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ASX Limited
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BPH investee Cortical commences USA FDA (510K) Filing application process

Cortical has now begun the FDA 510K filing process for BARM in the USA assisted by its strategic investor Intuitive X (IX)*.

The Food and Drug Administration (“**FDA**”) is the federal agency of the United States Department of Health and Human Services which regulates the sale of medical device products (including diagnostic tests) in the U.S. and monitors the safety of all regulated medical products. FDA approval is a necessary precursor for sales of BARM to commence in the USA.

Cortical already has achieved both CE (Europe) and TGA (Australian) registration and is currently awaiting final approval of the Company’s registration application to the Korean Ministry of Food and Drug Safety.

David Breeze (Director) authorised the release of this announcement to the market. BPH has a net interest of 16% in Cortical Dynamics Ltd. (<https://corticaldynamics.com/>).

Yours sincerely,

A handwritten signature in black ink, appearing to read "D. Breeze".

David Breeze
Executive Director

*IX (<https://www.intuitive-x.com/>) is a US life science accelerator, incubator and consulting service created to help its portfolio companies, inventors and entrepreneurs transform their ideas into products and services that scale into businesses which help patient’s lead healthier, more productive lives.

X helps catalyse medical innovation by increasing the probability of success for innovators by helping remove the complexities, cost barriers, and time sensitivities related to introducing new products into the market. From initial concept to final commercialization, IX have the in-house knowledge and network of resources to oversee product development, prototyping, FDA, FTC, and legal compliance. IX also connects their clients and portfolio companies with financing sources, create forecast models, and perform data analytics.



INTRODUCING BARM BRAIN FUNCTION MONITOR

- Developed in Australia by Cortical Dynamics to better detect the effect of anaesthetic agents on a patient's brain activities and aid anaesthetists in keeping patients optimally medicated
- The only system with methods (or algorithms) based on a model of brain electrical activity derived from physiological principles. Existing monitoring systems on the market use statistically based empirical approaches
- Offers improved patient health outcomes and reduces hospital costs
- BARM reliably quantifies and continuously monitors a patient's anaesthetic state.

Cortical Dynamics

About Cortical

Cortical is an Australian based medical device technology company that has developed a next generation Brain Function Monitor. The company is focused on commercialising the intellectual property developed at Swinburne University. The core-product the Brain Anaesthesia Response (BAR) monitor has been developed with the objective of better detecting the effect of anaesthetic agents on brain activity, aiding anaesthetists in keeping patients optimally anaesthetised.

The BAR monitor improves on currently used electroencephalogram (EEG) technologies by incorporating the latest advances in our understanding of how the brain's rhythmic electrical activity, the electroencephalogram (EEG), is produced. The approach used is fundamentally different from all other devices currently available in the market in that its underlying algorithm produces EEG indexes which are directly related to the physiological state of the patient's brain.

The global brain monitoring devices market is broadly segmented into three categories based on its product, application, and end-user. Fueling market growth is the various technological advancements which are leading to high functionality, lower costs, ease of operation, and miniaturization of devices.

Cortical will initially focus on the Total Intravenous Anaesthesia ("TIVA") market within Europe. TIVA provides a method of inducing and maintaining general anaesthesia without the use of any inhalation agents. The English healthcare body NICE (National Institute for Health and Care Excellence) has recommended EEG (electroencephalogram) based depth of anaesthesia monitors as options in patients receiving TIVA and in patients who are considered at higher risk of adverse outcomes during any type of general anaesthesia. This includes patients at higher risk of unintended awareness and/or excessively deep anaesthesia. It has been estimated that approximately 29 million major general surgery general anaesthetics are conducted in the EU each year of which 55% are balanced anaesthesia (using a combination of intravenous agents such as propofol and volatile gases) and 20% are total intravenous anaesthesia (TIVA) using propofol.

Cortical now has Seattle based, USA IntuitiveX ("IX") and Seoul based, Gentium Partners as shareholders. IX is a US life science accelerator, incubator and consulting service investor.