

# Annual General Meeting

November 2017

ASX: MEB

OTCQB: MDBIF



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## INVESTMENT HIGHLIGHTS

#### MEDIBIO'S FIRST PRODUCT RELEASE

Major transition of focus on delivery of product for the market and with clear product development plan

#### **INVESTMENT IN HUMAN CAPITAL**

Identification of best quality team assembled for future success

#### COMPLETION OF STRATEGIC PLANNING SESSION

Developed strategic plan that will carry business for 5 year growth plan

#### PRODUCT INTEGRATION AND LAUNCH

Developing the first objective testing system to diagnosis depression and other mental health disorders

#### **EXPANDING PATENTED PANEL OF BIOMARKERS**

Leveraging autonomic, circadian and sleep biomarkers to objectively characterize broad spectrum mental illness

## CLOUD-BASED PLATFORM ABLE TO OPERATE ON ANY SYSTEM

System and device agnostic - aim for a cost-effective delivery of information to healthcare providers or consumers

#### SUPERIOR VALUE PROPOSITION

- Objective approach to screening, diagnosing, monitoring, and management of Mental Illness

#### CLINICAL VALIDATION STUDIES WITH LEADING RESEARCH INSTITUTIONS

- Johns Hopkins, Mayo Clinic, Emory University, Ottawa University, BMRI

#### **REGULATORY PROCESS UNDERWAY**

- FDA clearance and CE Mark certification

## PARTNERS ACROSS VERTICALS WITH HIGH INTEREST TO COMMERCIALIZE

- Partnership opportunities under consideration include Wearables, Sleep Analysis and Treatment, Digital Health and Telepsych

## MAJOR ACHIEVEMENTS

#### **NEWLY APPOINTED CEO**

US Headquarters recently created with a renewed focus and expertise in medtech

#### HIGH PROFILE BOARD OF DIRECTORS

Strategically assembled board with a common focus and background of success

#### COMMERCIALISATION AT THE CORE OF GROWTH

Strategy and vision set for the company to commercialise for near term opportunities

### **RESOLUTION OF OUTSTANDING LEGACY MATTERS**

Leadership, governance and share registry matters addressed

#### **EXPANDING PATENT BASE**

Leveraging autonomic, circadian and sleep biomarkers to objectively characterize broad spectrum mental illness

### **RIGHT TEAM FOR THE JOB**

Assembled top industry experts in roles that contirbute directly to the strategy of the business

#### PARTNERSHIP WITH MAJOR ACADEMIC CENTER OF EXCELLENCE

Mayo Clinic two part agreement covering clinical studies as well as a strategic partnership and development agreement

#### FIRST REVENUE WITH MAJOR PHARMA PARTNER

Otsuka agreement gives additional validation to our science

#### FIRST INDEPENDENT VALIDATION STUDY PUBLISHED

Providing a roadmap for a rich pipeline of clinical evidence

## COMPLETION OF EXPLORATORY STUDY LEADING TO CONFIRMATORY IN PROGRESS

FDA De Novo application progressing with a clear path to completion

#### ON TRACK FOR CE MARK

Successful QMS system in place and being utilised for completion of upcoming QMS audit completion

#### RECENT SUCCESSFUL CAPITAL RAISE

Oversubscribed \$14M raise closed to to ensure full capitalisation

# CORPORATE STRUCTURE

# CAPITAL STRUCTURE (ASX:MEB) (OTCQB:MDBIF)

(amounts shown in AUD\$)

Mauliat Can

Cash Available

Share Price	\$0.32
as of 28 November 2017 Shares on Issue	197.9M
Market Cap (fully diluted) Share Price as of 28 November 2017	<b>\$71.2M</b> \$0.32
Fully diluted shares	224.0M

¢E2 7M

\$20.8M

(September 30, 2017 cash balance plus \$17.5M anticipated inflow over 9 months from October 2017 completed capital raise, R&D rebate received, and stock option exercise, & partly paid shares)



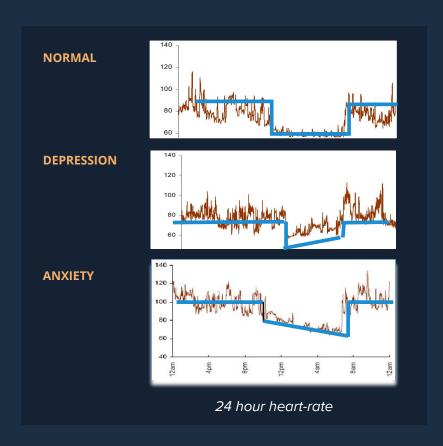
COMPANY VISION & OVERVIEW

# Medibio will be the company that changes the way the world sees mental health.

Medibio is a mental health technology company focused on standardized, objective measures to improve the screening, diagnosis, monitoring, and management of mental health conditions based on biomarkers and psycho-social inputs.

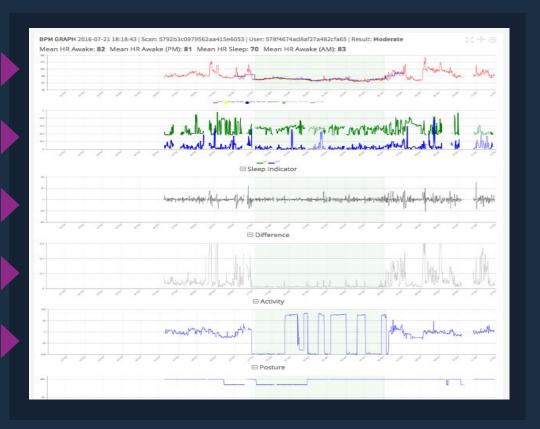
# SCIENCE BASED ON 16 YEARS OF CLINICAL RESEARCH

- Research initiated 16 years ago at University of Western Australia to test the theory that mental state is linked to autonomic nervous system (ANS), circadian and sleep disturbance
- Morphologic analysis of circadian heart rate waveforms (CHR) gives objective indications of 'core' physiological differences between different forms of mental illness such as anxiety and depression
- All serious mental illness (SMI) are associated with ANS and wider neuroendocrine dysregulation (especially affective disorders) and abnormalities in circadian regulation.
- Evidence of the state-dependent relationship between psychiatric status and CHR has come from serial monitoring of patients undergoing treatment – from individuals monitored days, weeks, months and years apart.



## BIOMARKERS PROVIDE RICH CHARACTERIZATION OF MENTAL STATE

HEART-RATE
AUTONOMIC FUNCTION
ACTIVITY
SLEEP
CIRCADIAN PATTERNS



## THE REASON WHY **PREVALENCE**

**26**% **ADULTS IN US** 

Leading cause of disability in the

#### REFERENCES

NIMH article

 World Health Organization. (WHO 2011a). Global status report on non-communicable diseases 2010. Geneva: WHO World Mental Health Day 2015

## 1 in 4 with Mental Health Diagnosis

# 350 MILLION

suffer from depression

# 1 in 13

suffer from anxiety

## **7.7M**

PTSD sufferers in the United States alone, or, 3.5% of the population

# **21M**

Suicide attempts from Mental Illness

**ADULTS IN EUROPE** 



OUR PRODUCTS

We use the body's biometric data to objectively measure mental health.

# **HEALTHCARE PROVIDER** Diagnostic Aid **PATIENT** Monitoring & Scoring Mental Health and Diagnostic Report Your Personal Wellness Score Mental Wellness Score medibio

# OBJECTIVE DATA TO DRIVE CLINICAL OUTCOMES

## Today's Approach

Subjective Measures

Symptom Based Diagnosis Screeners:

- DSM-5
- PHQ-9
- GAD-7
- GHQ-12
- PC-PTSD
- MDQ / MSS

Better **Screening** 

Better **Diagnoses** 

Better **Treatments** 

Better **Monitoring** 

Better **Outcomes** 

## **Medibio Data**

Objective Measures

#### Biometric Markers

- Circadian Heart Rate
- Sleep Cycles
- Autonomic System
- Actigraphy

## PATIENT JOURNEY

Early Detection by Primary Care Physician



**Treatment** 

Outcome(s)

Maintenance

**MONITOR & EVALUATE** 

## **SCREENING**

## MEDIBIO-ID

Direction of Psychiatric Condition

## **DIAGNOSIS**

## **MEDIBIO-DX**

Objective Biomarkers Guide Diagnosis

## **TREATMENT**

## **MEDIBIO-RX**

- Confines Therapy Effectiveness -Drug Selection and Titration
- Frequent monitoring provides early detection of ineffective protocols

## OUR MODEL **OBJECTIVE DATA TO DRIVE CLINICAL OUTCOMES**



**MEDIBIO-ID** 

**Patient Receives** Wearable

**Patient Screening** (\$15-\$20 Report)

**Patient Presents with Abnormal** Markers

**Primary Care** Visit

**Diagnostic Report** (\$180-\$240

**Annual Report)** 

Prescription Dispensed Treatment Regime Initiated

**MEDIBIO-RX** 

**Effectiveness Report** (\$15-\$20/ patient/ month)







**MEDIBIO-DX** 









Adjust medication

based on

**MEDIBIO-RX** 



# SIGNIFICANT VALIDATION SUPPORTING TECHNOLOGY

ACCURACY	STUDY OUTLINE	PARTNER
86%	<b>DEPRESSION</b> Retrospective Study, 889 patients (2 Nov 2016)	OTTAWA UNIVERSITY
81%	<b>DEPRESSION</b> Prospective Study, 26 patients (21 Dec 2016)	JOHNS HOPKINS
78-98%	DEPRESSION, ANXIETY DISORDER, SCHIZOPHRENIA Various historical studies (Medibio)	PEER REVIEWED
86-95%	SLEEP STAGING USING ECG DATA: 7500 patients completed 24 June 2016	JOHNS HOPKINS

## PATH TO REVENUE

Current primary care screening environment alone presents an **\$875M** opportunity. Another **50%** of population are unscreened. This test will be as common as taking a patient's vital signs.



Per Patient

Revenue

**PRODUCT** 

Estimated

Market Slze

**Estimated Market** 

Potential

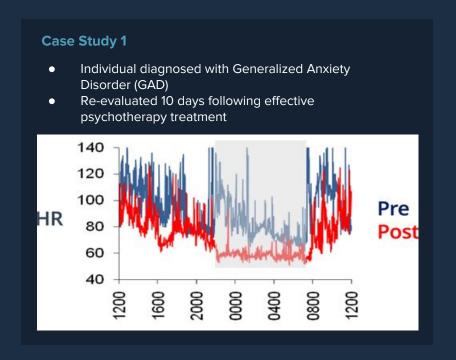
Does not include treatment, prevention, medication management, data, as well as all other market (paediatric and adolescent) and applications of our system.

## UPCOMING NEWS

TIMING	MILESTONE	STATUS
Q4, 2016	Pilot Study Validation Johns Hopkins University (Major Depressive Disorder n=20)	1
Q1, 2017	Strategic Research Partnership - Emory PTSD	<b>/</b>
Q2, 2017	Completion of John Hopkins University Validation Study (Major Depressive Disorder n=60) Publishing of Peer-reviewed paper - Emory University (PTSD)	<b>4</b>
Q3, 2017	Presentation of independent paper - University of Ottawa (Major Depressive) Announcement of results from the John Hopkins University Exploratory Study (Major Depressive Disorder n=60). Commencement of Confirmatory Study to provide data for FDA Submission (n=200)	<b>4</b>
Q3, 2017	Agreement with FDA on subject numbers required for depression confirmatory study Commencement of Confirmatory Study to provide data for FDA Submission (n=200)	
Q4, 2017	CE Mark submission (Platform, Major Depressive Disorder diagnostic aid) QMS Audit for CE Mark	
Q1, 2018	CE Mark and QMS certification (Platform, Major Depressive Disorder diagnostic aid)	
Q2, 2018	FDA submission (Major Depressive Disorder diagnostic aid)	



# OBJECTIVE ASSESSMENT OF THERAPY EFFECTIVENESS



## Biometrics normalize with effective treatment Sympathetic Tone Major Depression HR Entropy Circadian HR Normal HRI Sleep Disruption -Pre -Post

# COMPANY OUR BOARD



CHRIS INDERMAUR Chairman Seasoned ASX Chair



DR. ADAM DARKINS
Deputy Chairman
(Incoming Chairman)
Telehealth Thought Leader



PRENDERGAST
Non-Executive Director
Healthcare Luminary

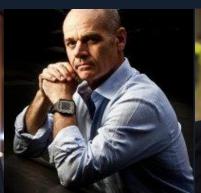
**DR. FRANKLIN** 



MICHAEL PHELPS
Non-Executive Director
World Class Athlete and Mental
Health Advocate



PATRICK KENNEDY
Non-Executive Director
Former US Congressman and
Mental Health Advocate



ANDREW MAXWELL Non-Executive Director Former Biotech CEO



JACK COSENTINO
Executive Director
CEO & Managing Director



PETER CARLISLE
Board Alternate
Attorney and Leading Sports Agent



