

# ASX Announcement

Medibio Limited – 19 January 2021



## Medibio Granted CE Mark Approval for MEBsleep

**Melbourne, Australia and Minneapolis, MN – 19 January 2021: Medibio Limited (MEB or the Company)(ASX: MEB)(OTCPINK: MDBIF), is pleased to announce that it has received CE Mark approval for its sleep staging software, MEBsleep.**

MEBsleep is a software-only medical device that analyses Electroencephalogram (EEG) and Electrocardiogram (ECG) data collected during polysomnography to verify sleep stages and heart rate variability (HRV) in patients suffering from primary or secondary sleep disturbances. MEBsleep uses artificial intelligence, deep learning algorithms and neural network methodology to analyse large amounts of raw data, including autonomic nervous system modulation throughout sleep stages, to highlight key information to assist the physician in understanding the patient's condition.

Currently, the gold standard for identifying sleep stages in a sleep laboratory setting is a 60 to 90 minute visual assessment conducted by a clinician. MEBsleep performs the same assessment in 60 to 90 seconds, thereby providing improved efficacy for overall patient evaluation by sleep medicine technicians, under the supervision of a physician.

CE Mark approval will allow Medibio to commercialise MEBsleep across the European Economic Community. The intended users of this device are sleep technicians and researchers. The path is now clear for Medibio to accelerate its commercialization activities for MEBsleep in the EEC. The company is currently exploring commercialization paths with European academic groups and pharma companies focused on behavioural sleep medicine.

Claude Solitario, Managing Director of Medibio, said the approval was a significant regulatory milestone.

"MEBsleep is our first marketable product with CE Mark and its approval is an important step on our path towards commercialisation. Furthermore, it is also an important validation as we advance development of our depressive burden software medical device MEB-001, of which MEBsleep is a component," said Mr Solitario.

The prevalence of sleep disorders, such as insomnia, sleep apnea, and Restless Leg Syndrome, has increased appreciably in recent years, as has general awareness of their debilitating effects. Consequently, the global market for sleep aids, which was valued at US\$71billion in 2018, is forecasted to grow at a compound annual rate of 7% between 2019 and 2025<sup>1</sup>. Europe and North America together account for more than 65% of total sales of sleep aids globally, with the United States, Germany, and the UK among the top markets.

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<sup>1</sup> <https://www.researchandmarkets.com/reports/5124672/global-sleep-aids-market-consumer-behavior>

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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) (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 wellbeing 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](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au).

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