



29<sup>th</sup> September 2019

Companies Announcement Office  
ASX Limited  
Exchange Centre  
Level 4, 20 Bridge Street  
Sydney, NSW 2000

Dear Sir/Madam

BPH Energy Ltd (ASX: BPH) investee Cortical Dynamics confirms Korean regulatory milestone

**Globaluck ,Cortical Dynamics South Korean exclusive distributor of the Brain Anaesthetic Response Monitoring system, has now received Korean KGMP certification**

Cortical Dynamics Ltd has announced its Korean distributor ,Globaluck, has received the KGMP certificate of approval for its BARM (Class II Medical Device) from the Korea Good Manufacturing Practice (KGMP) .

The approval followed an independent Korean audit of Cortical's facility in Scoresby, Victoria during July . Globaluck, are the exclusive distributor of Cortical's Brain Anaesthesia Monitoring System(BARM) medical device product in South Korea,

KGMP certification is required by the Korean Ministry of Food and Drug Safety (MFDS) before placement of Class II, III, and IV medical devices on the South Korean market. To obtain KGMP certification, a company must submit documentation to an MFDS authorized third party auditor, demonstrating that the device complies with design, risk, technical, and related KGMP quality system requirements. Following submission of the KGMP certification application, the manufacturing site undergoes inspection by a qualified third-party auditor and/or the MFDS depending on the device's classification.

Yours sincerely,

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

David Breeze

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Chairman

## **About the BARM System**

The Brain Anaesthesia Response (BARM) System measures a patient's brain electrical activity, the electroencephalogram (EEG), in order to indicate how deeply anaesthetised a patient is during an operation via an adhesive sensor applied to the forehead. The BARM System is designed to assist anaesthetists and intensive care staff in ensuring patients do not wake unexpectedly, as well as reducing the incidence of side effects associated with the anaesthetic.

## **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 (BARM) System 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 BARM System 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 market in 2012 was valued at \$1.08 billion and is poised to grow and reach \$1.63 billion by 2020. 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. In Italy the Society of Intravenous Anaesthesia has reported that TIVA usage has already reached 40% of all anaesthesia procedures.

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Cortical's technology has a versatility that goes beyond depth of anaesthesia and may be applied to other EEG based markets, such as Neuro-diagnostic, drug discovery, drug evaluation and the emerging Brain Computer Interface (BCI) market.

There are considerable opportunities offered by subsequent expansion of the company's core technology through developing the product to carry out additional functions including neuro-diagnostics of changes in brain and memory functions to provide early warning of degenerative diseases, pain response and tranquilizer monitoring for trauma patients in intensive care units.

While a number of EEG monitors are commercially available, one that is reliably able to quantify the patient's anaesthetic state is still desperately needed. The specific advantages of Cortical's BARM System over all other competing systems include: It produces EEG indexes which are based on physiological mechanisms direct from the patient, unlike other systems on the market which produces EEG indexes based on statistically based empirical approaches.

It is therefore fundamentally differentiated from the competitive technologies. It produces a reading within 3 seconds of start-up and an updated reading every second thereafter, compared to 30 second updates on competing systems. It has shown to be able to monitor hypnosis and analgesia independently by EEG. It provides much greater sensitivity, allowing the monitor to identify changes in brain function and detect several classes of anaesthesia and other brain disorders.

The BARM System is protected by five patent families in multiple jurisdictions worldwide consisting 22 granted patents

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