

Submission regarding tax incentives for early stage investors

24 02 2016

This submission is made in response to Consultation Paper release dated 15 02 2016

The comments are made only in relation to certain aspects of the proposed policy as outlined in releases

- The comments are made in relation to a specific example of an innovation company Cortical Dynamics Ltd which is a spin off from Swinburne University
- The company website is www.corticaldynamics.com
- Cortical was founded in 2004 to commercialise the intellectual property developed by Professor David Liley of Swinburne University.
- Cortical's Brain Anaesthesia Response (BAR) monitor measures brain electrical activity. The electrical activity recorded from the scalp, the **electroencephalogram** (EEG), is one of the most important quantifiable measures of brain function.
- Cortical Dynamics Ltd is a publicly unlisted medical device company focused on developing the next generation brain function monitors.
- The global market for brain function monitors used during anaesthesia is estimated to be over \$1 billion.
- To date approx. \$3 million has been spent on the development of the technology.
- Believed to be the only EEG based Depth of Anaesthesia monitor to measure both *hypnotic** and *analgesic* state. [#]*Hypnotic – level of unconsciousness* [#]*Analgesic – pain relief*
- Usually a combination of **hypnotic*** and **analgesic** [#] drugs are used to achieve a state of “balanced” general anaesthesia in the surgical patient.
- Current EEG based monitors operate in the context of a number of well documented limitations:
 - Incapable of monitoring the analgesic effects.
 - Not all hypnotic agents are reliably measured.
- Anaesthesia awareness or “intra-operative awareness” occurs during general anaesthesia when a patient is **not** sufficiently anaesthetised to prevent consciousness.
- Incidence rate is approximately 1 to 2 patients per 1000 receiving general anaesthesia.
- Administering **too** much anaesthetic agents results in nausea, increased length of hospital stay, Post Operative Cognitive Decline and Post Operative Delirium.
- The competitive advantages of this device are claimed to be
 - Capable of detecting anaesthetic agents other depth of anaesthesia monitors can't.
 - Capable of detecting the effects of analgesic agents, which no other depth of anaesthesia monitors can.
- Only monitor with algorithms based on a model of brain electrical activity.
- Cortical estimates that approximately 260 million people each year are administered general anaesthesia.
- 20 million of these are considered at a higher risk of adverse events
- Operating theatres represent BAR's initial market opportunity.
- There are an estimated 327,689 Operating Theatres world wide ¹ that are capable of adopting the BAR monitor ¹

The technology has been described independently as “It is a paradigm busting technology from an Australian based device house that really gives a significant advantage in this space”

This detail is provided because it enables this submission to provide an example to highlight the shortcomings of the proposed legislative framework

It has taken approximately ten years to develop the technology to a stage where it has just received formal notification from the Therapeutic Goods Administration (“TGA”) that a decision has been made to issue MRA EC certificates (“CE Mark”) to Cortical under the Mutual Recognition Agreement (MRA) with the European Union therefore allowing the CE mark to be applied to the BAR monitor.

In November 2015 Cortical’s Brain Anaesthesia Response (“BAR”) monitor was formally included on the Australian Register of Therapeutic Goods.

Having achieved TGA certification and the CE Mark, Cortical is now able to market the BAR monitor within Australia and Europe.

Three years of those ten years were taken up by the TGA approval process .Additional time was taken in hospital trials and work necessary to achieve these objectives

The proposed regulatory framework defines

A qualifying startup as:

- **an Australian company, which: was incorporated during the last 3 income years;**

This element of the proposed regulatory framework is totally unsuitable for a company such as Cortical .It takes no account of the time taken to develop companies of this nature .It does not take account of the way in which investors approach these investments

The further proposed framework includes

A qualifying investor is one who:

- **invests into either a qualifying fund or a qualifying startup; and**
- **is limited to making a maximum eligible investment of \$1,000,000 in any single qualifying startup or qualifying fund.**

Now that Cortical has achieved these milestones eligible investors may seek to invest greater amounts than \$1,000,000 and the proposed limit of \$1,000,000 is inconsistent with the market participant’s investment objectives.

In this regard I note that the European Economic Area legislative framework for **non prospectus** offering to the public was 2.5 million Euros and I understand this was being

raised to 5 million Euros .The proposed ceiling should be realistically set at least at \$5million AUD

In addition the proposed constraint to limit the availability of the tax incentive to “sophisticated Investors “does not reflect the very substantial investments made in Australian companies by a significant number of investors who have a strong interest in and commitment to investment and development of Australian companies like Cortical .The proposal to limit the tax incentive will in fact unfairly discriminate against those investors who do meet the “sophisticated investor “criteria.

This submission is made by David Breeze .I am Chairman of Cortical Dynamics and have been involved in capital raising and funding of companies since 1985 and my experience includes working as a corporate finance specialist with extensive experience in the stock broking industry and capital markets.My address and contact details is C/- Cortical Dynamics at 14 View St North Perth WA

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