



Leading FDA consultancy Emergo engaged

- *Neurotech and Emergo targeting Pre-Submission Meeting with the FDA in Q2 2017*
- *Emergo has demonstrated widespread success in successfully preparing and submitting FDA 510(k) submissions*
 - *Mente Autism on show at Arab Health conference*

Perth, Australia & Malta – 6 February 2017 – Neurotech International Limited (ASX: NTI) (“Neurotech” or “the Company”), developer of quality medical solutions in the neuroscience space, has engaged Emergo as its regulatory consultant in the USA.

Emergo is a leading consultancy with more than 2,800 medical device and in vitro diagnostic device (IVD) clients, offering a wide range of compliance and market access services. The firm is headquartered in the US and maintains offices worldwide. Among other things, Emergo assists companies with global regulatory strategy, device registration, quality management system compliance, and in-country regulatory representation. As an FDA consulting firm for medical devices and IVD, it has successfully prepared and submitted FDA 510(k) submissions for medical device and IVD companies from around the world seeking to sell in the United States.

Neurotech will work with Emergo to prepare and submit a Pre-Submission package to the FDA, with the aim of conducting a Pre-Submission Meeting with the FDA in Q2 2017. While the previous *Mente 2* device is already FDA listed, the purpose of this meeting will be to introduce Neurotech and the third iteration of the technology, *Mente Autism*, to the FDA prior to any formal submissions.

Wolfgang Storf, CEO of Neurotech International and its subsidiary AAT Medical, said: “The recent appointment of Emergo is a major step forward for the company as we seek regulatory approval of our technology in the US. The consultancy’s experience, particularly in obtaining FDA 510(k) clearance for medical devices, makes them a key partner as we move to market our innovative technology.

“The aim of the Pre-Submission Meeting is to obtain feedback from the FDA in response to specific questions related to marketing application, clinical study protocols and other requirements prior to the formal submission. This will be crucial to Neurotech’s strategy and plans to commercialise its technology in the US, in particular providing the market with a home-based, clinical quality EEG device that helps to calm the minds of children on the autism spectrum.

“In conjunction with Emergo we will also closely monitor any proposed changes to the FDA process and how they may impact our approval process.”

Neurotech attends Arab Health

Neurotech management has this week attended the 2017 Arab Health conference in Dubai, generating significant business development opportunities for the Company.

The commercial team from Neurotech including CEO Wolfgang Storf, attended the three-day conference, meeting with distributors and potential partners in the region. The *Mente Autism* device

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was demonstrated to potential partners from Saudi Arabia, United Arab Emirates, Bahrain, Qatar, Oman, Jordan and Kuwait.

Arab Health is the largest gathering of healthcare and trade professionals in the Middle East and North Africa region, attracting more than 4,000 healthcare companies from 70 countries.

“Arab Health is a very important event for us and a great region in which to do business,” Mr Storf said.

“We have seen an increase in awareness around autism and the need for new therapies to help children on the spectrum,” he said.

“During our meetings and demonstrations, potential distribution partners saw the Mente Autism device in use and commented how user-friendly it is. There was a lot of interest in how the system works and many potential partners we spoke to are very keen to test it in their region.

“Arab Health was a positive event for us and we look forward to building momentum in the region over the coming months.”

For more information about Neurotech and Mente Autism please visit:

<http://www.neurotechinternational.com>.

<http://www.mentetech.com>.

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About Neurotech

Neurotech International Limited is a medical device and solutions company incorporated in Australia and operating through its wholly-owned, Malta-based subsidiary AAT Research Limited. Neurotech’s primary mission is to improve the lives of people with neurological conditions, with a vision of becoming the global leader in home-use and clinical neurotechnology solutions that are both accessible and affordable. Through flagship device Mente Autism and its associated platform, Neurotech is focused on the development and commercialisation of technological solutions for the diagnosis and treatment of such conditions, starting with autism. For more information, visit: <http://www.neurotechinternational.com>.

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