

ASX Announcement

Medibio Limited – 2 NOV 2016



University of Ottawa Depression Study improves accuracy rate to an outstanding 86% in a far larger sample

- **Diagnostic accuracy increased to 86% for distinguishing individuals with Major Depressive Disorder (MDD) from non-depressed individuals.**
- **Additional 563 patients (272 with MDD and 291 controls) processed in the validation study in partnership with the University of Ottawa increasing the study sample size by 300%.**
- **Compares with the “clinical gold standard” diagnostic concordance of 33-50% at the primary care level and 70% among experienced psychiatrists. Represents an improvement over previous Medibio reported results of 83% based on a smaller study sample size.**
- **Study now includes 889 patients from the University of Ottawa with 630 (315 MDD & 315 controls) used for additional algorithm training and 259 (125 MDD & 134 controls) used for blind assessment.**
- **The retrospective data was compiled in partnership with the University of Ottawa and included overnight heart rate recordings, sleep annotations and clinical assessments of psychiatric status.**
- **The final 300 patients from the University of Ottawa will be used to generate an Independent Validation paper which will be peer reviewed and published by the University of Ottawa.**

Medibio Limited (ASX: MEB) (“Medibio” or the “Company”) is pleased to announce successful completion of Stage 2 of the 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 as it is based on a highly significant sample size of almost 900 patients.

Using objective biomarkers extracted from overnight physiological recordings, Medibio was able to classify individuals with MDD and non-depressed controls with an 86% accuracy. This compares with the initial 83% accuracy achieved on 326 patients and illustrates the improvement from machine learning as more data is processed by Medibio’s algorithm. For reference, the noted diagnostic concordance among experienced psychiatrists ⁽¹⁾ is (70%) while at the primary care level (US general practitioners), who account for nearly half of the MDD diagnoses, the diagnostic accuracy of MDD is 33-50% ⁽²⁾.

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 630 patients (315 MDD and 315 controls) and tested on a blinded data set of 259 individuals (125 MDD and 134 controls). The initial 83% diagnostic accuracy announced August 8th 2016 was based on 228 patient training (114 MDD and 114 controls) and tested on a blinded data set of 98 (54 MDD and 44 controls).

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Commenting on the study results Medibio CEO, Kris Knauer, said: ***“We’re excited by not only how our results compare using a far larger sample size but how the addition of more data for algorithm training is improving the diagnostic accuracy of our depression algorithm. The study result of 86% is a significant accuracy result and has the potential to put Medibio’s depression diagnostic at the forefront of future depression assessment”***.

Table of Results

	Accuracy	Sensitivity	Specificity
Blind assessment using (125 MDD & 134 controls) and 630 additional training files	86%	82%	88%

Next Steps

The final 300 patients from the University of Ottawa will be used to generate an Independent Validation paper which will be peer reviewed and published by the University of Ottawa.

Ongoing work includes 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. Following this Medibio will expand and validate its diagnostic algorithm for depression to identify the different presentations of depression, increasing its clinical utility. Results will be reported as they come to hand.

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 study aims to assess the validity and specificity of Medibio’s Circadian Heart Rate (CHR) technology to discriminate between individuals with mental disorders and with sleep disorders against healthy controls.

IMHR, an affiliate of Ottawa University, is one of Canada’s foremost mental health care and academic health science centres. Its simple mandate is *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. IMHR strives continuously to 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 spanning basic biology to the community.

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

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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 Ltd.