# **ASX Market Update**

Medibio Limited

Medibio Limited (ASX: MEB)

# Johns Hopkins University School of Medicine to Undertake US-based Clinical Validation Study on Medibio's Depression Test

- Johns Hopkins to Conduct a clinical study regarding the use of circadian heart rate variability ("CHR") designed to:
  - specifically determine whether CHR can provide objective physiological data to differentiate between individuals with clinical depression and individuals without clinical depression, and
  - assess the clinical validity of a proprietary software algorithm, developed by Medibio, that detects depression by measuring CHR variability clinically.
- Data collected from the study will be utilized to support FDA certification of Medibio's proprietary software algorithm.

**Sydney, Australia – 1 December 2014:** Medibio Ltd (**MEB** or the **Company**) is pleased to announce that it has entered into an agreement with The Johns Hopkins University School of Medicine (JHM), located in Baltimore, Maryland, USA, to undertake a US-based independent clinical validation study of the Company's Circadian Heart Rate ("CHR") Technology to assist clinicians in the diagnosis of depression.

#### **About Johns Hopkins School of Medicine**

The study will be carried out at The Johns Hopkins University School of Medicine, headquartered in Baltimore, Maryland. JHM is a \$7 billion integrated global health enterprise and one of the leading health care systems in the United States with over 124 years of commitment to community care with ground-breaking research, teaching, and medical services to patients worldwide. Johns Hopkins Medicine operates six academic and community hospitals, four suburban health care and surgery centres, and more than 30 primary health care outpatient sites. The Johns Hopkins Hospital, opened in 1889, has been ranked number one in the nation by U.S. News & World Report for 22 years of the survey's 25-year history, most recently in 2013.

# **Objectives of the Clinical Validation Study**

The study is expected to be completed within 12 months. It will be designed to clinically validate the use of MEB's CHR technology to differentiate between depressed and non-depressed individuals and to provide clinical data to support FDA certification of the company's proprietary software algorithm for use as an objective method to differentiate between depressed and non-depressed individuals.

Under the terms of the agreement JHM will design a clinical study protocol and conduct a clinical study regarding the use of CHR, specifically, to determine whether CHR can provide objective physiological data to differentiate between individuals with clinical depression and individuals without clinical depression; and to test the clinical validity of a proprietary software algorithm developed by MEB that detects depression by measuring CHR.

# **Principal Investigator**

The principal Investigator of the study will be Dr Naresh Punjabi, M.D., Ph.D., who is Associate Professor of Medicine in the Pulmonary and Critical Care division and department of sleep medicine at JHM. Professor Punjabi is one of the principal investigators for the multi-centre Sleep Heart Health Study which is an epidemiological study on the longitudinal effects of sleep apnoea on hypertension, cardiovascular disease, and mortality.

Dr Punjabi has published well over 100 research papers and is also an active teacher, presenting clinical instruction at The Johns Hopkins University School of Medicine as well as at the Bloomberg School of Public Health.

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#### **About Medibio Limited**

Medibio (ASX: MEB), formerly BioProspect Limited, changed its name following approval for a change of name at the company's AGM held on 24 November 2014. Medibio 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 and measures of heart rate variability. The technology is based on the scientific finding that circadian heart rates are sensitive measures for depression and other mental health disorders. 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 intends to undertake a number of pivotal studies to validate its clinical utility. Located in Melbourne, Victoria, Medibio is listed on the Australian Stock Exchange.

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Note - as Matt is based in USA he will be available until 3pm EST

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