

# ASX Announcement

Medibio Limited – 20 March 2017



## Company Update and Investor Presentations

**Sydney, Australia** – Medibio Limited (MEB or the Company), an evidence-based medical technology company with a platform that enables objective assessment and management of broad spectrum mental illness, today announced that Managing Director and CEO Jack Cosentino will be presenting at several investor events including the TechKnow conferences in Melbourne and Sydney. An updated investor presentation has been lodged with the ASX today, which includes the following update.

### **European Regulatory approval and time-to-market streamlined**

As part of its increased clinical focus Medibio is accelerating its time-to-market via the CE mark regulatory pathway. This process is well advanced and the company is on track to make its first CE mark submission by Q4 2017.

The application will cover both Medibio's first clinical product is Medibio-ID, for the detection of a psychiatric condition including the classification of major depression. This will allow broader product use for customer validation in H1, 2018 as well as the immediate commercialisation for depression post CE mark.

A Notified Body has been appointed with an affirmed plan to leverage blinded retrospective data from the University of Ottawa to support the company's first technical file submission. Sufficient retrospective data has been held back from the recently completed Ottawa validation studies and this data is now available for immediate processing.

In preparation for an ISO13485 certification and technical file submission, Medibio has established a Quality function along with a Quality Management System (QMS) and commencement of product phasing and development in accordance with regulatory standards.

### **Newly Appointed Med-tech Executive Team in Place**

Medibio welcomes two newly appointed full time leaders, Greg Moon, MD as Chief Medical Officer and Yashar Behzadi, PhD as Chief Product Officer. The two will head Medibio's newly established Silicon Valley Technology and Product Development Center.

Dr. Moon will lead the Clinical and Regulatory team as Medibio progresses through the CE and FDA phase. He holds both an MD from Stanford and MBA from UCLA, Berkeley. Prior to joining Medibio Greg Director Clinical Affairs at Proteus Digital Health. During his tenure at Proteus Dr. Moon led the company's FDA and CE mark approvals for the world's first digital medicines platform. This combined a cloud-connected platform and system of ingestible and wearable sensors. Dr. Moon also drove Proteus' first commercial launch of digital medicines in the US, working closely with health system and provider customers to integrate the offering smoothly into care pathways and to optimize its clinical utility for patients and clinicians alike.

Mr Behzadi will lead the platform, algorithm and product functions. His experience includes over 15 years of senior leadership and executive roles in medical device and technology companies. Prior to joining Medibio, Mr Behzadi

led the product, data sciences and application development teams at Proteus Digital Health. In this role Yashar was involved in the creation of every layer of the Proteus Digital Health solution. He is a leading algorithm specialists with a focus on algorithms for ECG data. Other notable accomplishments include launching the digital medicine software platform and product, Helius, which is commercially used in US/UK.

The company is in the final stages of hiring an experienced medical technology US based CFO.

#### **Investment in Extending World-Class Algorithm and Data Science Capability**

Medibio is continuing its investment in algorithm and data science with the addition of Nathan Kowahl, who will head algorithm development out of the Silicon Valley office. Nathan previously led wearable algorithm strategy at Intel across a broad set of devices and verticals. Previous to Intel, Nathan led algorithm development at Basis, the company that pioneered wrist-based heart-rate monitoring. Medibio will continue to recruit additional experts to further extend its analytics platform.

In commenting on the appointments Medibio CEO, Jack Cosentino said, ***"We are excited to welcome Yashar, Greg and Nathan to the team. They have a unique background in Digital Health and will bring a tremendous amount of depth and breadth to Medibio."***

***"Medibio has a ground-breaking technology, but the potential has been untapped. We are building a world-class team of digital health and medtech management, and putting in place the systems, processes and product development strategy that will allow us to bring this solution to market quickly, and capitalise on a range of opportunities that exist to change the way mental health is diagnosed, managed and treated."***

#### **Board Renewal Process Underway**

With the new additions of Dr. Franklyn Prendergast and Andrew Maxwell over the past year, we are aggressively shifting to enhance the board with industry experience and applicability. Newly named board members will follow in the oncoming weeks. Dr. Prendergast has been serving on the Board of Directors at Eli Lilly and Company since 1995 and was Past Chair of the Board of Governors of the Mayo Foundation, having spent nearly 40 years at Mayo Clinic. Andrew Maxwell has worked with innovators, entrepreneurs and established business owners to plan and execute over \$200m in equity and debt raisings, wealth creation plans, corporate transactions and international business development programs.

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<b>Further Information:</b>		Website: <a href="http://www.medibio.com.au">www.medibio.com.au</a>
<b>Medibio Shareholder Enquiries to:</b> Jack Cosentino CEO and Managing Director Medibio Limited <a href="mailto:jack.cosentino@medibio.com.au">jack.cosentino@medibio.com.au</a> T: + 1 612 314 7201	<b>Medibio Media Enquiries to:</b> Peter Taylor NWR Communications <a href="mailto:peter@nwrcommunications.com.au">peter@nwrcommunications.com.au</a> T: +61 (0)412 036 231	

## **About Medibio Limited**

Medibio (ASX: MEB), is an evidence-based medical technology company that will radically change how mental health care is delivered through objective, data driven assessment & management. Mental health represents the largest clinical problem today with an estimated 350M people world-wide suffering from depression. Given the subjective nature of the clinical assessments, less than 10% of patients receive optimal therapy on initial assessment. To address the clinical need, Medibio has developed an analytic platform that utilizes patented (and patent pending) panel of circadian, sleep and autonomic system biomarkers to objectively quantify and characterize mental illness. Medibio has a rich portfolio of products to address broad spectrum mental health with strong foundation IP. Medibio's first product, a depression diagnostic aid, is being validated in clinical studies undertaken by Johns Hopkins University School of Medicine and The University of Ottawa, among others. The clinical trials will support Medibio's application to become the first FDA approved, objective, and evidence based approach to the diagnosis of mental health disorders. Located in Melbourne (Vic) Medibio is listed on the Australian Securities Exchange Ltd.

## **Forward Looking Statements**

The purpose of the attached presentation is to provide an update of the business of Medibio Limited (ASX:MEB). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification.

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