ASX Announcement

Medibio Limited – 11 November 2021

Chair and CEO Address to the 2021 Annual General Meeting

Dear fellow shareholders,

2021 has been a pivotal year for Medibio.

With mental health emerging as a topic of global urgency due to the pandemic, Medibio has been laying the foundation for further expansion.

After years of research and patient trials, we are now leading the way towards FDA approval of our clinical depression algorithms, MEB-001.

Shareholders will be aware that the aim of MEB-001 is to identify depression objectively, using a patient's own biological markers.

We have chosen to conduct our trials with patients that suffer sleep disturbances and who undergo a sleep study in a sleep clinic. This is because of the high prevalence of depression that goes undiagnosed in this patient cohort.

I will quote from Mr John Mathias, Business Development Executive of our research partners, MedBridge Healthcare, who operate 141 sleep clinics across the USA and who is now a member of our advisory board:

"…we are excited about the potential of Medibio's technology and its clinical applications. The objective identification of depression in patients that suffer certain sleep disorders is an unmet need…"

As you may have read in our recent ASX announcement we have made tremendous progress this year in the development of MEB-001, which utilises inputs from electroencephalogram (EEG) and electrocardiogram (ECG) signals from polysomnography systems.

The objective result from MEB-001 is then compared to PHQ-9, a subjective questionnaire which is currently the clinical standard in the USA for screening for a current major depressive episode.

It is pleasing to report that MEB-001 is demonstrating accuracy of up to 79.97% when compared to PHQ-9.

This data analysis is from sleep clinics in Minnesota and Ohio. We are now expanding the patient population to include North Carolina, South Carolina, Florida, Missouri, and Connecticut.

As a result of this high level of accuracy, planning has now begun for the development of software which will incorporate the MEB-001 algorithms.

Furthermore, we are preparing the documentation required to accompany a request for a pre-submission meeting with the FDA, which will guide our final validation trial and chart the path for a De-Novo application.

We expect to file the request within days.

The pre-submission meeting is to obtain FDA feedback and agreement on the Indication for Use, the trial design, its endpoints, the patient trial numbers, the diversification of the patient population and how the software will be used in a clinical setting.

We will propose a clinical trial of 370 patients, which we believe will provide adequate power to satisfy the criteria for study success.

We will also propose a minimum performance threshold of 65%, however, as mentioned earlier, internal studies to date have demonstrated much higher levels of accuracy.

Once the validation trial parameters have been agreed, our clinical team will complete the trial as quickly as possible, after which we will submit the data for approval under a De Novo regulatory pathway.

FDA approval will allow us to lay claim to the world's first objective test for depression.

It will help mental health professionals confirm their diagnoses and importantly, monitor the effects of therapeutic and pharmaceutical treatments.

Furthermore, it will position Medibio as a world leader in the field of mental health.

Shareholders may also be aware that in October we launched our long-anticipated consumer app, LUCA, which connects to both Apple and Garmin wearbles to provide biometric as well as psychometric feedback – the only stress app on the market to do so.

LUCA is now available on the App Store (for iPhone) and Google Play (for Android) for an annual subscription price of US$47.99.

Medibio's relationship with Garmin continues to develop and grow.

We have entered into a cross-promotional agreement whereby Garmin will bundle an annual subscription for LUCA into the price of their wearable devices purchased from our LUCA website.

Garmin also nominated Medibio's corporate wellness app, ilumen for its 2021 Global Innovation Awards held in Lisbon on the 28th of October.

We are very proud that ilumen was recognized as one of three finalists from a field of 63 nominees in the healthcare category.

Corporate interest in ilumen remains strong, though ongoing COVID-19-related complications, such as border restrictions, have prolonged lead times and affected efforts to secure new commercial contracts.

As vaccination rates in Australia continue to increase, we are hopeful that restrictions will ease and the resumption of travel will allow us to aggressively promote our solutions, both domestically and internationally.

The USA is certainly open for business, and I do anticipate that Australia will soon follow.

As I write to you from the USA, there is much excitement about the future of Medibio.

In 2022 we will see new executive appointments in the USA to accelerate promotional activities and support the FDA program.

We will be committing substantial funds to marketing and sales activities for both LUCA and ilumen and stepping up efforts to complete our validation trial of MEB-001 as quickly as possible.

We have continued to build our advisory board by adding top mental health experts, including world expert on depression and anxiety disorder, Professor Giampaolo Perna of Humanitas University in Milan, prominent US-based psychologist, Dr Elizabeth Lombardo, and Business Development Executive John Mathias of MedBridge Healthcare, all of whom enthusiastically join existing members and mental health advocates Michael Phelps and Patrick Kennedy.

We are excited to have such high-calibre individuals involved to take us forward and increase our opportunities now that both ilumen and LUCA are in the marketplace.

As always, I would like to take this opportunity to thank our very dedicated employees, contractors, and consultants whose tireless work across numerous time zones enabled us to bring LUCA to market on time and on budget, and whose continuing efforts will help ensure LUCA's offering remains relevant in the marketplace.

2021 was a pivotal year for Medibio.

2022 will be an exciting year for the Company.

A year that I believe will see first material revenue from ilumen and LUCA – and importantly the validation of MEB-001.

I look forward to sharing more news in the coming weeks and months.

Claude Solitario
Chairman & Managing Director

This Announcement has been approved by the Board of Directors of Medibo Limited.

For Further information:

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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 well-being 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 and www.asx.com.au.