ASX Announcement

Medibio Limited – 02 AUGUST 2017

Medibio's Depression Diagnostic Ready for FDA Confirmatory Study

Excellent performance in prospective study representative of Primary Care setting

- **Medibio-DX Depression Diagnostic showed 82% accuracy, 78% sensitivity, and 84% specificity**
- **Study design in this phase aligned with FDA expectations for clearance of Medibio-DX as a diagnostic aid for depression**
- **Medibio-DX Depression Diagnostic now ready to enter confirmatory validation**

Sydney, Australia and Minneapolis, MN – 02 August 2017: Medibio Limited (**MEB** or the **Company**)(ASX: MEB)(OTCQB: MDBIF) a digital health company that has developed an objective testing system to assist in the screening, diagnosis and treatment effectiveness of depression, chronic stress and other mental health disorders, is pleased to announce results of performance validation in the Medibio Depression Diagnostic (Medibio-DX) MACH-3 study. MACH-3 was designed as the first prospective assessment of the Medibio-DX depression algorithm under more challenging conditions recommended by the FDA. These conditions are aligned with product deployment in the primary care setting, an important market in the United States where a tremendous need exists for improving the diagnosis of depression. 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 study has been successfully concluded, with results based on data from 44 additional subjects. Overall accuracy of 82%, specificity of 84%, and sensitivity of 78% under targeted use conditions represents an outstanding study outcome, far exceeding current clinical diagnostic performance; in the primary care setting, where more than half of depression is diagnosed and treated, accuracy ranges from 30-50%.[1] Repeatability of the Medibio-DX results was also excellent, with 76% intra-subject observed agreement between independent Depression Diagnostic classifications derived from first and second circadian heart rate recordings in the same subject (kappa 0.54). This agreement compares very favorably to inter-psychiatrist agreement surrounding the diagnosis of depression. As a case in point, field tests of the latest Diagnostic Statistical Manual (DSM)-V criteria for depression—the cornerstone of current diagnosis—kappa

[1] Depression in Primary Care Vol 1: US Department of Health and Human Services.

was only 0.28.[2]

Additionally, Medibio is pleased to report that the confirmatory validation study for the Medibio-DX as a diagnostic aid for depression is starting as per schedule this month. Medibio has now achieved all necessary ethics and IRB approvals to initiate the study.

"This is a pivotal achievement for our team as we aggressively continue to meet and exceed our key milestones. We're very pleased with the performance of the Depression Diagnostic in this much tougher phase of testing," says Medibio CEO and Managing Director Jack Cosentino. ***"As we enter the confirmatory validation study this month, we believe that we are very well positioned for FDA clearance next year."***

Background on the MACH-3 Study

The MACH-3 study assessed diagnostic performance under more challenging requirements, based upon important modifications to the study design recommended by the FDA during the 2016 Pre-Submission meeting. Specifically, FDA recommended that:

1. the control group be representative of patients presenting in the primary care setting and be age and gender matched with the MDD cohort. Such a control group presents a more difficult diagnostic problem due the baseline prevalence of potentially confounding, non-psychiatric comorbidities.
2. a repeatability analysis to quantify agreement between Medibio-DX Depression Diagnostic classification outputs obtained in the same subject within 1-2 weeks of each other.

These key modifications further aligned the validation pathway with FDA expectations for ultimate clearance of the device.

In MACH-3, diagnosis for all depressed and control subjects was confirmed via two independent, structured M.I.N.I. examinations, and agreement between the two evaluations was required for final clinical classification. To capture circadian heart rate and actigraphy-based inputs for the Medibio Depression Diagnostic, subjects underwent monitoring for two sleep-wake periods with a third-party recording device (Zephyr BioPatch, Medtronic, Inc.). Finally, each subject underwent Home Sleep Testing to identify and screen out subjects with un-diagnosed sleep apnea, a condition that can disrupt nighttime heart rate and sleep patterns.

In addition to demonstrating strong diagnostic performance, , the MACH-3 study provides further evidence

[2] Regier DA, Narrow WE, Clarke DE *et al*. DSM-5 Field Trials in the United States and Canada, Part II: Test-Retest Reliability of Selected Categorical Diagnoses. Am J Psychiatry. 2013;170:59-71.

that the Medibio solution is agnostic to the third-party input device. Namely, results were similar between the previously reported pilot study and MACH-3, even though the pilot study used a Holter monitor to capture physiologic data and the current study employed a compact and more wearable recorder in a 'patch' form factor.

About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a digital health 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. Founded in Perth, Australia with offices located in Melbourne (Vic), with U.S. offices in Minneapolis, MN and Palo Alto, CA. Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market www.otcmarkets.com and www.asx.com.au.

To learn more about Medibio visit www.Medibio.com.au

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