

RENERVE NEWSLETTER

August 2021



Dear Shareholders,

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In this time of COVID-19 uncertainty we hope that you and your family are safe and well.

ReNerve has continued to progress its product portfolio over the past quarter. Some notable quarterly highlights were:

- Presentation of ReNerve at the Royal Australian College of Surgeons Annual Scientific Meeting in Melbourne
- Launch of the company's new website *renerve.com.au*
- Successful quality audit of manufacturer of the NervAlign Nerve Cuff
- Production of commercial product for the NervAlign Nerve Cuff in anticipation of FDA marketing approval

FINANCIAL YEAR SUMMARY

ReNerve finished the financial year with A\$2.2M in the cash and an overall loss for the year of A\$1.15M. ReNerve will look to claim its 2020/21 FY R&D expenditure tax rebate before calendar year end.

COMPANY PROGRESS

ReNerve continues to progress its product portfolio as well as raising awareness of the company. During the quarter ReNerve attended the Royal Australian College of Surgeons conference (company booth pictured above). This was a great opportunity to speak to Australian surgeons and introduce them to the R&D programs at ReNerve, including showing the NervAlign Nerve Cuff.

The company continues to explore the potential for an ASX listing and will keep shareholders informed of its progress in this regard.

NERVALIGN™ NERVE CUFF

The NervAlign Nerve Cuff is currently under review by the US FDA for marketing approval. As previously reported, the Company received FDA feedback on its NervAlign Nerve Cuff marketing submission in January this year. Our activities since then have been focused on developing responses to the FDA, and in particular undertaking the bench testing required to generate the additional data required by the FDA. While COVID-related issues have in some cases hindered access to laboratories and other testing facilities, we have made good progress. All bench testing is underway with a majority of this to be completed by October 2021 and all to be completed in the 4th quarter of 2021.

We made further meaningful progress towards readying the NervAlign Nerve Cuff for market release:

1. The Company, in collaboration with its manufacturing partner, has completed three production runs, providing ReNerve with commercial product in its inventory, ready for sale in the US once the NervAlign Nerve Cuff gains marketing approval.
2. During the quarter ReNerve completed an independent audit of its manufacturing and quality system. This audit is important for the FDA submission process. It illustrates that the Company and its manufacturer comply with international standards and demonstrates that the product qualifies for commercial use in patients.

NERVALIGN™ NERVE GRAFT

COVID-related restrictions have delayed our sourcing of additional material as we work towards refining our NervAlign Nerve Graft. However, we have recently been able to source the required material and will commence pre-clinical testing as soon as access to facilities are available. The pre-clinical testing is designed to allow the Company to select the optimal combination of material and processing method, with a view to entering clinical trials.

COLLABORATION WITH VIVAZOME

In May ReNerve announced that it had entered a research collaboration with Vivazome, a company focused on the development of exosomes for treatment of diseases and regeneration. The collaboration will use the ReNerve NervAlign nerve cuff in combination with the Vivazome exosomes as a possible treatment of spinal cord injuries.

Currently there are limited options for treatment of spinal cord injuries. ReNerve and Vivazome will be looking to combine their two technologies to explore options to regenerate some function in the spinal cord. Using the NervAlign Nerve Cuff seeded with exosomes, the project has the potential to stimulate formation of new spinal cord nerve cells. The goal is to re-establish some spinal cord neural function which should then translate to the patient regaining some motor or sensory function. Even partial restoration of motor or sensory function can have enormous positive impacts on the lives of these patients.

AGM

ReNerve will hold its Annual General Meeting at 10am on the 23rd of November, via teleconference. The annual report and additional information on the AGM will be circulated closer to the time. We look forward to seeing you at the AGM and sharing more detail on ReNerve's progress.

NEAR TERM MILESTONES

ReNerve will continue to progress its pipeline. Its lead program, the NervAlign Nerve Cuff, is currently under review at the FDA for marketing approval in the US.

- FDA marketing approval for the NervAlign Nerve Cuff
- Nerve graft implantation study
- Scale production of the 'in-theater' "OR" tissue treatment kit

We look forward to providing shareholders with updates throughout the year.

ReNerve.com.au

Suite 3, 21 Vale St

North Melbourne. Vic. 3051