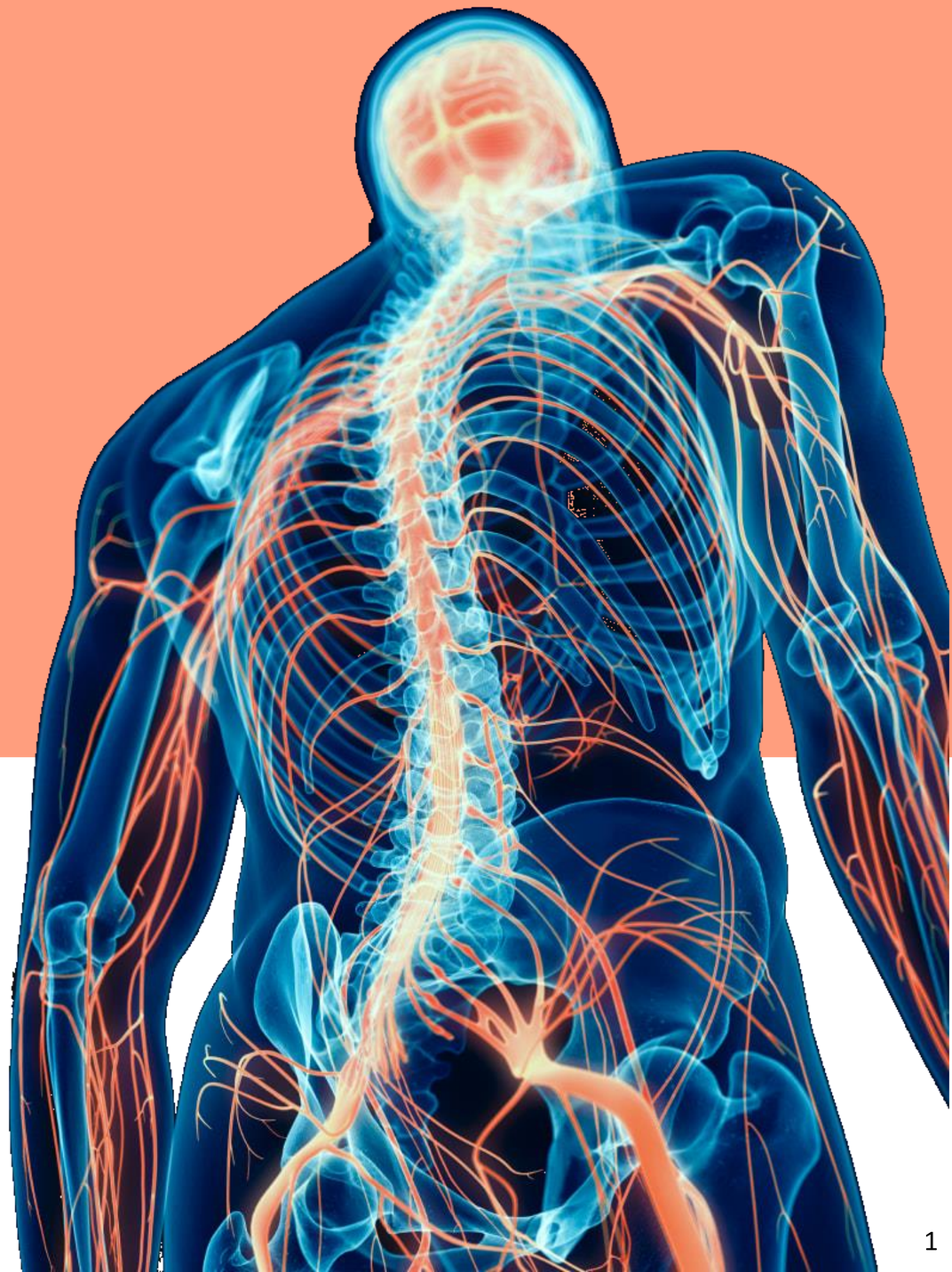
ReNerve

TRANSFORMING NERVE REPAIR THROUGH SCIENCE



Investor Presentation | November 2024

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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 clearance of 3+ products over the next 4 years.

Strong Sales & Distribution Presence

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

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 better patient recovery and 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

One product already on the market (NervAlign® Nerve Cuff), with an additional three under development (NervAlign® Nerve Conduit, Nerve Guide Matrix and Bionic Nerve).

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.

Company History

2017

ReNerve Ltd established with the aim to improve short and long-term outcomes for patients undergoing surgery relating to peripheral nerve damage.

2018

ReNerve entered into a development and manufacturing agreement with Biomedical Europe B.V.

2019

Positive animal studies for the Nerve Cuff and Nerve Guide Matrix.

2020

Established US warehousing and logistics ahead of US market approval.

2021

Received marketing approval for NervAlign® Nerve Cuff in New Zealand.

2022

Received FDA clearance for the NervAlign® Nerve Cuff, achieving first sales.

Entered into a commercial partnership with Yuan Yu to gain approval and market the product in Taiwan.

2023

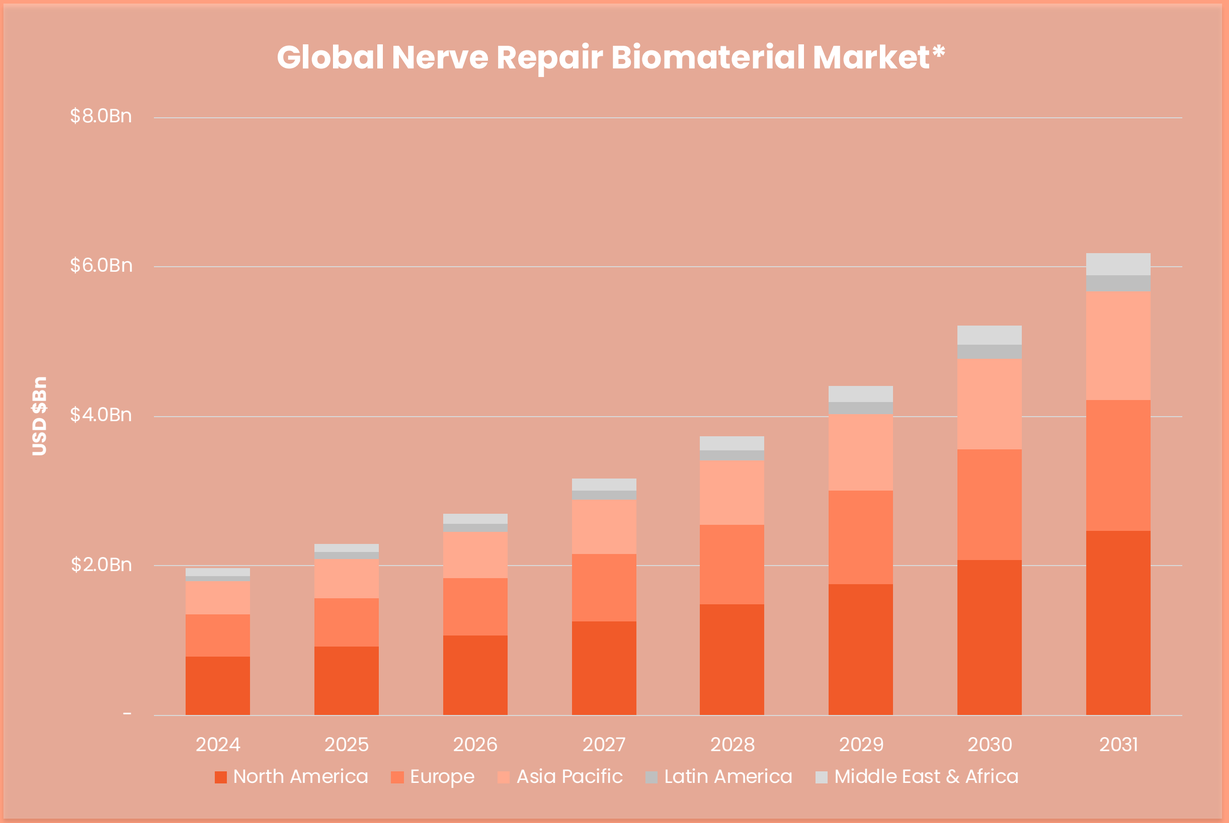
Entered into a commercial partnership with Collagen solutions for the Nerve Guide Matrix.

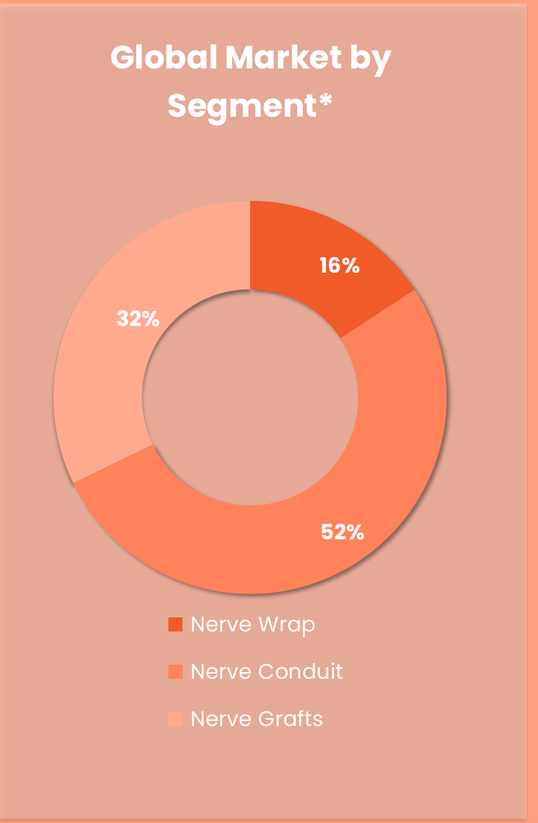
Received FDA guidance on pathway for market clearance for the Neve Guide Matrix.

2024

Initial Public Offering on the ASX.

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

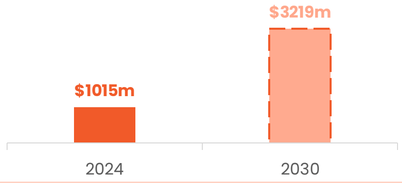
Nerve surgeries occur in the United States (US) per annum, with no more than 24% of nerve surgeries restoring to 'as good as it was'.

Nerve Compression

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

* Please refer to the **Global Nerve Repair Biomaterials Report (2020 – 2031)** and/or the **ReNerve Prospectus** for full details on Key Data for the Global Market

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 • 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
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	**FDA Cleared**	**Targeting Q4 CY25 filing**	**Targeting Q2 CY27 filing**	**Targeting Q3 CY28 filing**
TAM (USD)				

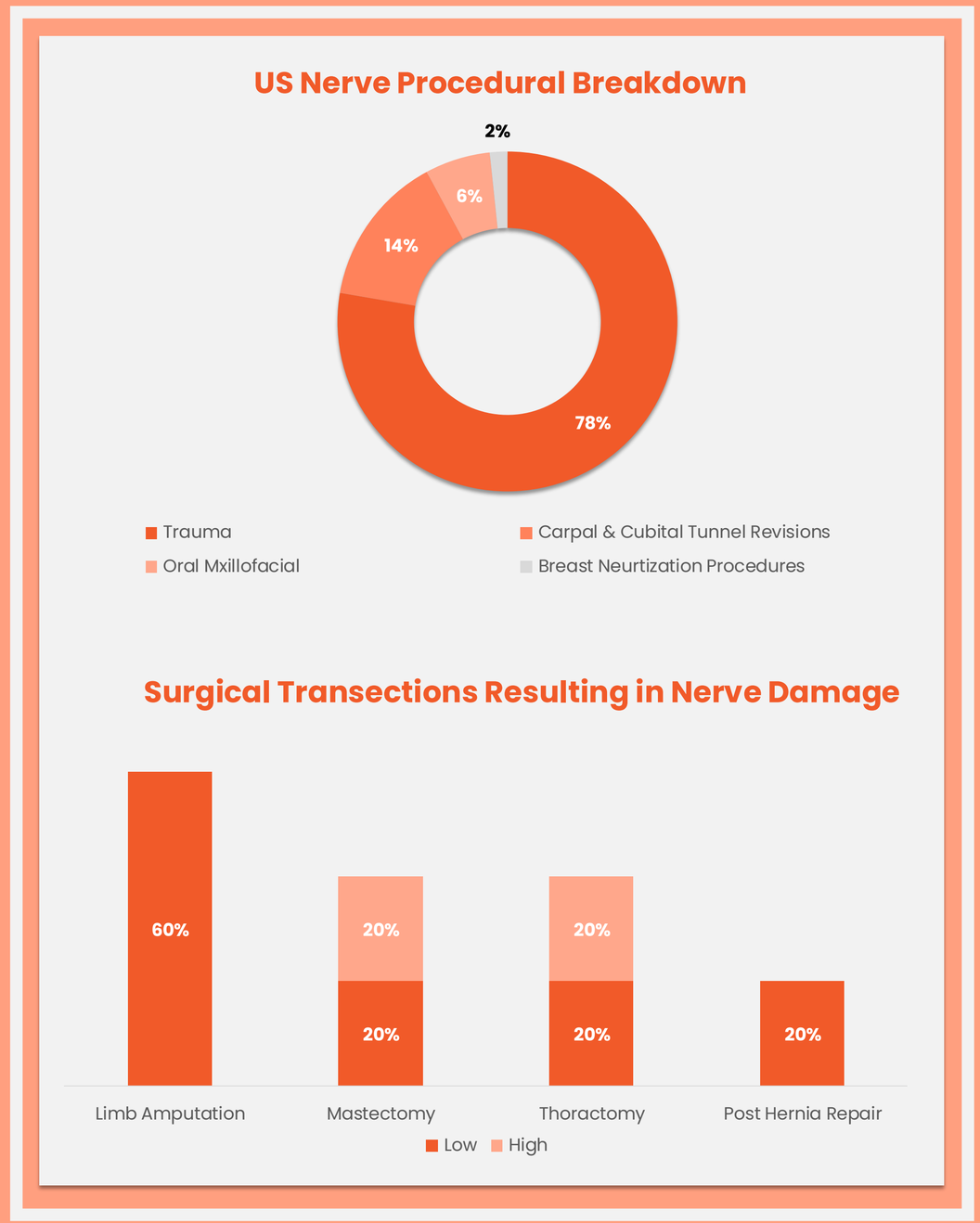
PNI Classification	Traditional Treatment Methods			ReNerve Solution
Transection	**Suture** • Can result in tension at repair site leading to ischemia • Concentrates sutures at coaptation site	**Autograft** • Loss of function at harvest site • Complication risk including chronic pain • Limited graft length	**Synthetic Conduits** • Limited direction for regrowth • Increased failure rate >5mm gaps • Repair relies on fibrin clot formation	
Compression	**Vein Wrapping** • Requires additional surgical time • Specific surgical skill • Creates secondary surgical site	**Hypothenar Fat Pad** • Only wraps part of the nerve circumference • Increases surgical procedure time • Creates an inhibitor to surrounding tissue	**Collagen Wraps** • Semi-rigid material limits surgical use • Degrades over time	
Stump Neuroma	**Transection Neurectomy** • Can lead to additional neuroma and secondary surgery • Traction injury • High risk of recurrence	**Burying in Muscle / Bone** • Can lead to additional neuroma and secondary surgery • Pain and localised pressure • Large surgical dissection	**Injections** • Success rate estimated ~40% • Temporary solution that reduces over time • Pharmacological side effects	

Existing PNI Treatment Methods

Issues with Existing Nerve Repair Methods

ReNerve's Opportunity

Method	Limitations	ReNerve Solution
Suture	• Can result in tension to the repair leading to ischemia. • Concentrates sutures at the coaptation site.	
Autograft	• Loss of function and sensation at donor site resulting in morbidity for the patient. • High complication rates including wound healing and chronic pain. • Mismatch in size and structure due to limited availability of graft length and diameter, affecting quality of nerve regeneration. • Variable functional recovery.	
Synthetic Conduits	• Limited to small gaps due to size and shape constraints, reducing efficacy and use. • Variable functional recovery.	
Nerve Transfer	• Sacrifice of function in the donor nerve's original target area. • Mismatch in size and structure. • Delayed reinnervation. • Variable functional recovery.	



Distribution Network

Defined sales strategy targeting the US as five regions, with aggressive focus to continue building regional sales representation.

Using third party distribution partnerships and 1099s.

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

Warehousing, invoicing and logistics all in place with additional infrastructure to support nerve conduit and guide matrix sales.

Anticipated Company Milestones
(Next 12 – 24 Months)

Ongoing

- Continue to Build Sales & Distribution Across US

Q1 2025

- NervAlign® Nerve Cuff Clinical Study Data and Presentation

Q4 2024 – Q4 2025

- Partnerships and Approvals for the NervAlign® Nerve Cuff in New Countries and Jurisdictions:
  - Asia
  - Central America
  - South America
  - Middle East
  - Europe

Mid-2025

- Progress Nerve Graft Towards GMP Manufacturing Run
- Testing of Bionic Nerve Prototype

2H 2025

- Complete Development for NervAlign® Nerve Conduit
- Commence Testing Conduit for FDA Filing
- Nerve Cuff Variant Launch

Q1 2026

- File New Nerve Conduit Indication with FDA
- Commence Final Product Testing for Nerve Graft FDA Submission

2026 Onwards

- First Clinical Graft Cases
- Progress Dura Mater Project to Pre-Submission Testing

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

- 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’.

Incorporating eCOO®Technology

eCOO® Technology

- Retains structural & mechanical properties.
- Environmentally friendly.
- Process ensures effective viral & pathogen inactivation.
- Minimal residues & hazardous materials.

eCOO® Clean

- Maintains natural crosslinking of extracellular matrix (ECM).
- Promotes cell attachment.
- Low immunogenic risk.
- Deep microstructural penetration.

Benefits Over Conventional Tissue Treatments

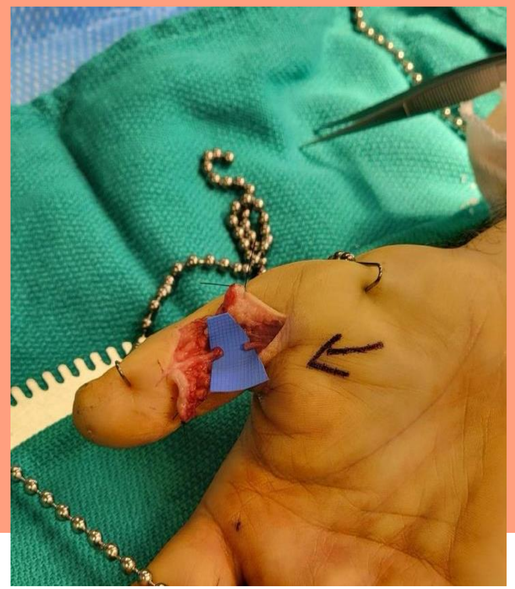
Uses carbon dioxide under pressure to create a gas and liquid state.

eCOO® Technology is ideal for cleaning and sterilising tissue as it permeates like a gas and cleans like a liquid.

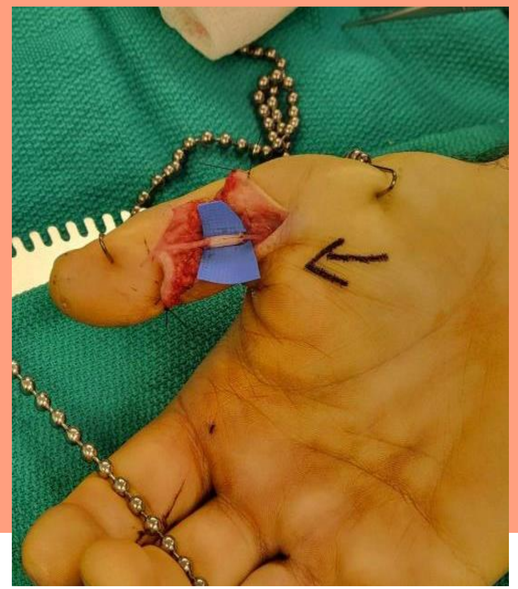
Contains no:

- Glutaraldehyde, Triton X-100, sodium dodecyl sulphate (SDS), acetone and enzymes; and
- Ethylene oxide (EtO).

Clinical Use

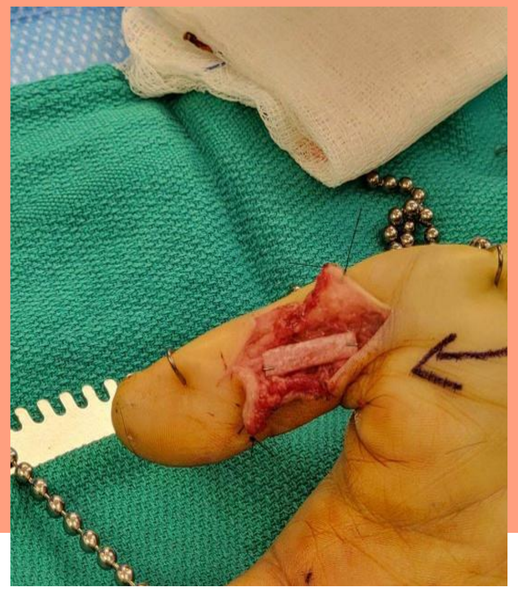


Damaged nerve removed from the right thumb



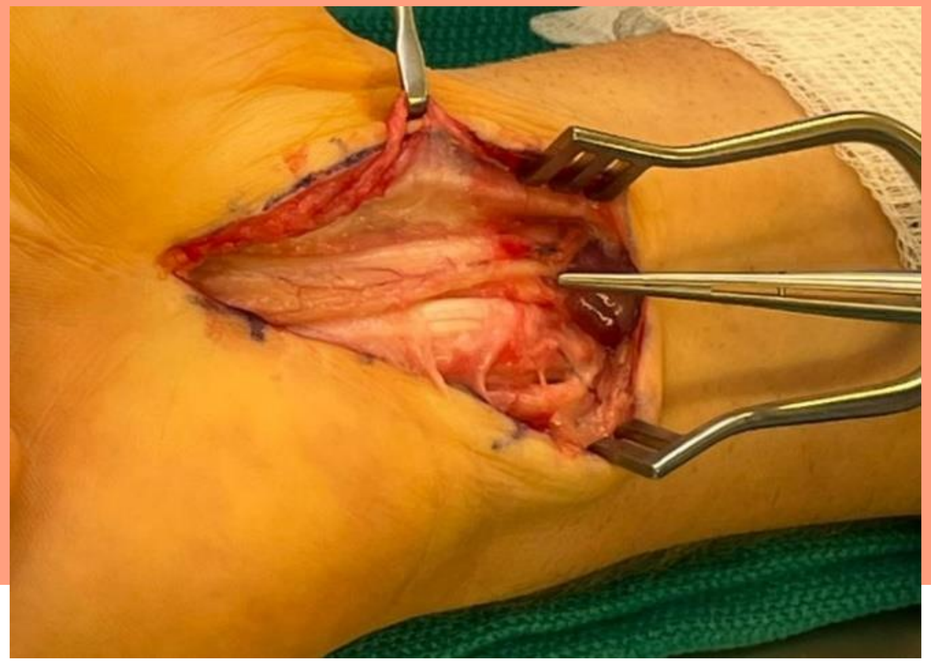
Removed gap filled with a conduit

NervAlign® Nerve Cuff used to protect the cuff conduit implant

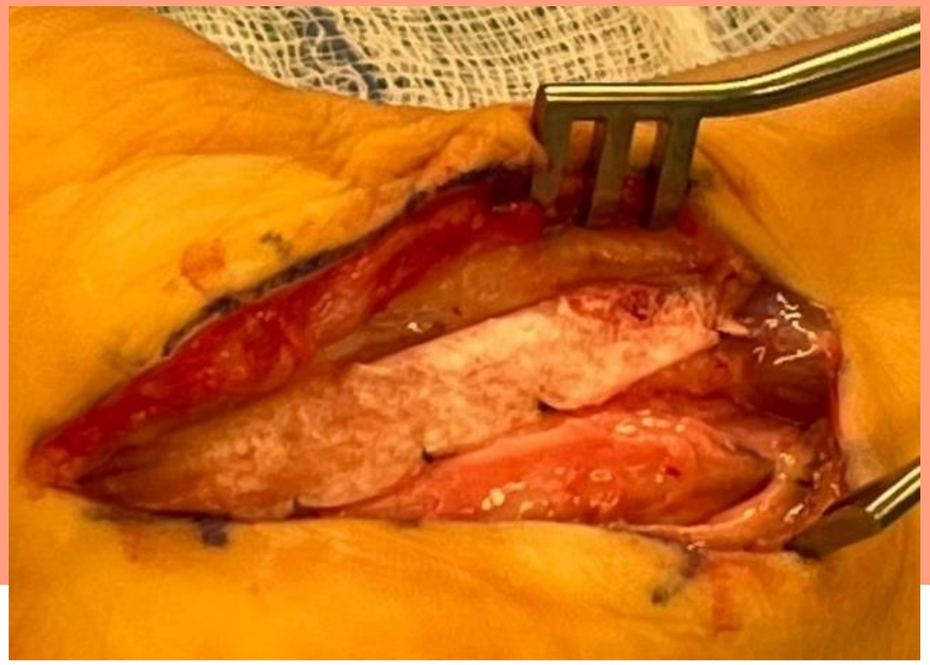


Completed repair held in place with micro clips

Clinical Use - Carpal Tunnel



Carpal tunnel revision – exposed nerve



Implanted NervAlign® Nerve Cuff
used as a protective layer between the nerve and surrounding fascia tissue. The cuff sutured in place using the ‘taco’ method.

NervAlign® Conduit

02

Key Features

- ReNerve is focused on developing a conduit from scCO2 tissue from the Nerve Cuff.
- ReNerve will be able to leverage existing data from the Nerve Cuff FDA application to accelerate FDA clearance.
- 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 is targeting a Q4 CY25 FDA filing.

NervAlign® Nerve Guide Matrix (Graft)

03

Key Features & Guide Matrix

Product

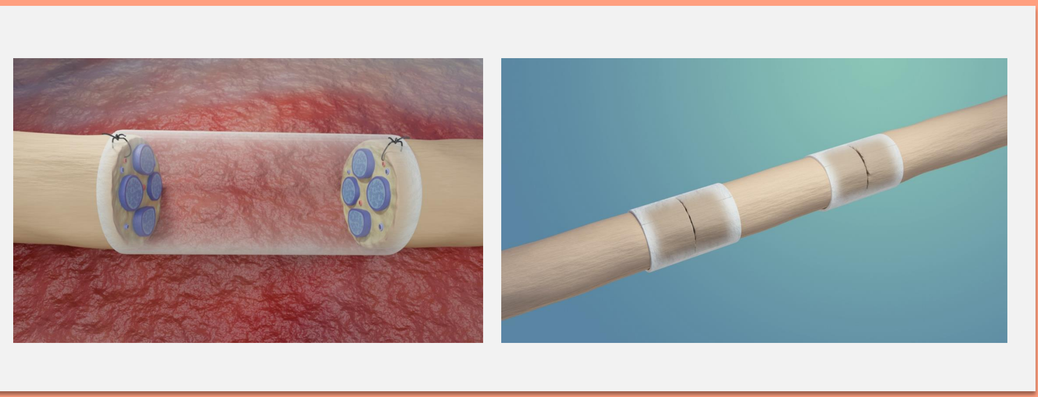
- The NervAlign® Neve Guide Matrix is an ‘off-the-shelf’, ready to use nerve graft replacement with internal guidance infrastructure.
- ReNerve is developing three product options:
  - Initial ‘wet’ prep nerve graft;
  - Dry version that's hydrated within 10 minutes; and
  - Longer lengths out to 7cms+.

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.



Autologous Implantation Study

Nerve graft models have shown:

- Restored ‘native’ state of nerves and function.
- Formation of functioning axons through full length of the nerve.
- Showed formation of fascicular like structures over the four-month implantation period.
- Nerve function at the distal end of the limbs.

The study also showed:

- Rapid recovery of the animals post-surgery.
- Walking with splint within hours.
- ~3 months to full recovery (‘normal walking’).
- Re-established motor and sensory function after implant surgery.
- No short- or long-term complications.

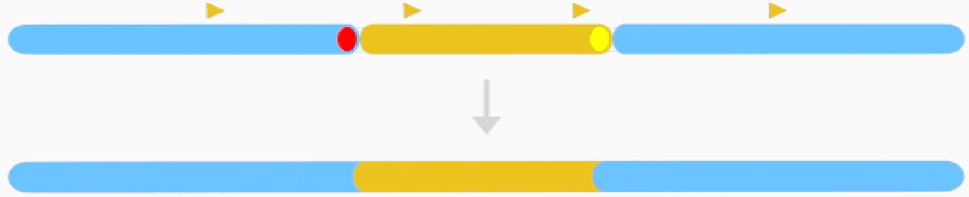
NervAlign® Nerve Guide Matrix (Graft)

Animal study results showed:

- ✓ Ready to implant and no special training required.
- ✓ Rapid recovery post surgery.
- ✓ Histology showed nerve regrowth through grafts equivalent to autologous (native) tissue.
- ✓ Full nerve formation through entire length of nerve graft – including new axon and fascicular formation and functional nerves.

Key findings across the 3, 6 and 10-month measurements showed:

- ✓ **3 Months**: Displayed typical post-surgery inflammation and gait of animals restored.
- ✓ **6 Months**: Inflammation in the graft and scar tissue around the implants had reduced.
- ✓ **10 Months**: Nerve conductance had been re-established to similar levels, indicating functionality of the nerves.



NervAlign® Nerve Guide Matrix Vs Autologous Implantation Study

Regulatory Framework

Ethics Approval

Received ethics approval for the animal model study including electrophysiology data.

Allowed for use of larger size implants.

FDA Meeting

Outlined positive path forward for ReNerve, requiring no initial clinical study in the US.

Opens market for the ROW.

Commercial Partnership

Executed partnership with Collagen Solutions for commercial scale production.

Phase 1 – Final product packing studies.
Phase 2 – Scale Production of the graft.
Phase 3 – Validation Batch Runs.
Phase 4 – Bench testing for FDA submissions.

FDA Clearance

ReNerve have established a clear path to FDA clearance and product launch.

Current animal study is testing electrophysiological development of the nerve regrowth through the graft with numerous implant results expected over next 10 months.

ReNerve

NervAlign® Bionic Nerve

R&D

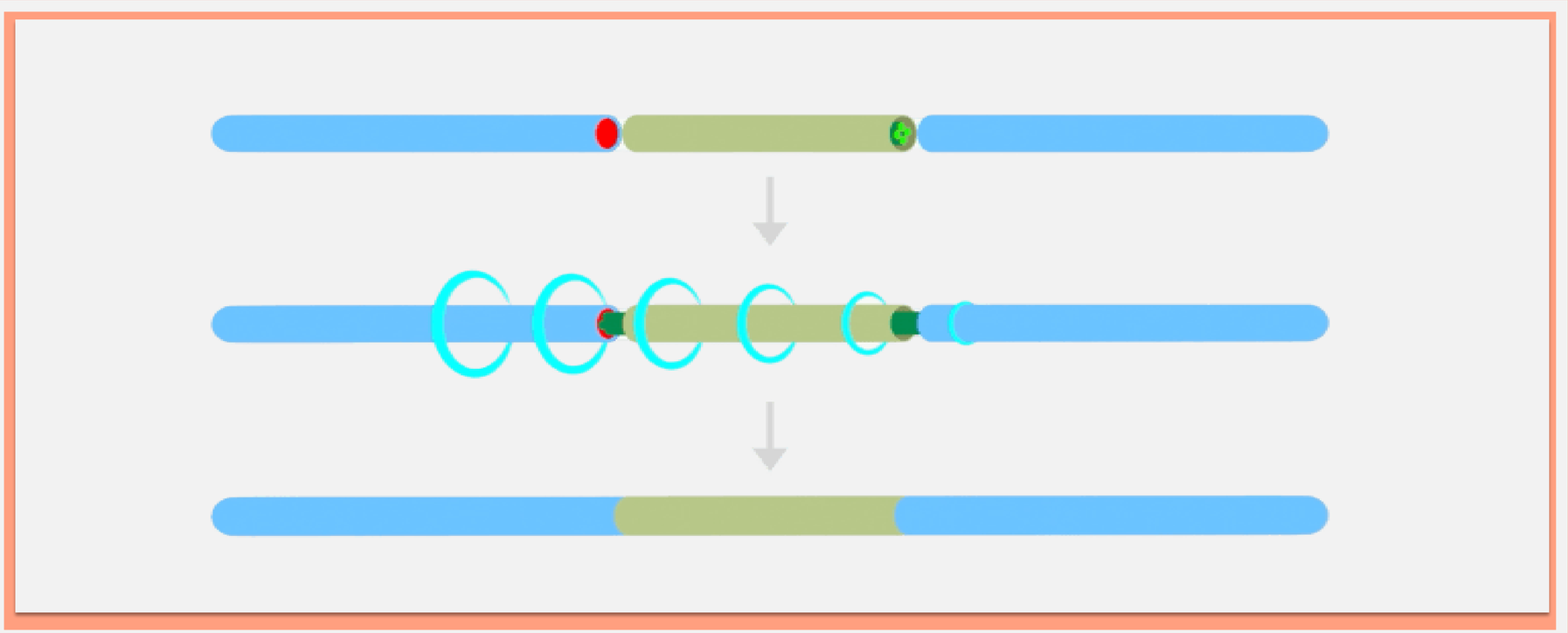
NervAlign® Bionic Nerve

ReNerve's NervAlign® Bionic Nerve is intended to be an off-the-shelf, continuous nerve replacement.

Current practice is to use donor or autologous nerves if possible, however is limited by length.

Generally, nerves regrow at or around 1mm per day in a stable environment, however outcomes are poor over 2cm-5cm, becoming progressively worse as regrowth distance increases.

- ReNerve are developing the Bionic Nerve to be in lengths from 1cm to 20cm+ long, in a ready to use nerve structure, to replace damaged nerves.
- ReNerve are seeking to develop an effective solution for the most challenging nerve repair.
- The Bionic Nerve will enable production of nerves of bespoke dimensions and incorporation of neurostimulation.
- ReNerve have recently executed a collaboration partnership with 3DBioFibR for the development of the Bionic Nerve.



Dura Mater Replacement

ReNerve are currently developing two products for the replacement of Dura Mater.

1

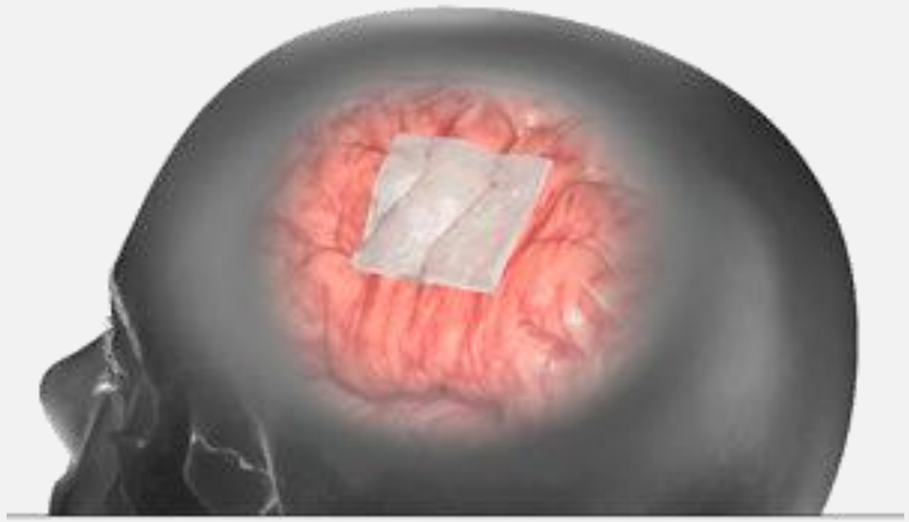
Product One – Short term, remodeling dura replacement

- For small craniotomies and back/spinal surgery.
- Dura tissue-based on the nerve cuff eCOO® Technology.
- Designed to be sutured in place and allow for remodeling repair.
- Very clean and avoids chemical meningitis seen with other products.

2

Product Two – Long term dura replacement

- Multi-functional product.
- Sealed, anti-adhesion product for all craniotomies and spinal surgery.
- Antibacterial to prevent surgical site infections.



- Aiming for first FDA submission within 18-months.
- ReNerve will seek to expand into novel multi-functional dura product.

ReNerve

Board & Management

Board & Management

STEPHEN COOPER
CHAIRMAN

Stephen was previously a 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 clearance 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 (acquired by Optium Inc), Energy Response (sold to EnerNoc Inc), ImpediMed Ltd, and Protagonist Therapeutics Inc.

He currently serves on the boards of MetaCDN Pty Ltd, Margin Clear Pty Ltd, Marp Therapeutics Pty Ltd and Cylite Pty Ltd.

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.

ReNerve

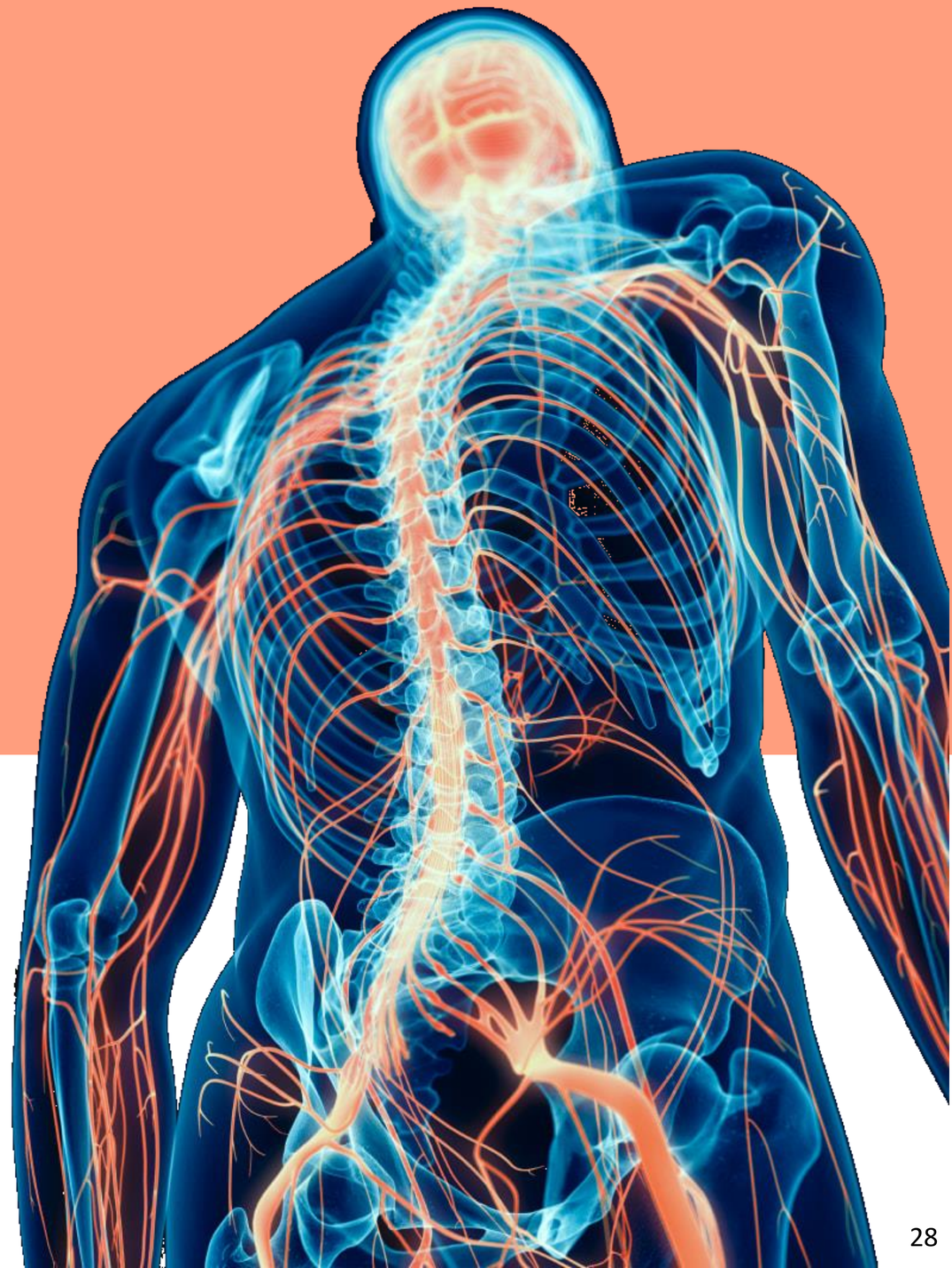
Contact

E: info@ReNerve.com.au

+61 (03) 9482 3940

157 Heidelberg Rd,
Northcote VIC 3070

www.renerve.com.au



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Appendix

Key Risks

Insufficient funding	ReNerve is in the medical devices business and such businesses require additional capital from time to time in order to progress development programs. There is no guarantee that ReNerve will be able to raise the funds required in a timely manner or at a reasonable cost when required by it.
Rejection or delay in receiving regulatory approvals	In February 2022, ReNerve received market clearance from the FDA for its primary product, the NervAlign® Nerve Cuff. FDA Market Clearance was granted in response to ReNerve's submissions and engagements with the FDA. The NervAlign® Nerve Cuff is designated as a Class II medical device. All ReNerve's other products will require regulatory approvals, in most cases as medical devices. Rejection, delay or subsequent loss of regulatory approvals could impact the business. Jurisdictions outside of the US will likely require clinical data and ReNerve is engaging surgeons in Australia and in the US. to support the generation of suitable data. In addition, once regulatory approval is obtained in the US, clinical data can be obtained and used to support additional regulatory filings. The Directors assess rejection or delay risks for other approvals as low given the Company's significant internal expertise in obtaining these types of clearances.
Non-acceptance of ReNerve products by surgeons	ReNerve's marketing strategy relies on acceptance of its products by surgeons. ReNerve has an advisory Board of established surgeons in the U.S. who provide guidance on product development and use the product in the U.S. and therefore the Directors are confident the products commencing with NervAlign® Nerve Cuff will be accepted by surgeons.
Competition	ReNerve competes against many existing and potential competitors. ReNerve's competitors may be able to increase market share through aggressive marketing campaigns, product improvements, acquisitions or price discounting which may affect ReNerve's market share and margins.
Limited history in sales	ReNerve has only two years of experience in the sales and marketing of nerve repair products in the U.S. market. There is no guarantee that it will be able to achieve its sales goals, particularly given the uncertain nature and extent of competition from established market participants and new entrants with new products.
Product pipeline and development of new products	ReNerve's ongoing commercial success is dependent on the continued advancement of existing products and the research and development of new products. Developing new products is expensive and time consuming and products may fail to reach market or sell.
Loss of EMCM exclusivity	ReNerve currently has exclusivity under the EMCM Agreement (its Manufacturing and Supply Agreement). Exclusivity is dependent on achieving certain production targets. Loss of exclusivity could expose the NervAlign Nerve Cuff to greater competition. See section 10.2 of the Prospectus for more information on the EMCM Agreement. ReNerve considers it unlikely that it will not be able to meet the terms of exclusivity in the EMCM Agreement and maintains a strong, ongoing relationship with EMCM.
Termination of EMCM Agreement	Termination of the EMCM Agreement is unlikely but is possible if ReNerve breaches its obligations or if EMCM became insolvent or otherwise incapable of performing its obligations. If it was terminated, ReNerve would be protected initially by the fact that ReNerve's NervAlign® Nerve Cuff product has a 30-month shelf life, meaning that ReNerve could service its market with existing product supplies until a new manufacturer could be established. ReNerve currently has a licence to the Leader IP (see section 2.13). The licence is revocable only in the case ReNerve breaches the terms of the licence or its obligations under the EMCM Agreement. ReNerve believes that if EMCM became insolvent or otherwise incapable of performing its obligations, ReNerve would not be prevented from continuing to manufacture and distribute the NervAlign® Nerve Cuff product through an alternative manufacturer. However ReNerve would need to work with such alternative manufacturer to develop a method and process for manufacturing the NervAlign® Nerve Cuff, which could be a substantial exercise.

Key Risks

Manufacturing and production risks - EMCM	EMCM has the technical experience and processes to manufacture the NervAlign® Nerve Cuff. If EMCM were unable to continue operations for example due to loss of accreditation or insolvency, or alternatively the agreement with EMCM was breached and terminated, ReNerve would then need to source a new manufacturer and complete technology transfer would be required. The new manufacturer would need to obtain access to the IP including know-how of EMCM. Naturally, there is also risk associated with increased production costs imposed by EMCM.
Manufacturing and production risks – manufacturing location / premises	ReNerve's products are manufactured in a single location by EMCM, and as such that location is exposed to risks of harm caused by natural or man-made disasters, or operation or human error, which may result in manufacturing disruptions or an inability to manufacture and produce its products for some time. This has the potential to limit, delay or prevent supply of ReNerve's products and have an adverse impact on the availability of ReNerve's products to customers, which would affect contractual obligations, particularly with respect to failure to supply. ReNerve has entered into a partnership with Collagen Solutions for the manufacturing of its nerve guide matrix. Collagen Solutions is also an alternative manufacturer of ReNerve's other products.
Manufacturing and production risks – raw materials	Key raw materials used in the manufacture of the product include pigs sourced from the Netherlands. In turn, if there is to be any virus or other external force majeure event that diminishes access to these resources, this could have an adverse effect on the manufacture of ReNerve's product (by causing delay). EMCM and ReNerve are assessing additional porcine raw material suppliers in the Netherlands. Similarly, in relation to all of the other items and materials used in assembling the final product – there could be changes or halt in production – in which case alternatives would be required / sought as well as revalidation testing
Product market acceptance	ReNerve's growth and the commercial success of ReNerve's products and future products is reliant on the acceptance of ReNerve's products by healthcare professionals, including surgeons and wound care specialists.
Reverse engineering / copycat by ReNerve competitors	A significant part of ReNerve's IP strategy is to rely on know-how and speed to market rather than patent protection, and there is a possibility that competitors will seek to replicate ReNerve's products.
Intellectual property generally	The value of ReNerve's products depends in part on its success in maintaining trade secrets and obtaining and maintaining issued patents, trademarks and other intellectual property rights to protect ReNerve's proprietary technologies. If ReNerve's intellectual property and proprietary technology is not adequately protected, competitors may be able to use the technologies or the goodwill ReNerve has acquired in the marketplace and erode or negate any competitive advantage ReNerve may have, which could harm ReNerve financially. In addition to its patent activities, ReNerve also relies on protecting its trade secrets especially with regard to its manufacturing processes. Although ReNerve implements reasonable endeavours to protect its trade secrets, these measures may not always be sufficient to protect its trade secrets. ReNerve may not be able to meaningfully protect its trade secrets and unpatented know-how and keep them secret. ReNerve also cannot be certain that others will not independently develop similar technologies on their own, gain access to ReNerve's trade secrets or have disclosed to them such technologies. This could allow competitors to commercialise products in competition with ReNerve's products and erode its competitive advantage.
Product liability	Any defects in ReNerve's products may harm ReNerve and its customers' reputation and business. ReNerve may also be subject to warranty and liability claims for damages related to defects in its products. There may also be adverse events reported from the use, misuse or defects of ReNerve's products which could expose ReNerve to product liability claims or litigation. Additionally, there may even be instances where if there is a serious adverse event, which is not explicitly linked to the product, such as the death of a patient (because of a clinician or natural causes) who has used the product, then this may trigger a product recall and or review.
Product recall	A product recall could be imposed if there is a serious adverse event (SAE). This risk exists even if a product is cleared or approved for commercial sale by the FDA or other regulatory authorities and manufactured in facilities licensed and regulated by the FDA or other regulatory authorities.

Key Risks

Reliance on key personnel	There can be no assurance that ReNerve will be able to retain key personnel. The departure of key personnel may adversely affect ReNerve until suitable replacements are recruited.
Further testing risk	ReNerve may be required to undertake further testing or clinical trials of its products (if it was direct to by regulators) which, by their very nature, are uncertain in their outcome. The trials also become more complex and larger over time. The trials may fail to reach their designated endpoints, the consequence being that ReNerve's proposed device may not be an effective treatment.
Limited history in product development	ReNerve has only successfully brought to market a single nerve repair product (the ReNerve NervAlign® Nerve Cuff) and is dependent on successfully developing and achieving regulatory approval for additional products to implement its strategy of offering a full range of nerve repair products in the U.S. market. There is no guarantee that it will be able to develop and/or achieve regulatory approval for such additional products withing the timeframes and/or costs expected. As a result, ReNerve's business prospects could be adversely affected, which could reduce ReNerve's revenues, profitability, standing in the investment community and negatively affect its share price.
Reputational risk	ReNerve's reputation is important to its position in the medical devices and nerve repair industries. Reputational damage may be caused in many ways, including adverse outcomes in clinical trials, adverse reactions to products, product contamination issues and employee malfeasance.
Activity levels in key industry sectors may change	ReNerve's client base is spread across the healthcare sector. Any adverse developments which impact the healthcare sector, could have the potential to in turn impact the demand for ReNerve's products, which could adversely impact the future financial performance of ReNerve.

Significant Contracts

Leader Development Agreement	On 4 May 2018 ReNerve entered into a Product Development and Supply Agreement (Leader Development Agreement) with Leader Biomedical Europe Holding B.V (Leader) under which ReNerve and Leader agreed to work on developing a collagen patch derived from porcine pericardium for use in the surgical repair of neural injuries. Over the next 4 years Leader and ReNerve worked to develop what has become the ReNerve NervAlign® Nerve Cuff and IP that has the potential to be used in the NervAlign® Nerve Conduit. Under the Leader Development Agreement Leader became the owner of the IP developed under the agreement and agreed to grant ReNerve a licence to it, subject to certain conditions. The results independently generated by ReNerve, including the Product Dossier which includes the comprehensive technical data necessary to obtain and maintain registration approval, are ReNerve's exclusive IP. The agreement contemplated that Leader would nominate its sister entity EMCM to undertake manufacturing and supply of the products developed under the agreement.
Leader License Deed	On or about 27 July 2023 Leader and ReNerve entered into a Deed of Termination, Release and Licence (Licence Deed) under which the 2018 Leader Development Agreement and all rights under it were terminated and Leader granted to ReNerve a non-exclusive, worldwide, revocable, perpetual, royalty-free licence of the IP developed under the Leader Development Agreement including intellectual property rights surrounding and supporting its eCOOTM technology, eCOOTM Clean and related intellectual property (Leader IP). The Licence is revocable by Leader if ReNerve breaches the terms of the licence or the EMCM Agreement. So long as the EMCM Agreement remains on foot ReNerve is not entitled to sublicence the Leader IP. If EMCM breaches the EMCM Agreement ReNerve may sublicence the Leader IP to an alternative manufacturer
EMCM Agreement	On 28 July 2023 ReNerve entered into a Product Development and Supply Agreement with EMCM B.V. (EMCM) (EMCM Agreement). This agreement was contemplated in the 2018 Leader Agreement and in the period leading up to 2023 Leader effectively ceased manufacturing operations and shifted them to EMCM. Under the EMCM Agreement, EMCM is responsible for the commercial manufacture and supply of the ReNerve NervAlign® Nerve Cuff product. The agreement provides that EMCM will manufacture and supply to ReNerve the products listed in Exhibit A to the agreement (Products). Exhibit A sets out the specifications for the NervAlign® Nerve Cuff. The Company will be responsible for paying EMCM fees with respect to the manufacture of the Products, but no royalty fees will be payable to EMCM. The EMCM Agreement requires EMCM to procure that Leader grant to ReNerve a licence to the Product IP to permit marketing of ReNerve's products. This licence was granted to ReNerve under the Leader Licence Deed. Under the EMCM Agreement ReNerve agrees not to arrange for a third party to manufacture the Products and EDMCM undertakes not to sell the Products to third parties. EMCM also agrees not to develop for its own commercial purposes or for third parties products of similar intended use to the Products. If ReNerve does not meet conditions referred to as "Exclusivity Conditions" which are effectively purchasing pre-agree quantities of the Products set out in Exhibit B to the agreement, this form of exclusivity will be lost and EMCM will be free to manufacture for itself or third parties. ReNerve has the ability to pay out E20,000 per cancelled batch to buy out the termination of exclusivity. ReNerve has met all of these requirements to date. Title in Products manufactured by EMCM passes to ReNerve on payment by ReNerve to EMCM. EMCM is entitled to increase the prices for Products annually by not more than Netherlands CPI. EMCM provides some limited warranties on the Products including a warranty that Products will have a shelf life of 30 months from delivery. Unless terminated for default or by agreement the EMCM Agreement remains in force for 5 years until 28 July 2028 after which it continues indefinitely until one of the parties gives 18 months' notice of termination.

Please refer to section 10 of the ReNerve Ltd Prospectus for full disclosure on all significant contracts.