ASX Announcement

Medibio Limited – 8 AUG 2016

Breakthrough validation of Medibio's algorithm for diagnosing depression using independent clinical data

- **A classification accuracy of 83% was achieved for distinguishing individuals with Major depressive disorder (MDD) from non-depressed individuals.**
- **Compares favourably to the "clinical gold standard" diagnostic concordance of 33-50% at the primary care level and 70% between experienced psychiatrists.**
- **Validation study completed with 326 patients from The University of Ottawa with 228 (114 MDD & 114 controls) used for algorithm training and 98 (54 MDD & 44 controls) used for blind assessment.**
- **The retrospective data was compiled in partnership with The University of Ottawa and included over-night heart rate recordings, sleep annotations and clinical assessments of psychiatric status.**
- **The University of Ottawa has now released all remaining data, from approximately 1300 patients, to Medibio to expand the study and improve diagnostic accuracy.**

Medibio Limited (ASX: MEB) ("Medibio" or the "Company") is pleased to announce that it has successfully undertaken validation of its depression classification algorithm using retrospective data sourced in partnership with The University of Ottawa. This validation is a significant milestone in the Company's development of a proprietary objective test for the diagnosis of depression.

Using objective biomarkers extracted from overnight physiologic recordings Medibio was able to accurately distinguish between individuals with Major depressive disorder (MDD) and non-depressed controls with a classification accuracy of 83%. This compares favourably to the noted diagnostic concordance between experienced psychiatrists [(1)] (70%) and that of primary care providers (GP equivalent in the US) [(2)] (33-50%), where nearly half of the diagnoses of MDD are made.

The classification algorithm leverages objective biomarkers computed from overnight heart rate recordings and sleep annotations to distinguish between the clinical groups. The clinical assessment was performed by two experienced psychiatrists from the University of Ottawa. The algorithm was trained on 228 patients (114 MDD and 114 controls) and tested on a blinded data set of 98 individuals (54 MDD and 44 controls).

In commenting on the study results Dr Franklyn Prendergast Medibio Director and former Director for Research at Mayo Clinic said ***"These latest data show how exquisitely well Medibio is moving toward full validation of its algorithms for the diagnosis of stress and depression from physiologic information.***

I'm especially delighted by the integration with ECG data for detection of sleep stages, to our knowledge the first time this has been achieved. Inevitably and inexorably the accuracy will get even better as we accumulate more data" he went on to say.

The results provide the first validation of Medibio's proposition that psychiatric conditions differentially affect the autonomic system resulting in condition specific heart rate morphology and sleep patterns using independent clinical data. This proposition is based on over 15 years' research, initiated at the University of Western Australia, investigating autonomic nervous system disturbances linked to mental state and their observation via the cardiovascular system during sleep when external influences are absent.

Table of Results

	Sensitivity	**Specificity**	**Accuracy**
Blind assessment using (54 MDD & 44 controls)	83%	82%	83%

Next Steps

The current result represents a significant advancement in validating Medibio's objective biomarker means of assessing patient mental health status. Future work will include further identification of discriminating biomarkers to improve the diagnostic accuracy of the algorithm, incorporation of the new data for further algorithm training, and validation of additional algorithms.

Medibio's technology exploits advanced machine learning. This means the algorithm employed to classify subjects according to the biomarkers examined in tests increases its accuracy through iterations. The addition of data from 1300 new patients into Medibio's depression classification algorithm should lead to an improvement in diagnostic accuracy from its machine learning algorithms

The immediate effort will also focus on incorporating additional diagnostic features including those derived from sleep stage classification based on Medibio's ability to use ECG data to accurately define sleep stages as outlined in the ASX Release dated June 24 2016.

Following this Medibio will expand and validate its diagnostic algorithm for depression to identify the different presentations of depression which would increase the clinical utility of its offering. Results will be reported as they come to hand.

The project is part of the company's collaborative research and development effort with leading international universities announced on 14 March 2016. Under this collaboration Medibio secured in excess of 120,000 hours of overnight physiological (ECG, EEG and other biometrics) data files to be analysed by Medibio's Digital Mental Health Platform. This allows Medibio and its research partners to generate proxy-clinical trial outcomes and meta-data analyses from more than 15,000 patients retrospectively.

Medibio, in collaboration with leading academic institutions, is continuing to compile additional retrospective data to further validate advanced algorithms to distinguish patients using objective biomarkers.

(1) *Psychiatry (Edgmont). 2006 Jan; Vol 3(1): 41–50*
(2) *Depression in Primary Care Vol 1: US Department of Health*

About The University of Ottawa

On 12 October 2015 Medibio Limited entered into a research agreement with The Royal's Institute of Mental Health Research (IMHR) and the University of Ottawa, to undertake a study titled" Detailed Analysis of Sleep Physiology in Mental Disorders". The aim of the study is to assess the validity and specificity of MEB's CHR technology to discriminate between individuals with mental disorders, individuals with sleep disorders, and healthy controls.

The Royal's Institute of Mental Health Research is affiliated with the University of Ottawa. The Royal is one of Canada's foremost mental health care and academic health science centres. Its mandate is simple: to help more people living with mental illness into recovery faster. The Royal combines the delivery of specialized mental health care, advocacy, research and education to transform the lives of people with complex and treatment resistant mental illness. The Royal's Institute of Mental Health Research (IMHR) strives to continuously improve mental health and well-being through leadership, collaborative discoveries and innovation in research, patient care and education. The IMHR's "neuron to neighbourhood" approach examines mental illness on a continuum that spans basic biology to the level of the community itself.

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About Medibio Limited

Medibio (ASX: MEB), is a medical technology company that has developed an objective test to assist in the diagnosis of depression, chronic stress and other mental health disorders. Based on research conducted over 15 years at the University of Western Australia, this test utilizes patented (and patent pending) circadian heart rate variability and cloud based proprietary algorithms delivering a quantifiable measure to assist in clinical diagnosis. Medibio's depression diagnostic is being validated in clinical studies undertaken by Johns Hopkins University School of Medicine and The University of Ottawa, among others. The clinical trials will support Medibio's application to become the first FDA approved, objective, and evidence based approach to the diagnosis of mental health disorders. Medibio's technology also provides an objective method for the assessment of stress and mental wellbeing that can be translated to the workplace stress/wellbeing market, wearable technology, and App market. Located in Melbourne, VIC, Medibio is listed on the Australian Securities Exchange.