# ReNerve

**ASX:RNV** 

## Transforming Nerve Repair Through Science

Investor Update | June 2025 Berkeley Biologics Partnership (Announced 2 June 2025)



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ReNerve Ltd ABN 23 614 848 216

## **Executive Summary**



### **Development of Novel Nerve Repair & Regenerative Tissue Products**

ReNerve is focused on developing a portfolio of products for the nerve repair and regenerative tissue 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 5+ product ranges over the next 4 years.



### Strong Sales & Distribution Presence

ReNerve have established logistics, warehouse and invoicing infrastructure with a growing sales distribution network able to sell all products.



### Swift 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.



## **ReNerve's Opportunity**

	ReNerve Nerve Cuff	ReNerve Nerve Conduit	ReNerve Nerve Guide Matrix	ReNerve Bionic Nerve
	Nervalign Nervalign Ben Br	Nerve Conduit	New function statutes New function Statutes Research Research Rese	NervAlign Derivation Brent line Brent line Brent line
Product	<ul> <li>Used on damaged or transected nerves with no gaps or gap closure</li> </ul>	<ul> <li>Improved Nerve Cuff developed from scCO2 tissue, offering better product profile</li> </ul>	<ul> <li>An 'off-the-shelf', ready to use nerve graft replacement with internal guidance infrastructure</li> </ul>	<ul> <li>An 'off-the-shelf', continuous nerve replacement, in a ready to use nerve structure</li> </ul>
Procedure Use	<ul> <li>End to end suturing covered with a wrap/cuff</li> <li>Protective cuff for grafts</li> </ul>	Protecting injured nerve repairs	<ul> <li>Replaces damaged nerve section instead of using donor or harvested tissue</li> </ul>	<ul> <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>
Application	<ul> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Oral &amp; maxillofacial surgery</li> </ul>	<ul> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Foot and ankle</li> </ul>	<ul> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopedics</li> <li>Hand &amp; wrist</li> </ul>	<ul> <li>Trauma</li> <li>Craniotomy</li> <li>Spinal cord injury</li> <li>Spinal cord surgery</li> </ul>
Benefit	<ul> <li>Bio-absorbed removing need for additional surgery</li> <li>Pliable and conforms</li> </ul>	<ul> <li>Improved product profile to Nerve Cuff</li> <li>Stronger patient reimbursement</li> </ul>	<ul> <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>	Enable production of nerves of bespoke dimension
FDA Status	Approved	Targeting Q4 CY25 filing \$3219m	Targeting Q2 CY27 filing	Targeting Q3 CY28 filing
TAM (USD)	\$975m \$314m	\$1015m	\$1991m \$635m	>\$400m
	2024 2030	2024 2030	2024 2030	2023

## **The Berkeley Biologics Partnership**

### Why?

- Provides immediate products into the company portfolio and therefore sales.
- Products now approved for the US market.
- Stimulated by feedback from surgeons using the ReNerve nerve products.
- The new products are used by the same surgeons for related procedures.
- More common use than nerve repairs alone.

### Synergies for ReNerve

- Produced through proprietary technology with strong science to the benefit of patients
- Two new complimentary product ranges
  - Dermal tissue product range.
  - Amniotic tissue ranges (three types of amniotic tissue products).
- Selling to the same target customers.
  - Orthopaedic, plastic and trauma surgery, breast reconstructions, etc.
- Selling through the same distribution channels and sales representatives.

Global Dermal & Amniotic Tissue Repair Markets

MarketWide Research – Dermal and Amniotic tissue market report 2025-2032, Published 2025.

### Dermal & Amniotic Tissue Sales for Specific Surgical Applications in USD\$M



Orthopedics (Tendon and Ligament Repair) Surgical Applications (Trauma, Plastic Surgery)



Dermal product range



### Key Features of Dermal Product Range



### In Keeping with ReNerve Core Innovate Products

Produced using proprietary processes, whilst retaining physiological benefits.



### **Preserve Natural Matrix**

Maintains structure like unprocessed dermis for improved tissue repair.



### **Porous Structure**

Facilitates faster cell infiltration for improved healing outcomes.



### Sterility-Assured and Room Temperature-Stored

Achieves high sterilisation while maintaining structurally-intact matrix.



### **Bioactive Components**

Retains similar collagen integrity, mechanical strength, and bioactive properties.

### **Complimentary Product**

The dermal tissue is used in procedures that existing ReNerve products are also already used in.

## **Key Benefits**

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Designed and processed to preserve the natural matrix as closely as possible to unprocessed dermis for optimal tissue repair and regeneration.



Closest to natural dermal tissue, compared to other dermal products<sup>1</sup>.



Achieves high sterility-assurance levels, while maintaining a structurally-intact matrix that retains similar collagen integrity, mechanical strength, and bioactive components as the natural dermis. Unprocessed Dermal Tissue



New ReNerve Dermal Product



Natural Dermal Integrity is Preserved



Amniotic product ranges



### Key Features of Amniotic Product Range





### Highly Complimentary Products Used Across Procedures

Most nerve repairs are related to some type of wound and require some level of wound care – particularly in plastic, micro, orthopaedic and trauma surgery.

### Ideal Wound Covering Options for Challenging Cases

- Natural barrier protects the wound during healing
- Easy to us and apply, with no rehydration needed
- Contains levels of growth factors and cytokines to benefit healing

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### **Room Temperature-Stored**

- Whilst achieving high sterilisation standards
- Synergistic to existing ReNerve products logistically

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### **Three Amniotic Product Ranges**

- Amniotic layer with chorion
- Amniotic layer with no chorion
- Bi-layer amniotic tissue

## **Partnership Highlights**

### **In-Market Products**

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Gives ReNerve two new synergistic product ranges coming to market within months to build sales revenue

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### **Diverse Product Portfolio**

Expands the product portfolio with complimentary products and expands the addressable target markets for ReNerve

### **Immediate Market Need**

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The new products are used by surgeons with an immediate target market that is complimentary to the existing ReNerve business

## Near Term Milestones - 2025

### 1H 2025

27 February 2025 Partnership Signed for Mexico Market

*March 2025* Clinical Study Data

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

*28 May 2025* NervAlign Nerve Cuff approved in Bahrain

*2 June 2025* Partnership with Berkeley Biologics for new product ranges

### 2H 2025

Additional NervAlign® Nerve Cuff Clinical Data

NervAlign® Nerve Conduit into Market (Q4 2025)

Initial Clinical Cases for the Nerve Conduit

First sales of the dermal tissue product range

First sale of the amniotic tissue product range

### **Near Term**

Progression of the Nerve Guide Matrix to Stage 3 of Development

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

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## **Investment Highlights**

Now have three product ranges in the

market and more coming



Continuing to build sales representation with a targeted-direct sales approach. Highly accomplished executive team with a proven track record in the development & commercialisation of

medical opportunities.

# ReNerve

**ASX:**RNV

## Contact

### **ReNerve Limited**

- +61 (03) 9482 3940
- info@renerve.com.au

• Level 10/99 Queen St, Melbourne, Victoria 3000 Australia

