

ASX Announcement

Medibio Limited – 21 April 2016



Medibio Shareholder Newsletter

Medibio Limited (ASX: MEB) ("Medibio" or the "Company") provides a copy of a newsletter which is being mailed to shareholders today.

About Medibio Limited

Medibio (ASX: MEB), is a medical technology company that has developed an objective test to assist in the diagnosis of depression, chronic stress and other mental health disorders. Based on research conducted over 15 years at the University of Western Australia, this test utilizes patented (pending) circadian heart rate variability and cloud based proprietary algorithms to deliver a quantifiable measure to assist in a clinical diagnosis. Clinical studies are being undertaken by Johns Hopkins University School of Medicine and Ottawa University, among others, to validate the test. This will potentially enable Medibio's technology to be the first FDA approved, objective, evidence based approach to the diagnosis of mental health disorders for the medical industry. The technology also provides an objective method for the assessment of stress and mental wellbeing which can be translated to the workplace stress/wellbeing market, wearable technology, and App market. Located in Sydney, NSW, Medibio is listed on the Australian Stock Exchange.

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Dear Shareholder,

Your company, Medibio Ltd (MEB), is driven to make a quantitative method for diagnosing depression and other mental health disorders available to the health care industry. Our aim is for Medibio's technology to be the gold standard for diagnosing and monitoring mental health.

The US National Institute of Mental Health in May 2013 said categorically:

"We will no longer endorse DSM5, as it has fundamental flaws. We are actively seeking a diagnostic system that is evidence based. It is critical to realise that we cannot succeed if we use DSM categories as the gold standard... We need a quantitative method for diagnosing depression."

Medibio's quantitative diagnostic, based on the relationship between circadian heart rate variability (CHR-V) and psychological states aims to offer the first FDA approved objective, clinical diagnostic for depression. This underlies our optimism and unabashed enthusiasm for Medibio's technology to become the gold standard for diagnosing psychological states.

By the end of this year we expect the results from the clinical trial conducted at John's Hopkins University School of Medicine by the principal investigator, Dr Naresh Punjabi. Dr Punjabi is Professor of Medicine and Associate Director of Graduate Training at Johns Hopkins and he has published more than 100 research papers.

The trial aims to validate Medibio's technology to differentiate between depressed and non-depressed individuals. It is also designed to support the Company's application for FDA approval to market Medibio's test in the US for the diagnosis of depression.

Why is Medibio's test so important and what makes it that much better than existing diagnostic tools for mental illness?

Presently, psychiatrists determine mental health states, like depression, by patient behaviour, observation, interview and subjective assessment (DSM5 protocol). Essentially, the diagnostic procedure is totally subjective.

As you well appreciate subjective diagnosis has a lot more tolerance of inherent bias and error. This over-diagnosis, under-diagnosis and misdiagnosis of depression and other mental illnesses places a significant cost burden on the healthcare system, sufferers and their families.

Dr Thomas Insel, MD, the former Director of the US National Institute of Mental Health, best described the problem: *"The economic costs of mental illness will be more than cancer, diabetes and respiratory ailments put together."*

Successful meeting with the FDA

In late March we had positive Pre-Submission meeting with the United States Food and Drug Administration (FDA) to discuss our proposed diagnostic for depression. While always confident we were on the right regulatory pathway it was a significant milestone to have the FDA's confirmation. We were also pleased with the high level of engagement with the FDA and the collaborative nature of the meeting.

Eli Lilly director Dr Franklyn G Prendergast MD PhD likes what he sees in MEB

Recently, your Company announced Dr Franklyn Prendergast's appointment to the Company's board as a non-executive Director. He also serves on our Medical Advisory Board. I trust you see this in a similar light to me as a major endorsement of our Company and its technology.

Dr Prendergast has a long and distinguished career in the US Healthcare industry. In particular, he has been a board member of Eli Lilly, since 1995. Eli Lilly is the world's largest manufacturer and distributor of medications for psychiatric and mental health-related conditions including clinical depression, generalised anxiety disorder, bipolar disorder and schizophrenia since 1995.

This is what Dr Prendergast said about the Company on joining the Board:

"I have been keenly watching Medibio's progress and I feel now is the right time to increase my involvement. This next year could be a watershed for the Company as it moves towards independent validation and regulatory approval."

"I am thrilled they are bringing an objective, evidence based test to the field of mental illness, where none has existed before. This is a ground-breaking area..."

"Medibio is a pioneer in mental health biomarker solutions for the improvement of patient care. The future of mental health care lies in the increased precision of assessment and timely effectiveness of treatments. The Medibio Digital Mental Health Platform will be needed to realise this vision."

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Medibio redefines mental health by making the intangible, tangible.



THE IMPACT OF STRESS

Your body responds to stress by releasing hormones and increasing your heart and breathing rates. Your brain gets more oxygen, giving you an edge in responding to a problem. In the short term, stress helps you cope with tough situations.

Chronic stress, however, can cause a variety of symptoms and can affect your overall health and well-being.

Every \$1 spent on mental health services saves \$5 in overall healthcare costs.

— American Psychological Association

It is well recognised that stress is one of the primary precursors to mental illness. Additionally, the physical problems related to chronic stress include the impairment of the immune response, increased blood pressure, and chronic muscle tension.

These problems can eventually lead to serious life-threatening illnesses. Studies have found that individuals who have undergone significant stress have a much higher probability of developing serious illness such as heart attacks, kidney disease, and cancer, than non-stressed individuals.

Your body responds to stress.

- 1 Nervous System
- 2 Musculoskeletal System
- 3 Respiratory System
- 4 Cardiovascular System
- 5 Endocrine System
- 6 Gastrointestinal System
- 7 Reproductive System



Medibio provides objective indications of workplace stress

TECHNOLOGY

Medibio's proprietary technology provides objective analysis of biological information based on our unique, novel algorithms.

When you sleep, Medibio goes to work collecting vital diagnostic data.

We analyse the Circadian Heart Rate (CHR) and focus on activity during sleep when external influences are absent.

Proprietary algorithm development has been achieved with advanced machine learning techniques.

Medibio's Corporate Stress Product objectively classifies individuals into six categories based on the impact stress has had on their CHR:

NONE (1)

No signs of stress

SLIGHT (2)

Some signs of stress, no action required

MILD (3)

Some signs of stress, action required to prevent escalation

MODERATE (4)

Multiple signs of stress, action recommended

SEVERE (5)

Signs of significant stress, immediate action required to prevent development of long term mental health problems

VERY SEVERE (6)

Multiple signs of significant stress, immediate action required to prevent development of long term mental health problems

Medibio is working with leading institutions including the University of Sydney and Brain Mind Research Institute to research and develop our objective test further for stress.

Internal testing returned excellent results for our stress algorithms with sensitivities and specificities exceeding 80%.

Medibio provides objective measures of the impact of stress on employees and the impact of changes aimed at reducing stress.

Our assessment of mental health status is objective and outperforms other current tools that rely on self-reporting and subjective testing.



Industry heavyweights also taking notice

Late last year Medibio signed a Memorandum of Understanding with Medtronic Inc, the world's leading medical device company. Bearing in mind MEB acquired this technology less than a year ago it's worth noting a major international corporate takes MEB's potential sufficiently serious to signal it wants to explore getting on board at this stage in potential clinical applications.

Similar to the other corporate, medical and technical relationships your Company has developed, it represents another plank in our strategy to make our technology accessible, user-friendly and widely available. This can only happen with the right partners and the best available conduit technologies. We expect to be announcing developments of increased significance as we build our narrative on technical and clinical advancements.

In particular, I'd like to say more about our partnership with Swinburne Software Innovation Labs at Swinburne University in Victoria. Our collaboration with Swinburne Labs is about our other main area of focus: STRESS.

Stress: A major, insidious drag on all of us

Stress is a major social, health and economic problem. Stress affects all of us at many points of our lives to various degrees. Some forms of stress can be beneficial, helping drive performance in the short term. Long term chronic stress, however, is harmful and has been shown to lead to cancer, heart disease and mental health problems.

Stress is a huge workplace problem. It effects not only worker performance, it can be self-reinforcing and infectious in the work community, diminishing productivity and success.

Stress is estimated to affect adversely 43% of adults in the US at an annualised cost \$US300 billion. Some 550 million workdays are lost each year in the US due to the adverse effects of stress and stress also causes one third of employee turnover. US employers are beginning to understand this with the combined spend on corporate wellness programmes in the US around \$US4 billion a year.

Australia's experience of the adverse effects of stress is not unlike the US or most other developed nations. In its recent report "Creating a mentally healthy workplace", done in conjunction with Beyond Blue, Price Waterhouse Coopers estimated mental health costs Australian employers approximately \$11 billion per year.

With the problem so widespread and entrenched, technologies for dealing with stress need to be nimble, versatile, accurate and cheap. They also have to differentiate the degrees of stress and, importantly, be able to monitor therapies to treat the problem. We believe our technology addresses all these parameters. Medibio's Digital Mental Health Platform (DMHP) is a cloud-based scalable product that includes real-time ECG data streaming, algorithm processing and data analytics. It can grade stress levels using proprietary (patent pending) algorithms which are at the core of our technology.

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

Our Corporate Stress Product is a world first.

Medibio's product is the first objective test to measure the level of stress and its impact.

As we announced at the beginning of March 2016, we (in conjunction with Swinburne Labs) have integrated the DMHP with wearable wrist devices. Swinburne Labs work concluded the Apple Watch and the Fitbit Surge were the best devices for our purpose. They tick all the boxes for us and will make our DMHP vastly more accessible and, therefore, more marketable. It's a tremendous breakthrough being able to harness the rapid adoption and growth rates of these wellness-driven products in the public marketplace.

Swinburne Labs also assisted Medibio in calibrating the stress algorithm with various measures based on these average data blocks and were able to achieve accuracies of up to 94%, 87%, and 93% in distinguishing the 'Mild', 'Moderate' and 'Severe stress' cases. This is comparable to the best results achieved using ECG data. As I write Swinburne are working with us to double the number of stress categories to six.

MEB's horizon to market is much shorter for its stress product than for clinical diagnostics.

As announced previously, Medibio is involved with pilot studies in stress management with several corporates. Early feedback has been very positive and we anticipate success in the pilot studies to translate into wider adoption of the programmes through their workforces and take-up by other organisations seeing the benefits. We look forward to sharing further developments with you soon including the integration with wrist wearables from which we envisage a bigger and faster uptake of the product.

MEB's going App

Apps are all the rage and wearable devices are the next big thing. With the successful testing of wearables MEB sees a great opportunity to produce a consumer App for its Corporate Stress device. This will make MEB's stress management technology (DMHP) available to the everyday man and woman and, we hope, see sales and use continue to accelerate.

Don't get too stressed

The middle section of this newsletter is about stress and its potential health impacts on you. I hope you find it useful and informative. A copy of the complete Corporate Stress brochure is available at www.medibio.com.au

As long as you don't get too stressed by the share market and the stock price gyrations we've experienced lately, being a Medibio shareholder could prove very rewarding. But if you are too stressed by it all, then we may have a product for you!

Best regards,



Kris Knauer