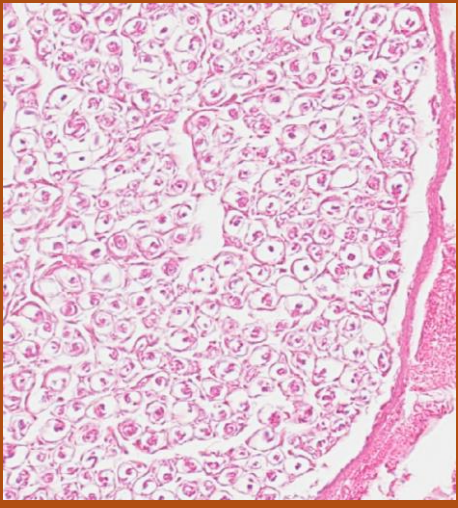


# RENERVE NEWSLETTER

Issue 2 / May 2018

## EXCLUSIVE DEVELOPMENT OF NERVE WRAP TECHNOLOGY

ReNerve finalized exclusive worldwide agreement for Nerve Wrap technology and is progressing towards regulatory clearance.



## PROGRESS

Dear Shareholders,

ReNerve is pleased to report meaningful progress since our last shareholder Newsletter. We have made significant advances with each of our three nerve repair technologies. Importantly, we have concluded a licensing and supply agreement that will accelerate the route to market for our intended first product, an innovative nerve wrap product. We have strengthened our Board of Directors and will soon be undertaking a capital raising to fund the continued development of our three major programs. This Newsletter provides an update on ReNerve's major activities over the past nine months.

### New Director Appointment

ReNerve is delighted to announce that Dr Michael Panaccio has agreed to join our Board of Directors. Dr Panaccio's experience in the medtech and healthcare sectors, particularly in working with and investing in companies developing new technologies, will be invaluable to ReNerve. Dr Panaccio has founded and managed various bioscience focused venture capital funds (Starfish Ventures and JAFCO Investment (Asia Pacific)) and has sat on the boards of several medical device companies including Sirtex (~~recently~~ currently being sold with latest offer of \$1.9Bn for \$1.6bn) and the ASX-listed Impedimed. His experience includes capital raising, program management, product commercialization and value realization.

## Technology Updates

ReNerve has made progress on several fronts with the development and commercialization of its three main technologies.

### Nerve Wrap Technologies:

ReNerve has finalised a licensing and supply agreement to access a nerve wrap material that has its basis in a novel non-toxic supercritical CO<sub>2</sub> cleaning process. This agreement provides ReNerve with exclusive worldwide rights for the sale of this product for use in nerve and neural repair. ReNerve will complete the required preclinical development of this product and submit the dossier for US regulatory clearance, with the objective of launching the product initially in the US.

ReNerve expects that the studies required for submission for registration approval will be completed over the next 12 months. Importantly, the manufacturing technology and tissue under the license has been validated for human use through another product already approved in Europe for dental applications.

The product has applications both as a standalone nerve wrap product and also potentially in combination with ReNerve's future conduit technologies. The market size for the nerve wrap technology is estimated at over US\$1bn p.a.

### Nerve Conduit Technologies:

ReNerve is finalising two potential methods of production of nerve conduits using its proprietary treatment method and two different processing technologies. The more recent processing methodology developments have the potential to further reduce preparation time and thereby reduce cost of goods and increase product margins.

ReNerve has also furthered its work on harvesting a wide range of sizes and diameters of nerve materials as a source of its nerve conduits. It has engaged an established tissue supplier to assist in developing tissue supply chain methodologies suitable for scaled up manufacturing in the future.

ReNerve in conjunction with CSIRO is in the process of securing a 12 month loan of a supercritical CO<sub>2</sub> instrument to further the development of additional tissue preparation and sterilisation processes. ReNerve believes supercritical CO<sub>2</sub> processing may provide significant advantages in the preparation of tissue repair products such as nerve conduits, and that the use of this technology would give ReNerve a unique product in the surgical nerve repair market.

In preparation for animal testing of its nerve conduit prototypes, ReNerve has developed expertise with a large animal model and is progressing towards conducting proof of concept studies in this model. Due to the sizes and locations of nerves used in these models the results will likely be more reflective of outcomes expected in humans than standard rat models, which correlate poorly with clinical efficacy.

### Long Nerve Replacement Technologies:

ReNerve continues to strengthen its links with CSIRO in the development of new conduit technologies and is initiating a program to access information and polymers derived over a 10 year period at CSIRO, which includes positive animal data, and apply these to the development of long nerve repair conduits.

### **IP and Trademarks**

ReNerve has had its Trademark application for the name ReNerve accepted in Australia and has filed an international extension for protection in US and several jurisdictions in Europe. This is important in the development of its brand name and product range across the world. With the signing of the nerve wrap license agreement, ReNerve is progressing the development and protection of the names for its range of products. The Company is also working on branding names for the product ranges across the cuff and nerve conduit products.

### **Additional Technology development support:**

In conjunction with CSIRO and Monash University ReNerve has a PhD student commence to explore new technologies and designs in the production of nerve replacements.

### **Grant support:**

ReNerve continues to pursue a variety of additional non-dilutive funding opportunities to leverage shareholders' investments in the company.

ReNerve has received its R&D Tax incentive payment from activities conducted in FY17 and plans to file for the R&D tax incentive for FY18 soon after the completion of FY18.

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