

# ASX Announcement

Medibio Limited – 16 July 2018



## Medibio Submits FDA De Novo Application

**Sydney, Australia and Minneapolis, MN USA – 16 July 2018: Medibio Limited (MEB or the Company)**(ASX: MEB)(OTCQB: MDBIF), a mental health technology company, today announced the U.S. Food and Drug Administration (FDA) De Novo submission for its Clinical Decision Support System (System) and the first of many modules that addresses the aid to the diagnosis of mental health disorders. The formal submission to the FDA was completed on Friday, July 13, following the successful 230-person clinical study at eight clinical sites and an in-person meeting with key members of the FDA and Medibio leadership team.

Medibio's System will provide an infrastructure for physicians to review objective data in the clinical evaluation stages of the patient care continuum, as an aid in the diagnosis to ongoing monitoring and management of mental illness. This System also includes a two-way interface of objective biomarker data between the clinician and patient, enabling real-time digital biometric monitoring in a remote patient setting. The De Novo pathway was utilized given there is no current FDA-cleared predicate product or device for a mental health system for diagnostic indication. Subject to FDA clearance, the Medibio System will provide the predicate for future submissions of modules addressing additional mental health disorders. Subject to FDA processes, the Company anticipates attaining clearance on the submission by the end of calendar year 2018.

Our Major Depressive Disorder module includes an algorithmic approach to address the need for improved diagnostic support tools for clinicians. The current gold standard used by clinicians utilizes subjective based assessments. The Medibio System provides a digital biomarker that baselines the patient at the time of reading and identifies changes within the patient's physiological system throughout the diagnosis and treatment process.

"With this significant submission, we are positioned to provide an end-to-end solution for mental health monitoring and management at all stages of the patients' care. We anticipate that the Medibio Clinical Decision Support System will vastly improve the quality of services and patient management that clinicians can provide, thereby improving outcomes for those suffering from mental health disorders," Jack Cosentino, CEO and Managing Director stated.

"This submission underpins a strong evidence based approach to the Corporate Health, Consumer and Integrated Health verticals that provide our pathways to market."

The FDA De Novo submission continues a transformational year during which Medibio has significantly expanded our patent portfolio, built a world-class technology, data science and medicine team, completed an acquisition, received ISO 13485, CE Mark, and TGA approval, written peer reviewed scientific publications, created a robust pipeline of products, and have begun our journey into commercialization.

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## Scientific and Technology Background

Medibio has a strong digital technology and scientific platform that is delivered using web-based Artificial Intelligence to evaluate mental illness phenotypes, combined with dimensional circadian heart - sleep biometrics and physiological biomarkers. In simple terms, it provides a non-invasive, user-friendly, comprehensive, mental health evaluation in the palm of your hands.

Medibio's technology will enhance the ability to empower clinicians, patients, employers and loved ones by screening, aiding the diagnosis, monitoring and managing mental illness, with the mission of improving quality of lives around the world, objectively.

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## About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company that has pioneered the use of objective digital biomarkers to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company was founded in Australia, with offices located in Melbourne (Vic), Perth and U.S. offices in 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](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au)

### Further Information:

Website: [www.medibio.com.au](http://www.medibio.com.au)

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