

INNOVATION IN MIND

## Medibio Investor Presentation August 2017

ASX: MEB OTCQB: MDBIF

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# CHANGING THE WAY MENTAL HEALTH CARE IS DELIVERED

#### CORPORATE OVERVIEW

#### Who are we?

Medibio is a Digital Mental Health pioneer who has developed the first objective testing system for the diagnosis of depression and other mental health disorders

#### What are we doing?

By leveraging a panel of patented autonomic, circadian and sleep biomarkers, Medibio is able to objectively characterize broad spectrum mental illness

#### The problem

Depression is a global epidemic affecting over 350M people world-wide. Given the current subjective nature of diagnosis and clinical decisions, less than 10% of patients receive optimal care. The problem is further amplified by the lack of access to psychiatrists resulting in under-qualified GPs shouldering the burden

#### The solution

Medibio's proprietary Digital Mental Health Platform enables GPs and mental health clinicians to cost-effectively screen, precisely diagnose and objectively confirm treatment effectiveness to better manage patients

#### Why invest in us?

- **Innovative technology** The potential to be the world's first objective system for the diagnosis of a largely intangible health epidemic
- **Targeting a large market** Depression is estimated to cost US economy US\$210 billion a year with the cost in Australia estimated at \$12.6 billion annually
- Superior value proposition Quick, objective and non-intrusive method which enables early identification, confirms treatment efficacy and enables data-driven patient management
- Validation studies with leading researchers in the industry Johns Hopkins, Mayo Clinic, Emory University, Ottawa University, BMRI
- Global partnerships with notable players in the market: Medtronic, Preventice, Zephyr Biopatch, and currently rolling out our Corporate Stress Product with Wellness Channel partners
  - Patent protected technology Based on 20 years of research
- Regulatory approvals underway Plans to file for FDA approval and CE Mark approval

#### CORPORATE STRUCTURE

#### CAPITAL STRUCTURE (ASX:MEB) (OTCQB:MDBIF) (amounts shown in AUD\$)

| Market Cap<br>Share Price<br>as of 1 August 2017 | <b>\$58.0</b><br>\$0.39 |
|--|-------------------------|
| Shares on Issue                                  | 148.7M                  |
| Market Cap (fully diluted)                       | \$67.9                  |
| Share Price<br>as of 1 August 2017               | \$0.39                  |

#### **Cash Available**

#### \$10M

Μ

(June 30, 2017 cash balance plus \$5M anticipated inflow over 9 months from R&D rebate, stock option exercise, & partly paid shares)

ANALYST RESEARCH & COVERAGE Morgans: ADD; Target price: A\$1.20 Baillieu Holst: BUY; Price target A\$0.60

#### SUBSTANTIAL SHAREHOLDERS

10.5% FIDELITY Institutional holder

7.2%

**CLAUDE SOLITARIO** Held since 2015, co-founder

52.4%

#### OUR UNIQUE POSITION TO IMPACT MENTAL ILLNESS



CHRIS INDERMAUR Chairman Seasoned ASX Chair **DR. ADAM DARKINS** Deputy Chairman (Incoming Chairman) *Telehealth Icon*  DR. FRANKLIN PRENDERGAST Non-Executive Director Healthcare Luminary



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



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

KRIS KNAUER Non-Executive Director Investor



ANDREW MAXWELL Non-Executive Director Former Biotech CEO JACK COSENTINO CEO/Managing Director

#### DR. ADAM DARKINS

"As Medibio's unique technology is maturing, it has the potential to support new models of mental health care that focus on wellness. By objectifying diagnosis and management to specifically address the rapidly growing health care needs of this population, business growth will be driven organically, and help transform mental health care delivery worldwide"

Dr. Adam Darkins, MD, MPHM, FRCS

DR FRANKLYN PRENDERGAST

"During my career at Mayo the key thing that stood out to me is that the mental health care system is broken. I joined Medibio because they have a tool that can address it""

Dr Frank Prendergast, M.D., Ph.D.

MICHAEL PHELPS

"I have personally experienced Medibio's technology and believe it can help make a profound impact in diagnosing mental health and empowering people to seek the help and support they may need"

**Michael Phelps** 

photo credit "Aqua Sphere"

PATRICK KENNEDY

"I see a future where everyone who needs mental health care gets it. We must end the separate and unequal treatment of mental health and addiction, and ensure each of us is able to achieve a full, meaningful life."

Patrick Kennedy Founder, The Kennedy Forum photo : NBC News

# "The single greatest illness that affects humankind"

Professor Stephen Lawrie Head of Psychiatry at Edinburgh

## THE REASON WHY **PREVALENCE**

## **350 MILLON** suffer from depression

26% Adults in us

Leading cause of disability in the US

## lin 13 suffer from anxiety

27% ADULTS IN EUROPE

### **7.7M**

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

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THE REASON WHY 2 2 1 in 4 ADULTS WILL HAVE A MENTAL HEALTH DIAGNOSIS PATIENT CARE DISCONNECT 2 A 2 A 2 A 2 A 2 A 2 A 2 A 2 A 2 A 

#### THE REASON WHY SUB-OPTIMAL TREATMENT

## OUT OF 350 MILLION

patients globally

# < 7% total

receive optimal treatment

## **ONLY 50%**

are ever diagnosed (Gonzalez, 2010)

SCREENING

**30%** are incorrectly diagnosed

(Angst, 2011)

DIAGNOSIS

20% receive optimal treatment (Barbui, 2006)

TREATMENT

THE REASON WHY COST



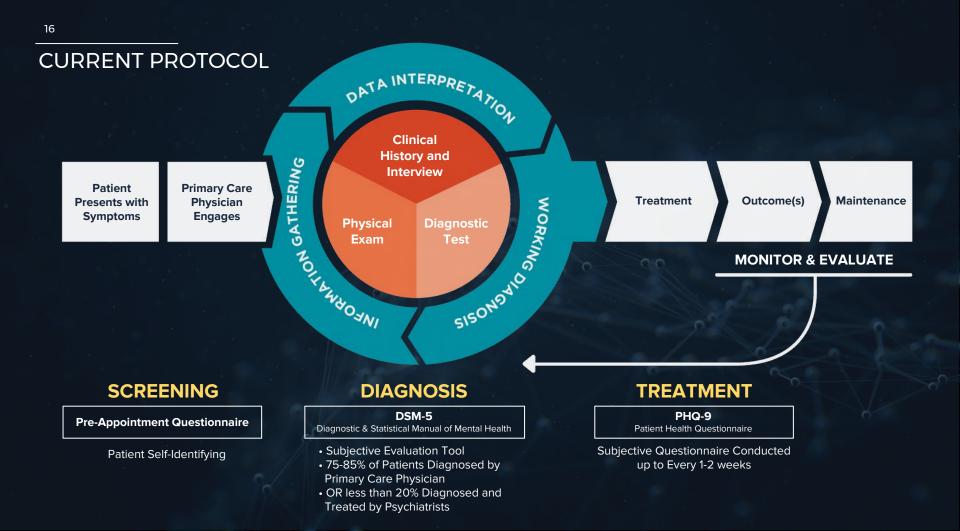
*"Mental illness will result in \$6 trillion in health-care costs, globally"* 

- WHO

#### REFERENCES

NIMH article

 World Health Organization. (WHO 2011a). Global status report on non-communicable diseases 2010. Geneva: WHO World Mental Health Day 2015 **\$12.6B** Direct cost to treat Depression annually in Australia



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## WE MUST MOVE BEYOND **SUBJECTIVE DIAGNOSIS**

GNOSTIC AND STATISTICAL

MENTAL DISORDERS

FIFTH EDITION

"The strength of each of the editions of DSM has been "reliability" each edition has ensured that clinicians use the same terms in the same ways.

#### THE WEAKNESS IS ITS LACK OF VALIDITY

In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the guality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment."

THOMAS INSEL, FORMER HEAD OF NIMH

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

Adjust medication based on MEDIBIO-RX



#### MEDIBIO-ID

Patient Receives Wearable

ves Patient Screening

Patient 9 Presents with Abnormal Markers

Primary Care Visit **Diagnostic Report** 

**MEDIBIO-DX** 

Prescription Dispensed Treatment Regime Initiated

## **⊿**⊖ **∞**

#### MEDIBIO-RX

**Effectiveness Report** 

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**30 DAY** Follow-Up Program

#### SCREENING

#### MEDIBIO-ID

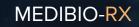
Direction of Psychiatric Condition

#### DIAGNOSIS

MEDIBIO-DX

Objective Biomarkers Guide Diagnosis

#### TREATMENT



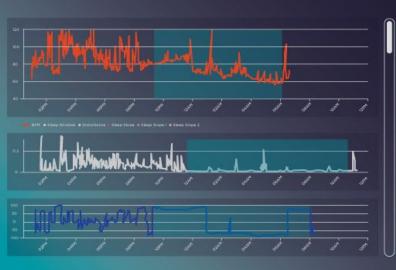
- Confines Therapy Effectiveness -Drug Selection and Titration
- Frequent monitoring provides early detection of ineffective protocols

#### BIOMETRIC-BASED OBJECTIVE DIAGNOSIS

## A Focused Approach to Treatment:

Panel of circadian, sleep and automatic system biomarkers enables automated, repeatable, and objective characterization of the impact of mental illness on physiologic state

The heart-rate morphology, rate variability and overall sympathetic tone are indicative of the presence of depression.





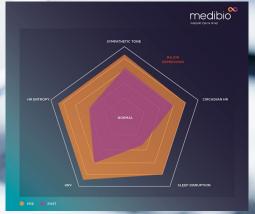


Lara gets a screening with **MEDIBIO-ID** to determine the severity of her symptoms. She is now equipped to approach alternative resources that specialize in helping those without insurance find care.

Alex receives a detailed Diagnostic Report from **MEDIBIO-DX** and is able to present it along with his disability application. With a detailed account of his PTSD, he is able to qualify and receive benefits for treatment.

|                    | AVAIL | SCORE |
|--------------------|-------|-------|
| Sleep Mean 🖚       | Ø     | 00000 |
| Awake Mean 🚥       | C     | 00000 |
| Awake Sleep Diff.  | Ø     | 0000  |
| Sleep Diff Mean 🚥  | Ø     | 0000  |
| Awake Diff Mean 👀  | C     | 0000  |
| Sleep Slope 🚥      | Ø     | 00000 |
| Sleep Slope 1 🥶    | Ø     | 0000  |
| Sleep Slope 2      | 0     | 00000 |
| Sleep St Dev 🚥     | Ø     | 00000 |
| Rate Variability 🚥 | Ø     | 0000  |
| Sleep Depth 🚥      | Ø     | 0000  |
| Sleep Quality 48   | Ø     | 00000 |

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#### HOW WE INNOVATE

PHYSIOLOGICAL DATA (ECG, EEG, ACTIGRAPHY)





Device Agnostic approach



#### APPLICATIONS

Full Spectrum Mental Health

Major Depression Disorder (MDD) Generalized Anxiety Disorder (GAD)

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Post Traumatic Stress Disorder (PTSD) Schizophrenia Disorder Bipolar/Unipolar Disorder OUR ECOSYSTEM

Medibio sits in a unique position to address the communities of interest around the world...

#### **PATIENT INPUTS**



with a data driven solution.

#### **CLINICIAN OUTPUTS**



Telehealth Platforms

Pharma

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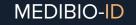
#### REVENUE OPPORTUNITIES



Report Generated (\$15-\$20 per report)



Patient Screening 1-time GP visit



Diagnostic & Decision Support Monthly Specialist Visit

MEDIBIO-DX



Patient Management

Pharma prescription management & adherence

MEDIBIO-RX

**Predictive Population Management** 

Insurance Company/ Government Pharma

#### 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.



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

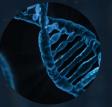
#### OUR MILESTONES

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



# Addendum

Current diagnostic tests rely on clinical interviews with subjective interpretation



#### **OUR SOLUTION**

**Quantitative and objective** diagnostic based on biomarkers



Concordance rates near 70% for psychiatrists and 33-50% for primary care physicians



**Repeatable, reliable test** with demonstrated classification accuracy of >80%



No objective measure of treatment effectiveness leads to long titration cycles

The standard of care is assessment by a primary care physician > Higher cost due to misdiagnosis



Provides objective indication of treatment efficacy enabling time to optimal treatment

**Cost-effective, scalable solution** that can be administered at the primary care or specialty level > more reliable, repeatable and low cost

OUR IMPACT

## **CONTINUUM OF CARE**



Integrated Mental Health System

Primary Care Physicians Standard Screener

Communities of Interest VA, DOD, NIH, NIMH Standard Screener

Psychiatrists/ Psychologists Improved Diagnostic Accuracy Pharmaceuticals Improves Patient Experience Adherence & Treatment Efficacy

> Telehealth Platforms Medibio System Integrations

> > Corporate Wellness Home Test & Medication Management

Reimbursement for Improved Health Score

AD2



#### PARTNERS IN GROWTH



# **Vital** Conversations

## Medtronic



#### **EMORY** UNIVERSITY





JOHNS HOPKINS HEALTH SYSTEM

#### OBJECTIVE DATA TO DRIVE CLINICAL OUTCOMES

Early Detection by Primary Care Physician

Treatment

Maintenance

#### **MONITOR & EVALUATE**

Outcome(s)

#### SCREENING

#### MEDIBIO-ID

Direction of Psychiatric Condition

#### DIAGNOSIS

HEDBIO PREDICTIVE ANALLIC

0

MEDIBIO-DX

Objective Biomarkers Guide Diagnosis

#### TREATMENT

#### MEDIBIO-RX

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



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