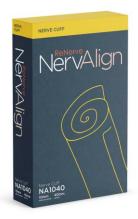
# **RENERVE NEWSLETTER**

January 2019

#### RENERVE AWARDED ACCELERATING COMMERCIALISATION GRANT

ReNerve has been awarded a \$590,000 non-dilutive commercialisation grant from the Australian Government through Accelerating Commercialisation, an element of the Entrepreneurs' Programme.

The Grant covers additional testing of the ReNerve NervAlign<sup>™</sup> nerve cuff and other activities required for regulatory approval and product commercialization. This will include raising global awareness of ReNerve and its technologies for the repair of damaged peripheral nerves, particularly through engagement with key international surgical opinion leaders in this market.



## PROGRESS

Dear Shareholders,

Firstly, we would like to offer a warm welcome to our new shareholders and thank them and existing shareholders for their support in the capital raising in the second half of 2018. We are pleased to report significant progress since our last newsletter. In particular:

- the Company raised a total of \$800,000 through the capital raising completed in September 2018. Since then, the Company has been awarded an Accelerating Commercialisation grant with an estimated value of \$590,000. The grant will further support the development of the Company's NervAlign<sup>™</sup> nerve cuff product;
- we have commenced the testing and regulatory activities required to progress the NervAlign<sup>™</sup> cuff product to market; and
- initial testing of our nerve conduit technology has produced highly encouraging results.

## **NERVE WRAP TECHNOLOGIES**

ReNerve continues to engage with Leader BioMedical, the manufacturer of the NervAlign<sup>™</sup> nerve cuff. Leader is completing pilot scale manufacturing of 3 small batches of the product. ReNerve will use these batches for final testing, including implantation tests, and to support the completion of an FDA regulatory submission package. The completed package will be filed with the FDA to seek marketing clearance for the NervAlign<sup>™</sup> cuff. The Company anticipates that final testing of the nerve cuff product will be completed during 2019.

ReNerve has commenced the development of its Quality Management Systems and documentation that will be required to progress the NervAlign<sup>™</sup> product to market. A key element of this will be a Quality Audit of the Leader production facilities, scheduled for the first quarter of this year, ahead of ongoing product testing and the preparation of the FDA marketing clearance package.

## **NERVE CONDUIT TECHNOLOGIES**

ReNerve continues to progress its nerve conduit program. We recently reached a major milestone with the completion of the first of our initial large animal implant studies. In this study, the ReNerve nerve conduit was used to replace a piece of native nerve and the clinical results were compared directly to an adjacent autologous nerve graft. The autologous nerve graft comparison replicates the current clinical gold standard for peripheral nerve gap repair, in which a patient's own nerves are transplanted as an autologous graft in an attempt to repair damaged nerves. This study design provides ReNerve with a direct comparison of the efficacy of its nerve conduits relative to the current clinical gold standard.

Four months after nerve conduit implantation, the animals had regained partial function through the repair of the nerves, indicative of positive clinical progress with the conduit. The nerves were explanted and assessed. The data showed that the ReNerve conduits exhibited patterns of nerve regrowth similar to those of the autologous nerves. Significantly, nerve growth in the ReNerve conduits occurred throughout the length of the 2cm implanted conduits, an extremely encouraging result for our first-generation conduit product. While the results are from very early stage testing, they provide confirmation of the potential of our conduit technology to supplant both autologous graft surgical practice and the allograft nerve repair technology of industry leader Axogen Inc.

In the next round of studies, planned to commence shortly, ReNerve intends to combine the NervAlign<sup>™</sup> nerve cuff with its conduit implants, seeking both to improve clinical outcomes and to generate additional data to support an extension of the range of applications of the NervAlign<sup>™</sup> nerve cuff.

### **REPLACEMENT NERVES**

ReNerve has been awarded a \$25,000 CSIRO Kickstart grant and is working with CSIRO to design and develop materials suited to replacing long nerves. In a separate program, ReNerve is working with Monash University, sponsoring a PhD student to explore and develop a range of polymer materials for applications in the repair of long nerve defects.

### **FINANCIAL UPDATE**

In addition to the capital raising completed in September 2018 and the award of the Accelerating Commercialisation Grant, the Company's financial position has been bolstered by the receipt of a refund of R&D expenditure of \$109,000 under the Australian Taxation Office's Research and Development tax incentive. The refund represents 43.5% of R&D expenditure for FY18 and will be reinvested into ReNerve's projects.

As of the 20<sup>th</sup> of January, ReNerve had over \$700,000 cash on hand. In addition, we have initiated the Accelerating Commercialisation grant funding, which will be received progressively over the next four quarters on a matching basis as expenditure is incurred on progressing the NervAlign<sup>™</sup> nerve cuff project.

## TAX INCENTIVES FOR EARLY STAGE INVESTORS

ReNerve has received advice that it complies with the early stage investors (ESIC) program for eligible shareholders. ReNerve has notified the ATO of its ESIC status.

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

## **NEAR TERM MILESTONES**

The Company is planning a number of key activities in the first half of 2019, including:

- Audit and regulatory planning with Leader and its manufacturing facilities in Europe
- Initiation of the NervAlign<sup>™</sup> nerve cuff implantation study
- Initiation of additional nerve conduit studies including a combination of the nerve conduit and nerve wrap