RENERVE LIMITED (ASX:RNV)

Equity Research Report – 29 January 2025

Capital Structure	
Current price per share	A$0.135
Intrinsic value per share	A$0.365
Potential upside	170%
Ordinary shares on issue	141,837,806
Market capitalisation	A$18.4m
Options outstanding*	5,801,594
Total shares and options	147,639,400

*Includes 750,000 40c options and 750,000 50c options held by Canary Capital Pty Ltd expiring 25/03/2025

Major Shareholders	
Dr Julian Chick	9.82%
Dr David Rhodes	8.13%
Stephen Cooper	7.17%
Ropehawn Investments	4.26%
Alexios Adamides	3.46%

Board of Directors

- Stephen Cooper – Non-Exec. Chairman
- Dr Julian Chick – Exec. Director and CEO
- Dr David Rhodes – Executive Director and Chief Scientific Officer
- Dr Michael Panaccio – Non-Exec. Director

Key Achievements To Date

- Achieved FDA approval for its first product, the NervAlign® Nerve Cuff, commencing sales in the US in 2022.
- Generated $177k in revenue in FY24, up 38% from $128k in FY23.
- Successfully raised $7m - the maximum subscription amount for its IPO to fund further product development of its NervAlign® product portfolio.

Research Team

Stuart Craigie – Associate Director

Nathan Oyet – Head of Research

Introduction. ReNerve Limited (ASX:RNV) is an Australian medical device company focused on developing and marketing medical devices to enhance surgical procedures and patient outcomes for invasive nerve surgery. The company's first product, the FDA-approved NervAlign® Nerve Cuff, is already available in the U.S. market, with three additional products currently in development.

The Scale of the Global Nerve Repair Market Continues to Grow. The global market for biological medical devices for peripheral nerve injury (PNI) repair was valued at USD$1.68Bn in 2023 and is forecast to grow to US$6.2Bn in 2031. ReNerve aims to capitalise on this growth through a multi-product strategy and by expanding into additional jurisdictions beyond the U.S., where its NervAlign® Nerve Cuff product is currently available. This approach positions the company to capture market share in a PNI market largely dominated by products that do not provide optimal patient outcomes, giving ReNerve a significant competitive advantage.

Strong Market Traction and Growing Adoption. ReNerve has demonstrated market traction since the recent launch of the NervAlign® Nerve Cuff in 2022. Sales reached $177k in FY24, marking a 38% increase from $128k in FY23. This growth reflects the increasing awareness of the NervAlign® Nerve Cuff's ability to deliver superior patient outcomes, driving its adoption among hospitals and surgeons across the U.S. ReNerve's ongoing investment in a targeted sales and marketing strategy is expected to further accelerate revenue growth and solidify its position as a superior product in the market.

Significantly Undervalued on an Intrinsic Basis. ReNerve presents a compelling investment opportunity, with its intrinsic value significantly underappreciated by the market. Driven by the increasing adoption of its products in the U.S. and the anticipated launch of new offerings, we project the company will generate $16.8m in revenue by FY34. With the high-margin profile of its product portfolio, ReNerve is expected to achieve free cash flow margins of 27%. Using a discounted cash flow (DCF) valuation, we estimate the company's fair value per share at $0.37, implying a substantial upside potential of approximately 170% from its most recent closing price.

INTRODUCTION

Company Overview

ReNerve is a company focused on developing and marketing innovative medical devices designed to improve surgical procedures and patient outcomes in nerve surgery. The company was founded to create a comprehensive portfolio of products tailored for hand and wrist, foot and ankle, breast, neurosurgical, and plastic surgical procedures. These products aim to enhance the repair and regeneration of peripheral nerves, ultimately delivering superior patient outcomes. ReNerve seeks to achieve this by developing and offering solutions that:

- protect nerve regrowth from scarring and the negative effects of inflammation;
- provide an ideal, debris-free environment for the nerves to regenerate and re-establish nerve function back to native condition and promote cell proliferation;
- absorbed naturally within 6 months which minimises the risks of post-surgery complications and longer-term detriment to the patient; and
- offer convenience and surgical ease of use to surgeons engaged in peripheral nerve injury repairs.

Peripheral Nerve Injuries Explained

Peripheral nerves are those located outside the spinal cord and central nervous system, playing a crucial role in everyday functions such as movement, walking, running, speaking, jumping, and eating. The proper functioning of peripheral nerves is essential for daily life. However, these nerves are vulnerable to damage from trauma, accidents, surgeries, or congenital conditions. As a result, restoring injured peripheral nerves is critical for improving quality of life and ensuring patients regain their essential abilities.

Peripheral nerve injuries (PNI) can result from trauma in one of three ways:

- Transections (cut) – nerves that have been partially or completely cut through severing the connection. Causes include knife wounds, gunshot wounds, motor vehicle accidents, surgical injuries and power tool accidents.
- Compression – crushing or compression of the nerve due to trauma or inflammation such as carpal and cubital tunnel.
- Neuroma – the result of amputations, ectomies such as mastectomies and gastrectomies.

All three of these nerve injury categories can severely impact the peripheral nervous system, adversely affecting the patient's sensory, motor and mixed functions. ReNerve is focused on developing products to better treat PNI, improve patients' quality of life and promote independence post-surgery.

Market Overview

ReNerve competes in the global nerve repair and surgical reconstruction markets. The global market for biological medical devices for peripheral nerve injury repair was valued at USD$1.68Bn in 2023 and is forecast to grow to US$6.2Bn in 2031, representing a compound annual growth rate (CAGR) of 17.8% (Global Nerve Repair Biomaterials Market Research Report, 2020-2031). In addition to the healthcare and economic burden (estimated in the US at US$4bn per annum), the impact on productivity of PNI is significant as most patients are of productive age and can face long periods of rehabilitation and varied post-surgery outcomes.

Product Overview

ReNerve is confident that its products offer superior nerve regeneration for patients with PNI when compared to existing treatment methods and competing nerve repair products. The company believes that incorporating its products into PNI surgical procedures can lead to significant improvements in patient outcomes, including reduced pain, enhanced motor function, increased flexibility, and better overall nerve recovery.

ReNerve currently has one (1) product with regulatory clearance for use in the US market along with a portfolio of three (3) additional products at varying stages of development:

- the NervAlign® Nerve Cuff (FDA approved and in market)
- the NervAlign® Nerve Conduit (in commercial development)
- the NervAlign® Nerve Guide Matrix (in commerical development)
- the NervAlign® Bionic Nerve (in research and development)

ReNerve will focus its resources on growing sales of the NervAlign® Nerve Cuff and advancing the development and commercialisation of other products for the U.S. and global markets. With a network of sales agents in the U.S., the company expects that expanding its product portfolio will drive incremental sales growth. Direct sales staff may be considered once the portfolio and sales volume warrant a more direct approach.

RENERVE FOUNDING STORY

Experience with the Problem

Founded in 2017, ReNerve was established by Dr Alex Adamides, Dr Julian Chick, and Dr David Rhodes, who brought together their expertise to improve both short- and long-term outcomes for patients undergoing surgery for peripheral nerve damage. Dr Adamides is a neurosurgeon, while Dr Chick and Dr Rhodes specialise in core science, biotechnology development, and commercialisation, with a focus on tissue-based medical devices.

Founded to Fill a Gap

Most nerve repair products are part of broader portfolios, with Axogen being the only medical device company focused exclusively on peripheral nerve repair. ReNerve was founded to develop a specialised portfolio that addresses the surgical and physiological needs of peripheral nerve injury repair, offering surgeons easy-to-use, convenient products that complement their skills and improve patient outcomes.

EXISTING PNI TREATMENT METHODS

Few Effective Options Available

Effective options for peripheral nerve injury repair are limited, and long-term patient outcomes are often poor, with many experiencing some level of lost functionality and related physical and mental health challenges. ReNerve's products are designed to enhance the repair, regeneration, and regrowth of damaged peripheral nerves, leading to improved sensory and motor function and better long-term quality of life for patients.

Suboptimal Patient Outcomes

Historically, the gold standard for repairing severely damaged peripheral nerves has been autologous nerve grafts, where nerves are harvested from the patient's own body. This process can lead to comorbidities and lasting damage at the harvest site. Donor tissue is an alternative but yields mixed patient outcomes and can involve surgical complications. Currently, there is no truly functional, off-the-shelf graft solution for nerve replacement that supports regeneration and restores mobility. ReNerve's products aim to fill this gap.

The table below provides details on the prevailing PNI treatment methods.

PNI Classification	Traditional Treatment Methods			ReNerve Alternatives
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 risks including chronic pain • Limited by the graft length	**Synthetic Conduits** • Limited direction for regrowth. • Increased failure rate >5mm gaps. • Repair relies on fibrin clot formation	NervAlign® Nerve Cuff NervAlign® Conduit NervAlign® Guide Matrix
Compression	**Vein Wrapping** • Requires additional surgical time • Specific surgical skill • Creates second 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	NervAlign® Nerve Cuff NervAlign® Guide Matrix
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** • Estimated success rate is only ~40.0% • Temporary solution that reduces over time • Pharmacological side effects	NervAlign® Nerve Cuff NervAlign® Guide Matrix

Product Portfolio Strategy

ReNerve is focused on expanding its pipeline of nerve repair products to offer surgeons a comprehensive portfolio that enhances post-surgery outcomes for patients. Once these products are on the market, the company plans to leverage its expertise and infrastructure to develop additional offerings. With its core technologies and capabilities, ReNerve is well-positioned to extend its product pipeline into related fields such as dura mater replacement and soft tissue repairs, where current patient outcomes are sub-optimal and treatment options are limited.

RENERVE PRODUCT PORTFOLIO

Nerve injury outcomes vary, with more extensive damage—such as longer nerve injuries—typically leading to poorer patient outcomes due to limited treatment options. ReNerve is developing a portfolio of tissue-based nerve repair products that are safer and cleaner than existing alternatives, aiming to deliver improved patient outcomes. These products target the repair or replacement of peripheral nerves damaged by trauma, malignancy, or surgery. Designed for ease of use, they also help reduce hospital waste and costs, making them a practical choice for surgeons.

To offer newer, better solutions, ReNerve has four key products, each of which is at a different stage of development and commercialisation.

	NervAlign® Nerve Cuff	NervAlign® Nerve Conduit	NervAlign® Nerve Guide Matrix	NervAlign® Bionic Nerve
				
Product	Used on damaged or transected nerves with no gaps or gap closure	Improved Nerve Cuff developed from $scCO_2$ tissue, offering a 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	Uses the nerve guide matrix with ionic polymers to replace injured and damaged nerves with 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
Benefits	• Bio-absorbed removing the 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

eCOO™ Technology

An Effective Method to Clean Tissue. ReNerve's first two products, the NervAlign® Nerve Cuff and NervAlign® Nerve Conduit, are based on technology developed in collaboration with Leader Biomedical Europe B.V. (Leader) and its sister company, European Medical Contract Manufacturing B.V. (EMCM). Leader owns the proprietary eCOO™ technology, which uses supercritical CO_2 in the eCOO™ clean method to decellularise porcine tissue for nerve repair. This process removes organic materials, nuclei, and cellular proteins, inactivates potential pathogens, and leaves a clean scaffold for tissue repair. ReNerve holds an exclusive license from Leader to use the eCOO™ Clean method for producing nerve repair products.

Supercritical CO_2 Explained. Supercritical CO_2 is carbon dioxide in a pressurised state that exhibits both gas and liquid properties. As a non-toxic, powerful solvent, it effectively penetrates tissue, removing cells and organic matter while preserving the extracellular collagen matrix. This makes it ideal for cleaning and sterilising tissue, as it permeates like a gas, cleans like a liquid, and is easily removed by pressure release. The CO_2 cleaning method produces tissue scaffolds that retain their structural and mechanical properties while being free from cell debris and reducing pathogen contamination. The eCOO™ Clean method further minimises processing residuals and denaturation of the extracellular matrix, ensuring that porcine tissue is clean, safe, and facilitates FDA clearance.

The Ideal Final Product for Nerve Regrowth. The final tissue product is an inert Type 1 collagen membrane that retains its natural cross-linking for strength and structural integrity while promoting cell attachment and enabling tissue regrowth. Its properties make it ideal for reconstructive and repair surgeries. As it is prepared without detergents or ethylene oxide, it is considered safer for patients than competing products, reducing potential litigation risks for hospitals.

NERVALIGN® NERVE CUFF

Product Overview

ReNerve's first product, the NervAlign® Nerve Cuff, was developed over four years in collaboration with Leader and EMCM, based on the eCOO™ Technology. It received FDA clearance as a medical device in February 2022 and is manufactured by EMCM using porcine tissue cleaned with eCOO™ Technology. The Nerve Cuff is currently available in the US and New Zealand.

Better Patient Outcomes Backed by Scientific Studies

The ReNerve NervAlign® Nerve Cuff is a pliable, semi-permeable, resorbable collagen membrane designed to protect traumatised but intact nerves, short gap nerve repairs, and suture sites of nerve grafts. Because the tissue product is biodegradable, it prevents scarring and excess inflammation while allowing nutrients and neurotrophic factors to facilitate nerve repair. Studies show that when implanted around nerves, the cuff prevents neuroma formation, causes no adverse nerve changes, and is fully resorbed, allowing for full nerve recovery within six months. Highly rated for its pliability and ease of use in surgery, the NervAlign® Nerve Cuff can also be combined with cell and regenerative therapies to improve patient recovery, making it suitable for a broad range of nerve repair and replacement procedures.

Competing Alternatives Offer Subpar Value

Several nerve cuff and wrap products are available, including FDA-approved options from companies like Integra, Stryker, and Axogen. However, many use traditional detergents and toxic chemicals in manufacturing, with some sterilised using ethylene oxide. None of these products utilise the eCOO™ Technology or offer the combination of surgical ease, structural, and mechanical properties that promote cell attachment and full resorption post-surgery.

The NervAlign® Nerve Cuff can be used alone as a protective wrap around damaged or replaced nerves, or in combination with the NervAlign® Nerve Guide Matrix and Bionic Nerve replacement to safeguard suture sites. It is also suitable for nerve transfer, 'supercharging' procedures, and reimplantation of harvested grafts or allografts.

Low Cost of Production

The ReNerve NervAlign® Nerve Cuff is cost-effective to produce, with a scalable manufacturing process. Its production cost is under 10% of the list prices of competing products.

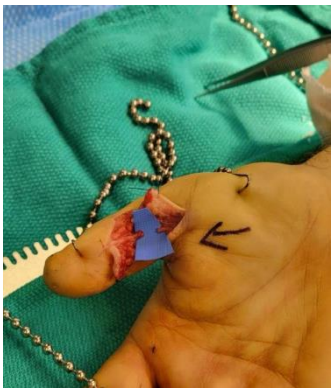
ReNerve NervAlign® Nerve Cuff Benefits

The key benefits of the NervAlign® Nerve Cuff are:

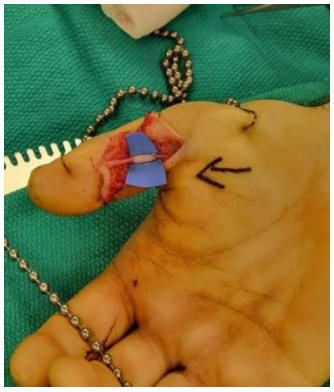
- Semi-permeable – permits small nutrients and neurotrophic factors to pass through while blocking scar-forming cells. Studies show post-implantation remodelling and neovascularisation in the fascia surrounding the nerve cuff.
- Highly biocompatible – porcine Type 1 collagen is non-inflammatory and well-accepted by the body.
- Completely absorbable – the collagen matrix degrades whilst the nerve is repairing. It is degraded and resorbed by normal metabolic processes.

- Easy to use – the NervAlign® Nerve Cuff can be applied as a flat or tubular implant to protect repaired nerve injuries. Its pliability allows it to conform to the shape of the nerve, enabling tension-free repair of transected nerves.
- Non-toxic manufacturing process – important with changing requirements for devices in theatre. No ethylene oxide sterilisation.
- Low immunogenicity and no residual cells or nuclei.
- High surgical performance rating as the material is pliable and conforms around the nerve.
- Strong and yet thin making it suitable for all transected nerve repairs, particularly fingers, hands and feet.

NervAlign® Nerve Cuff used in the repair of nerve damage in the thumb

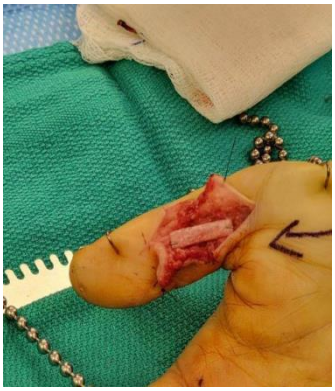


Damaged nerve removed from the right thumb



Removed gap filled with a conduit

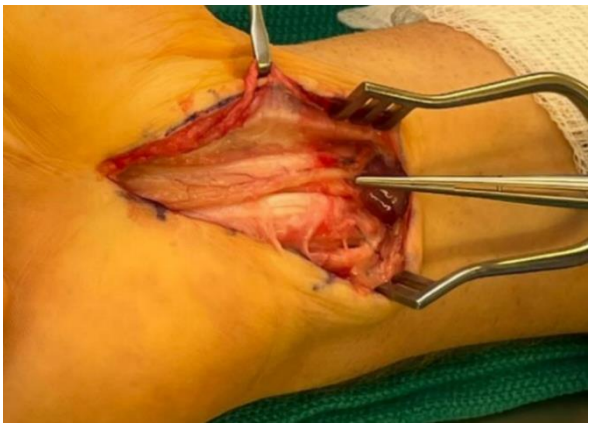
ReNerve NervAlign® used to protect the cuff conduit implant



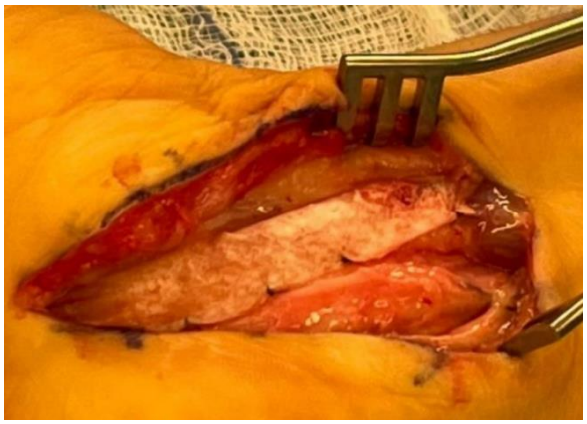
Completed repair held in place with micro clips

Source: ReNerve

NervAlign® Nerve Cuff used in carpal tunnel PNI repair



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

Source: ReNerve

NERVALIGN® NERVE CONDUIT

Product Overview

ReNerve's second product, the NervAlign® Nerve Conduit, is being developed for the repair of peripheral nerves with small gaps caused by injury or damage. Using the same eCOO™ clean method as the NervAlign® Nerve Cuff, the conduit will be made from porcine tissue. Designed to be implanted between the cut ends of a nerve, it provides structural support and guides natural regeneration across gaps typically less than 2cm. Like the NervAlign® Nerve Cuff, it will be fully absorbed over time. Nerve conduit products also benefit from higher reimbursement rates in the US, leading to more frequent use in some hospital systems.

Developing a Commercial Scale Manufacturing Process

ReNerve has successfully developed prototypes of the NervAlign® Nerve Conduit in collaboration with EMCM. Initial tensile, compression, and rehydration stability tests have confirmed the prototypes possess the desired physical characteristics. These prototypes were hand-produced on a small scale, with the remaining challenge being the development of a process for commercial-scale manufacturing. ReNerve is exploring options for rolling equipment to enable large-scale production. Before seeking FDA clearance, the company plans to conduct several bench tests to demonstrate the conduit's strength, shelf life, and efficacy in a rat model for nerve gap repair.

Synergy with the NervAlign® Nerve Cuff

The NervAlign® Nerve Conduit complements the NervAlign® Nerve Cuff, targeting larger nerve defects. Both products will be distributed through the same sales infrastructure to the same customer base, offering more comprehensive nerve repair solutions. ReNerve anticipates that demand for the Nerve Conduit will be driven by its greater reimbursability and lower effective cost in certain US regions.

NERVALIGN® NERVE GUIDE MATRIX (GRAFT)

Product Overview

ReNerve is currently in the early stages of developing its Nerve Guide Matrix product. The NervAlign® Nerve Guide Matrix is intended to be a size-based range of 'off-the-shelf' Nerve Guides for the repair of damaged nerves, as alternatives to autologous harvested nerves and donor nerves.

Existing Methods Face Significant Challenges

Currently, when direct end-to-end repair of an injured nerve is not possible, the damaged segment is excised and bridged with a healthy autologous nerve graft, typically from the sural nerve, which supplies the foot. This approach requires an additional procedure and results in permanent sensory loss (numbness) and the potential for painful neuromas. Moreover, the sural nerve's diameter and structure may not match the damaged nerve, leading to size mismatches and suboptimal outcomes. In cases of extensive injuries requiring long or multiple grafts, the availability of healthy autologous nerves may be limited. Overall, using patient-harvested nerves for repair has several drawbacks, including longer surgery times, loss of function at the harvest site, and an increased risk of infection.

Processed nerves from human cadavers, such as Axogen's Avance product, provide an "off-the-shelf" alternative to autologous grafts. However, cadaveric tissue availability is limited, and the product requires freezer storage, with the added drawback that it cannot be refrozen once thawed. This makes it less practical than alternatives that can be stored at cold (4°C) or room temperature.

Enhancing Patient Outcomes with Precise Nerve Grafts

ReNerve's Nerve Guide Matrix aims to address nerve repair challenges by developing a large-scale process to isolate and decellularise nerves of various diameters and lengths, providing tailored nerve guide matrices. This approach is expected to deliver better patient outcomes by promoting stronger nerve regrowth compared to using harvested grafts, which are often mismatched in size. The NervAlign® Nerve Guide Matrix enables surgeons to repair transected nerves without the need for donor nerve harvest, reducing both the economic and physical impact of the procedure. Designed for immediate use, it facilitates nerve regeneration without requiring secondary surgery.

Development Progress

ReNerve has completed in-house development and sheep testing of the product, which is proposed to be made from porcine tissue using a unique cleaning process different from that used for the NervAlign® Nerve Cuff and Nerve Conduit. This cleaning process involves specific chemicals, treatment order, and times, with scaffolds packaged and sterilised by irradiation. ReNerve's method aims to achieve complete decellularisation, ensuring the body does not recognise the implant as foreign, thus reducing the risk of rejection and inflammation and eliminating the need for immunosuppressants. Prototypes have shown excellent results in sheep models, with nerve conductance returning to levels comparable to autologous repair at 10 months post-implantation.

Working Towards FDA Clearance

On 3 July 2023, ReNerve signed a Services Agreement with Collagen Solutions (US) LLC (Collagen USA). Under this agreement, Collagen USA will provide development services to help ReNerve obtain FDA regulatory clearance for its product as a medical device. Collagen USA has GMP capability and experience in developing products for clearance by the FDA. Collagen USA will have first right to propose manufacturing terms to ReNerve should regulatory clearance be obtained.

NERVALIGN® BIONIC NERVE

Product Overview

ReNerve is developing a 'bionic' nerve graft (Bionic Nerve) for repairing long nerve gaps. Initial prototypes are exploring natural collagen fibres and polymer technologies, aiming to create an off-the-shelf nerve graft that can be customised to replace damaged nerves. Currently, there are no effective options for replacing longer nerves (>3-5 cm), with existing solutions (donor or autologous tissue) offering inconsistent results. The NervAlign® Bionic Nerve will enable custom manufacturing of grafts in various lengths and diameters, incorporating electroconductive polymers to support electrical stimulation and accelerate nerve regeneration. ReNerve has two partnerships focused on developing bionic nerves: one with 3D BioFibR (Canada), using collagen fibres, and another with Monash University, using patterned polymers.

Collagen Fibre-Based Bionic Nerves

ReNerve is collaborating with 3D BioFibR to leverage their proprietary, scalable collagen fibre deposition technology, which allows for the production of aligned collagen fibres that can be customised in diameter and length. This builds on previous research showing that nerve cells grow along patterned surfaces, guiding their growth. By directing nerve growth more effectively, it is believed that misdirected neurite extensions, which can lead to neuromas, can be reduced, promoting faster and more accurate regeneration. Additionally, the customisable fibres can incorporate molecules or conductive elements to further enhance nerve regrowth. Combined with the NervAlign® Nerve Conduit, these fibres form a complete nerve graft material.

Patterned Polymer-Based Bionic Nerves

ReNerve is collaborating with Monash University to develop patterned synthetic nerve repair materials, which have shown effectiveness in vitro in directing neuron growth. These materials exhibit good biocompatibility and are now undergoing animal testing to assess their suitability for nerve implantation and repair enhancement. Additionally, prototype patterned polymers coated with electroconductive materials are being tested for their potential to accelerate nerve recovery. This program holds promise for PNI and other nerve repair applications.

Prototype Development Ongoing

Bionic technologies have the potential to create "bionic nerves" of various diameters and lengths, offering simple off-the-shelf surgical solutions. The product is expected to be provided dry for long shelf life at room temperature, with rehydration before use. ReNerve believes the technology could extend beyond peripheral nerve repair, with potential applications in the central nervous system. The company will continue developing this program, aiming to create a prototype for testing in animal models.

INTELLECTUAL PROPERTY OVERVIEW

NervAlign® Nerve Cuff

In May 2018, ReNerve and Leader entered into a Product Development and Supply Agreement to develop a collagen patch from porcine pericardium for neural injury repair. Over four years, they developed the NervAlign® Nerve Cuff, supported by extensive research, including preclinical studies in rabbits and rats, which formed a key part of the data submitted to the FDA.

ReNerve claims ownership of the Product Dossier and the pivotal data required to obtain FDA clearance for the NervAlign® Nerve Cuff. In 2023, they signed a new agreement where Leader terminated the original 2018 agreement and granted ReNerve a non-exclusive, worldwide, royalty-free license to Leader's intellectual property, with exclusivity for nerve and neural repair products.

In the same year, ReNerve also entered into a Manufacturing and Supply Agreement with EMCM. Under this agreement, EMCM will exclusively supply the core product to ReNerve until July 2028, subject to ReNerve meeting specific obligations. As of now, ReNerve has complied with all its agreement terms. The license to Leader's IP remains valid as long as the EMCM agreement is in force and ReNerve continues to meet its requirements.

NervAlign® Nerve Conduit

ReNerve is advancing the development of the NervAlign® Nerve Conduit using eCOO™-treated porcine pericardium, the same material featured in its FDA-cleared NervAlign® Nerve Cuff. ReNerve plans to leverage the existing safety data package from the Nerve Cuff's approval process to streamline regulatory approvals for the Nerve Conduit. As eCOO™ technology is proprietary to EMCM, the manufacturing of the Conduit will also be handled by EMCM. While ReNerve and EMCM have collaborative arrangements in place for the Conduit's development, they have not yet formalised these arrangements into a definitive agreement.

NervAlign® Nerve Guide Matrix

ReNerve has developed a proprietary process for creating nerve guide matrix products that more precisely match human nerve structures. Their unique method effectively cleans nerve tissues while maintaining structural integrity, potentially improving patient outcomes by enhancing nerve regrowth. To protect its intellectual property, ReNerve will maintain the process as a trade secret, safeguarded through confidentiality agreements. While currently focusing on keeping the core process confidential, the company is exploring patent protection for the sterilisation and storage solutions used in preserving the final product.

NervAlign® Bionic Nerve

ReNerve has a collaborative research and development agreement with 3D BioFibR whereby the parties will conduct collaborative research, with 3D BioFibR using its proprietary technologies to create custom collagen parallel fibre arrays for use by ReNerve. Simultaneously, ReNerve is working with Monash University through the ARC Training Centre for Cell and Tissue Engineering Technologies to develop technologies for the development of patterned polymer-based bionic nerves. Monash University owns the project's intellectual property and has granted ReNerve an option to exclusively license the technology, with both parties committed to negotiating license terms that benefit Australia.

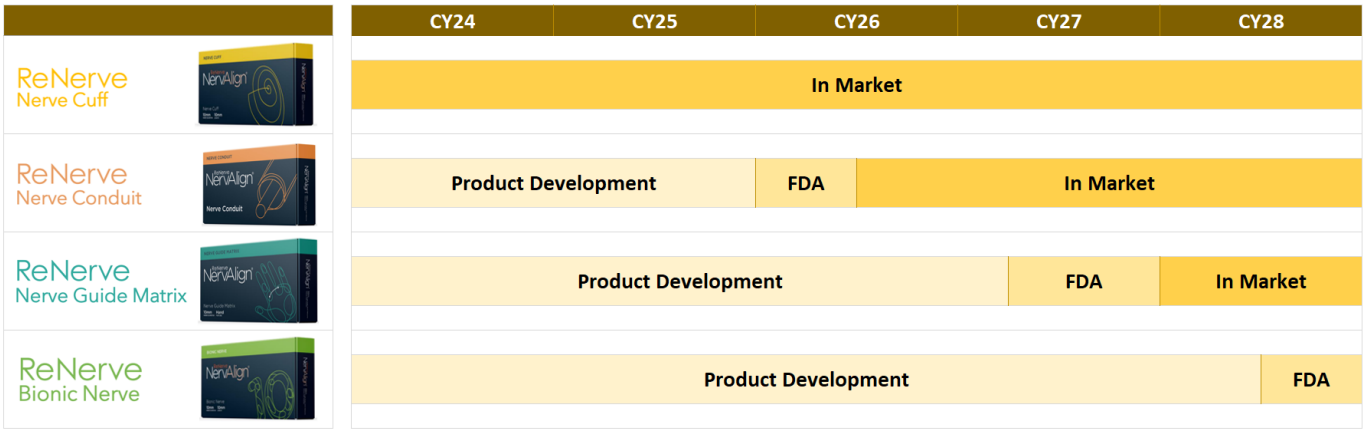
In-House Research and Development

ReNerve has established an in-house research facility in Melbourne, to accelerate the development of its NervAlign® Nerve Guide Matrix and NervAlign® Bionic Nerve technologies. By providing dedicated laboratory space and full-time access for its research staff, the company aims to streamline its innovation process from technological development through to manufacturing. Complementing this internal capability, ReNerve will continue to collaborate with universities and research organisations to leverage additional technological expertise.

Commercialisation Timeline

The NervAlign® Nerve Cuff is currently available on the market, while the NervAlign® Nerve Conduit, Nerve Guide Matrix, and Bionic Nerve are in development. ReNerve anticipates completing development of the NervAlign® Nerve Conduit in the second half of 2025, aiming for FDA approval and a market launch in early 2026. Development of the NervAlign® Nerve Guide Matrix is projected to conclude in the first half of 2027, with FDA approval and market introduction targeted for early 2028. Meanwhile, the NervAlign® Bionic Nerve remains in ongoing development, with a launch timeline yet to be determined.

ReNerve is progressing towards the commercialisation of additional NervAlign® products to complement the NervAlign® Nerve Cuff that is currently in market



Source: ReNerve

ReNerve currently relies on EMCM to manufacture and package the NervAlign® Nerve Cuff for global distribution, with Kuro handling third-party logistics to the US market. While EMCM is expected to potentially manufacture the NervAlign® Nerve Conduit, no formal agreements are in place. Additionally, ReNerve has partnered with Collagen Solutions to develop and produce a GMP-manufactured Nerve Guide Matrix, which the company plans to distribute through its existing US channels.

SALES AND MARKETING STRATEGY

Overview

ReNerve has an initial focus on the US market, having achieved FDA clearance for marketing in this jurisdiction. However, ReNerve will look to expand sales to other countries, particularly as it finds partners in other attractive markets.

United States

In February 2022, ReNerve received FDA 510(k) clearance for its NervAlign® Nerve Cuff. After registering as an establishment in May 2022, the company made its first US sales in July and initiated a soft product launch in October.

ReNerve has implemented a cost-efficient sales and marketing strategy focused on minimising fixed expenses by utilising commission-based sales agents. The company has strategically divided the United States into five key regions and aims to establish at least one productive sales agent in each area. Their recruitment strategy prioritises agents with expertise in biological tissue products and existing connections with surgeons specialising in peripheral nerve injury repairs. Currently, they have a lead sales agent in California (Emerging Surgical) and are developing sales relationships across the country. As the Company expands its product portfolio and achieves higher sales volumes, ReNerve will evaluate the potential benefits of employing direct sales personnel to enhance and complement its existing sales and marketing infrastructure.

ReNerve's market entry into the US has enabled the company to generate sales, raise brand awareness, build a customer base of hospitals and surgeons, and establish a foothold in the US medical device market. Going forward, a key factor in delivering sales growth will be ensuring hospital entrance and reimbursement. Both the NervAlign® Nerve Conduit and the NervAlign® Nerve Guide Matrix are covered under existing FDA Current Procedural Terminology (CPT) coding which cover nerve repairs and nervous system procedures.

New Zealand

ReNerve registered the NervAlign® Nerve Cuff in New Zealand through its local sponsor, CARSL Consulting, in late December 2021 via the Web Assisted Notification of Devices (WAND), which is administered by the New Zealand Medicines and Medical Devices Safety Authority (MedSafe). The company is exploring partnerships with local medical device and product distributors to distribute the NervAlign® Nerve Cuff.

Taiwan

In August 2022, ReNerve entered into a commercial partnership with Yuan Yu in Taiwan to gain approval for and market the product in Taiwan. The two companies are well advanced through the product registration process and anticipate approval of the NervAlign® Nerve Cuff in early 2025.

Hong Kong and Macau

In early December 2024, ReNerve announced it had partnered with Accession Medical Supplies Co into an exclusive distribution agreement for sales and marketing in Hong Kong and Macau. The agreement relates to ReNerve's primary product, the NervAlign® Nerve Cuff. ReNerve will leverage Accession's existing relationships with local hospitals and surgeons to drive sales, which in turn will assist in gaining regulatory approval and act as a gateway to the broader Greater Bay Area.

Middle East

On December the 10th 2024, ReNerve announced an exclusive partnership with Union MediScience B.S.C. The agreement covers five countries across the Middle East: Bahrain, Saudia Arabia, Kuwait, UAE/Dubai and Qatar. The agreement is for the exclusive distribution for the sales and marketing of the NervAlign® Nerve Cuff.

Additional jurisdictions

ReNerve will leverage its FDA 510(k) market clearance to seek regulatory approval for the NervAlign® Nerve Cuff in additional jurisdictions, such as Europe, South America and Australia. ReNerve will aim to work with local distributors to gain market approval and sales in these jurisdictions. Opportunities to enter additional markets will be evaluated on a case-by-case basis, considering estimated time and costs to achieve market entry as well as sales potential.

To support this international expansion, ReNerve is conducting comprehensive clinical studies to build a robust clinical data repository which will strengthen their regulatory submissions across different jurisdictions. As the company develops its product portfolio, the NervAlign® Nerve Cuff will benefit from a complementary product strategy. By offering a comprehensive suite of PNI repair solutions, ReNerve aims to position itself as a one-stop vendor for surgeons, potentially increasing market adoption.

INDUSTRY OVERVIEW

Introduction

ReNerve operates in the medical device sector, which is diverse and comprises devices from basic syringes and thermometers to surgical implantable tissue products. The annual global market for medical devices across all types is estimated to be in excess of USD$500bn. ReNerve is focused on the peripheral nerve injury repair market and some associated surgical applications. Specifically, ReNerve's technologies fall largely within the biomaterials market within medical devices and are included within the medical implantable biomaterials sector. The broader biomaterials market is projected to reach USD$47.5bn by 2025. The current market estimate for biological products in peripheral nerve repair is around USD$1.6bn.

Market Size

ReNerve primarily focuses on the US market, although over time it will also seek to enter the market in other jurisdictions. While estimates of the total size of the global peripheral nerve market vary, the Global Nerve Repair Biomaterials report (2024) values the total market size at USD$1.688bn. The report projects that the market will grow at a rate of 17.8% per annum through 2031. The current market and its growth are being driven by advances in biomaterials, new products coming to market, and an increased awareness of the opportunities for the treatment of nerve repair.

Estimates from the Global Nerve Repair Biomaterials report suggest that the global market size for the three product ranges that ReNerve is developing are as follows:

Product Type	2024 Estimated Market (USD$M)	2030 Estimated Market (USD$M)	Estimated Annual Growth Rate
Nerve Cuff	$314m	$975m	17.56%
Nerve Conduit	$1,015m	$3,219m	17.91%
Nerve Guide Matrix	$635m	$1,991m	17.71%
Total	$1,965m	$6,186m	17.8%

Source: Global Nerve Repair Biomaterials Market Research Report, 2020-2031

COMPETITIVE LANDSCAPE

Several companies have products on the market for peripheral nerve injury repair. Axogen is the market leader and has a full range of products on the market (2024 sales anticipated to be ~US$184m (A$300m). Following Axogen are Integra and Stryker, which also offer a range of products. A few other companies offer nerve wraps but do not have a broader range of products. These include Orthocell, Checkpoint Surgical, Alafair Biosciences and Biocircuit. The following table summarises the major market participants and the main products on the market.

Company	Product	ReNerve Alternative
Axogen	Nerve Protector	NervAlign® Nerve Cuff
	Nerve Connector	NervAlign® Nerve Conduit
	Avance Nerve Graft	NervAlign® Nerve Guide Matrix
Integra	NeuraGen Nerve Cuff	NervAlign® Nerve Cuff
	NeuraGen 3D Guide Matrix	NervAlign® Nerve Guide Matrix
Stryker	Neuroflex	NervAlign® Nerve Cuff
	NeuroMend	NervAlign® Nerve Conduit
	NeuroMatrix	NervAlign® Nerve Cuff
Orthocell	Remplir	NervAlign® Nerve Cuff
Checkpoint Surgical	NeuroShield Cuff	NervAlign® Nerve Cuff
Alafair Biosciences	Versawrap Cuff	NervAlign® Nerve Cuff
Biocircuit	Nerve Tape	NervAlign® Nerve Cuff

The NervAlign® Competitive Advantage

Several companies offer nerve cuff or wrap products, but these often have significant limitations. Many tissue-based medical devices were originally developed for other applications and lack the specialised characteristics needed for effective peripheral nerve repair. Consequently, many existing products deliver sub-optimal outcomes. In contrast, ReNerve designs its products specifically to meet the unique physiological and clinical requirements of nerve injury repair.

As a result of a targeted product development program, ReNerve products aim to provide both surgical convenience and better patient outcomes. In particular, ReNerve's products are designed and engineered to deliver:

- Therapeutic advantages and superior patient outcomes, with the following advantages:
  - specifically designed for the treatment of PNI
  - clean and green
  - minimisation of scarring
  - promotion of nerve re-growth
  - full absorption through natural body processes
- Convenience and ease of use for surgeons – designed with surgery in mind
- Low cost, thus allowing competitive pricing

Overall, ReNerve is aiming to build a competitive position in the market with a comprehensive portfolio of products to offer to surgeons. Given that all the ReNerve products are being designed to be stored at room temperature, they provide surgeons with the flexibility in theatre to select the product best suited for any particular peripheral nerve injury repair. The breadth of the product range will mean that ReNerve's products will provide solutions for all possible patient repairs.

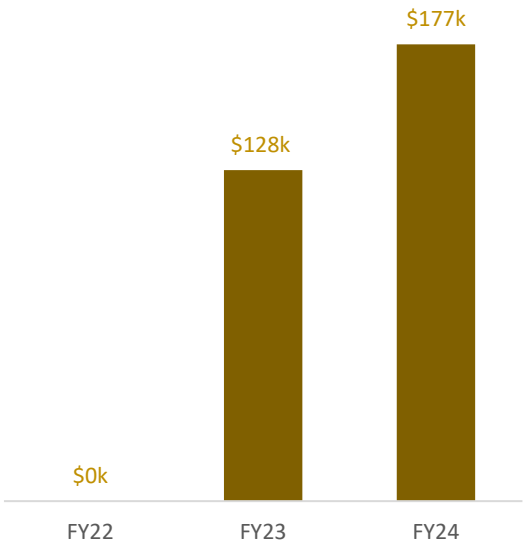
FINANCIAL OVERVIEW

Financial Performance

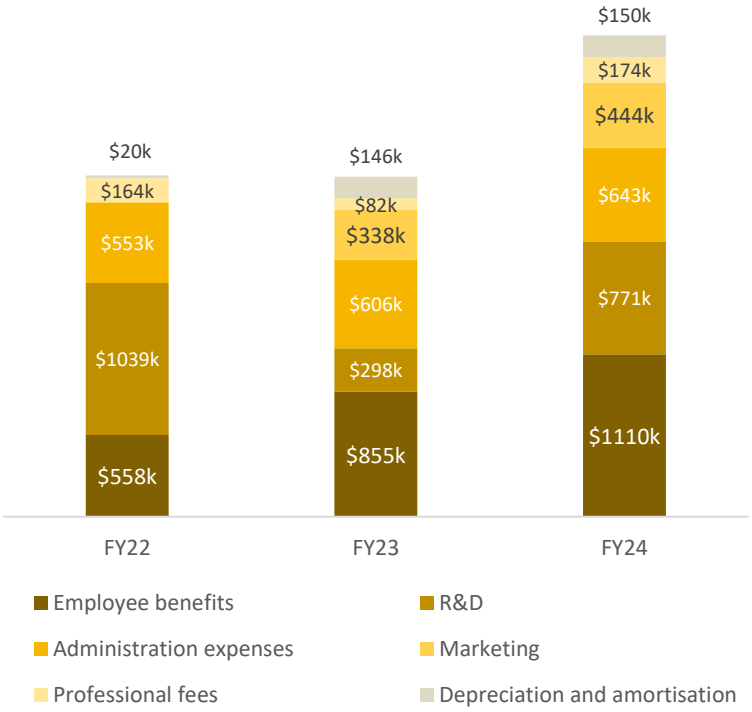
Growth in High-Margin Sales Revenue. Since launching its first commercial product, the NervAlign® Nerve Cuff, in July 2022, ReNerve has demonstrated solid revenue growth. The company generated $128k in revenue in FY23, which increased by 38% to $177k in FY24, fueled by rising adoption among hospitals and surgeons across the U.S. Notably, ReNerve maintained 90% gross profit margins in both fiscal years, reflecting the low production costs of the NervAlign® Nerve Cuff relative to the selling price.

Operating Expenditure Focused Product Development and Go to Market. In FY24, ReNerve's operating expenses totalled $3.3m, including $772k allocated to research and development (R&D) and $1.1m for employee salaries. The R&D investment focused on advancing the development of the NervAlign® Nerve Conduit and NervAlign® Nerve Guide Matrix, which the company views as strategic investments to drive future high-margin sales revenue. In addition to compensating management and directors, ReNerve invested in hiring sales agents in the US in line with its targeted sales strategy for the region.

Starting from a revenue base of zero in FY22, ReNerve has grown revenue significantly…..



….whilst investing heavily in product innovation and its sales engine



Source: ReNerve

IPO Capital Raise

On 26 November 2024, ReNerve successfully listed on the ASX, securing $7m - the maximum subscription amount for its IPO. The company intends to allocate these funds primarily to advance the development of its NervAlign® Nerve Conduit and NervAlign® Nerve Guide Matrix. Additionally, the proceeds will support working capital needs and cover ongoing operating expenses.

Use of funds	Amount
NervAlign® Nerve Conduit studies	$1.1m
Post-market study of the NervAlign® Nerve Cuff	$0.3m
NervAlign® Nerve Guide Matrix program	$3.0m
IPO costs	$0.9m
Working capital and operating expenses	$1.7m
Total	$7.0m

Financial Position

Following its IPO capital raise, ReNerve is estimated to have approximately $6.4m in cash on hand. With an operating cash burn of around $2.3m in FY24, the company is well-positioned to fund its operations and R&D programs without requiring additional capital in the short to medium term. ReNerve has zero debt meaning the company has a favourable net cash position which enhances its financial stability.

VALUATION

Overview

To arrive at an intrinsic valuation of ReNerve, a 10-year (FY25 – FY34) discounted cash flow model was used. We believe a 10-year forecast period is sufficient for the company to experience revenue growth from the commercialisation of its current product development pipeline, excluding the NervAlign® Bionic Nerve whose launch timeline is yet to be determined.

Revenue

Forecast Methodology. The revenue forecast for ReNerve during the projected period was derived by individually estimating revenue contributions from the NervAlign® Nerve Cuff, NervAlign® Nerve Conduit, and NervAlign® Nerve Guide Matrix product lines. A top-down approach guided this analysis, beginning with an estimation of the annual number of PNI repair surgeries conducted in the U.S., which market research places at approximately 900,000 in 2024. Between FY25 and FY34, we expect the number of surgeries to experience an annual growth rate of 0.50%. From this baseline, the adoption rate for ReNerve's products—defined as the proportion of surgeries expected to utilise each NervAlign® product - was estimated for the forecast period. This method allowed for a precise assessment of potential market penetration for each product line. A conservative assumption was made that each PNI surgical procedure involving a specific NervAlign® product would utilise only a single unit of that product.

NervAlign® Nerve Cuff Revenue. In FY24, the NervAlign® Nerve Cuff achieved an estimated adoption rate of 0.013% of total PNI surgeries, generating $177k in sales at a price per unit of ~$1,500. During the forecast period, this adoption rate is projected to grow significantly, driven by increasing awareness of the product's superiority and the expansion of ReNerve's sales and marketing efforts, including the hiring of direct sales personnel. The adoption rate is expected to rise to 0.020% in FY25 and 0.030% in FY26, resulting in revenues of $271k and $409k, respectively. Beyond FY26, adoption is anticipated to grow steadily, reaching 0.332% by FY34, corresponding to projected revenue of $4.7m.

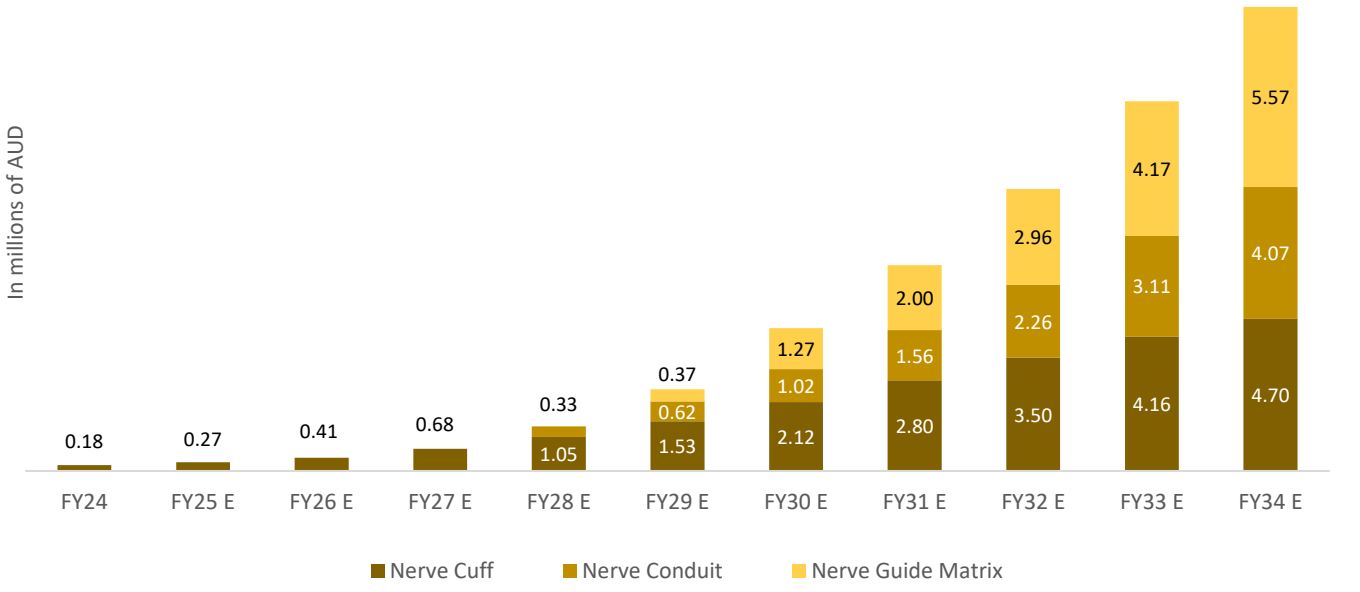
NervAlign® Nerve Conduit Revenue. We project the NervAlign® Nerve Conduit to launch at the start of FY27 at an estimated price of $2,100. Given the complementary nature of ReNerve's products in PNI repair procedures, we anticipate a higher initial adoption rate for the NervAlign® Nerve Conduit compared to the NervAlign® Nerve Cuff's first year on the market. Specifically, we expect the adoption rate for the NervAlign® Nerve Conduit to reach 0.017% in FY27, generating an estimated revenue of $325k.

As awareness grows among surgeons about the superior patient outcomes associated with the NervAlign® Nerve Conduit, the adoption rate is projected to climb steadily, reaching 0.255% by FY34, with an estimated revenue of $5.06m.

NervAlign® Nerve Guide Matrix Revenue. With FDA approval for the NervAlign® Nerve Guide Matrix anticipated by the end of CY27, sales are projected to begin in the second half of FY28 at approximately $4,800 per unit. By the time of its launch, ReNerve is expected to have significantly expanded its distribution network across the U.S. Consequently, the NervAlign® Nerve Guide Matrix is forecasted to achieve an annualised adoption rate of 0.025% during its initial half-year of sales, generating approximately $368k in revenue for FY28. This adoption rate is projected to increase steadily, reaching 0.234% by FY34, corresponding to an estimated revenue of $7.08m.

Consolidated Revenue. ReNerve's total revenue is expected to be $271k in FY25 and $409k in FY26 solely derived from sales of the NervAlign® Nerve Cuff. With the revenue contribution of the NervAlign® Nerve Conduit and NervAlign® Nerve Guide Matrix, total revenue is expected to reach $16.8m in FY34, implying a CAGR of ~51% from FY24.

Anticipated growth in market awareness of NervAlign®'s superior patient outcomes is expected to drive revenue growth across ReNerve's current and future products



Source: Canary Capital Estimates

Profitability and Free Cash Flow

Gross Profit Margin. Throughout the forecast period, we expect RNV's gross margin to remain flat at 90%. This is conservatively lower than the 99% gross margin that the company generated in FY24.

Operating Expenses. We project RNV will incur total operating expenses of approximately $3.9m in FY25 and $4.0m in FY26. Employee benefits are expected to account for the largest share of these expenses, totalling $1.49m in FY25 and $1.64m in FY26, driven by the planned expansion of the U.S. sales team. Additionally, RNV is forecasted to allocate $814k in FY25 and $1.43m in FY26 to R&D expenditure, reflecting ongoing investment in its product development initiatives.

As the company scales, operating leverage is anticipated from its fixed cost base, leading to a gradual reduction in employee benefits and administrative expenses as a percentage of revenue. Similarly, R&D expenses are expected to decline proportionally as more products currently under development enter the market. Consequently, operating expenses as a percentage of revenue are projected to decrease significantly, dropping from 1,857% in FY24 and 1,444% in FY25 to 68% by FY34.

Operating Income and Net Operating Income After Tax (NOPAT). As RNV continues to benefit from operating leverage, its operating profit margin is projected to improve significantly, rising from -1,756% in FY24 to 22% by FY34. This improvement is expected to generate operating income of $3.7m in FY34, with the company anticipated to reach break-even by FY32.

Additionally, RNV has an estimated net operating tax loss of ~$9.5m, which can be applied to offset future taxable income. As a result, the company is not expected to pay taxes on its operating income during the forecast period. Consequently, RNV's net operating profit after tax (NOPAT) will be equal to its operating income throughout the forecast period.

Free Cash Flow (FCF). NOPAT is adjusted for net capital expenditures and changes in net working capital to calculate free cash flow (FCF). ReNerve is also projected to continue receiving R&D tax rebates based on eligible R&D expenditures. We conservatively estimate that the company will receive, on average, 42.5% of its R&D spending as a cash refund, compared to the 58.6% average received over the past three years. This R&D refund is included in the FCF to determine the adjusted FCF. In FY25, ReNerve is projected to report an adjusted negative free cash flow (FCF) of $3.14m, with a turnaround expected by FY34, when FCF is anticipated to reach $4.62m, reflecting a strong margin of 27%.

In millions of AUD	FY24	FY25 E	FY26 E	FY27 E	FY28 E	FY29 E	FY30 E	FY31 E	FY32 E	FY33 E	FY34 E
Revenue	0.18	0.27	0.41	1.01	2.04	3.82	5.69	8.02	10.77	13.80	16.85
% Growth (YoY)	*38.0%*	*53.1%*	*50.8%*	*146.5%*	*102.1%*	*87.4%*	*48.8%*	*41.0%*	*34.3%*	*28.1%*	*22.1%*
Operating Income	(3.12)	(3.68)	(3.69)	(3.15)	(3.81)	(3.87)	(2.52)	(1.04)	0.33	2.00	3.71
% Margin	*-1756.3%*	*-1354.0%*	*-900.0%*	*-312.0%*	*-187.0%*	*-101.3%*	*-44.4%*	*-13.0%*	*3.1%*	*14.5%*	*22.0%*
Adjusted FCF	(2.15)	(3.14)	(2.84)	(2.76)	(3.31)	(3.47)	(2.16)	(0.68)	0.86	2.71	4.62
% Margin	*-1210.7%*	*-1155.1%*	*-693.3%*	*-273.4%*	*-162.3%*	*-90.7%*	*-38.0%*	*-8.4%*	*8.0%*	*19.6%*	*27.4%*

Equity Valuation

Discount Rate. The WACC methodology was used to calculate the discount rate for ReNerve's future cash flows. The cost of equity, set at 7.41%, was derived using an implied risk premium of 4.04% and the Australian 10-year T-Bond rate of 4.30%. The biotechnology industry average unlevered beta of 0.77 for Australia and New Zealand was applied to calculate levered beta. As ReNerve has no debt, its WACC equals its cost of equity at 7.41%. To account for the higher risk of being a small-cap company, a 2.5% small-cap premium was added, resulting in a final discount rate of 10.41%.

Intrinsic Valuation. Using the discount rate, ReNerve's cash flows and terminal value, calculated using the Gordon growth model, were discounted to arrive at an enterprise value of $45.40m. Adding RNV's estimated net cash of $6.4m results in an equity valuation of $51.80m. Given the total shares outstanding of 141.84 million, the company's estimated fair value per share is $0.365, representing a significant upside potential of 170% from its latest closing price of $0.135.

It is important to highlight that our revenue forecasts used in the valuation are conservatively limited to the U.S. market and do not account for potential expansion into international markets such as Australia, Europe, and the Middle East. Additionally, the projections exclude potential revenue from the NervAlign® Bionic Nerve, which could represent a substantial revenue growth opportunity.

Comparable Company Analysis

Companies operating in the PNI repair market comparable to ReNerve command significantly higher market valuations, underscoring the substantial value potential within this sector. ReNerve's products, which deliver superior patient outcomes compared to those of its peers, position the company to narrow the valuation gap as its revenue base expands. We anticipate that as ReNerve scales its operations and captures greater market share, its market valuation will align more closely with more mature peers in the PNI repair market.

In millions of AUD	Market Cap	Enterprise Value	Last FY Revenue
Integra Lifesciences	2,909	5,594	2,418
Axogen Inc	977	1,039	249
Orthocell Limited	274	240	5

Source: As at 16/12/2024

KEY PEOPLE

Board and Management

Stephen Cooper (Non-Executive Chairman). Stephen Cooper is a director of Grant Samuel Group Pty Limited, a leading independent Australian investment banking business. 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. He has served as the chairman of an ASX-listed biotechnology company, Avexa Ltd.

Michael Panaccio (Non-Executive Director). Michael Panaccio is a co-founder of Starfish Ventures, a venture capital firm specialising in early-stage technology companies, where he actively manages its portfolio. He has served as a director for numerous tech businesses in Australia and the US, including SIRTeX Medical Ltd, Engana Pty Ltd (acquired by Optium Inc), Energy Response (sold to EnerNoc Inc), ImpediMed Ltd, and Protagonist Therapeutics Inc. Currently, he sits on the boards of dorsaVi Ltd, MetaCDN Pty Ltd, Margin Clear Pty Ltd, Marp Therapeutics Pty Ltd, and Cylite Pty Ltd.

Julian Chick (Executive Director and Chief Executive Officer). Dr Julian Chick is an experienced healthcare executive with over 25 years' experience in senior management including in Avexa and Admedus. His roles have included 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. Dr Chick 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. He has ten years of experience in investment banking and advisory and has also held a role as an analyst reviewing healthcare and biotechnology investment opportunities for private equity investors and venture capitalists. Julian has a PhD in Muscle Physiology and is currently a non-executive Director of LTR Pharma (ASX: LTP).

Dr David Rhodes (Executive Director and Chief Scientific Officer). Dr David Rhodes brings over 20 years of experience in the healthcare and biotechnology sectors, holding senior roles across several ASX-listed companies. His previous positions include Senior Researcher at Amrad, Chief Scientific Officer at Admedus Ltd, and Senior Vice President of Biology and Head of Drug Discovery at Avexa Ltd.

Dr Rhodes has successfully led numerous technology development programs, securing substantial funding from State and Federal Government initiatives and research institutes. A published author in high-impact journals and inventor on multiple patents, he is also an Adjunct Associate Professor in the Faculty of Engineering at Monash University and formerly served on the Australian Regenerative Medicine Institute Leadership Advisory Board. Dr Rhodes holds a PhD in Biochemistry.

Scientific Advisory Board

Dr Michael Findlay (Chairperson). Dr Findlay is an Academic Reconstructive Plastic, Hand, and Microsurgeon from Melbourne, Australia, with prior appointments at Stanford University, USA, under Professor Geoffrey C. Gurtner. As a Fulbright Scholar and the inaugural Stanford Applied Regenerative Medicine (SARM) Fellow, he held roles as Visiting Assistant Professor (Research) and Clinical Instructor. His translational research in stem cell and tissue engineering focuses on addressing acquired defects in regenerative capacity to enable reproducible, transformative tissue regeneration for clinical use. During his PhD with Professor Wayne Morrison at the O'Brien Institute, Melbourne, he developed the world's first large-animal model for tissue-engineered breast reconstruction. Dr Findlay's clinical practice specialises in reconstructive surgery.

Dr Paige Fox (Stanford Medical). Dr Paige Fox is Board Certified Plastic Surgeon who specialises in hand surgery, reconstructive microsurgery, as well as peripheral nerve and brachial plexus surgery. Dr Paige Fox is an Associate Professor in the Division of Plastic and Reconstructive Surgery in the Department of Surgery. Dr Paige Fox works with adult and pediatric patients. Her research focuses on wound healing, disorders of the upper extremity, and surgical biosensors. Dr Paige Fox has a passion for sustainability and health care's effect on the environment. She is involved in efforts to green the OR and the clinics at Stanford University.

Dr Bryan Loeffler (Orthocarolina). Dr Loeffler specialises in the entire spectrum of hand and upper extremity disorders from the fingertips to the shoulder. Dr Loeffler has been awarded multiple research grants to fund various clinical studies as well as a basic science study on biological solutions to improve rotator cuff healing. Dr Loeffler has authored numerous book chapters and peer-reviewed articles on topics ranging from forearm injuries to shoulder and elbow replacement. Dr Loeffler has received numerous academic honours and achievements ranging from excellence in surgery to resident teaching awards. He has also participated in two international medical missions, providing orthopaedic surgical care in underserved areas.

Dr Mihir Desai (Associate Professor, Division of Hand and Upper Extremity). Dr Desai is a leading hand surgeon based in Tennessee. Dr Desai has worked in nerve surgery and nerve repair for over 10 years. Dr Desai specialises in hand and orthopedic surgery, fractures and sports medicine.

INVESTMENT THESIS

Clear Business Strategy

ReNerve is strategically positioning itself in the PNI repair market by focusing on the development of a portfolio of PNI repair products that will be marketed globally. After successfully obtaining marketing clearance for its flagship NervAlign® Nerve Cuff in the United States in 2022, the company is now focusing on international market penetration. By establishing partnerships with regional and country-based distributors, ReNerve aims to create a global footprint for its innovative medical technologies.

The company's near-term strategy involves seeking regulatory approvals for the NervAlign® Nerve Cuff in European markets and other key jurisdictions. Concurrently, ReNerve is developing two additional products - the NervAlign® Nerve Conduit and NervAlign® Nerve Guide Matrix - which will complement its existing offering. This multi-product approach is designed to position ReNerve as a comprehensive solution provider for surgical nerve repair.

By creating a diverse product portfolio, ReNerve intends to address the significant global shortage of optimised PNI repair products. The company's multi-product approach is expected to attract surgeons and hospitals seeking integrated, high-quality solutions, potentially unlocking substantial revenue opportunities across international markets.

High Barriers to Entry

ReNerve is well-positioned to maintain a competitive edge in the peripheral nerve injury (PNI) repair market, thanks to its robust IP portfolio, which creates significant barriers to entry for potential competitors. The company's strategic agreements with key partners, including Leader Biomedical and EMCM, provide a strong foundation for its IP protections. In May 2018, ReNerve entered into a Product Development and Supply Agreement with Leader Biomedical to develop a collagen patch for neural injury repair. This collaboration incorporated Leader's proprietary supercritical CO_2 manufacturing process and NovaSterilis' cleaning and sterilisation IP, contributing to the uniqueness of ReNerve's products. Additionally, ReNerve owns the product dossier and the pivotal clinical data required to obtain FDA clearance for its flagship product, the NervAlign® Nerve Cuff. This data, along with its ongoing clinical studies, strengthens ReNerve's ability to maintain regulatory exclusivity.

Beyond its partnerships, ReNerve's own innovation plays a crucial role in creating barriers to entry. The company has developed proprietary knowledge around nerve repair technologies, particularly in the preparation and manufacturing of the NervAlign® Nerve Graft. While currently maintained as a trade secret, ReNerve may consider pursuing patent protection as clinical testing progresses, further safeguarding its technological edge.

Moreover, ReNerve's in-house research facilities in Melbourne, coupled with its collaborations with leading universities and research organizations, provide ongoing opportunities to expand its IP portfolio. This commitment to innovation not only strengthens the company's position in the market but also acts as a significant deterrent for competitors attempting to replicate or surpass ReNerve's proprietary technologies.

Successful Management

ReNerve was established through the joining of minds from leading CSIRO researchers, a neurosurgeon and material researchers with a background in biochemistry and physiology. Dr. Julian Chick, CEO and Co-founder, brings extensive experience from senior management roles at medical device companies, including Admedus. He has leveraged this experience to effectively guide ReNerve in executing its business strategy. Strengthening the management team further is Dr. David Rhodes, Chief Scientific Officer and Co-founder, who possesses deep expertise in biotechnology, both in managerial and research roles. Dr. Rhodes has applied his leadership in numerous R&D programs to shape ReNerve's product development and drive its success.

The company is chaired by Stephen Cooper, a director at Grant Samuel, a leading independent Australian investment bank. Drawing on his investment banking background, Stephen provides invaluable guidance on ReNerve's corporate and business strategy. With this experienced management team and board, we are confident that ReNerve is well-positioned to execute its product development strategy and go-to-market plans.

Scalable Business Strategy

To support its global expansion, ReNerve plans to leverage its US approvals to gain access to additional markets. The company is conducting extensive clinical studies to build a strong data repository that will bolster regulatory submissions in various regions. On the product side, ReNerve's agreements with Leader and EMCM provide the flexibility to scale production as demand grows. This combination of a strategic regulatory approach, data-backed clinical validation, and robust manufacturing partnerships lays a solid foundation for sustainable growth. We expect this strategy to enable efficient market penetration and establish a competitive global presence.

Significant Investment Upside

ReNerve has positioned itself to capitalise on the lucrative global peripheral nerve injury (PNI) repair market, projected to reach $6.2 billion by 2030. Leveraging a multi-product strategy built around its innovative NervAlign® portfolio, ReNerve aims to appeal strongly to surgeons and hospitals. This strategic approach is expected to drive product adoption and accelerate market share growth within this significant and expanding global market. We believe this will significantly drive ReNerve's revenue to $16.8m in FY34, implying a CAGR of ~51% from FY24.

Furthermore, the low production costs of the NervAlign® product line enable the company to maintain a high gross margin. As ReNerve completes its core R&D programs, reduces R&D expenditures, and benefits from operating leverage in its cost structure, its operating margin and free cash flow margin are anticipated to reach 22% and 27%, respectively, by FY34.

Driven by forecasted strong revenue growth at highly profitable margins, ReNerve's fair value per share is estimated at $0.37, representing a significant upside potential of 163% from its latest closing price of $0.14. This valuation is based solely on the U.S. market, and we believe the company's fair value could be significantly higher once expansion into additional markets such as Europe and Asia are factored in.

INVESTMENT RISKS

Regulatory Approvals

In February 2022, ReNerve received FDA market clearance for its primary product, the NervAlign® Nerve Cuff. All future products will require regulatory approval, typically as medical devices, and any rejection, delay, or loss of approval would significantly impact the business. Gaining approval in markets outside the US will likely require clinical data, which ReNerve is gathering through collaborations with surgeons in Australia and the US. Additionally, once US approval is secured, the resulting clinical data can support submissions in other markets.

Market Traction and Competition

ReNerve's success relies heavily on surgeon adoption of its innovative nerve repair technologies. To address market entry challenges, the company has formed an advisory board of experienced U.S. surgeons who provide valuable insights into product development and clinical use, bolstering confidence in the market potential of the NervAlign® Nerve Cuff.

However, the medical device market is highly competitive. Established and emerging players can quickly disrupt the landscape through aggressive marketing, technological advancements, acquisitions, or competitive pricing strategies. With only two years of experience in U.S. nerve repair sales, ReNerve faces uncertainties in achieving its market penetration and revenue targets. Its ability to compete will depend on effectively differentiating its products, proving clinical value, and adapting to competitive pressures from both current players and new entrants.

Loss of Exclusivity Agreements

ReNerve holds an exclusive manufacturing agreement with European Medical Contract Manufacturing B.V. (EMCM), subject to meeting specific production targets. While losing exclusivity could pose competitive risks to the NervAlign® Nerve Cuff, this is deemed unlikely due to the company's strong relationship with EMCM.

The agreement can only be terminated in limited cases, such as a material breach by ReNerve or EMCM's insolvency. Mitigations are in place to address such risks, including the NervAlign® Nerve Cuff's 30-month shelf life, which ensures market supply continuity while securing an alternative manufacturer. ReNerve is confident that even in the unlikely event of EMCM's failure, it could transition manufacturing to alternative partners without disruption. Additionally, ReNerve's licence for Leader Biomedical Europe B.V.'s proprietary eCOO technology remains secure, with revocation limited to instances of major contractual breaches.

Intellectual Property

ReNerve's IP strategy focuses on proprietary know-how and rapid market entry rather than traditional patent protection, which presents potential competitive risks. By relying on trade secrets and first-mover advantage, the company is vulnerable to product replication. If competitors manage to reverse-engineer or develop similar technologies, they could weaken ReNerve's market position and impact its financial performance.

ReNerve Ltd is a Canary Capital-mandated company. Canary Capital Pty Ltd, its directors and associates own shares and options in ReNerve Ltd.

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