

ASX Announcement

11 May 2015

## Medibio Ltd processes first participant in UNSW/Black Dog Institute depression test validation study

- **Study is designed to demonstrate two primary endpoints. That Medibio's technology provides:**
  - **the first objective diagnostic test differentiating between melancholic and non-melancholic depression**
  - **the first objective tool to determine the effectiveness of depression treatment**
- **The study population will comprise of up to 80 participants split between those with melancholic and non-melancholic depression**
- **The study is on track to be completed and have results published in the fourth quarter this year.**

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Medibio Limited (**MEB** or the **Company**) is pleased to announce that its first pivotal study, being conducted by the University of New South Wales (**UNSW**) and the Black Dog institute (**BDI**), has processed its first participant. It is expected that all of the 80 planned participants will have been assessed by the end of the third quarter and the study remains on track to be completed, and have results published, this year.

The Study is designed to demonstrate that MEB's Circadian Heart Rate Variability (CHR-V) technology is the first objective diagnostic tool able to distinguish between the two subsets of depression: melancholic and non-melancholic depression. The study will also involve serial monitoring of the participants before and after treatment to validate the technology's use as an objective measure to determine the effectiveness of the treatment.

A positive finding, that CHR-V technology can provide the first objective diagnostic tool between the two sub-types of depression, would be a significant finding in global mental health research. Similarly, validation that the technology can be used as a means to determine the effectiveness of treatment for both melancholic and non-melancholic depression would represent a major breakthrough for those with depression. This would make a significant impact on the treatment of depression, both economically, and in terms of producing better patient outcomes.

The principal researcher for the study is 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.

### Overview of the study

Under the study protocol, participants in the study will be assessed by two independent BDI clinicians with their ECG data collected over a 24 hour period to measure their CHR-V at baseline. The diagnosis based on Medibio's CHR-V technology will be compared to the two independent clinician diagnoses and other clinical, and self-report assessment measures.

After 4-6 weeks, the same participants, who may receive a new treatment plan, will be asked to return for a second measurement point designed to measure the client's current symptomology. These participants will

be reassessed using the same measurements as at the first time point, including interview by a BDI clinician, self-report measures, and a recording of their ECG data over a 24 hour period. The results of the second battery of measures will be compared to the first to validate the use of CHR-V as an objective diagnostic tool and to determine the effectiveness of treatment.

The study has been appropriately powered to show a statistically significant conclusion, and requires 30-40 participants in each group. Unlike traditional drug trials the study is expected to be of a relatively short duration with each participant only needing to be assessed once initially and then once 4-6 weeks later.

### **About 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.

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

Depression is a common illness worldwide, with an estimated 350 million people affected, and 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.

A quantitative distinction between melancholic and non-melancholic depression is crucial to ensure the most efficacious patient outcomes. Melancholic depression is considered a biologically based condition that responds to biologically based treatments including antidepressant medication. In contrast, non-melancholic depression may be associated with acute or chronic stresses, and may be related to coping strategies and personality styles.

Importantly, around half the cases of non-melancholic depression do not respond to antidepressants. Understanding the different types of depression is essential to ensuring that sufferers receive the specific treatment they need. The availability of objective markers of these subtypes of depression would greatly increase the probability of developing better targeted treatment approaches to depression which is a severe disabling disorder with a significant personal and economic burden.

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## **About Medibio Limited**

Medibio (ASX: MEB), is a medical technology company developing a new objective test to assist in the diagnosis of depression, other mental health disorders and chronic stress. This test utilizes circadian heart rate variability. The technology is based on the scientific finding that circadian heart rate variability is a sensitive measure for depression and other mental health disorders and chronic stress. The technology consists of a heart monitor that sends ECG recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable measure which can be used by a clinician to assist in diagnosis. The Technology has the potential to be the first FDA Approved objective, evidence based approach to the diagnosis of depression and other mental health disorders. The technology has already benefited from 10 years of laboratory research and Medibio is undertaking a number of pivotal studies to validate its clinical utility. Medibio is not just a traditional Medical Device play with revenue dependent upon FDA certification. It has the only new and credible method for the diagnosis of stress and mental wellbeing which can be easily translated to the workplace stress/wellbeing market, wearable technology, and App market. This stress market can be accessed prior to FDA Certification of the traditional Medical Device. Located in Sydney, NSW, Medibio is listed on the Australian Stock Exchange.