

ASX Announcement

28 May 2025

Market Approval in Bahrain for the NervAlign® Nerve Cuff™

HIGHLIGHTS

- ReNerve has successfully gained marketing approval in Bahrain in the Middle East.
- This is the Company's first approval with its Middle East Partner, Union MediScience B.S.C.
- The total Middle East and North Africa market is worth over USD\$80M per annum and growing at 35%.
- The Global Nerve Repair Biomaterials Market was valued at USD\$1.96 billion in 2024 and is projected to grow at a CAGR of 17.8% from 2024 to 2031 to USD\$6.19 billion¹.

ReNerve Limited (ASX:RNV) ("ReNerve" or the "Company"), a pioneering medical device company transforming peripheral nerve repair, is pleased to announce that it has received marketing approval in Bahrain. The approval comes as a result of ReNerve having worked with its partner in the region, **Union MediScience B.S.C** ("**Union MediScience**").

The two companies will now work to commercialise the NervAlign® Nerve Cuff™ product in Bahrain, and utilise information generated from early cases to expand further regional approvals.

Commenting on the approval, ReNerve Director, Dr Julian Chick, stated: *"The ReNerve team has done a great job on the approvals, and working with the wonderful people at Union MediScience has been excellent. We look forward to the commercialisation in Bahrain and further expanding our sales and marketing efforts in the region."*

Middle East Market Opportunity

The Middle East region, as a market opportunity, poses strong growth potential alongside other key markets as awareness and demand for nerve repair and replacement steadily increases. Market reports suggest the total Middle East and North Africa (MENA) market is worth over USD\$80M per annum and growing at over 35%². The market also has fewer competitors compared to the larger markets like the US.

Union MediScience Partnership

Announced 10 December 2024³, ReNerve entered an exclusive distribution partnership with Union MediScience, granting them the rights to market and sell ReNerve's flagship product, the NervAlign® Nerve Cuff, across five key Middle Eastern countries: Bahrain, Saudi Arabia, Kuwait, the United Arab Emirates (UAE), and Qatar. The

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

² Ibid.

³ ASX Announcement (10 December 2024) – "ReNerve Signs Exclusive Partnerships with Established Supplier in the Middle east to Further Accelerate International Expansion"

partnership aims to leverage Union MediScience's established regional network and expertise in medical products (including tissue-based products) to expedite ReNerve's international expansion.

About Union MediScience B.S.C

Established in 1988, Union MediScience B.S.C 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 over two decades and has built a reputation in the industry for its ability to satisfy customer requirements for supplying, installing, and commissioning specified products on time.

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

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About ReNerve Limited (ASX:RNV)

ReNerve Limited (ASX:RNV) is transforming nerve repair and improving lives through breakthrough medical technology. Founded by a neurosurgeon and medtech researchers, ReNerve is a rapidly growing medical device company that has revolutionised peripheral nerve surgery with its innovative, ready-to-use solutions for peripheral nerve injuries (PNI). Our scientifically-backed products are delivering measurably better outcomes for patients worldwide.

Proven Clinical Success

ReNerve's first flagship product, the FDA-cleared **NervAlign® Nerve Cuff™**, is already making a dramatic difference in surgical outcomes across the United States. Recent clinical studies have demonstrated remarkable results, showing that patients treated with the NervAlign® Nerve Cuff experienced post-surgical pain scores dropping from 7.1 to just 0.4, compared to from 7.1 to 3.3 without the device being used – a statistically significant improvement that's changing lives.

Comprehensive Product Portfolio

ReNerve is advancing a complete suite of nerve repair solutions:

- **NervAlign® Nerve Cuff™** – Our bioabsorbable protective wrap, naturally absorbed within six months of surgery.
- **NervAlign® Nerve Graft** – Eliminating the need for patients to undergo additional sural nerve harvesting.

- **NervAlign® Bionic Nerve** – Next-generation combination technology for the most challenging nerve repairs.

Market Leadership and Growth

With demonstrated market traction since the Company's 2022 product launch, ReNerve achieved 38% revenue growth in FY24, reaching \$177k in sales. Our high-margin, scalable products are positioning us as the go-to solution for surgeons seeking superior patient outcomes in the rapidly expanding global nerve repair market, valued at US\$1.96 billion in 2024 and is projected to reach \$6.2 billion by 2031.⁴

Vision and Values

We're not just developing medical devices – we're engineering hope. By creating the ideal healing environment for nerve repair and regeneration, ReNerve bridges critical gaps in healthcare while empowering the human body's natural healing process. Our cleaner, safer, and more effective solutions represent the future of peripheral nerve surgery.

⁴ Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)