15th February 2021

Company announcement

Major progress on FDA marketing approval application – UPDATE

ReNerve Limited ABN 23 614 848 216 (**ReNerve**) is pleased to provide an update on its US Food and Drug Administration (**FDA**)marketing authorisation application. ReNerve initially submitted its FDA application in August 2020 and progressed to the substantive review process in November 2020. The company has had several rounds of questions and interactions with the FDA and believes it is now in the final round of questions from the FDA ahead of marketing approval.

Since making the application to the FDA, ReNerve has engaged with the FDA to answer a number of follow up questions from FDA. Based on discussions with FDA, ReNerve is confident it will successfully obtain marketing approval in the United States for the NervAlign Nerve Cuff product in the early 2022. To date all interactions with the FDA have been positive and all questions asked by the agency have been addressable by the company.

As a result, ReNerve has increased its efforts to reach out to surgeons based in the United States to raise the profile of the company, its brand NervAlign and the Nerve Cuff product. Additionally, ReNerve is continuing to pursue obtaining approval for the NervAlign Nerve Cuff in Hong Kong and South Africa, as well as continuing to work on engaging with surgeons in Australia and beyond to explore clinical studies with the NervAlign Nerve Cuff and the Nerve Graft.

About ReNerve:

ReNerve Limited is an Australian public unlisted medical device company dedicated to developing genuine solutions to peripheral nerve repair and related procedures. Our goal is to develop and bring to market a range of products. Our most advanced product, the NervAlign Nerve Cuff, is currently subject to substantive review by the FDA for marketing clearance in the US. We have enjoyed positive interactions with the FDA and are confident that we have a well-defined path to securing FDA approval. We are pursuing marketing approval for the product in other countries and expect that FDA clearance will support this process. ReNerve intends to use regional or country focused distributors to help market and sell the product. ReNerve continues to develop its NervAlign Nerve Graft. This is a “ready to use” replacement nerve that comes off the shelf, allowing surgeons to avoid the need to harvest functional nerves from the patient. The company is currently undertaking additional preclinical testing with a goal to progressing the product to a clinical trial in advance of seeking marketing approval. The NervAlign Nerve Graft can be used in conjunction with the ReNerve Nerve Cuff and could be sold separately or bundled together. The company will continue with its R&D projects around a ‘bionic’ replacement nerve and the operating room ‘OR’ tissue treatment kit.