ReNerve

29 January 2025

Quarterly Activities Report for the Period Ended 31 December 2024

Highlights:

- ReNerve Limited ("ReNerve" or "the Company") commenced trading on the ASX on 26 November 2024 following a heavily oversubscribed initial public offering, which raised the maximum amount of A$7 million (before costs) at $0.20 per share.
- The Company has achieved strong sales growth. Sales for Q2 FY25 of A$52K represented a 260% increase on sales for the prior comparable period (PCP) (Q2 FY24). Preliminary unaudited sales for 1H FY25 of A$102K represent a 167% increase on the PCP.
- ReNerve continues to focus on expanding sales of its NervAlign® Nerve Cuff product in its core US market. In addition, the Company announced sales and marketing agreements for new jurisdictions in December 2024.
- A clinical study investigating ReNerve's NervAlign® Nerve Cuff on neurectomies repair is ongoing, with clinical study data anticipated to be released late in Q3 FY25. The study will focus on post-operative pain among two cohorts; one treated with the NervAlign® Nerve Cuff and the other without it. ReNerve has been blinded to the trial.
- On 3 December 2024, ReNerve announced an exclusive distribution agreement with Accession Medical Supplies Co. for sales and marketing of ReNerve's primary product, the NervAlign® Nerve Cuff in Hong Kong and Macau.
- On 12 December 2024, ReNerve partnered with Union MediScience B.S.C. in an exclusive distribution agreement for the sales and marketing of the NervAlign® Nerve Cuff in the Middle East. The agreement covers Bahrain, Saudia Arabia, Kuwait, UAE/Dubai and Qatar.
- ReNerve had a strong cash position of $6.4 million at 31 December 2024.

ReNerve Limited (**ASX:RNV**, "**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 December 2024 ("**Q2 FY25**", or the "**Quarter**").

Initial Public Offering & Commencement of Trading

Following its successful initial public offering ("IPO") and listing on the ASX on 26 November 2024, the Company issued 35 million shares at $0.20 per share to raise A$7 million. The funds raised through the IPO are being used to accelerate the development of its peripheral nerve repair and replacement products, which are anticipated to complement ReNerve's existing NervAlign® Nerve Cuff product. The NervAlign® Nerve Cuff has received market clearance from the Federal Drug Administration ("FDA"), is achieving growing sales and is now used by a number of surgeons in the USA. The Company is also using the funds raised in the IPO to accelerate sales growth, through a variety of sales and marketing initiatives in the US and through developing other markets. In particular, since

listing, ReNerve has executed two exclusive distribution partnerships for the sales and marketing of its NervAlign® Nerve Cuff product into Hong Kong and the Middle East. Further details are included below.

Developing PNI Product Portfolio

ReNerve's NervAlign® Nerve Cuff is achieving growing sales in the US, with increasing numbers of surgeons and hospitals using the product on a repeat basis. In addition, the Company has a clear commercial 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 US 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:

- can be sutured, micro-clipped, glued or, if surgeon deems appropriate, secured with no suture or a single suture (anchor suture) in place;
- is designed to be pliable and easy to apply;
- is thin, being suitable for use in constricted tissue environments;
- is bioresorbable;
- protects nerves from negative inflammatory responses or scarring; and
- supports cell proliferation and nerve regeneration.

Clinical Study Update

ReNerve anticipates that the results of its NervAlign® Nerve Cuff study data will be presented at the American College of Foot and Ankle Surgeons Conference taking place March 27th to 30th 2025.

The study is 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 will look at pre- and post-surgery pain as well as overall patient recovery. The pain assessment will be undertaken by an independent group. The study will explore any potential statistically significant differences and benefits to patient outcomes in using the NervAlign® Nerve Cuff.

NervAlign® Nerve Conduit (In Development)

The Company's NervAlign® Nerve Conduit represents a further development of the Nerve Cuff, using the same core eCOO technology, and will be suitable for use to repair short nerve gaps and for use in compression and stump neuroma PNIs.

ReNerve is currently targeting submission to the FDA in Q4 of CY2025. FDA clearance is expected to be accelerated due to the Company leveraging its prior existing clearance for the product's predecessor (the Nerve Cuff).

NervAlign® Nerve Guide Matrix (In Development)

The NervAlign® Nerve Guide Matrix aims to offer a ready-to-use alternative to existing nerve grafts. It eliminates the need for donor tissue, simplifying many surgical procedures (for example, there is no need for additional surgical sites). Animal studies have demonstrated rapid recoveries, restored sensory and motor functions, as well as achieving other positive results.

The Company is targeting filing for FDA clearance in Q2 of CY2027.

NervAlign® Bionic Nerve (In Development)

The NervAlign® Bionic Nerve seeks to provide a continuous nerve replacement solution for extensive nerve damage (i.e., up to 20cm and above). The product incorporates novel technologies and aims to address the current limitations of donor nerve availability to provide greater nerve regrowth efficacy over longer distances.

The Company is targeting filing for FDA clearance in Q3 of CY2028.

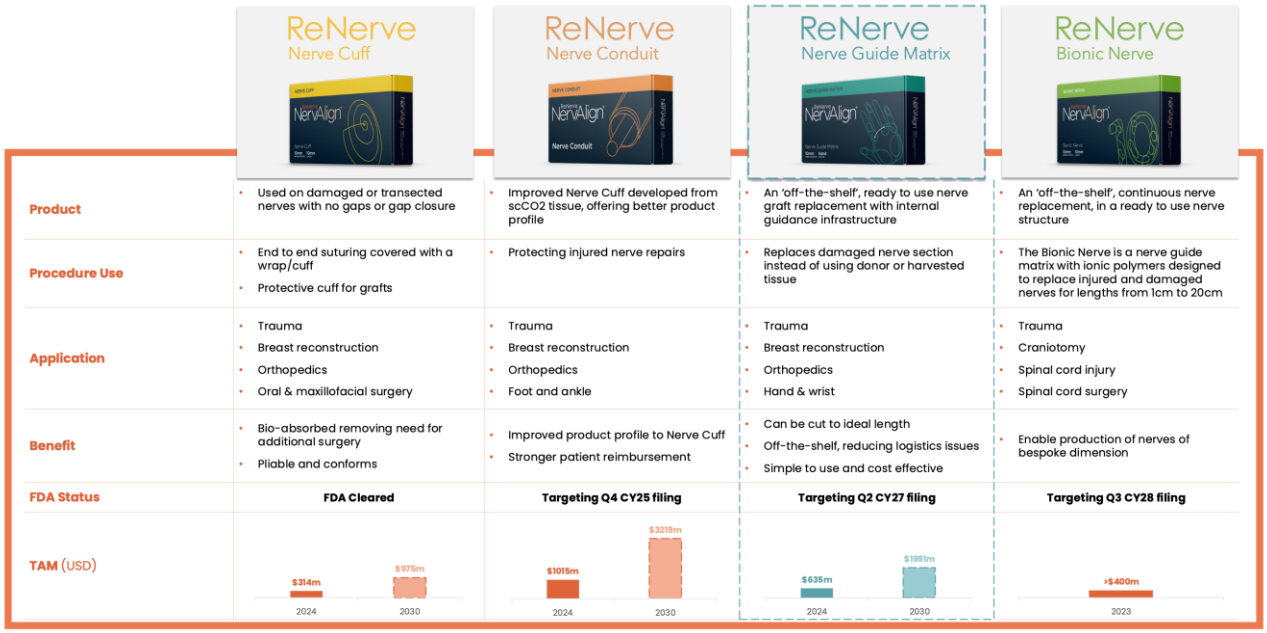

Figure 1 – ReNerve Product Portfolio

Figure 2 – ReNerve's Anticipated Company Milestone Timeline

Sales & Marketing

Sales for the Quarter were A$52K, representing a 260% increase on sales for the PCP (Q2 FY24). The Q2 FY25 result contributed to the Company generating total sales of A$102K for 1H FY25, a 167% increase on the PCP, reinforcing the growth the Company is experiencing as it achieves further market penetration in the US.

ReNerve will be leveraging its growing acceptance in the US to expand into new markets (see additional commentary below). Following the Company's IPO, CEO & Managing Director Julian Chick undertook a global product roadshow visiting Key Opinion Leaders ("KOLs"), surgeons, group purchasing organisations ("GPOs"), distributors and partners in Asia, Europe, Middle East and the US. Already, ReNerve has been able to execute sales and distribution partnerships to expand product availability in the Middle East and Asia.

Importantly, the product roadshow allowed senior management to educate surgeons, KOLs and GPOs in the key US market on the significant benefits of the NervAlign® Nerve Cuff and provide insight into the Company's product portfolio.

Subsequent to the end of the quarter the Company exhibited at the American Association for Hand Surgery Annual Meeting, a critical meeting for leading hand surgeons and medical professionals.

Exclusive Partnership with Accession Medical Supplies Co.

Accession Medical Supplies Co. ("Accession") is a leading supplier of medical devices in Hong Kong, China and Taiwan. Accession specialises in sourcing and distributing innovative medical devices and pharmaceutical products by partnering with world class companies that share its vision for innovation in improving patient outcomes.

On 3 December 2024, ReNerve announced that it had partnered with Accession, as they have the appropriate warehousing, distribution, sales and marketing capacities in the China/Hong Kong region, as well as existing relationships with leading local surgeons, which will help ReNerve enter the Guangdong-Hong Kong-Macau Greater Bay Area's market, with a population of over 86 million.

As part of the Agreement, Accession will purchase the ReNerve product range as a wholesaler, with ReNerve supporting Accession in its sales and marketing activities. The two companies will work together to gain regulatory approval in Hong Kong by leveraging Accession's existing relationships with local hospitals and day surgeries to drive sales and increase product demand. ReNerve also announced that it has filed for regulatory approval in Hong Kong and anticipates the appropriate approvals to be granted in mid-2025.

Exclusive Partnership with Union MediScience

Established in 1988, Union MediScience is a leading company in the Middle East that represents well-known manufacturers worldwide through the supply of medical equipment, medical goods and medicines. It has been one of the leading suppliers in the Bahrain market for more than two decades and has built a reputation in the industry for its ability to satisfy customer requirements and supply, install and commission specified products on time.

The agreement covers five countries across the Middle East: Bahrain, Kuwait, Dubai/UAE, Qatar and Saudi Arabia. With the total Middle East & North Africa ("MENA") region worth over US$80M per annum and growing at over 35% per annum, the agreement provides a significant opportunity for ReNerve to enter a market with fewer competitors than in more developed markets such as the US.

Corporate

ReNerve's net cash position at the end of the quarter was $6.4 million.

The company's net cash flows from operating activities for the quarter were an outflow of $1.2 million. The largest operating expenses were staff costs of $0.3 million and administrative and corporate costs of $0.6 million. Administrative and corporate costs for the quarter included legal, accounting, other professional advice and other costs relating to the company's IPO in November last year, totalling approximately $246K, that are not expected to recur in future periods. For the half year to 31 December 2024, administration and corporate costs included IPO-related costs of $363K.

Net cash inflows from financing activities of $6.556 million were net of transaction costs of $560K, representing

further cash expenses relating to the company's IPO. These were also one-off costs and will not be recurring in future quarters.

As stated in Item 6.1 in the accompanying Appendix 4C, ReNerve made aggregate payments to related parties and their associates totalling $157K 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 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.

Use of Funds*	Expenditure allocated under prospectus (2 year period)	Actual expenditure to date 31 December 2024**
NervAlign Nerve Conduit Studies	$1,100,000	$18,904
Post market study for Nerve Cuff	$300,000	$22,540
Nerve Guide Matrix program	$3,000,000	$44,625
IPO costs	$900,000	$937,243
Working capital and operating expenses	$1,700,000	$506,698
Total Funds Allocated	**$7,000,000**	**$1,530,010**

** 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.*

*** The Company incurred cash outflows before 26 November 2024 which have been added into this table to reflect the use of funds more accurately in relation to the IPO prospectus.*

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

- ENDS -

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About ReNerve Limited

ReNerve Limited (ASX:RNV) is an Australian-based biotechnology 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 December 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	33	112
1.2	Payments for		
	(a) research and development	(139)	(276)
	(b) product manufacturing and operating costs	(35)	(106)
	(c) advertising and marketing	(177)	(211)
	(d) leased assets		
	(e) staff costs	(271)	(538)
	(f) administration and corporate costs	(621)	(845)
1.3	Dividends received (see note 3)		
1.4	Interest received	4	11
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		377
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(1,206)**	**(1,476)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		(3)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**-**	**527**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,000	7,000
3.2	Proceeds from issue of convertible debt securities	96	755
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(560)	(600)
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**	**6,536**	**7,155**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,058	182
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,206)	(1,476)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	527

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,536	7,155
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**6,388**	**6,388**

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	2,888	1,058
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (Term Deposits)	3,500	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**6,388**	**1,058**

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	157
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)	(1,206)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,388
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	6,388
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5

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 January 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.