ASX Announcement

Medibio Limited – 26 October 2021

FDA STRATEGY AND REGULATORY UPDATE

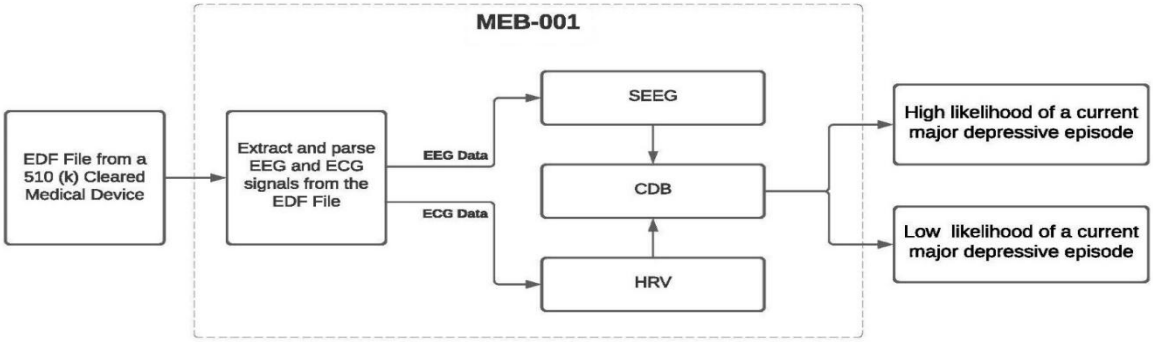
Melbourne, Australia and Minneapolis, USA – 26 October 2021: Medibio Limited (**MEB** or the **Company**) (ASX: MEB)(OTCPINK: MDBIF), a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions, provides the following FDA strategy and regulatory update:

Sleep Analysis of Depressive Burden study (SADB) (MEB-001)

The SADB algorithm development, known as MEB-001, is entering validation trials of the study**;** and to date, data analysis has demonstrated high levels of performance in overall accuracy, sensitivity, and specificity relative to the current best practice standard for measurement of depression in the US, PHQ-9. The SADB study population has now expanded to include sleep centers in Minnesota, Ohio, North Carolina, South Carolina, Florida, Missouri, and Connecticut to expedite the clinical study timelines.

The MEB-001 algorithm has been developed to utilise inputs from FDA-cleared polysomnography (PSG) systems, which are used for sleep studies to diagnose sleep disorders. The algorithm performs a parsing analysis of electroencephalogram (EEG) and electrocardiogram (ECG) biological signals to identify the likelihood of current major depressive episode in patients referring to sleep clinics for sleep disturbances. Thus far, the Company's clinical analysis has shown significant patterns of discrimination for moderate to severe cases of depressive burden[1].

Using physiological data (ECG and EEG) collected during a sleep study, MEB-001 utilizes machine learning algorithms to predict the likelihood that the patient is experiencing a current major depressive episode. This prediction is designed to be comparable to a PHQ-9 score >= 10, which is the clinical standard and best practice for screening for a current major depressive event. MEB-001 will report the screening result to the clinician. See graph below.



Development of Software Medical Device (MEB-001SaMD)

As a result of the success of the SADB exploratory and late feasibility phase trials, planning has now begun for the development of the cloud-based software medical device platform known as MEB-001SaMD

[1] Dacco S, Grassi M, Caldirola D, Cuniberti F, Defillo A, and Perna G. "Detecting clinically significant depressive burden in sleep clinics through physiological parameters: Preliminary data as to sleep stages and heart rate." number "ABS-WS-2022-00431" World Sleep Congress, Rome 2022.

(which incorporates the MEB-001 algorithms). Medibio will seek FDA De Novo approval for the Cloud-based Software Medical Device (MEB-001SaMD) during calendar year 2022.

MEB-001SaMD is intended to assist physicians in determining whether a patient should be referred for a more in-depth mental health evaluation. We believe MEB-001SaMD can ultimately be utilized within the USA by a primary care physician, sleep physician, neurologist, cardiologist, or ENT surgeon, as they are responsible for completing a referral to a mental health professional for evaluation. Medibio is currently in discussions with some of the largest U.S.-based medical insurance carriers to understand and confirm the clinical utility and commercial value to clinicians in the United States.

Given these developments, Medibio's clinical staff and its FDA consultants DuVal & Associates are now preparing the documentation required to accompany a request in November 2021 for a pre-submission meeting with the FDA. The purpose of such pre-submission meeting is to obtain FDA feedback on the Indication for Use (IFU), the trial design, its endpoints, the patient trial numbers, and the diversification of the patient population; it will also detail the Intended Use of the MEB-001SaMD and how it will be used in a clinical setting.

The proposed FDA validation trial is designed to compare the results from MEB-001SaMD with the results for moderate to severe depression as determined by the PHQ-9 (best practice standard for measurement of depression in the US). Medibio will propose a minimum performance of 65% to satisfy the criteria for study success. However, internal studies have demonstrated higher levels of performance at 75%. We estimate a total of 370 patients will provide adequate power to satisfy the two primary endpoints.

Update on MEBsleep

On the 27th of August 2021, Medibio was scheduled to meet with the FDA regarding MEBsleep; prior to the meeting, the FDA indicated that because of MEBsleep's innovative approach, a 510(k) would not be the best regulatory pathway to regulatory clearance. Subsequent to the FDA meeting, it was concluded that MEBsleep's current design would require modification of Intended Use and possibly a new De Novo regulatory pathway prior to commercialization.

During the FDA meeting, Medibio's clinical team took the opportunity to discuss the strategy for MEB-001SaMD trial, given the similarities with MEBsleep. The FDA team provided valuable detailed feedback, which has guided Medibio's clinical team in relation to the MEB-001SaMD pre-submission meeting outlined above.

"Having carefully considered the FDA feedback, the Board of Medibio has determined that the time and resources required for a new regulatory pathway for MEBsleep is prohibitive and cannot be justified," said Medibio CEO Claude Solitario. *"Further, the Board has concluded that given the promising progress of the MEB-001 algorithms, resources are best allocated to the De Novo application for MEB-001SaMD. Therefore, we are pivoting our efforts from MEBsleep's 510(k) pathway to the De Novo application for MEB-001SaMD. This targeted approach is in line with Medibio's product development strategy and we are confident it will accelerate our progress towards commercialization."*

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Medibio will provide further updates as developments of a material nature come to hand.

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

About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: MDBIF) is a 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 U.S. offices in Minneapolis, MN. Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTC Pink Open Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au.

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