

RENERVE NEWSLETTER

October 2022

Dear Shareholders,

Company update

SALES AND MARKETING MOMENTUM IN THE USA

ReNerve is pleased to announce that the Company's initial sales and marketing initiatives in the USA have shown that there is considerable market interest in our product portfolio.

Following receipt of full FDA product registration for the NervAlign® Nerve Cuff in May, ReNerve has continued to grow the US market awareness of the Nerve Cuff product. ReNerve has appointed Emerging Surgical and MLM Medical as sales distributors for California and the US East Coast. During September, ReNerve attended the American Society for Surgery of the Hand (ASSH) conference in Boston, where it received strong positive feedback on the Cuff. In general, surgeons have commented very favourably on the Cuff's key characteristics (particularly its ease of handling, pliability and bio-absorption) by comparison with the major competing products in the US market.

Together with its distributors, ReNerve has worked with a number of major hospital and surgical groups to secure group purchasing approvals for the NervAlign® Nerve Cuff. While these approval processes can be protracted, ReNerve is delighted to announce that they have culminated in a number of initial orders for the Cuff, with total sales for October expected to approach A\$40,000. ReNerve expects that sales will be lumpy in the short term, as hospitals place initial stocking orders, surgeons become familiar with and use the Cuff and new customers are secured. Nevertheless, the very positive endorsements of a number of eminent surgeons and the initial sales success represent a powerful validation of the NervAlign® Nerve Cuff.

To support its US market entrance, ReNerve is in the process of establishing a US based scientific advisory board (SAB). This will comprise a selection of experienced surgeons who have a deep understanding of nerve repair and who will support ReNerve in its product portfolio development as well as clinical support. To extend its US coverage, ReNerve is also seeking to appoint distributors to cover the US Midwest and the Northwest.

While ReNerve's sales and marketing focus will be on the US market, ReNerve will also leverage its US FDA market clearance to achieve market entry in other countries. ReNerve has partnered with Endosport in New Zealand and has marketing approval in that market. ReNerve has entered into a partnership with Kou's Yuan to apply for marketing approval for the NervAlign® Nerve Cuff in Taiwan and to launch the product. ReNerve is working with a potential partner in South Africa on product assessment ahead of market approval. The Company is also considering opportunities in other countries.

PRODUCT DEVELOPMENT

NervAlign Nerve Graft

ReNerve continues to progress the development of its NervAlign® Nerve Graft. In particular, the Company has continued development activities to refine the production methodology and the final product format. These refinements also utilize data from ongoing small animal studies which are planned for completion in early 2023. ReNerve then plans to trial the finalized technology in another round of sheep studies anticipated to commence in early 2023. Simultaneously, ReNerve is looking to partner with a 3rd party manufacturer that will work with ReNerve to scale the manufacturing to generate product for the formal studies required for an FDA submission as well as ready it for commercial scale.

Suite 3, 21 Vale St North Melbourne Vic 3051

ReNerve is considering splitting the development of the nerve graft into two separate products: a shorter Nerve graft product, which may be able to take advantage of a simplified regulatory approvals process and accordingly could achieve marketing approval via an accelerated timeline, and a longer product, available in a variety of lengths and diameters, which would potentially follow on to expand the graft product offering.

Significantly, market feedback in the US, gathered in the context of sales and marketing activity in relation to the NervAlign® Nerve Cuff, confirms very real market interest in ReNerve’s nerve graft product. Based on our interaction with the market, it is clear that there is considerable unmet medical demand for a nerve graft product such as the NervAlign® Nerve Graft, and that ReNerve has an opportunity to build a valuable position in the market for the replacement of damaged nerves, in conjunction with the Company’s complementary NervAlign® Nerve Cuff product.

Dura mater project

ReNerve has announced the expansion of its product portfolio into the dura mater replacement market. The dura mater is the outermost layer of the three meninges (connective tissue layers) that surround and protect the brain and spinal cord. The Company plans to develop two dura mater products:

1. Leveraging the supercritical CO₂ technology (used to produce the NervAlign® Nerve Cuff product), ReNerve will initially focus on a smaller dura mater replacement product. ReNerve believes that it can develop a dura mater replacement product based on the supercritical CO₂ technology to push for a filing of the product at the FDA within 15 to 18 months. This product would focus on being a cleaner, safer material that is remodeled during the patient recovery period.
2. The second product would be a unique multi-layered product. The product would have a non-adhesive layer as well as the ability to deliver antibacterial agents at the site of repair. This would prevent local adhesion, an issue faced by neurosurgeons with several existing products, as well as prevent the onset of post operative infections.

FINANCIAL

ReNerve has released its Annual Report, and this is available to shareholders upon request. The highlights of the full year report are:

Item	2021/22	2020/21
Revenue	\$578,171	\$490,581
R&D Cash rebate	\$350,486	\$272,448
Total current assets	\$2,655,866	\$2,535,957
Closing cash balance	\$1,710,186	\$2,169,676
Net Profit/loss	-\$1,757,480	-\$875,027

Most of the revenue for the period came from Government R&D tax rebates. Total current assets at 30 June 2022, which include product inventory, were marginally higher than for the prior corresponding period. The Company’s net loss for the year increased to \$1,757,480, reflecting increased spending during the year on the NervAlign® Nerve Cuff and its FDA market clearance enabling studies.

CAPITAL RAISING

At its AGM on 18 October 2022, ReNerve announced that it will be looking to raise fresh equity. Shareholders will be aware that during 2022 the Company has continued to explore a possible listing on the Australian Stock Exchange. However, current market conditions mean that ReNerve is unlikely to be able to complete an IPO in the short term. Given the position of ReNerve and the opportunities ahead, the Company believes that securing additional growth capital now will have major benefits, allowing the Company to accelerate its sales and marketing efforts in the USA Suite 3, 21 Vale St North Melbourne Vic 3051

and progress the development of the NervAlign® Nerve Graft, in turn strengthening the Company's position in a future IPO.

ReNerve has appointed Canary Capital to raise up to \$2 million, via a capital raising priced at \$0.20 per share, with priority being given to existing shareholders. The raising is planned to close on the 18th of November with settlement anticipated for the 24th of November. Canary Capital will shortly contact shareholders. ReNerve directors recommend that shareholders give careful consideration to participating in the capital raising and will themselves subscribe for new shares. In addition, ReNerve plans to engage with potential new institutional and other shareholders with a view to raising additional capital if available. To this end, ReNerve has received shareholder approval (through a resolution of shareholders voting more than 50% of ReNerve shares on issue) to raise additional capital by way of an issue to new investors of shares representing up to 25% of ReNerve's current shares on issue, at an issue price of \$0.20 per share.

2022/23 MILESTONES

In the coming 12 to 24 months the company anticipates the following milestones:

- Growth of NervAlign® Nerve Cuff sales
- NervAlign® Nerve Cuff clinical study
- NervAlign® Nerve Graft development and manufacturing partnership
- NervAlign® Nerve Graft entering formal studies ahead of clinical trials
- Dura mater animal and bridging in vitro tests for FDA submission
- Dura mater first FDA submission

Any shareholder seeking further information about ReNerve, its progress or the upcoming capital raising should feel free to call Chief Executive Julian Chick on 0417137291 or Chairman Stephen Cooper on 0419 344 336.

ReNerve.com.au

Suite 3, 21 Vale St

North Melbourne. Vic. 3051