# RENERVE NEWSLETTER

February 2021



#### Dear Shareholders,

Firstly, we would like to offer a warm welcome to all the new ReNerve shareholders who participated in the company's most recent capital raising, and thank all shareholders for their ongoing support of the company. Following the capital raising, the company is in a strong financial position and well placed to achieve substantial progress in 2021.

Since our last newsletter, our NervAlign™ Nerve Cuff FDA submission has advanced to the substantive review stage and we have been encouraged by our positive ongoing interactions with the FDA.

#### **CAPITAL RAISING**

To ensure that its capital structure is optimized for future equity raisings, ReNerve converted to a public company and completed a 29 for 1 share split in late 2020. Thereafter, with the assistance of Canary Capital, the company completed a AUD\$2M capital raising at an issue price of \$0.16 per share (equivalent to \$4.64 on a pre-share split basis). Attached is your holding statement which shows your updated shareholding in the company following the share split and capital raising.

### **COMPANY STRATEGY**

ReNerve is a medical device company dedicated to developing genuine solutions to peripheral nerve repair and related procedures. Our goal is to develop and bring to market a range of products. Our most advanced product, the NervAlign Nerve Cuff, is currently subject to substantive review by the FDA for marketing clearance in the US. We have enjoyed positive interactions with the FDA and are confident that we have a well defined path to securing FDA approval. We are pursuing marketing approval for the product in other countries and expect that FDA clearance will support this process. ReNerve intends to use regional or country focused distributors to help market and sell the product.

ReNerve continues to develop its Nervalign Nerve Graft. This is a "ready to use" replacement nerve that comes off the shelf, allowing surgeons to avoid the need to harvest functional nerves from the patient. The company is currently undertaking additional preclinical testing with a goal to progressing the product to a clinical trial in advance of seeking marketing approval. The Nervalign Nerve Graft can be used in conjunction with the ReNerve Nerve Cuff and could be sold separately or bundled together.

The company will continue with its R&D projects around a 'bionic' replacement nerve and the operating room 'OR' tissue treatment kit.

## **NEAR TERM MILESTONES**

We anticipate the following major milestones for 2021, as ReNerve transitions from an R&D company into a commercially based business:

- FDA marketing approval for the NervAlign Nerve Cuff
- Nerve Graft implantation study

 $scale\ production\ of the \ 'in-theatre'\ "OR"\ tissue\ treatment\ kit$ 

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