ASX Announcement

24 July 2023

Phase 1 trial completed for Sleep Signal Analysis of Depression Burden Study (SAMDE) with promising initial results

Highlights:

- **Aim of Phase 1 trial was to detect the likelihood of a current major depressive episode (cMDE) in individuals referred to a sleep clinic for PSG assessment using MEB's innovative AI-backed algorithm**
- **There is a robust bidirectional relationship between mental illness and sleep, making sleep analysis a perfect environment for behavioral health research and development. This highlighting a significant market opportunity for MEB**
- **Phase 1 tested 313 subjects across 12 sleep centres in five U.S. states with data to be used towards ongoing algorithm development and cMDE clinical validation during H1CY2024**
- **Preliminary results exceed the current standard of care used to screen for the likelihood of cMDE in individuals referred to sleep clinics for a polysomnography assessment**
- **Initial results indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value of 35.38%, and a Negative Predictive Value of 92.11% when tested within the development sample**
- **Phase 2 enrolment set to complete shortly with data to be used for ongoing algorithm development and near term FDA submission objectives via the De Novo pathway to classify novel medical devices**

Perth, Australia, and Minneapolis, USA: Medibio Limited (**MEB** or the **Company**) (ASX: MEB) (OTCPINK: MDBIF) is pleased to advise that it has completed the first phase of its Sleep Signal Analysis for Current Major Depressive Episode study (SAMDE) and received initial results which highlight the significant potential of MEB's algorithm to assist in the diagnosis of a current major depressive episode (cMDE).

Pleasingly, preliminary results from phase 1 of the trial have 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.

Phase I trial background:

The clinical trial aimed to detect the likelihood of a current major depressive episode in individuals referred to sleep clinics for PSG assessment. A robust bidirectional relationship exists between mental illness and sleep disturbances, and depression is highly prevalent in individuals with sleep disorders. Despite this, there is insufficient depression screening in sleep clinics.

The trial commenced in July 2022 (refer ASX announcement: 21 July 2022) and enrolled 313 subjects through 12 sleep centres across five states in the U.S. The nationwide enrolment was critical in demonstrating clinical and geographical diversity in the patient cohort, which are vital components of the U.S. Food and Drug Administration's (FDA) standards.

The process for phase 1 of the trial included collection of each subject's objective biometric signals during in-lab PSG studies, self-administered Patient Health Questionnaire (PHQ-9), self-administered Mini International Neuropsychiatric Interview (MINI) assessment, and socio-demographic information.

Promising results highlight the significant potential for MEB's offering:

Following the completion of phase 1 trial protocols, Medibio's management team compiled data generated from 313 subjects. 293 participants delivered usable data for algorithm development, which includes 274 full-night studies, and 19 split-night studies.

Upon completion of approximately two-thirds of all trial participants, Medibio developed a cMDE detection algorithm using a selection of predictors that demonstrated the stronger individual association with the self-administrated MINI cMDE result. The preliminary results from sleep data collected indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value of 35.38%, and a Negative Predictive Value of 92.11% when tested within the development sample with a cross-validation protocol (refer table below).

The preliminary results for Sensitivity are particularly promising with reference to current U.S. industry standards, where data compiled by Kaiser Permanente for the U.S. Department of Health & Human Services[1] for clinician recognition of depression ranges between 21% to 76% of cases. Around half of these estimates fall above and the remainder fall below the international pooled average of 47.3%. Other studies have also reported a sensitivity of 49.3% and specificity of 81.1% for U.S. primary care providers in accurately identifying cMDE.

Measure	Description	MEB preliminary result	Current standard of care
Sensitivity	Ability for the test to correctly identify patients with the disease	**71.65%**	49.3%
Specificity	Ability to designate an individual who does not have the disease as negative	**71.43%**	81.1%
Positive Predictive Value	Likelihood that a person who has a positive test result does have the disease or condition.	**35.38%**	NA
Negative Predictive Value	Likelihood that an individual with a negative test result does not have the disease or condition	**92.11%**	NA

Statistical analysis of all phase 1 data is ongoing and will seek to investigate the association between the preliminary predictors and depression. Further, the Company intends to conduct additional algorithm training using all 274 phase 1 full-diagnostic studies. The sample size is anticipated to introduce new strategies that have been implemented to enhance the algorithm's stability across different sleep clinics and provide new performance estimates of MEB's proprietary algorithm when applied to new sleep clinics.

Additional work using both full-night and split-night data to identify predictors common to both study types is also planned. Based on the strength of the preliminary data, additional analysis of the preliminary results is expected to result in further refinement of the cMDE detection algorithm that exceeds the current industry standard of care.

Next steps and phase 2 trial initiatives:

The Company continues to undertake steps towards the second phase of the SAMDE trial, which has a target enrolment of 400 subjects. During phase 2, the clinicians will administer 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 measures of MEB's innovative algorithm, when compared to the existing standard of care.

The Company expects to commence its Phase 2 trial shortly and will provide ongoing updates to shareholders as developments materialise.

Management commentary:

CEO Dr Tom Young said: *"To have achieved these results based on preliminary testing, in the first phase of our SAMDE trial highlights the significant potential for the Company's algorithmic offering when compared to the current standard of care. The preliminary results for the accuracy of our AI-based algorithm for the sensitivity component exceeded our expectations, and the initial indications now provide the Company with a strong framework for ongoing analysis of the phase 1 results through to the commencement of the phase 2 trial. With enrolment for the second phase of the trial on schedule to start very soon, we look forward to providing more updates in the second half of 2023 on our comprehensive clinical trial strategy and regulatory roadmap, which will form the basis of a De Novo submission and potential FDA approval."*

[1] Screening for Depression in Adults: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force. Prepared by: Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2016, for the Agency for Healthcare Research and Quality, (U.S. Department of Health and Human Services).

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

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Investor Enquiries:

investors@medibio.com.au
+61 8 6189 1155

Henry Jordan – Six Degrees Investor Relations
Henry.jordan@sdir.com.au
+61 431 271 538

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.