medibio

INNOVATION IN MIND

Issue 5 - January 2017

Dear Shareholder,

Traditionally at this time of year, we reflect on the year past and look forward to the new year.

We ended the year on a high note. The results published last week from the pilot phase of the John Hopkins University study of Medibio's clinical diagnostic for depression didn't disappoint. They were exactly what we hoped to achieve and well above that required to support the intended claims in our FDA application.

Our proprietary technology registered 81% accuracy diagnosing the 26 patients, 11 with Major Depressive Disorder (MDD) and 15 normal controls, JHU assessed. Sensitivity and specificity measures were in the same ballpark.

Importantly, these results also provided an indication that Medibio's diagnostic is robust in the face of ongoing pharmacological therapy for depression. Seven of the MDD subjects were on medication for depression (with 5 of these on multiple medications), and 6 of 7 of these subjects were correctly identified as being actively depressed, an 86% accuracy.

This is a major achievement. Medibio now can confidently state it has the tools enabling independent third parties to diagnose MDD objectively.

It confirms the results we published early November from studies conducted with the University of Ottawa on almost 900 patients using its retrospective data. In those studies, diagnostic accuracy of 86% was achieved for distinguishing individuals with MDD from non-depressed individuals. Sensitivity and specificity measures were commensurate at 82% and 88%, respectively.

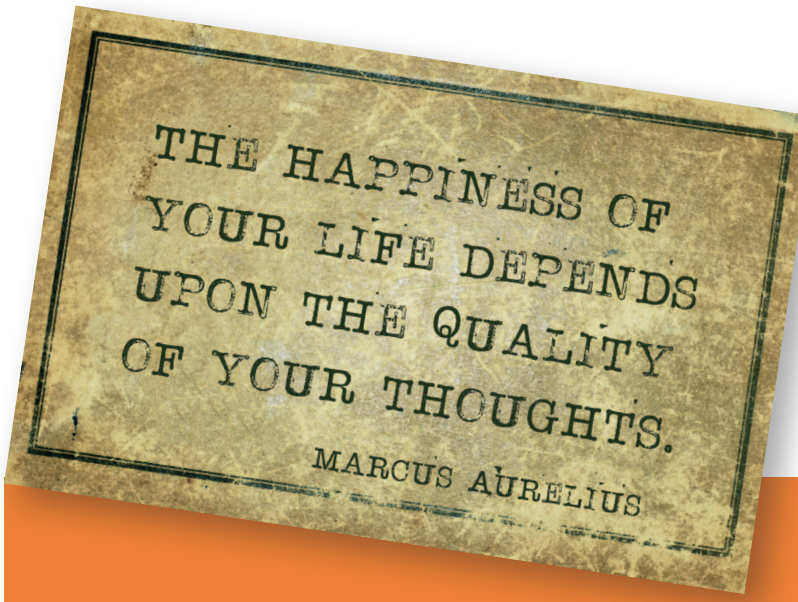
The slightly higher accuracy of the Ottawa study reflected the benefit from the machine learning feature of Medibio's analytical algorithm used on the much larger sample size.

We see no reason for the recently commenced exploratory study on a further 60 subjects and the following confirmatory study (providing clinical data to support our FDA submission) not to reproduce clinical results similar to those reported on diagnosing MDD from normal.

With the published concordance among GP's (general practitioners) in diagnosing depression at 30% to 50% accuracy, the Company has solid expectations of commercial acceptance following regulatory approval.

Concordance among psychiatrists is around 70% but GPs are our primary target market as they're at the front line of patient presentation and lack the resources to diagnose and manage mental health disorders. GPs do more than half the mental health diagnoses in both Australia and the US and prescribe the majority of antidepressants in both countries.

By this time next year, the Company anticipates European Union Medical Devices Directorate approval for its MDD diagnostic followed by US FDA market approval not too long after this, if all goes according to plan.



***Medibio** redefines mental health by making the intangible, tangible.*

Preliminary advice to the Company is the EUMDD approval may be gained on the strength of the Ottawa studies without the support of contemporaneous clinical trial data. On this basis, our submission for European market approval can be completed much sooner.

The US FDA mandates a clinical trial. (*For more detail please see slide 25 of Medibio's 2016 AGM presentation published on 29 November 2016.)*

The Company strengthened its balance sheet significantly as well in November with an oversubscribed $13.5 million capital raise. We're now well positioned to fund an ambitious programme in 2017 not only commercializing our flagship application for depression but, also, expanded clinical applications into post traumatic stress disorder and anxiety disorder. Each of these are major health issues with large human and economic tolls.

Medibio's rolling-out its Corporate Wellness product, too. This will segue into the launch of a consumer Stress App later in 2017.

The University of Sydney (SU) expects to publish its peer reviewed paper on Medibio's stress test validation study on 300 subjects next year. This paper should provide the independent, scientific review underpinning the credibility of our product.

Medibio's stress test is not a clinical diagnostic and therefore not subject to regulatory approval. Medibio rates SU's Brain and Mind Centre's (BMC) imprimatur highly and a crucial endorsement for our proprietary application for stress testing.

We believe BMC's independent study will open many markets reluctant to use an unacclaimed product.

To achieve our commercial and clinical goals, the Company is actively recruiting talent to strengthen the Board, its Medical and Scientific Advisory Board, as well as executives and consultants as and when required over the next 12 months. Particularly in the areas of regulatory affairs, sales & marketing and R&D. Shareholders may expect updates on all significant appointments.

All this was made possible by our clinical successes to date with relatively modest resources and the support of great collaborators such as the University of Ottawa, John Hopkins University, Monash University, The University of Sydney, Medtronics Inc, Vital Conversations and, of course, the Medibio team and the technology's inventors, eminent psychiatrists Dr Stephen Addis and Professor Hans Stampfer.

Dr Addis is Head of Psychiatry and Service Director at Fremantle Hospital, a large university teaching hospital in Fremantle, Western Australia.

Professor Stampfer (MB BS, FRANZCP), is a Professor of Psychiatry at the University of Western Australia and Consultant Psychiatrist at Joondalup teaching Hospital. Professor Stampfer is the discoverer of the relationship between circadian heart rate and mental illness, the foundation of Medibio's technology.

These achievements were rewarded by the significant support from institutions and professional investors in the recent capital raise.

With the plethora of opportunity presenting to the Company because of its versatile technology platform, the Board's mindful of staying focused on commercialization as its chief priority. Other opportunities are pursued after careful consideration of internal resource allocation, time-to-market horizon and global market potential.

If it's outside our core target markets in mental health such as its application in monitoring sleep staging, technology sub-licensing is the first consideration.

We want to assure shareholders we have the same goal to attain the best return on investment in a socially and ethically responsible manner as we aim to improve the lives of our fellows.

Overall, we expect significant wins in 2017 on regulatory approvals, commercialization, R&D and corporate partnerships.

Finally, the Company and I welcome new shareholders and, along with our existing shareholders, I would like to thank you for your continued support and to wish you and your families well for the Festive Season and the year ahead.

Warmest regards,

Kris Knauer
CEO

We believe individuals, families and carers affected by mental health can live full, happy & healthy lives.