nerve Guide Matrix                                                                                                                                               | ReNerve Bionic Nerve                                                                                                                                                                       |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product</b>       | <ul style="list-style-type: none"> <li>Used on damaged or transected nerves with no gaps or gap closure</li> </ul>                                     | <ul style="list-style-type: none"> <li>Developed using same technology (scCOO2) as the nerve cuff</li> </ul>                         | <ul style="list-style-type: none"> <li>An 'off-the-shelf', ready to use nerve graft replacement with internal guidance infrastructure</li> </ul>                         | <ul style="list-style-type: none"> <li>An 'off-the-shelf', continuous nerve replacement, in a ready to use nerve structure</li> </ul>                                                      |
| <b>Procedure Use</b> | <ul style="list-style-type: none"> <li>End to end suturing covered with a wrap/cuff</li> <li>Protective cuff for grafts</li> </ul>                     | <ul style="list-style-type: none"> <li>Protecting injured nerve repairs</li> </ul>                                                   | <ul style="list-style-type: none"> <li>Replaces damaged nerve section instead of using donor or harvested tissue</li> </ul>                                              | <ul style="list-style-type: none"> <li>The Bionic Nerve is a nerve guide matrix with ionic polymers designed to replace injured and damaged nerves for lengths from 1cm to 20cm</li> </ul> |
| <b>Application</b>   | <ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Oral &amp; maxillofacial surgery</li> </ul> | <ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Foot and ankle</li> </ul> | <ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Hand &amp; wrist</li> </ul>                                   | <ul style="list-style-type: none"> <li>Trauma</li> <li>Craniotomy</li> <li>Spinal cord injury</li> <li>Spinal cord surgery</li> </ul>                                                      |
| <b>Benefit</b>       | <ul style="list-style-type: none"> <li>Bio-absorbed removing need for additional surgery</li> <li>Pliable and conforms</li> </ul>                      | <ul style="list-style-type: none"> <li>Improved product profile to Nerve Cuff</li> <li>Stronger patient reimbursement</li> </ul>     | <ul style="list-style-type: none"> <li>Can be cut to ideal length</li> <li>Off-the-shelf, reducing logistics issues</li> <li>Simple to use and cost effective</li> </ul> | <ul style="list-style-type: none"> <li>Enable production of nerves of bespoke dimension</li> </ul>                                                                                         |
| <b>FDA Status</b>    | <b>Approved</b>                                                                                                                                        | <b>Targeting Q4 CY25 filing</b>                                                                                                      | <b>Targeting Q2 CY27 filing</b>                                                                                                                                          | <b>Targeting Q3 CY28 filing</b>                                                                                                                                                            |
| <b>TAM* (USD)</b>    |                                                                                                                                                        |                                                                                                                                      |                                                                                                                                                                          |                                                                                                                                                                                            |

\* Taken from Markets and Markets nerve repair and regeneration report -Global forecast to 2025 -July 2020

# Global Nerve Repair Biomaterial Market



**USD\$1.69Bn**

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.\*



**~900k**

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.\*

\* Taken from Markets and Markets nerve repair and regeneration report -Global forecast to 2025 -July 2020

ReNerve

For personal use only

# NervAlign<sup>®</sup> Nerve Cuff



## Quarterly Sales update

# Sales & Marketing

For personal use only

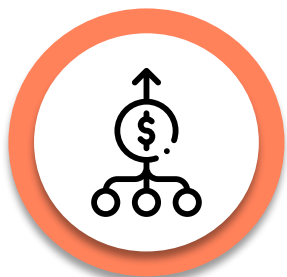
## Sales Highlights



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%.

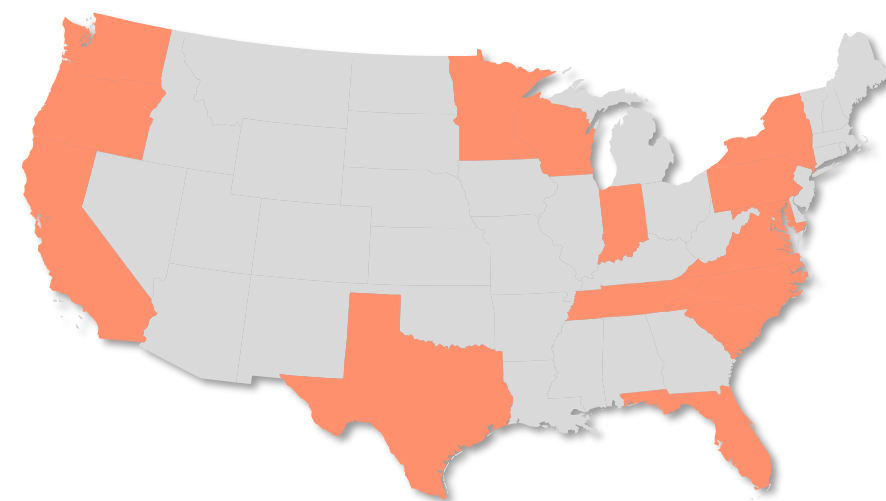


Closed the quarter with \$6.4m in cash.

## ReNerve Distribution

### U.S.

■ ReNerve sales agent in place



- 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.

### MIDDLE EAST



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

## Key Hire

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



- 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.



ReNerve

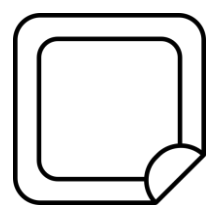
For personal use only

# NervAlign<sup>®</sup> Nerve Cuff



## Clinical trial update

# 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.

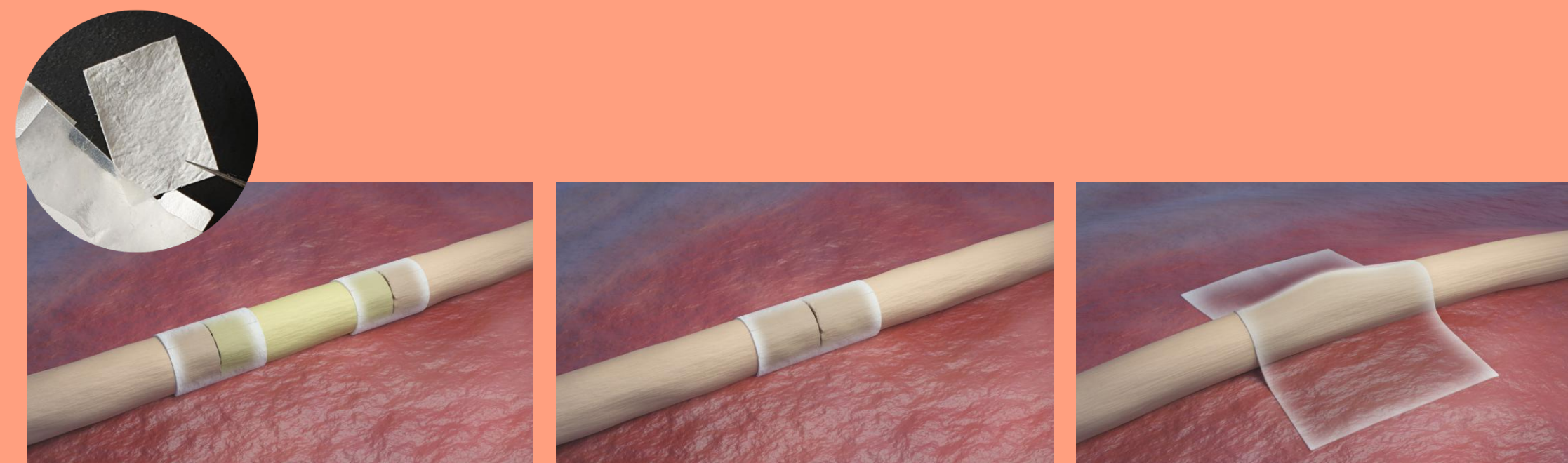
# Clinical Use

## Patient Results

- 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'.



# 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.



## 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.



### **NervAlign® Nerve Conduit**

ReNerve focus is on moving towards commercial manufacturing batches.

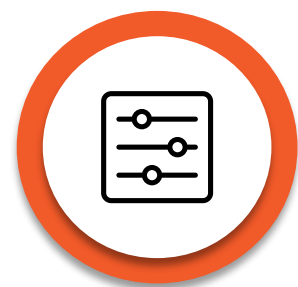


### **NervAlign® Nerve Guide Matrix**

ReNerve is focused on progressing through the second stage of commercial development.

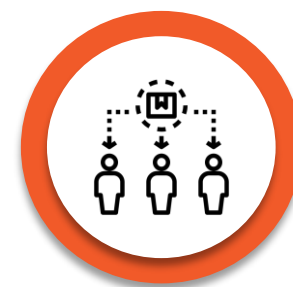
# Research & Development Update

# 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.



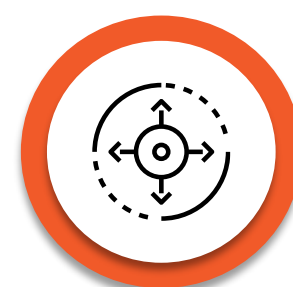
## GROWING MARKET

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



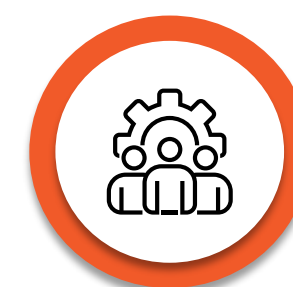
## DIVERSE PRODUCT PORTFOLIO

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



## GROWING DISTRIBUTION

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



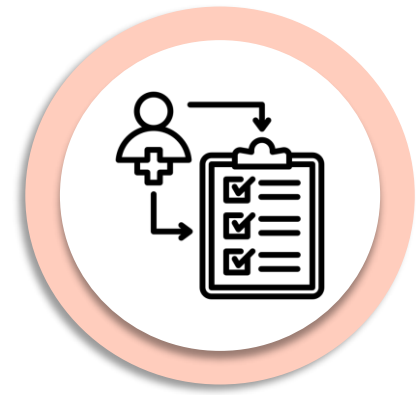
## BOARD & MANAGEMENT

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

\* Taken from Markets and Markets nerve repair and regeneration report -Global forecast to 2025 -July 2020

# Near Term Milestones – 2025

For personal use only



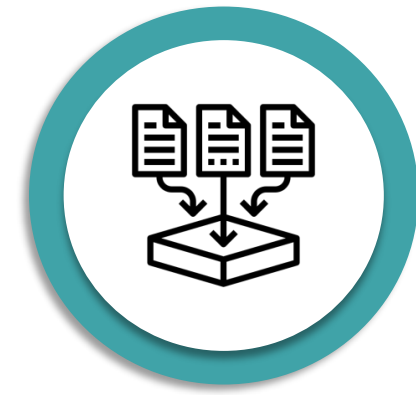
**Clinical Study Data**  
(March 2025)



**NervAlign® Nerve Cuff Approvals in New Countries & Territories**



**NervAlign® Nerve Conduit into Market**  
(Q4 2025)



**Progression of the Nerve Guide Matrix to Stage 3 of Development**

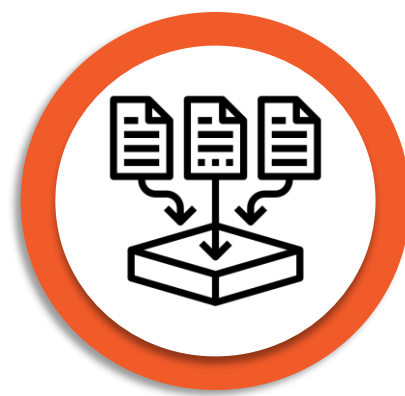
**1H 2025**

**2H 2025**

**Near Term**



**Additional partnerships Globally**



**Additional NervAlign® Nerve Cuff Clinical Data**



**Initial Clinical Cases for the Nerve Conduit**

# ReNerve

## Questions

Julian Chick – CEO & Managing Director

[jchick@renerve.com.au](mailto:jchick@renerve.com.au)

