# **ASX Announcement**

Medibio Limited – 21 March 2019



# **Medibio Limited Shareholder Update and Outlook**

Melbourne, Australia and Minneapolis, MN – 21 March 2019: Medibio Limited (MEB or the Company)(ASX: MEB)(OTCQB: MDBIF), a mental health technology company is pleased to provide to shareholders an update on current activities and operations.

### **REGULATORY & QUALITY**

The Company's U.S. regulatory focus continues to be on one or more 510(k) submissions. Clearance is expected in the first half of 2019, which will lead to U.S. commercialisation strategy by the end of CY2019. Initial commercialisation for regulated product will be based primarily around physician prescribed inpatient sleep studies. The Company will explore license agreements and other forms of commercialisation for Medibio's technology.

Parallel to the 510(k) efforts the Company has begun positive dialogue with the FDA on the current De Novo submission. The original submission has shortcomings and the Company is now assessing the most appropriate way forward. The FDA is helping to guide the Company through the process related to the De Novo submission and has provided excellent directional feedback about our technology. The Company is encouraged by the dialogue with the FDA and this regulatory process is moving forward, with the end point anticipated late CY2020, as previously disclosed.

Medibio is finalising the details of a sponsored research agreement with a European university/hospital system, with an announcement of this collaboration expected soon. This agreement will extend Medibio's clinical team and reinforce clinical relevance needed to align with regulatory guidance and market needs. This agreement has been budgeted within the CY2019 forecast and spending target.

## **PRODUCT ADVANCEMENT & COMMERCIALSATION**

Earlier this month the Company announced the successful completion of the first pilot program of ilumen<sup>TM</sup>. The program achieved voluntary participation of 1,675 out of 7,500 employees, 22% of the workforce, exceeding management's expectation and far exceeding the 600 participants of this client's previous programs. Additionally, the program completed seamlessly, efficiently and trouble-free with regard to employee and corporate client experience with the technology. Additional program results can be viewed here.

In November 2018 Medibio was pleased to have signed an exclusive agreement with AIAA for a pilot program which will commence this month. It is anticipated that additional collaboration programs will be discussed as this pilot unfolds. AIAA is one of Australia's leading life insurers with more than 4 million policyholders. It is part of the AIA Group, the second largest life insurer in the world, with a presence in 18 markets around the Asia-Pacific region and serving the holders of more than 29 million individual policies. The full announcement can be viewed here.

The Company continues to advance and consider unsolicited approaches from major global companies, the implementation of which will have regard to the Company's limited resources at this time, while continuing to seek large scale commercialisation of ilumen<sup>TM</sup>.

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Medibio will aim to integrate ilumen<sup>TM</sup> into organisations with global distribution channels. In doing so the Company will seek to generate revenue from annual license fees and royalties based on usage. Medibio will also, as and when appropriate, recoup setup costs for client customisation.

Medibio recently announced the outsourcing of psychology services in support of ilumen<sup>TM</sup>, whilst retaining a highly experienced commercial team in Australia. This reorganisation aligns with the company's focus on cost reductions while continuing to promote, implement and support corporate customers. Medibio will continue to own the Vital Conversations business it acquired in April 2018. As part of this reorganisation the company has downsized its premise in Perth and is working to sublet or reassign the current lease on the property.

#### **CASH ACTIVITY & CASH POSITION**

Medibio recently completed a Convertible Note Issue and an Entitlement Issue, raising \$3.7M (net of costs). The Company is seeking to fulfil the shortfall on the Entitlement issue, which will provide a longer-term runway.

Management is very mindful of the cash position and the Company has taken cost reduction actions, including termination of vendor contracts and significant but appropriate reduction in staff, to reduce net future quarterly cash outlays. Medibio has identified a target of less than \$500K average monthly spend, plus past due payables, for future months of 2019. The Company will continue to evaluate spending at all levels of the organisation to achieve this target while maintaining an adequate infrastructure to support organisational goals.

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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 biometrics to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company offers comprehensive mental health solutions for business through its Corporate Health programs and is developing products to serve both the consumer and regulated healthcare provider markets. 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 OTCQB Venture Market. Investors can find additional information on <a href="https://www.otcmarkets.com">www.otcmarkets.com</a> and <a href="https://www.asx.com.au">www.asx.com.au</a>.

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