

ASX Announcement



Medibio Limited – 16 November 2018

Chairman's Address to Shareholders

Melbourne, Australia and Minneapolis, MN USA – 16 November 2018: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCQB: MDBIF), a mental health technology company, today provides shareholders with the Chairman's Address for the Company's Annual General Meeting, to be presented by Mr Christopher Indermaur.

"The 2017-2018 year was a busy time for Medibio. It was a stage of the company where we built the substance of our business at our new home in Minnesota. We need that substance to progress through the FDA clearance process and be ready for the marketing phase once clearance is granted.

As we have previously announced, the FDA has responded to our De Novo application submitted to the FDA in July. This response requires us to provide additional information to the FDA which we are working on. This process will require additional time above and beyond our original thinking. There is no specific timeline to provide given the complexity of the process with the FDA. Also, as we have announced, we are embarking on a secondary strategy that will continue to focus on the De Novo application while also working in parallel to file 1 or more applications to the FDA under the 510k process. This additional pathway could end with 1 or more clearances from the FDA within the first four months of 2019. Assuming that is the case, we should be able to achieve initial commercialisation during 2019. We have obtained European CE mark and Australian TGA approval, but FDA clearance is the gold standard.

During the year we developed our secondary product, ilumen, which is a software application that uses biomarkers to help self-assess individual's mental health. This is initially targeted at the corporate wellness market.

Since the end of the year we have changed CEO from Jack Cosentino to David Kaysen. I would like to take this opportunity to thank Jack for his work in adding structure to the business.

David has a great deal of experience in the FDA clearance process and importantly marketing newly approved medical products in the USA. This year our focus will be on achieving exactly this.

Like all other shareholders I am disappointed in the recent share price. However, the fundamentals of our technology and the market place remain strong. No one has questioned the benefit or potential of objective measures of mental health. We have never been closer to FDA clearance and sales of our objective measures.

I would like to conclude by thanking my fellow directors and staff who have been a solid team throughout the year."

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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 (WA) 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 and www.asx.com.au.

Further Information:

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