

ASX Announcement

Medibio Limited – 31 August 2020



FDA STRATEGY AND REGULATORY UPDATE

Melbourne, Australia and Minneapolis, USA – 31 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.

FDA 510(k) Application for MEBsleep

As reported on 30 April, Medibio submitted an FDA 510(k) application for its sleep staging medical software, MEBsleep. 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 its depressive burden algorithms and related platform MEB-001.** However, MEBsleep has commercial value in its own right.

Following the 501(k) submission, Medibio responded to queries from the FDA to provide clarification of the intended use for MEBsleep and questions related to its predicate device. Requests of this nature are common as part of the 510(k) review process given this particular submission pathway rests on the submitted device being 'substantially equivalent' to a predicate device.

Following on from our update dated 7th August 2020, on the 24th August 2020, US Central Time, Medibio received communication from the FDA that its application was found to contain all the necessary elements and information needed to proceed with a substantive review. As a result, Medibio can now confirm its application has progressed to the FDA's substantive review phase.

CE Mark Application for MEBsleep

Medibio has now submitted the Technical File for MEBsleep, as a Depression Diagnostic Aid, to the European Regulatory Body for CE Marking certification.

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

– ENDS –

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

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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:

Medibio Investor and Media Enquiries:

Arthur Chan

WE Communications

T: +61 (0) 404 369 388

WE-AUMedibio@we-worldwide.com