ReNerve

ASX Announcement
29 April 2025

Quarterly Activities Report for the Period Ended 31 March 2025

Key Performance Highlights

Clinical Validation of the benefits of the NervAlign® Nerve Cuff

- **Superior pain reduction**: Patients with NervAlign® Nerve Cuff reported mean post-operative pain score reduction from 7.1 to 0.4, compared to control group reduction from 7.1 to 3.3
- **Enhanced patient satisfaction**: 93% of NervAlign® Nerve Cuff recipients indicated willingness to undergo surgery again versus 70% in the control group

Financial Performance

- **Revenue Performance**: Q3 FY25 sales reached A$75,000, representing a 39% increase over the previous quarter
- **Operating Expenses**: Maintained disciplined cost management with quarterly operating cash outflow of A$585,000.
- **Capital Position**: Maintained robust cash reserves of A$5.8 million, providing sufficient runway for ongoing operations and strategic initiatives.

ReNerve Limited (ASX, "**ReNerve**" or "**the Company**"), an Australian biotechnology company developing innovative products for peripheral nerve injury ("**PNI**") repair, is pleased to present its Quarterly Report ("**Report**") for the period ended 31 March 2025 ("**Q3 FY25**", or the "**Quarter**").

Overall, the quarter was a busy period for ReNerve with growth in sales continuing, expansion through several non-US partnerships and the presentation of positive clinical study data for the NervAlign® Nerve Cuff. During the period the company also appointed Mr Eric Feliciano as its VP of Sales and Marketing in the US, to focus on building ReNerve's sales and marketing presence and operations across the US.

Commenting on the activities for the Quarter, Director, Dr Julian Chick, stated:

"During the quarter ReNerve continued to build commercial momentum, growing revenue and expanding our sales and marketing capability in the US, while the benefits of our NervAlign® Nerve Cuff were reinforced by compelling clinical validation data. The outcomes presented at the American College of Foot and Ankle Surgeons Conference provide robust evidence of NervAlign® Nerve Cuff's contribution to improved patient outcomes in peripheral nerve repair procedures. These outcomes reinforce our value proposition to surgeons, hospitals, and most importantly, to patients requiring peripheral nerve surgery.

Our disciplined approach to capital allocation continues to support both near-term commercial expansion and longer-term product development initiatives, ensuring we maintain our innovation pipeline while driving current product adoption."

Financials

The company continued to build its sales during the period as use of the NervAlign® Nerve Cuff increases and the Company gains approvals in more hospital systems. The sales for the quarter reached A$75,000, representing a 39% increase over the previous quarter and contributing to cumulative FY25 nine-month sales of A$177,000.

The Company's net cash flows from operating activities for the quarter were an outflow of $585k. The largest operating expenses were staff costs of $244k, research and developments costs of $277k and sales and marketing costs of $196k.

ReNerve's net cash position at the end of the quarter was $5.8 million.

Developing PNI Product Portfolio

ReNerve's NervAlign® Nerve Cuff is achieving growing sales with increasing numbers of surgeons and hospitals using the product on a repeat basis. In addition, the Company has a clear pathway for FDA clearance of three additional PNI products over the next four years.

NervAlign® Nerve Cuff (In Market)

The NervAlign® Nerve Cuff is used for the repair of recently damaged or transected nerves. It is easy to use in surgery for PNIs, requiring no changes to standard surgical techniques, but offering several benefits in terms of flexibility, sizing, and other needs. The Nerve Cuff has received positive feedback from surgeons using the product, predominantly in hand and wrist surgeries, but its use is also applicable to breast, orthopaedic, and several other types of surgery.

The NervAlign® Nerve Cuff utilizes proprietary eCOO technology and is specifically designed for repair of recently damaged or transected peripheral nerves. The product offers distinct advantages while requiring no modification to standard surgical techniques:

- **Surgical Versatility:** Compatible with various fixation methods including sutures, micro-clips, surgical adhesives, or anchor suture approaches
- **Enhanced Usability:** Engineered for optimal pliability and ease of application in surgical settings
- **Anatomical Compatibility:** Ultra-thin profile enabling use in anatomically constricted environments
- **Biocompatibility:** Fully bioresorbable composition
- **Neuroprotection:** Shields repaired nerves from inflammatory responses and adverse scarring
- **Regenerative Support:** Facilitates cellular proliferation and nerve regeneration
- **Clinical performance:** Shown to clinically benefit patient outcomes

The product has gained adoption in hand and wrist surgeries, with expanding applications in breast reconstruction, orthopaedic procedures, and other surgical specialties requiring peripheral nerve repair.

Clinical Validation of NervAlign® Nerve Cuff

On 28 March 2025, ReNerve announced that recent clinical research (presented at the American College of Foot and Ankle Surgeons Conference, 27 – 30 March 2025) had demonstrated statistically significant improvements in patient outcomes via a comparative clinical study evaluating the NervAlign® Nerve Cuff in peripheral nerve repair surgery.

The study was a comparative study with two cohorts. The first cohort comprises patients with neurectomy repairs (nerve repair) using the current standard surgical repair approach and products. The second cohort consists of patients with neurectomy repairs where the site of the repair is protected with ReNerve's NervAlign® Nerve Cuff.

The study looked at pre- and post-surgery pain scores, patient's likelihood to have the surgery again as an indication of satisfaction with the surgery, as well as overall patient recovery. The pain assessment was undertaken by an independent group.

The study demonstrated that patients who received treatment with the NervAlign® Nerve Cuff experienced a greater reduction in reported post-operative pain scores, as well as higher overall satisfaction with their surgery, compared to the control group.

Patients using the NervAlign® Nerve Cuff reported a decreased mean post-operative pain score, going from 7.1 to 0.4, compared with a reduction from 7.1 to 3.3 in the control group (patients that did not receive the Cuff).

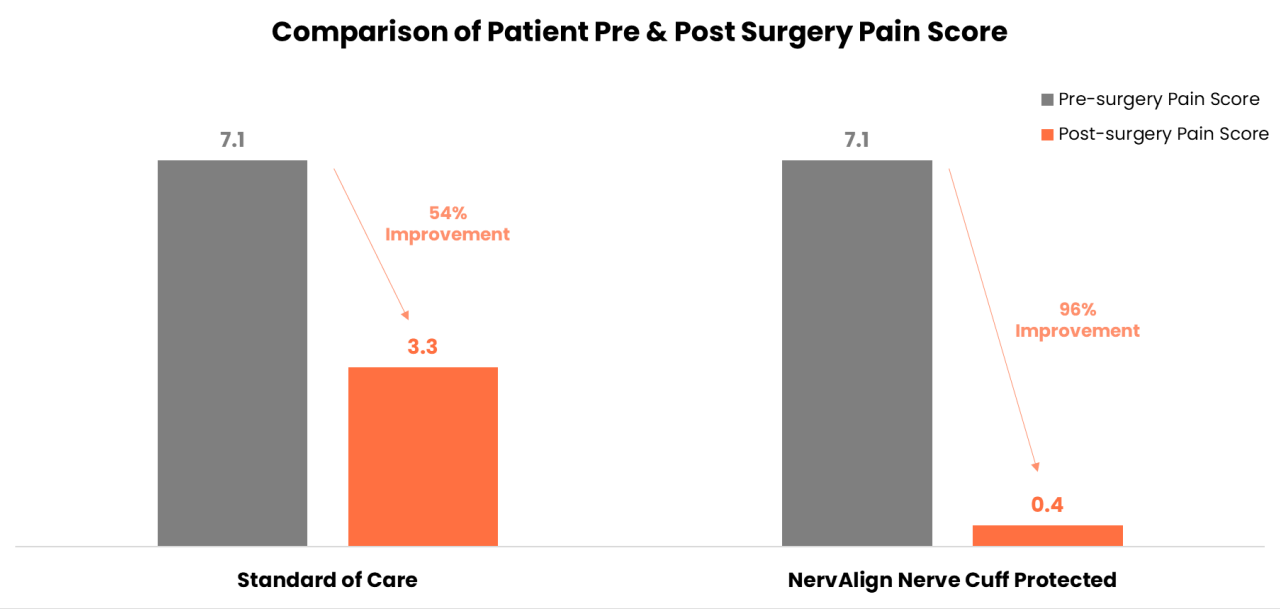

Figure 1. The comparison of pain scores between the two cohorts of patients

Additionally, 93% of patients that received the Cuff indicated they would elect to undergo surgery again, compared to 70% of patients in the control group.

Additional R&D Tax Incentive Refund Received

On 7 March 2025, ReNerve announced that it has received an additional $139,537 refund under the R&D Tax Incentive program in Australia for its eligible overseas R&D activities for its nerve repair products.

This additional refund brings the total tax incentives that have been awarded in FY2025 to $516,606.

Global Market Business Development[1]

During the period ReNerve entered several regional partnerships to pursue product approval outside the US. The Company remains focused on the US. However, through local or regional partnerships, the Company will look for additional commercial opportunities. During the period ReNerve undertook the following commercial partnerships and commercial activities:

- **Latin America**: Executed exclusive distribution agreement with Imbiomex in Mexico, targeting a USD$74 million nerve repair biomaterials market growing at 17% annually.
- **Southeast Asia**: Secured commercial marketing approval in Thailand, enabling access to a population of 70+ million and the region's medical tourism market.
- **East Asia**: Confirmed first hospital sales in Hong Kong, establishing clinical presence in a key Asian market.
- **Indian Subcontinent**: Formed strategic partnership with NetCentrix Ventures to pursue regulatory approval in India's rapidly expanding nerve repair market (USD$115 million per annum, projected to reach USD$270+ million by 2030 at 18.5% CAGR).

Corporate

During the quarter, net cash outflows included $25k for plant and equipment, primarily associated with research and development activities, and $9k for trademark applications.

Financing activities resulted in net cash outflows of $11k, representing a residual portion of IPO costs incurred in the prior quarter, paid in the current period. These costs are not expected to recur.

As stated in Item 6.1 in the accompanying Appendix 4C, ReNerve made aggregate payments to related parties and their associates totalling $143k during the quarter. The payments consist of salary and associated payroll costs of executive directors.

Comparison to IPO prospectus

Pursuant to Listing Rule 4.7C.2, the Company confirms that, in the second quarter since listing on the ASX, the Company's expenditure profile is largely in line with the use of funds set out in its Prospectus, as detailed in the table below. The Company is well funded to achieve its strategic objectives and planned activities.

[1] Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)

Use of Funds*	Expenditure allocated under prospectus (2 year period)	Actual expenditure to date 31 March 2025**
NervAlign Nerve Conduit Studies	$1,100,000	$59,151
Post market study for Nerve Cuff	$300,000	$90,004
Nerve Guide Matrix program	$3,000,000	$216,386
IPO costs	$900,000	$955,079
Working capital and operating expenses	$1,700,000	$1,141,313
Total Funds Allocated	**$7,000,000**	**$2,461,933**

** This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budgets or development expenses. The Board may alter the way funds are applied in the future.*

*** Actual expenditure to date 31 March 2025 per the above table reflects expenditures for the two quarters ended 31 March 2025, thus including expenditures incurred before the Company's ASX Listing on 26 November 2024.*

- ENDS -

This announcement has been approved for release by the Company's Board of Directors.

For further information and enquiries, please contact:

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About ReNerve Limited

ReNerve Limited (ASX:RNV) is a medical device company specialising in advanced nerve repair and regeneration solutions. The Company is focused on commercialising cutting-edge medical devices and tissue-engineering products that seek to address significant unmet needs for patients with peripheral nerve damage – a critical gap in healthcare. ReNerve aims to improve patient outcomes through scientifically backed products that have been developed to enhance the human body's natural healing process, while commercialising cutting-edge, scalable products for the healthcare market. ReNerve wishes to acknowledge AusIndustry's Accelerating Commercialisation program for its support through many of the activities required to commercialise the NervAlign® Nerve Cuff.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
ReNerve Limited	
ABN	**Quarter ended ("current quarter")**
23 614 848 216	31 March 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	73	185
1.2	Payments for		
	(a) research and development	(277)	(553)
	(b) product manufacturing and operating costs	(36)	(142)
	(c) advertising and marketing	(156)	(367)
	(d) leased assets		
	(e) staff costs	(244)	(782)
	(f) administration and corporate costs	(165)	(1,010)
1.3	Dividends received (see note 3)		
1.4	Interest received	80	91
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	140	517
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(585)**	**(2,061)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(25)	(28)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets	(9)	(9)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (Term Deposits)		530
2.6	**Net cash from / (used in) investing activities**	**(34)**	**493**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		7,000
3.2	Proceeds from issue of convertible debt securities		755
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(11)	(611)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
3.10	**Net cash from / (used in) financing activities**	**(11)**	**7,144**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,388	182
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(585)	(2,061)
note 64.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	493

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(11)	7,144
4.5	Effect of movement in exchange rates on cash held	10	10
4.6	**Cash and cash equivalents at end of period**	**5,768**	**5,768**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	1,036	2,888
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (Term Deposits)	4,732	3,500
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**5,768**	**6,388**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	143
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(585)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,768
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	5,768
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: .....29 April 2025.....

Authorised by: …By the Board of Directors of ReNerve Limited.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.