

RENERVE NEWSLETTER

December 2021

Dear Shareholders,

End of Year Update

Notwithstanding the COVID-related challenges that 2021 has posed, ReNerve has made considerable progress over the past twelve months. ReNerve is well capitalised, optimistic that we will be able to secure FDA marketing approval for our NervAlign™ Nerve Cuff in early 2022 and generate first sales and looking forward to progressing our broader product portfolio.

FINANCIAL

ReNerve has recently completed a capital raising of AUD\$1.7M through the issue of 8,500,000 shares at \$0.20 per share. As a result, the Company will end the year with a bank balance of approximately \$2.5M. In addition, the Company expects to receive a R&D tax rebate of around \$330,000. The combination of the Company's cash balance and the anticipated R&D tax rebate places the Company in a solid financial position and allows us to approach 2022 with confidence. Moreover, the Company completed several manufacturing runs for the NervAlign™ Nerve Cuff during 2021, giving us inventory ready to sell in markets where the company achieves marketing approval.

We would like to thank all shareholders for their support during the capital raising and welcome those new shareholders who have joined the ReNerve share register.

PRODUCT PORTFOLIO

The Company's focus for the year has been to address the regulatory requirements for marketing clearance and product approval for the NervAlign™ Nerve Cuff. Following interaction with the FDA during the first quarter of 2021, the Company has conducted several additional studies to provide the data required to address various questions raised by the FDA in relation to our application for marketing approval.

ReNerve has now completed all studies required to address the FDA questions, is finalising its formal responses to the FDA and will submit these in early January. The results of the studies have been positive, and no issues have arisen. ReNerve expects that the data from the studies will allow us to provide satisfactory responses to the FDA's questions. The most significant of the studies was a comparative analysis in a rat model in which the NervAlign™ Nerve Cuff was effectively compared against the Axogen Axoguard product. The results from the independent study are that the outcomes, in terms of protecting nerves, for the NervAlign™ Nerve Cuff arm of the study were at least as good as, and in some respects appeared superior to, the results from the Axogen Axoguard arm and the control arm of the study. The study surgeon also commented that the NervAlign™ Nerve Cuff handled well, was easy to use and performed as expected in terms of safety and protecting the repaired nerve. The study also showed that the NervAlign™ Nerve Cuff was near fully reabsorbed by week 13, an ideal outcome for these types of surgical procedures.

Our focus for 2022 will be to secure FDA marketing clearance (approval) for the US and commence initial US sales. ReNerve will also seek other opportunities for early commercialization of the NervAlign™ Nerve Cuff in markets that do not require FDA approval. We are actively pursuing opportunities for sales in the New Zealand market.

In addition, we will move aggressively to progress the rest of the portfolio. We will be aiming to get the NervAlign™ Nerve Graft into a final pre-clinical study before progressing to clinical studies. We will be looking to progress the Operating Room (OR) kit and illustrate the utility of the process on treating tissue-like nerves as well as vascular and tendon tissue. Simultaneously we will seek to finalise the product design and manufacturing process for the OR kit so that we can enter the market with a commercial, scalable, and cost-effective product.

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We intend to progress the 'bionic' nerve into an initial animal study. We look forward to getting the initial in vitro study results from the collaboration with Vivazome in spinal cord repair. This will provide us with insight into how well the NervAlign™ Nerve Cuff can be used as a local delivery platform for exosomes and potentially other cell therapies.

ANNUAL REPORT

ReNerve has released its annual report and hopefully all shareholders have received a copy. If any shareholders have not received a copy or have any questions, please do not hesitate to contact us!

2022

Given the Company's strong financial position and the growing maturity of our product portfolio, the ReNerve team is looking forward to 2022. Our major anticipated milestones for 2022 are:

- **First sales of the NervAlign™ Nerve Cuff**
- **FDA marketing clearance (approval) for the NervAlign™ Nerve Cuff**
- **First sales in the US of the NervAlign™ Nerve Cuff**
- **NervAlign™ Nerve Graft pre-clinical study data**
- **OR theatre kit proof of concept study data**
- **Initial vitro study results from the Vivazome – ReNerve collaboration in spinal cord repair**
- **'Bionic' nerve initial pre-clinical study data**

We hope that you and your families have a safe and joyful festive season and a healthy, happy, and prosperous New Year.

ReNerve.com.au

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