ASX Announcement

Medibio Limited – 21 AUGUST 2017

Medibio Initiates Enrollment for Its Depression Diagnostic Confirmatory Study to Support FDA Clearance

- **Builds on strong results of the recently reported exploratory study**
- **Current study being conducted at several prominent US and Australian sites**
- **Company on schedule for Calendar Q2 2018 FDA submission**

Sydney, Australia and Minneapolis, MN – 21 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 and other mental health disorders, is pleased to announce the commencement of its Depression Diagnostic confirmatory study. The study will serve as the centerpiece of the company's FDA 510(k) *De Novo* submission in Calendar Q2 next year.

The preceding exploratory study demonstrated excellent performance of the Depression Diagnostic, with overall accuracy of 82%, specificity of 84%, and sensitivity of 78%. FDA input was heavily incorporated into the design of the exploratory study, which was conducted to de-risk the confirmatory study and to optimize its timely execution. The current study design replicates the framework of the exploratory study, using the same endpoints (sensitivity, specificity, and repeatability) and the same methodology (comparing Depression Diagnostic classification to the gold-standard of structured clinical interviews for diagnosis). The sample size of the study has been scaled to meet FDA expectations for generalizability, and the study cohort will be split evenly between individuals with Major Depressive Disorder (MDD) and non-depressed controls.

"The results from the exploratory study gave us considerable confidence heading into the confirmatory study," says Dr. Greg Moon, Medibio's Chief Medical Officer. ***"We have since partnered with a terrific group of mental health researchers at very seasoned sites in order to deliver this important study on time and on target."***

The current study will be conducted at multiple sites in the United States and Australia, including Epworth Hospital in Melbourne and The Melbourne Clinic.

"This study will play a key role in securing FDA clearance of the world's first device-based diagnostic for depression," says Medibio CEO and Managing Director Jack Cosentino. ***"In parallel, we are extending these same research approaches to validate a rich pipeline of diagnostic and monitoring products for***

post-traumatic stress disorder, anxiety, bipolar disorder, and other mental illnesses at other key Centers of Excellence around the world. The study involves researchers and investigators with a combined 100 years or more studying mental illness."

About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a digital health company that has pioneered the use of objective biometrics to assist in the diagnosis and treatment of depression and other mental health disorders. Medibio's proprietary Digital Mental Health Platform uses advanced, cloud-based analytics to enable GPs and mental health clinicians to cost-effectively screen, precisely diagnose, and objectively confirm treatment effectiveness to better manage patients. Medibio's technology also provides an objective method for the assessment of stress and mental well-being that can be translated to the non-medical workplace stress/well-being, wearable technology, and app markets. The company was founded in Australia, with offices located in Melbourne (Vic), and 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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