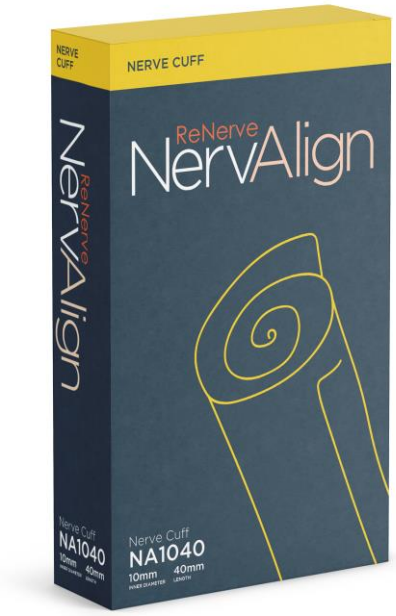
RENERVE NEWSLETTER

September 2019



PROGRESS

Dear Shareholders,

ReNerve continues to make progress towards developing products for the global nerve repair and replacement market. In particular:

- the company remains on track to have an FDA filing package for marketing approval of the NervAlign™ nerve cuff in the first half of 2020;
- prototype testing of our nerve conduit product (via large animal implant studies) has yielded highly positive preliminary results, reinforcing the opportunity to develop a product clearly superior to the current industry standard of care; and
- ReNerve anticipates further study and test results over the next six months that will underpin development of both the NervAlign™ nerve cuff and our nerve conduit product.

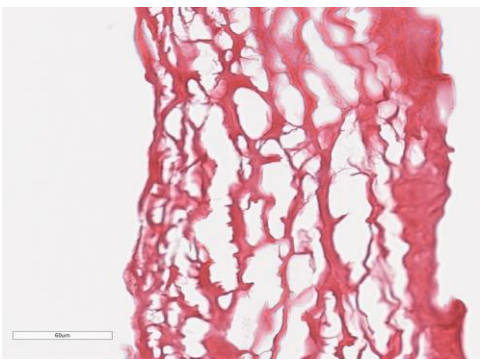
NERVE WRAP TECHNOLOGIES

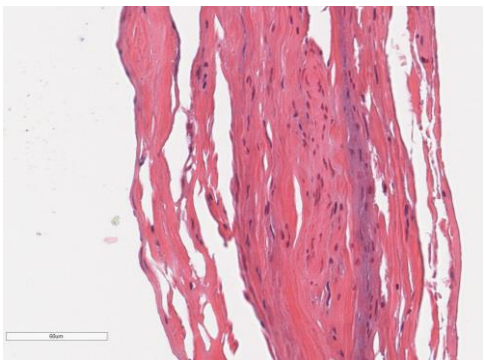
ReNerve plans to leverage the FDA approval of a technical predicate material to support the approval of the NervAlign™ nerve cuff in the US. In addition, ReNerve is completing several studies required for submission of the NervAlign™ data package for regulatory review.

Of these, ReNerve has:

- completed bench testing of the nerve cuff required for the FDA filing package;
- commenced the final implantation study, with all samples implanted. Early indications suggest the material is performing in line with expectations with the final data due in the first quarter of CY20

From a commercial and clinical perspective, we believe that the NervAlign™ nerve cuff will have significant advantages relative to products currently in the market, with very low costs of manufacture allowing it to be highly price competitive and very benign clinical characteristics. The diagrams below compare NervAlign™ material with the market leading AxoGuard Protector competitor:

A). 

B). 

Histological comparison of the NervAlign™ sample **(A)** with that of the AxoGuard Protector competitor **(B)** demonstrates that the NervALign™ material provides a far "cleaner" collagen scaffold (represented by the reddish/pink staining), almost completely free of the blue/dark purple staining nuclei visible in the AxoGuard material.

NERVE CONDUIT TECHNOLOGIES

ReNerve continues to progress its nerve conduit program. Following our recent milestone of completion of the first of our initial large animal implant studies, we have commenced the second part of this study with additional animals and improved conduit preparations.

In this series of studies the ReNerve nerve conduit was used to replace a piece of native nerve and the results will be 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.

After approximately two and half months, which is even sooner than for the first round of implants, several animals containing the second generation conduit are showing significant improvement in leg function. They have improved from a poorly functioning leg immediately following the surgical introduction of nerve defects and the concomitant nerve implants, to a near fully functional leg as a result of nerve repair.

These outcomes provide considerable cause for confidence that we will be able to produce an off-the-shelf nerve conduit that can be used in the repair of damaged nerves. In particular, the preliminary results from the large animal study suggest that there is a real opportunity to develop a product that will have major cost and clinical benefits relative to the only product currently in the nerve conduit market, Axogen's Avance® Nerve Graft product.

Additional animals are scheduled to receive an even longer conduit implant, which, if successful, will put the conduit at the top of the range for longest nerve repair products. The implant studies, on conclusion, will also allow us to compare the efficacy of our nerve conduits with the animal's autologous nerve grafts. This will be particularly meaningful, given the clear message in recent discussions with various Key Opinion Leaders (KOLs) that there is a pressing market need for nerve conduit options to replace autologous grafts, both to improve efficacy and to avoid the litigation risks associated with areas of numbness /lack of sensation that result from the harvesting of donor autologous nerves.

In future studies, ReNerve will assess the combination of its NervAlign™ 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™ nerve cuff.

EXPANSION USE OF THE CORE TECHNOLGY

ReNerve has begun discussions with donor tissue banks to explore the use of ReNerve's core technology (as used to produce the nerve conduits) into the production of tissue from donors. The application would be to use the tissue treatment process developed by ReNerve to prepare heart valves, pericardium tissue, vascular tissue, donor nerve tissue and tendons for ACL repairs. The process may need adaption in some cases; however, this would provide another validation source for the technology as well as expansion of the technology into new markets.

REPLACEMENT NERVES

To extend the ability to match diameters and internal structures of nerves requiring repair, ReNerve's replacement nerve program is focusing on the development of a range of synthetic fiber materials to enable the production of custom nerve sizes.

To date ReNerve has investigated the ability to support cell growth of several synthetic polymers and polymers blended with extracellular matrix materials extracted from ReNerve's proprietary conduits. Data shows these materials are compatible with cells.

As part of the program of nerve characterisation, ReNerve has developed custom patterns to be utilised in fibre production and is developing commercial scale techniques for production of these new types of conduits.

Materials will be produced with structures to guide nerve regrowth and to limit the negative impacts of scar tissue and neuroma formation.

FINANCIAL UPDATE

As at the end of August 2019, ReNerve had approximately $330,000 of cash on hand, with its annual R&D tax rebate claim to be filed in the month of September. The company has submitted an advanced application to the ATO to ensure that it is able to claim overseas costs for studies that cannot be undertaken in Australia, such as the nerve cuff implantation study to FDA standards. In addition, expenditure incurred on the NervAlign™ nerve cuff program will continue to attract matching funding under the Australian Federal Government's Accelerating Commercialisation grant.

CAPITAL RAISING

Completion of the NervAlign™ nerve cuff filing package and application for marketing approval in the US, together with progression of the Company's nerve conduit program towards clinical studies, will require additional capital. ReNerve is currently planning on raising capital towards the end of 2019 or early in 2020. A number of funding options are being explored.

TAX INCENTIVES FOR EARLY STAGE INVESTORS

ReNerve has received advice that it complies with the early stage investors (ESIC) program for eligible shareholders. ReNerve will notify the ATO of its ESIC status for the FY19 period, enabling investors to participate in this program if they desire.

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

- completion of the nerve cuff implantation study
- completion of the second round of nerve conduit sheep studies and analysis of nerve growth; and
- development of the NervAlign tissue treatment kit in conjunction with donor tissue banks within Australia