

ASX Announcement



Medibio Limited – 21 July 2022

Sleep Analysis of Depressive Burden Study Clinical Trial Commencement

Key highlights:

- Sleep Analysis of Depressive Burden study (SAMDE) is open to enrolment;
- The study's goal is to re-train the algorithm based on the additional primary endpoint (MINI) and test algorithm performance for sensitivity, specificity, and negative and positive predictive values; and
- Algorithm lockdown will take place after the FDA pre-submission meeting upon completion of the study, expected to be completed in 15-16 weeks from commencement.

Melbourne, Australia and Minneapolis, MN – 21 July 2022: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF), is pleased to announce the opening of the Sleep Analysis of Major Depressive Episode (SAMDE) clinical trial, the final stage prior to commencement of the FDA validation phase.

This clinical trial aims to detect the likelihood of a current major depressive episode in individuals referred to sleep clinics for polysomnography assessment. There is a robust bidirectional relationship between mental illness and sleep disturbances. Depression is highly prevalent in individuals with sleep disorders. However, there is insufficient depression screening in sleep facilities.

The trial aims to involve at least 17 sleep centres across the US in recruiting patients for the study. Nationwide enrolment is critical to the study to demonstrate clinical and geographical diversity, two key components of FDA standards. The Company's project aims to contribute to overcoming current unmet medical needs and foster the implementation of depression screening in sleep clinics.

For future realisation of the work being undertaken, the Company has identified the major market-share holding companies in the sleep health environment, which may benefit from the integration of the Company's technology.

Throughout the clinical trial, the Company will continue with the algorithm and software development according to the outcome of discussions held with the FDA. Algorithm and technology development must be completed by the time the Company enrolls the first patient in our clinical validation phase.

ENDS

This announcement is authorised for release to the market by the Board of Directors of Medibio Limited.

About

Medibio

Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. The Company was founded in Australia, with offices located in Melbourne (Vic) and Minneapolis (MN). Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au.

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