ASX Announcement

Medibio Limited – 21 DEC 2016

Medibio's Depression Diagnostic demonstrates excellent performance in the pilot phase of its US Validation Study

- **Diagnostic accuracy 81% and sensitivity 82% for delineating individuals with Major Depressive Disorder (MDD) from non-depressed individuals**
- **First prospective validation for Depression done with a leading US university**
- **The study is intended to support FDA clearance of Medibio's depression algorithm**
- **Significantly outperforms existing standard-of-care diagnosis in the US primary care setting (33-50% accuracy) and among psychiatrists (70% concordance)**

Sydney, Australia – 21 December 2016: Medibio Limited (**MEB** or the **Company**) is pleased to announce the preliminary results from the pilot phase of its first prospective study of its Depression Diagnostic. The principal investigators for the study were Dr. Naresh Punjabi (Professor, Johns Hopkins Medicine) and Dr. Francis Mondimore (Director, Mood Disorders Clinic Johns Hopkins Medicine). The results represent a significant positive step in validating the Medibio approach of using objective biometrics for the diagnosis and management of depression, a disease afflicting 350 million people worldwide.

The study analysis is based on full datasets from 26 subjects (11 with MDD, 15 healthy controls). To generate measures of circadian heart rate (CHR), subjects underwent heart rate monitoring using a 3rd-party Holter (ECG) monitor for a period encompassing one day's sleep cycle. Sleep onset and waking times were independently confirmed with an actigraphy watch. As the 'gold standard' comparator for the CHR metrics, subjects were classified as depressed or non-depressed via two independent psychiatrists, who each performed a structured, full M.I.N.I. [(2)] examination. Agreement was required between the two psychiatrists for final classification as depressed or non-depressed and to be included in the analysis.

Following de-noising of the heart rate data, individual CHR tracings were then evaluated using Medibio's proprietary diagnostic approach, in which interpretation was blinded to the clinical classification. The results were excellent, with diagnostic accuracy of 81%, sensitivity of 82%, and specificity of 80%. For reference, the noted diagnostic concordance for MDD among experienced psychiatrists is 70%, while at the primary care level (where more than half of all depression diagnoses occur), the diagnostic agreement falls to 33-55% [(1)].

Importantly, these results provide a preliminary indication that Medibio's diagnostic is robust in the face of ongoing pharmacological therapy for depression. Seven of the MDD subjects were on medication for depression at the time of CHR data gathering (with 5 of these on multiple medications), and 6 of 7 of these subjects were correctly identified as being actively depressed, **for an 86% accuracy,** similar to the overall cohort.

Finally, the results provided an indication that Medibio's diagnostic is state dependent (currently depressed or non-depressed). Namely, two of the control subjects had a *history* of depression but were clinically judged to be non-depressed *at the time of* CHR data gathering. Both were correctly classified by Medibio's diganostic as non-depressed.

"These first results from our US based depression study are exactly what we were hoping to achieve and are well above what is required to support the claims we intend to make in our application to the FDA," said Medibio CEO Kris Knauer. ***"The study cohort was also typical of the GP setting, with a range of co-morbidities and a high prevalence of polypharmacy. It's clear that our Depression Diagnostic, based on these results, should prove a valuable tool in the under resourced GP setting."***

The main phase of the study , now underway at multiple sites in the the United States has been informed by these positive results. These studies are intended to support FDA clearance of the company's proprietary software algorithm to differentiate between depressed and non-depressed individuals. The studies are using the Medtronic BioPatch, a compact and user-friendly next-generation device, as part of Medibio's formal partnership with Medtronic.

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(1) Depression in Primary Care Vol 1: US Dept. Health

(2) (The Mini-International Neuropsychiatric Interview (M.I.N.I.) is a short structured diagnostic interview, developed jointly by psychiatrists and clinicians in the United States and Europe, for DSM-IV and ICD-10 psychiatric disorders.)

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 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.