ASX Announcement

4 September 2023

Phase 2 trial for Sleep Signal Analysis for Current Major Depressive Episode Study (SAMDE) underway

Highlights:

- **Aim of Phase 2 trial is to detect the likelihood of a current major depressive episode (cMDE) using Clinician Reported Outcome (CRO) assessment in individuals referred to a sleep clinic for polysomnography (PSG) assessment using MEB's innovative AI-backed algorithm**
- **There is a robust bidirectional relationship between mental illness and sleep – highlighting a major market opportunity for MEB and its proprietary technology**
- **Phase 2 seeks to test up to 400 participants from 14 sleep centres across the US and anticipated to be completed in Q2 CY2024**
- **Phase 2 results will provide training data for final algorithm development, which includes determining overall accuracy and algorithm performance**
- **Commencement follows promising Phase 1 results which indicated sensitivity of 71.65%, specificity of 71.43%, Positive Predictive Value (PPV) of 35.38%, and Negative Predictive Value (NPV) of 92.11% when tested within the development sample**
  - **Sensitivity reflects MEB-001's ability to correctly identify cMDE cases (~72 out of 100 cases during Phase 1)**
  - **Specifity highlights the algorithm's ability to exclude patients without cMDE (71 correct identifications out of 100 during Phase 1)**
  - **PPV and NPV indicate MEB-001's percentage of false positive and false negative results predicting cMDE presence**
- **Phase 1 preliminary results exceed the current standard of care currently used to screen for the likelihood of cMDE in individuals referred to sleep clinics for a PSG assessment**
- **Phase 2 enrolment set to complete with data to be used for ongoing algorithm development and near-term FDA pre-submission objectives**

Perth, Australia, and Minneapolis, USA: Medibio Limited (**MEB** or the **Company**) (ASX: MEB) (OTCPINK: MDBIF) is pleased to advise that it has commenced its Phase 2 trial for its Sleep Signal Analysis for Current Major Depressive Episode study (SAMDE). The Company's SAMDE study aims to continue to build and train Medibio's innovative algorithm (MEB-001) to assist in the screening for a current major depressive episode (cMDE) in test subjects.

Phase 2 of the trial seeks to test 400 participants from 14 sleep centres across the US. During the trial, clinicians (CRO) will administer a Mini International Neuropsychiatric Interview (MINI) for each subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding current Major Depressive Episode status.

This step is necessary in preparation for the upcoming clinical validation study which will be an imperative part of the Company's FDA submission and upcoming clinical validation study. Phase 2 of the trial also has the potential to increase the key performance of MEB's proprietary and innovative algorithm, when compared to the existing standard of care.

Commencement of Phase 2 follows promising results generated from the first trial phase, which indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value (PPV) of 35.38%, and a Negative Predictive

Value (NPV) of 92.11% when tested within the development sample with a cross-validation protocol (refer ASX announcement: 24 July 2023).

Sensitivity is MEB-001's capacity to correctly identify cMDE cases, which was approximately 72 of every 100 cMDE cases during Phase 1. While specificity highlights MEB-001's ability to accurately exclude patients without cMDE, highlighting approximately 71 correct identifications out of 100 subjects.

For screening purposes, NPV is important because it measures the rate of false negatives, preventing patients from receiving early proper care. MEB-001's NPV was approximately 92%.

The preliminary results generated from phase 1 considerably exceeded the current international pooled average standard of care used to screen for the likelihood of cMDE in individuals referred to sleep clinics for polysomnography (PSG) assessment (refer ASX announcement: 24 July 2023).

Medibio tested its first patient under phase 2 protocols at a sleep centre in Blaine, Minnesota. The Company expects to complete Phase 2 in Q2 CY2024 (contingent upon enrollment). Additional updates will be provided as developments materialise.

Concurrently, Medibio also intends to schedule a presubmission meeting with the US Food and Drug Administration (FDA) to seek agreement on the final clinical validation of its technology via the De Novo regulatory pathway. The Company expects to schedule the meeting with the FDA in Q1 CY2024, which will provide a clear timeframe on the regulatory approval process.

Management commentary:

CEO Dr Tom Young said: *"We are very excited to commence our Phase 2 trial. The initiative is anticipated to generate additional data which provides a much better understanding of MEB-001 and its potential to assist in the objective screening for depression, which is not being undertaken extensively through primary care providers.*

"Phase 2 commencement follows strong foundational results achieved in the first phase of the Company's SAMDE trial. These results exceeded our expectations and will form a basis for our engagement with the FDA in the coming months. We look forward to providing updates on Phase 2, as well as other initiatives over the coming months."

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

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About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: 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 Perth (Western Australia) and Minneapolis (MN, USA). 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.