

## ASX Market Update

5 November 2014

### The First Independent Validation Trial

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**Sydney, Australia – 5 November 2014:** [Medibio](#) Ltd ([MEB](#) or the **Company**) is pleased to announce that it has entered into an agreement with the University of New South Wales to undertake the first independent trial of the Company's Heart Rate Technology for the diagnosis of mental health conditions. The study will be designed to demonstrate that [MEB's](#) Heart Rate Technology can provide the first objective diagnostic tool between the two hypothesised subsets of depression: melancholic and non-melancholic depression. The study will be conducted at the Black Dog Institute.

The Black Dog Institute is a world-leader in the diagnosis, treatment and prevention of depression, bipolar disorder and suicide. Founded in 2002, the Institute has over 150 research and clinical staff and is an independent not-for-profit organisation. Its strategic plan focuses on the rapid translation of quality mental health research into improved clinical practice, increased accessibility for consumers, and delivery of long-term public health solutions. Its unique model incorporates expertise in clinical management with cutting edge research, health professional training and community education to ensure that it is having a positive impact at all stages from prevention and early intervention, through to patient treatment and recovery.

The principal researcher for the study will be Professor Gordon Parker. Professor Parker is Scientia Professor of Psychiatry at the University of New South Wales, specialising in clinical research into mental health. Professor Parker is regarded as one of the world's leading authorities on depression and bipolar disorder. On 14 June 2010, Professor Parker became an Officer of the Order of Australia. He is the original founder of the Black Dog Institute and his past positions have included serving as the Head of the School of Psychiatry at the University of New South Wales (1983-2002), and Director of Psychiatry, Prince of Wales/Prince Henry Hospitals (1983-1996).

A positive finding that [MEB's](#) Heart Rate Technology can provide the first objective diagnostic tool between the two subtypes of depression would be one of the most significant findings in mental health research in the past decade. Similarly validation that the technology is sensitive to changes in symptomology, and can be used as a means to determine the effectiveness of the treatment for both melancholic and non-melancholic depression would represent a major breakthrough. This would make a significant impact on the treatment of depression both economically and in terms of producing much better patient outcomes.

In commenting on the study Professor Gordon Parker, the principal researcher from the Black Dog Institute said: ***"Our group has long focussed on melancholia, viewing it as a separate depressive condition and therefore we have pursued measures differentiating it from other depressive conditions, its causes, and its optimal treatments. If the diagnostic tool under study has specificity in identifying those with and without melancholia we would anticipate distinct advances in pursuing causes and in directing preferential treatments to those with melancholia."***

### **Mental Health industry and the problem**

Depression is a common illness worldwide, with an estimated 350 million people affected, it is a major contributor to the global burden of disease. Despite intensive research over many decades, there is still no reliable quantitative, evidence-based test for depression, or to determine the effectiveness of prescribed treatment. The two hypothesised subtypes of depression are melancholic and non-melancholic depression. Melancholic depression is a biologically based condition that generally responds to treatment by anti-depression drugs while non-melancholic depression is associated with acute or chronic stresses and/or particular personality styles. Importantly around half the cases of non-melancholic depression do not respond to anti-depressants and another challenge faced by general practitioners in treating this group is the high rate of spontaneous remission, hence, accurate assessment of treatment can be difficult.

### **Overview of the study**

The study will be designed to demonstrate that **MEB's** Heart Rate Technology can provide the first objective diagnostic tool between the two hypothesised subsets of depression: melancholic and non-melancholic depression. Currently the distinction between melancholic and non-melancholic depression is based purely on clinical grounds and is not always reliable. A quantitative distinction between these two sub-types of depression is crucial for best patient outcomes. Melancholic depression is considered a biologically based condition that responds to biologically based treatments including anti-depression drugs. In contrast, non-melancholic depression is associated with acute or chronic stresses, and may be related to particular personality styles. Importantly, around half the cases of non-melancholic depression do not respond to anti-depressants. In addition, challenges faced by general practitioners in treating this group are the high rates of spontaneous remission, and uncertainty over the qualitative measurement of symptoms, which make accurate assessment of treatment response difficult.

Physiological evidence of a difference between melancholic and non-melancholic depression would provide objective support and objective markers to guide treatment. Understanding the different types of depression is essential to ensuring those with symptoms receive the treatment they need. The availability of objective indicators would greatly increase the probability of developing better targeted treatment approaches to melancholic depression that is a severe, disabling disorder with a significant personal and economic burden.

The study will also involve serial monitoring of the subjects before and after treatment to validate claims that the technology is sensitive to changes in patient symptomology, and can be used as a means to determine the effectiveness of the treatment for both melancholic and non-melancholic depression. Further usefulness for a purely physical test for depression is in patient groups with compromised ability to communicate their symptoms; this includes those post-stroke, persons with dementia, learning disabilities and others with compromised communication. These provide enormous clinical challenges to correct diagnoses and treatment, and there is currently little to assist clinicians.

The study will begin immediately and unlike traditional drug trials the study is expected to be of a relatively short duration. It is anticipated that the study will be completed and the findings published in a leading peer-reviewed international publication in the second half of 2015. **MEB** will provide quarterly updates as to the progress of the study.

In commenting on the commencement of the trial, Dr Hans Stampfer, the inventor of the technology and member of **MEB's** Advisory Board said: ***"The study announced today is based on over 10 years of research. I am extremely proud to be associated with the University of NSW and Black Dog Institute, which is***

***Australia's foremost mental health research organisation. The anticipated success of the independent trial announced today with such a prestigious mental health research organisation will go a long way in confirming our depression test as a reliable and robust quantitative test for a debilitating condition that affects millions of people worldwide."***

**About [Medibio](#) Limited**

[Medibio](#) (ASX:[MEB](#)) is a medical technology company developing a new diagnostic test for depression and other mental health disorders. This test is based on measured differences in circadian heart rate data and measures of heart rate variability. The technology is based on the scientific finding that human heart rates, including certain tell-tale changes, are sensitive measures for depression - particularly in the early stages when traditional diagnostic interviews are less sensitive. The technology consists of a heart monitor that sends recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable diagnosis. The Technology has the potential to be the first FDA Approved objective, evidence based approach to the diagnosis of depression and other affective disorders. The technology has already benefited from 10 years of laboratory research and [Medibio](#) is intends to undertake a number of pivotal trials to validate its clinical utility. Located in Melbourne, Victoria, [Medibio](#) is listed on the Australian Stock Exchange.

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