

ASX Announcement

Medibio Limited – 30th April 2020



MEDIBIO SUBMITS FDA 510K APPLICATION TO THE FDA FOR ITS SLEEP STAGING MEDICAL SOFTWARE DEVICE

Melbourne, Australia and Minneapolis, MN – 30 April 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, is pleased to announce that on Wednesday, 29th April, US Central Time, it submitted an application to the FDA for its sleep staging medical software “MEBSleep” (previously known by its working title, STAGER).

Medibio’s Chief Medical Officer, Dr Archie Defillo says:

“I am pleased to announce today that Medibio has lodged its 510K application to the Food & Drug Administration (FDA) for our sleep staging software “MEBSleep”. I am particularly proud to inform shareholders that MEBSleep has been developed and submitted on time and below budget. This is a significant step in the path to our depressive burden medical software device for patients with primary and secondary sleep disturbance. It is also important to note that MEBSleep has a commercial path in itself and we are actively seeking collaborations for commercialisation in the USA”.

In the final analysis for the purposes of the 510K application, MEBSleep has shown superior results - 85% overall agreement with a consensus panel of certified sleep technicians - when compared to its chosen predicate device with 73% overall accuracy.

Importantly from a market perspective, it is comparable to certified sleep technicians, who are currently considered the gold standard in sleep staging identification. However, manual identification by certified sleep technicians is time consuming, costly and requires significant expertise. MEBSleep uses artificial intelligence, deep learning algorithms and neural network methodology to identify the five important sleep stages that is required for the accurate identification of sleep disorders. Its speed, accuracy and the AI characteristics offer a significant market advantage.

Further details of the MEBSleep trial and the related FDA submission can be found in the Company’s March Quarterly Activities Report due to be lodged with the ASX later today.

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This announcement is authorised for release to the market by the Board of Directors of Medibio Ltd.

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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.

Further Information

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