

# ASX Market Update

Medibio Limited  
(ASX:MEB)



31 October 2016

## Highlights

- Depression classification algorithm validated using retrospective data sourced in partnership with The University of Ottawa - a significant milestone in the Company's development of a proprietary objective test for the diagnosis of Major Depressive Disorder (MDD)
- 83% classification accuracy achieved in diagnosing Major Depressive Disorder (MDD) with this Ottawa University data
- Partnership established with the Sydney University Brain Mind Centre - clinical research study commenced for corporate workplace stress assessment
- Partnership established with the Monash Institute of Cognitive and Clinical Neurosciences (MICCN) to explore innovative solutions for improving sleep and mental health outcomes

## Corporate

- \$3,074,224 received from the Australian Taxation Office under the Research and Development Tax Incentive Program after the end of the quarter on 14 October 2016.
- \$450,000 received through early option exercise after the end of the quarter with commitments for an additional \$480,000 of early option exercise.
- The Company expects a \$2-3m R&D cash rebate for the year ending 30 June 2017 to be received in about 11 months.
- Search for a Non-executive director with candidates short-listed for interview

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### **University of Ottawa partnership: 83% classification accuracy in diagnosing Major Depressive Disorder (MDD)**

During the quarter, the Company successfully validated its depression classification algorithm using retrospective data sourced from its research partner, The University of Ottawa.

Using objective biomarkers extracted from overnight physiologic recordings, Medibio was able to distinguish between individuals with Major Depressive Disorder (MDD) and non-depressed controls with a classification accuracy of 83%.

The algorithm was trained on 228 patients (114 MDD and 114 controls) and tested on a blinded data set of 98 individuals (54 MDD and 44 controls).

The classification accuracy of 83% compares with 70% averages for experienced psychiatrists <sup>(1)</sup> and 30-55% for primary care providers US general practitioners <sup>(2)</sup>.

It was the first validation using independent data proving Medibio's proposition that psychiatric conditions differentially affect the autonomic system, resulting in condition-specific heart rate morphology and sleep patterns.

Upcoming work will include further identification of discriminating biomarkers to improve the diagnostic accuracy of Medibio's algorithm, incorporation of the new data for further algorithm training and validation of additional algorithms.

(1) Psychiatry (Edmont). 2006 Jan; Vol 3(1): 41–50

(2) Depression in Primary Care Vol 1: US Department of Health

### **Sydney University Brain Mind Centre Clinical Study**

Medibio is undertaking a trial of its Mental Wellness solution with a major Australian corporate customer. The University of Sydney is using this commercial trial to do a 'Workplace Stress Assessment' clinical research study.

The Mental Wellness solution is Medibio's proprietary objective stress assessment test and intervention programme.

The study aims to investigate the potential relationship between an individual's mood and stress levels and Circadian Heart Rate (CHR) patterns. The study also aims to investigate whether symptoms of anxiety and depression are associated with distinctive pattern deviations in CHR. The clinical study involves measuring 150 employees' stress at two separate points. Professor Nick Glozier heads the study done by the University of Sydney's Brain and Mind Centre (BMC).

Results will allow the Company to confidently target markets such as the public service, health insurance providers, the military, aviation and the public health system, where it believes independent validation is a pre-requisite for widespread take-up of its Mental Wellness solution.

During the quarter phase 1 of the study was completed. 150 participants underwent the first of two Medibio objective stress tests and traditional psychiatric measures. Phase 2 and 3 of the study are scheduled for data collection to be complete by year end.

### **Medibio-MICCN partnership – innovations for sleep and mental health**

During the quarter, Medibio established a partnership with the Monash Institute of Cognitive and Clinical Neurosciences (MICCN) to innovative approaches for improved sleep and mental health outcomes in the general population.

The MICCN is the largest Institute of its type in the Asia Pacific region, uniting more than 200 world-class researchers with cutting-edge research infrastructure. The Institute is dedicated to understanding the brain and mind – specifically in key integrated research programs of attention and memory, sleep and addiction. It seeks directly and actively to support the use of this knowledge in the clinic, the workplace and, also, through collaborations with industry and the community.

The Medibio-MICCN partnership involves a broad range of initiatives focused on further development of

Medibio's early detection and monitoring solutions and MICCN's advanced research and treatment approaches for sleep and circadian disorders for the clinical and work setting.

This partnership opens opportunities for access to a wealth of data from sleep disorder and other groups of patients through the Monash Sleep Network.

### **Mental Health Week Partnership with HBF and Vital Conversations**

On 11 October, the Company announced signing on as a delivery partner alongside corporate wellness consultants Vital Conversations and not-for-profit health insurer HBF. The partnership launched Australia's Biggest Mental Health Check-in campaign. It encourages Australians to undertake a mental health check facilitated by Vital Conversations and utilising Medibio's supplied device and technology. HBF will encourage its corporate clients to participate in the initiative. The campaign will result in a significant workplace trial of Medibio's diagnostic methodology.

Other real benefits to Medibio will be the increased awareness created of its workplace stress product prior to commercial launch, along with the expected 3,000 new de-identified data files with corresponding stress assessments. This data will more than quadruple the size of Medibio's dedicated overnight CHR file database and corresponding stress assessments.

The launch coincided with World Mental Health Day; the beginning of Mental Health Week in Western Australia and other mental health awareness periods across Australia during October. Shareholders are invited to register to participate in the programme at [www.mentalhealthcheckin.com](http://www.mentalhealthcheckin.com)

## **Corporate**

### **Cash**

The Company received a \$3,074,224 in cash from an R&D refund tax offset after the quarter's end. The company also received \$450,000 through early option exercise after the end of the quarter, with commitments for an additional \$480,000 of early option exercise.

### **Funding update**

On 23 September 2016 Medibio lodged an Accelerating Commercialisation EOI for a \$1m grant to help fast-track the commercialisation of the Company's diagnostic technology. Medibio also is finalising an application for a \$3m CRC-P grant. The Company will update the market as these applications progress and expects to know the outcome of both applications by early 2017.

The Company anticipates receiving a \$2-3 million R&D rebate for the year ending June 30 2017 in 11-12 months.

### **Non-Executive Director Search**

During the quarter James Campbell retired as a Non-Executive Director due to the workload associated with other external commitments. Medibio thanks him for his valuable contribution to the Board and the Company's development over the past two years. The Company engaged consultants to search for a replacement. The Company is about to interview shortlisted candidates.

## Quarterly Expenditure

Total expenditure of \$1.255 million during the quarter was in line with budgeted expenditure. Budgeted expenditure next quarter is \$1.1 million.

## About Medibio Limited

*Medibio (ASX: MEB) is a medical technology company developing a new objective test to assist in the diagnosis of depression and other mental health disorders and chronic stress. This test utilises circadian heart rate variability. The technology is based on measured differences in circadian heart rate and measures of heart rate variability. The technology is based on the scientific finding that circadian heart rate variability is a sensitive measure for depression, other mental health disorders and chronic stress. The technology consists of a heart monitor that sends ECG recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable measure which can be used by a clinician to assist in diagnosis. The Technology has the potential to be the first FDA-approved objective, evidence based approach to the diagnosis of depression and other mental health disorders. The technology has already benefited from 10 years of laboratory research and Medibio is undertaking a number of pivotal studies to validate its clinical utility.*

<b>Further Information:</b>	
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