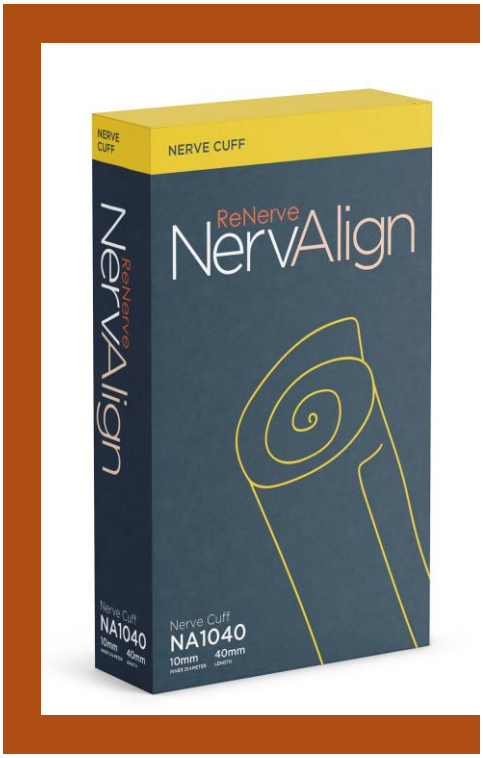
RENERVE NEWSLETTER

April 2020



PROGRESS

Dear Shareholders,

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

We would like to thank all shareholders for their support in the recent capital raising by ReNerve and, in particular, welcome those who have become shareholders for the first time.

ReNerve has made significant progress since our last newsletter. Some notable highlights are:

- the completion of a capital raising to raise $1.1 million of new equity
- highly encouraging test results from the third series of our prototype NervAlign™ nerve graft/conduit
- completion of the NervAlign™ nerve cuff studies and good progress in the compilation of the package to be submitted for FDA marketing approval

IMPACT OF COVID-19

Like many other companies across Australia, ReNerve has been affected by the COVID-19 outbreak. In particular, there has been an unavoidable slowing of our earlier stage projects, as our laboratories within CSIRO have been closed with only COVID-19 related activities able to continue. On the other hand, ReNerve continues to make good progress with the key activities that we believe will deliver short to medium term value, including with the progress of the NervAlign™ nerve cuff towards the FDA submission, quality systems certification, ongoing development of the tissue treatment kits and additional nerve graft studies at Melbourne University.

NERVE CUFF

In February, ReNerve received the results from its third study on the NervAlign™ nerve cuff. These results showed that the NervAlign™ cuff is safe and suitable for use as a nerve wrap. The study indicated that the NervAlign™ cuff provides a firm, but not overly tight, 'wrap' around the site of repair, indicating an ability to assist with holding nerves together. More importantly, the study showed that over time there was considerable vascular regrowth and re-establishment of external tissue around and through the wrap. So, while providing a protective layer around the repaired nerve, the nerve cuff also allowed recovery and repair around the site of the procedure. This final study will be added to the FDA submission.

The ReNerve team is now compiling its FDA 510(k) submission package, with a goal of submitting the package to the FDA around May this year. ReNerve is working closely with its manufacturing partner in assessing the final validation and process information. The FDA has issued a note suggesting that COVID-19 could result in some delays in its application review process. However, to the best of our knowledge there have not yet been any major COVID-19 related delays of medical device marketing approval submissions. We will continue to monitor the issue carefully.

Submission of the NervAlign™ nerve cuff marketing application to the FDA will be a significant milestone for ReNerve.

NERVE GRAFTS

ReNerve has now completed three series of sheep trials of its prototype nerve grafts, with the third series showing the most promise. The trials involved the implantation of ReNerve nerve grafts to replace sheep leg nerves, with a concurrent autologous transplant (i.e. using the sheep's own nerve) to provide a comparator. As many ReNerve shareholders will have seen in our recent slide presentation, the sheep were walking within hours of surgery, and within three months had gained normal function in the leg where the ReNerve graft had been implanted. As importantly, the ReNerve nerve grafts appeared to deliver a functioning re-established nerve equal to results seen with the autologous grafts, making it similar to the outcomes seen in patients with the current standard of care but without the need for secondary surgery and the related comorbidities. These results are extremely promising, and confirm our view that we have an opportunity to create a new nerve graft product that will have compelling competitive advantages.

The next steps in this programme will be to finalise the method of preparation and raw material sourcing for the grafts and consider testing of longer graft implants. In addition, we will commence preparation for clinical studies.

TISSUE TREATMENT KIT

ReNerve continues to develop the design of a tissue treatment kit. Recent results from using the treatment process clearly show a debridement and cleaning of tissue is possible within 20 minutes in a surgical theater setting. ReNerve continues to work with designers to perfect a kit prototype that is both effective and inexpensive to manufacture and supply.

Illustration of the ReNerve tissue treatment kit prototype that allows for the debridement of extracellular tissue, lipids and nucleic materials from autologous tissue during a surgical procedure. The kit can be used to "clean" nerves as well as other tissues like vascular tissue, pericardium and tendons in theatre prior to being implanted with an aim to speed patient recover and result in better post-surgery outcomes for patients.

REPLACEMENT NERVES

The replacement nerve program has continued to progress, benefitting from the development of the nerve graft as well as making progress on the extrusion of polymers blended with materials prepared from its proprietary nerve graft scaffolds. The blends will ultimately include ionic polymers. Together with Monash University, ReNerve has developed techniques to enable the production of a range of nerve guiding shaped polymer materials.

With the COVID-19 shutdown the laboratory-based activities have been halted. However planning activities continue and will enable a rapid restart when the facilities re-open.

ReNerve has also entered into discussions with Melbourne University in relation to a program that is an extension of its research into nerve and neural related repairs. ReNerve in collaboration with Melbourne University has applied for supporting collaboration grant funding to progress the project to develop novel bio-membranes that have potential in nerve repairs as well as other surgical procedures such as replacement of the dura mater.

CAPITAL RAISING

ReNerve completed a capital raising in March 2020, with the company raising just over $1.1M in new equity. As a result, the Company is well positioned to progress the NervAlign™ nerve cuff programme through to FDA submission and approval, and progress our other key programmes into 2021.

As discussed with a number of shareholders, the Company has been investigating the feasibility of an IPO. With the COVID-19 outbreak and its impact on the capital markets, this process has been postponed. However, ReNerve will continue to make preparations in anticipation of an IPO once market conditions become more conducive.

TAX INCENTIVES FOR EARLY STAGE INVESTORS

ReNerve has previously received advice that it complies with the early stage investors (ESIC) program for eligible shareholders. If you are interested in participating in this program, please discuss this with your accountant and/or financial advisor.

Please refer to the Australian Tax Office website https://www.ato.gov.au/Business/Tax-incentives-for-innovation/In-detail/Tax-incentives-for-early-stage-investors/ for further information.

NEAR TERM MILESTONES

The following are the main milestones for ReNerve during 2020:

- submission to the FDA for marketing approval for the NervAlign nerve wrap
- nerve graft implantation study completion
- completion of prototype design for the tissue treatment kit