ASX Announcement

Medibio Limited – 14th February 2020

STRATEGIC PLAN FOR FDA AND CE MARK APPROVAL

Melbourne, Australia and Minneapolis, MN – 14th February 2020: Medibio Limited (**MEB** or the **Company**)(ASX: MEB)(OTCQB: MDBIF), a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions, is pleased to submit the following summary of its regulatory path for 2020.

Medibio is working to develop a unique Software Medical Device (SoMD) to objectively identify depressive burden in patients with primary (e.g. hypersomnia, insomnia) and secondary (e.g. obstructive sleep apnea) sleep disorders. The depressive burden is defined as the number of depressive symptoms in a patient. This SoMD will greatly assist sleep clinicians in screening those patients that have coexisting sleep disturbance and depression. The importance of this technology is to enable clinicians to target and monitor the patient's treatment regime, by identifying autonomic modulation (the balance between sympathetic and parasympathetic nervous system) throughout sleep stages, as well as monitor long term improvement over time.

The De Novo Application for Depressive Burden (MEB-001)

In March 2019, the depressive burden concept was presented and discussed in a pre-submission meeting with the FDA. The FDA recognized a potential clinical value. In October 2019, our Sleep Analysis of Depressive Burden study (SADB) was approved by a US-based Institutional Review Board (IRB). The approval has allowed us to begin a clinical study that will generate clinical data to support a future FDA De Novo submission.

The MEB-001 is a platform with 3 main components:

1. A sleep staging algorithm,
2. An overlaying resting heart rate and heart rate variability algorithm, leading to the
3. depressive burden analysis.

Data analysis will be performed for every 50 patients. Once the study reaches sufficient statistical power, it will be placed on hold and a full statistical analysis will be performed. The result of this analysis will be used for a pre-submission meeting with the FDA to agree on endpoints and prepare for the final Pivotal study. We will inform shareholders when the statistical power analysis study stage is complete.

For the Pivotal study, the FDA will require patients from a number of different US-based centers. The sleep centers under consideration include Lakeland Health Services, University of Florida, Mayo Clinic and Mount Sinai. We are forecasting an enrolment pivotal study consisting of 300 patients, which will form the basis for the De Novo submission.

We will inform shareholders when this Pivotal study is complete and when the FDA De Novo application is submitted. The FDA approval process will take 6-9 months from submission.

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The 510K submission for Sleep Staging and Heart Rate Variability Algorithms (STAGER) in 2020

A first and essential step in the development of the clinically depressive burden algorithm is the identification of 5 sleep stages. Accordingly, we have developed an algorithm (known as STAGER), using Artificial Intelligence and neural network methodology, that will identify these important sleep stages. STAGER development is now complete and in the pre-validation phase to optimize the algorithms.

STAGER forms a part of our depressive burden SoMD; however, we believe it has commercial value in itself. Therefore, as part of our strategic plan to identify early regulated market opportunities, STAGER will be the subject of an FDA 510(k) submission early in the June quarter of 2020.

The identification of sleep stages is important in the identification of sleep disorders. Currently, the identification of sleep staging is performed manually by certified sleep technicians. This is time consuming, costly and requires expertise. We believe STAGER presents an opportunity for sleep technicians and doctors to improve diagnosis and/or serve larger patient populations without adding to their workload. This is particularly relevant as sleep analysis transitions from hospital outpatient departments and freestanding sleep clinics to home sleep testing.

STAGER has been developed and tested using close to 1 million epochs (an epoch is a 30-second sleep interval) in over 1,000 individuals. STAGER is currently showing an overall accuracy of 84%. This exceeds the accuracy of our chosen predicate device and is comparable to human raters. We continue to validate STAGER against human raters and a predicate device to prove substantial equivalence, which is a key to FDA clearance and market acceptance.

We are now in the pre-validation phase (i.e. 30 individuals). At the conclusion of this phase, STAGER will be "locked" (i.e. no further changes can be made during the following validation stage). The validation phase (which now has IRB approval for up to 70 patients) will be completed early in the June quarter 2020. We will inform shareholders when STAGER validation is complete and when the FDA 510K application has been submitted.

It is important to note that the development of the STAGER SoMD will not add to, or distract from, the time frame for the MEB-001 SoMD.

Potential CE Mark submission for STAGER in 2020.

The Company is always seeking to find the quickest path to commercialization with its regulated products. In this regard, a meeting is scheduled in May 2020 with DQS (MEB's Regulatory Body in Germany) in relation to the potential to file a CE Mark application for STAGER, which will enable commercialization in Europe. We will update the market with the result of this meeting.

Claude Solitario
Managing Director

Archie Defillo M.D.
Chief Medical Officer

Level 4, 100 Albert Road, South Melbourne, Vic 3205
Email: info@medibio.com.au | www.medibio.com.au

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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.

Further Information:	Website: www.medibio.com.au
Medibio Investor and Media Enquiries: Peter Taylor NWR Communications peter@nwrcommunications.com.au T: +61 (0) 412 036 231	