ASX Announcement

Medibio Limited – 7th August 2020

FDA STRATEGY AND REGULATORY UPDATE

Melbourne, Australia and Minneapolis, USA – 7th August 2020: 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 update on its regulatory path for 2020.

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

In December 2019, Medibio's Sleep Analysis of Depressive Burden study (SADB) commenced enrolment. The aim of SADB is to identify clinical depressive burden in patients with sleep disturbance who undergo a sleep study in a clinical environment.

The SADB trial involves the development of the depressive burden platform known as MEB-001 consisting of 3 main components:

1. The sleep staging algorithm, known as MEBsleep (see Development of Sleep Staging Software below);
2. An overlaying resting heart rate and heart rate variability algorithms, leading to:
3. Depressive burden analysis.

During the SADB, data analysis will be performed for every 50 patients. Once the study reaches sufficient statistical power 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 SADB "Pivotal Study". For the Pivotal Study, the FDA will require an agreed number of patients from different US-based sleep centres, the data of which will then form the basis for the De Novo submission.

As announced on 30 April, the COVID-19 outbreak had led to sleep clinic closures, as a result, the progress of the SADB was affected. As sleep clinics have now begun to reopen in the US, Medibio is in the process of expanding engagement to continue enrolment.

We will keep the market informed of our recruitment/enrolment progress. The FDA approval process is expected to take 6-9 months from acceptance of the submission, however it is an iterative process, particularly in light of the ongoing pandemic.

Development of Sleep Staging Software - MEBsleep

As aforementioned, an initial step in the development of the depressive burden platform MEB-001, is the identification of sleep stages (i.e. Wake, N1, N2, N3, REM). To this end, Medibio has developed sleep staging algorithms and related software, known as MEBsleep.

MEBsleep was developed and tested using more than 1 million epochs (an epoch is a 30-second sleep interval) in over 1,000 patients. MEBsleep uses artificial intelligence, deep learning algorithms and neural network methodology to identify the five important sleep stages that are required for the accurate identification of sleep disorders. **The primary purpose of MEBsleep is the identification of sleep stages, which is a critical part of the depressive burden platform MEB-001**. However, as Medibio believes

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MEBsleep has commercial value in its own right as a useful tool for the identification of sleep stages, it filed a 510(k) application for MEBsleep (refer to announcement on 30 April).

FDA 510(k) Application for MEBsleep

In line with the typical 510(k) evaluation process, Medibio recently received queries from the FDA prior to its submission being officially accepted for review. The queries are largely around clarification of intended use and substantial equivalence to the chosen predicate device. Substantial equivalence requires that MEBsleep has the same intended use as the chosen predicate device and has the same technological characteristics, or has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as the chosen predicate device.

The Company has responded to the FDA's queries and awaits further correspondence. Upon FDA's satisfaction of Medibio's response, MEBsleep will be officially accepted for review. Medibio remains positive of clearance and is actively seeking commercial collaborations and opportunities for MEBsleep in anticipation of FDA clearance.

CE Mark for MEBsleep

Due to COVID-19 the meeting with DQS (MEB's Regulatory Body in Germany) in relation to the CE Mark application for MEBsleep, has been postponed until the end of August 2020. We will update the market with the result of this meeting.

– ENDS –

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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