

# ASX Announcement

Medibio Limited – 30 November 2017

## Chairman's Address to AGM and CEO Presentation

Last year was a year of transition for Medibio. We started laying the foundation for a strategy to put us on a path toward long-term, profitable growth that creates lasting shareholder value and ultimately changes the way mental healthcare is delivered.

We've implemented a number of changes that we believe will set us up for future success. **We addressed the composition of the team, reviewed the vision and commenced introducing rigorous business processes.** We are establishing the framework that we need to commercialise our technology on a large scale.

We made several key additions to both our Board and our senior management team, beginning with new CEO/ Managing Director Jack Cosentino, who joined us midway through the year. Jack has already begun building out his management team and implementing our new strategy and vision for the future.

We are fortunate to have been able to attract to our Board several high profile directors who have a strong interest in mental health and see the potential of our product. These include Michael Phelps, Peter Carlisle; Dr. Frank Prendergast; former U.S. Congressman and mental health advocate Patrick Kennedy; former biotech CEO Andrew Maxwell; and respected telehealth expert and incoming Deputy Chairman Dr. Adam Darkins. Each new board member is already making an impact to help elevate our business profile while still maintaining long-term continuity.

Since then Kris Knauer has left the board to pursue other interests. Kris was the driving force for the rebirth of our company from a listed shell and the acquisition of our technology. He was the entrepreneur who set this company up in its early days I take this opportunity to thank Kris on behalf of the company and wish him well for his next endeavor.

We are still transitioning from a small listed company with few staff to a company with the personnel, structure, systems and procedures required to exploit our technology around the world. Core knowledge and functions are being brought inhouse to our offices in Minneapolis and Melbourne. This process is well underway and I am confident we have the people for the task.

It's an exciting time to be a part of Medibio Limited. On behalf of our board and senior management team, I thank you for your continued support and look forward to our future successes together.



# 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 contribute 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 ensure full capitalisation



# CORPORATE STRUCTURE

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

(amounts shown in AUD\$)

### Market Cap

Share Price  
as of 28 November 2017  
Shares on Issue

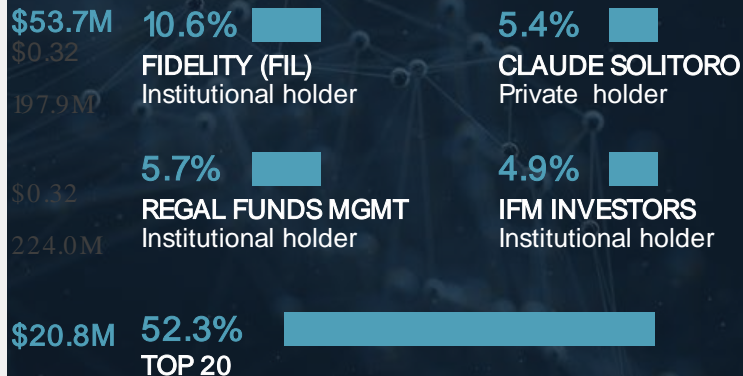
**Market Cap (fully diluted)      \$71.2M**

Share Price  
as of 28 November 2017  
Fully diluted shares  
(per November 14, 2017 Appendix 3B)

### Cash Available

(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)

## SUBSTANTIAL SHAREHOLDERS







## 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.

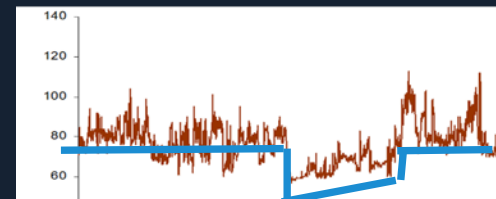
## SCIENCE BASED ON 16 YEARS OF CLINICAL RESEARCH

- 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.

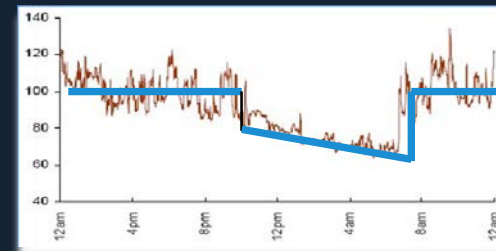
### NORMAL



### DEPRESSION



### ANXIETY



*24 hour heart-rate*

# BIOMARKERS PROVIDE RICH CHARACTERIZATION OF MENTAL STATE

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HEART-RATE

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AUTONOMIC FUNCTION

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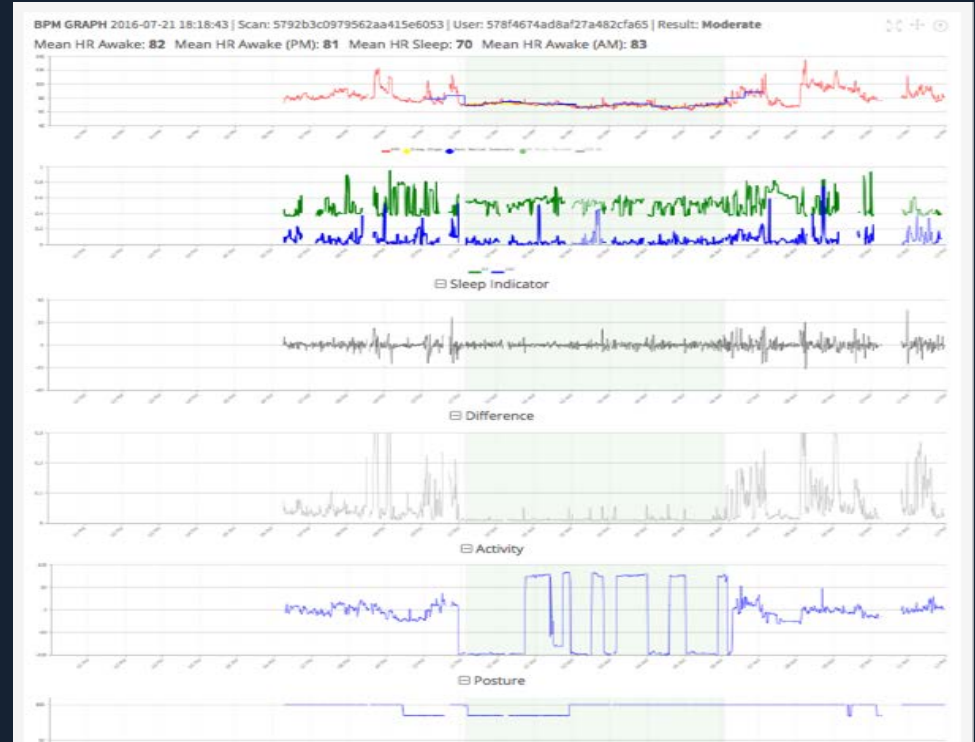
ACTIVITY

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SLEEP

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CIRCADIAN PATTERNS



## THE REASON WHY *PREVALENCE*

**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

**26%**

ADULTS IN US

Leading cause of disability in the  
US

**27%**

ADULTS IN EUROPE

### REFERENCES

- NIMH [article](#)
- World Health Organization. (WHO 2011a).  
*Global status report on non-communicable diseases 2010*.  
Geneva: WHO World Mental Health Day 2015

## OUR PRODUCTS

### CONSUMER *unregulated*

- Screening
- Risk Stratification
- Wellness Scoring
- Wellness Monitoring

MENTAL **WELLNESS**

### MEDICAL *regulated*

- Pre-Screening
- Differential Diagnosis
- Treatment Adherence Tracking
- Treatment Efficacy Monitoring

MENTAL **ILLNESS**





## OUR PRODUCTS

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

### HEALTHCARE PROVIDER *Diagnostic Aid*



### PATIENT *Monitoring & Scoring*





# 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***

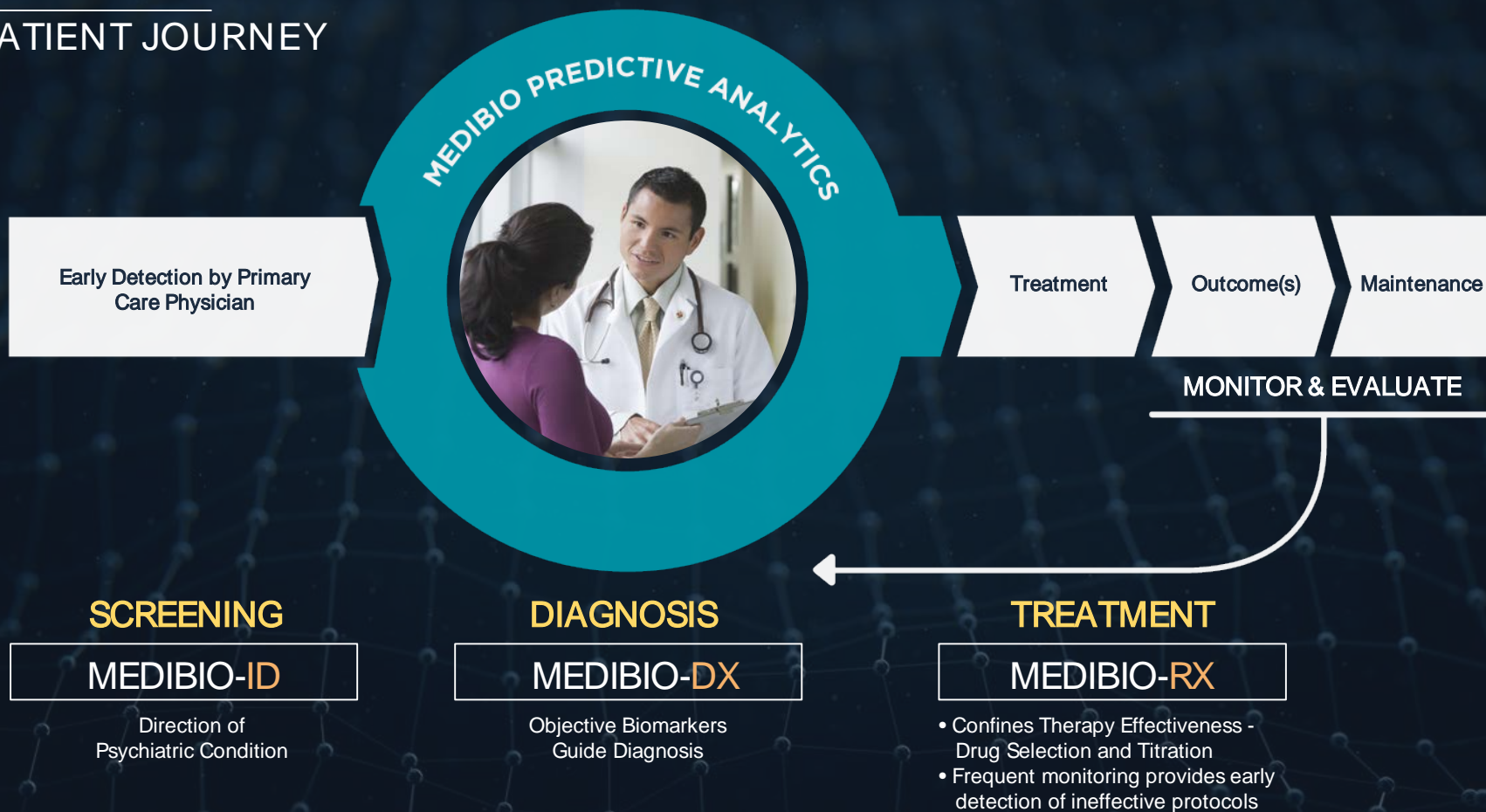
## Medibio Data *Objective Measures*

*Biometric Markers:*

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

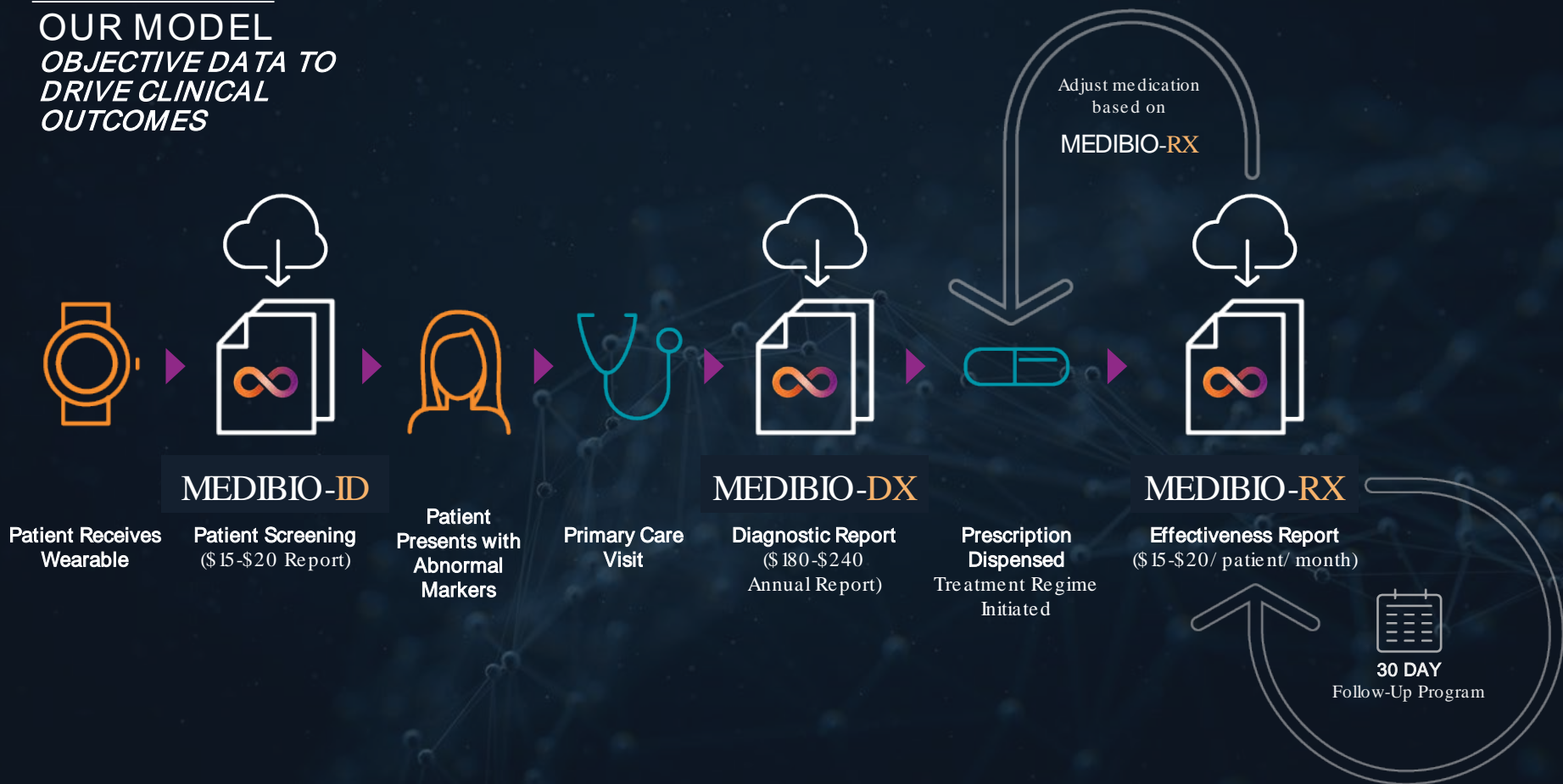


# PATIENT JOURNEY



## OUR MODEL

*OBJECTIVE DATA TO  
DRIVE CLINICAL  
OUTCOMES*



## SIGNIFICANT VALIDATION SUPPORTING TECHNOLOGY

### ACCURACY

### STUDY OUTLINE

### PARTNER

86%

#### DEPRESSION

Retrospective Study, 889 patients (2 Nov 2016)

OTTAWA UNIVERSITY

81%

#### DEPRESSION

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

Versus 33-50% - Diagnostic accuracy in the Primary Care Setting<sup>(1)</sup>

<sup>(1)</sup> Depression in Primary Care Vol. 1: U.S. Department of Health



## 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.

PRODUCT	Per Patient Revenue	Estimated Market Size	Estimated Market Potential
EARLY DETECTION SCREENING <b>MEDIBIO-ID</b>	<b>\$15-\$20</b> per patient session	<b>43.8 million</b> U.S. adults suffer mental illness annually	<b>\$875 million</b> U.S. Market
ACCURATE DIAGNOSIS <b>MEDIBIO-DX</b>	<b>\$180-\$240</b> patient/ annually	<b>21.9 million</b> U.S. adults are diagnosed (50% rate)	<b>\$5.3 Billion</b> U.S. Market
RIGHT DRUG TREATMENT <b>MEDIBIO-RX</b>	<b>\$180-\$240</b> patient/ annually	<b>15.3 million</b> U.S. adults accurately treated (70%)	<b>\$3.7 Billion</b> U.S. Market

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)	✓
Q1, 2017	Strategic Research Partnership - Emory PTSD	✓
Q2, 2017	Completion of John Hopkins University Validation Study (Major Depressive Disorder n=60) Publishing of Peer-reviewed paper - Emory University (PTSD)	✓
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)	✓
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)	



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## WORD FROM MICHAEL PHELPS



# Addendum

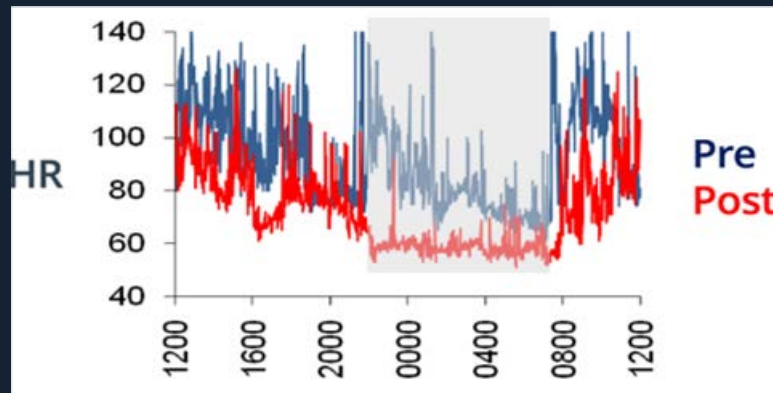




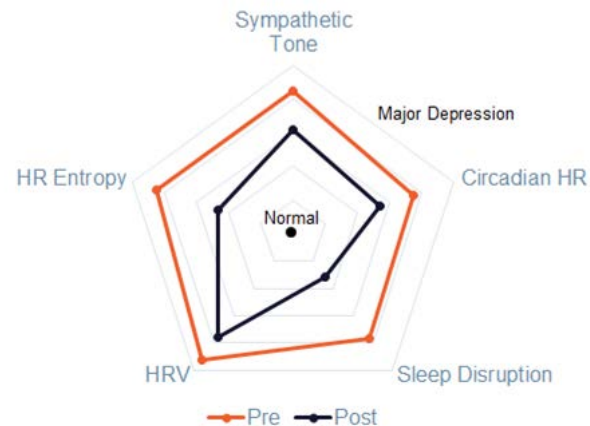
# OBJECTIVE ASSESSMENT OF THERAPY EFFECTIVENESS

## Case Study 1

- Individual diagnosed with Generalized Anxiety Disorder (GAD)
- Re-evaluated 10 days following effective psychotherapy treatment



## Biometrics normalize with effective treatment





# COMPANY

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## OUR BOARD



**CHRIS INDERMAUR**  
Chairman  
*Seasoned ASX Chair*



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



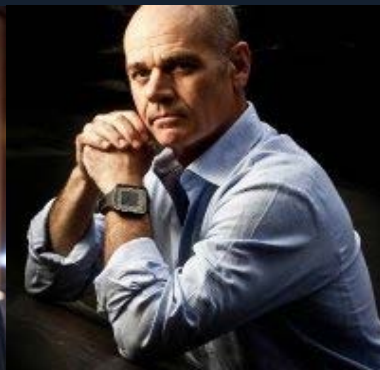
**DR. FRANKLIN  
PRENDERGAST**  
Non-Executive Director  
*Healthcare Luminary*



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



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



**ANDREW MAXWELL**  
Non-Executive Director  
*Former Biotech CEO*



**JACK COSENTINO**  
Executive Director  
*CEO & Managing Director*



**PETER CARLISLE**  
Board Alternate  
*Attorney and Leading Sports Agent*



A3

## 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"





A4

## 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

