# medibio

# Investor Presentation

June 2018

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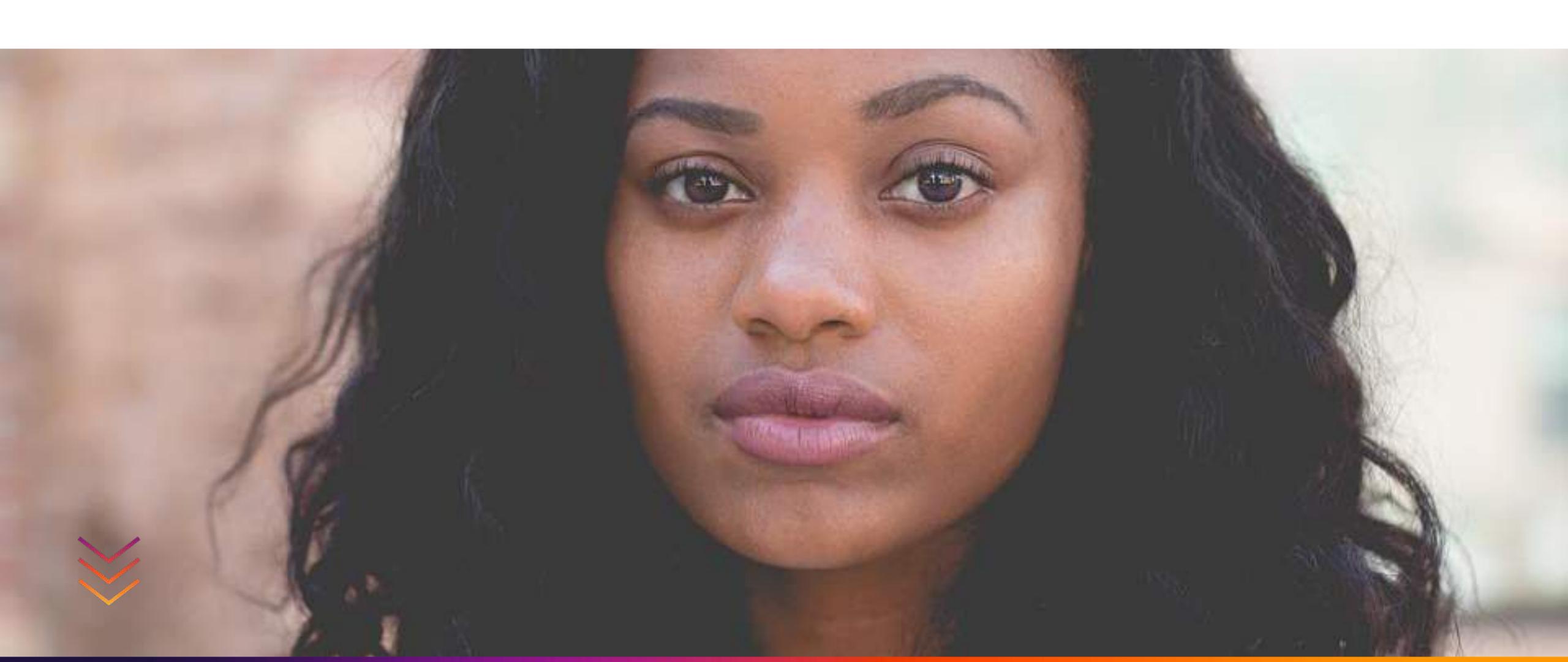
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# medibio

The mental health technology and services company using objective physiologic data to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions.

# The Challenge



### THE CHALLENGE BY NUMBERS

## In **Organizations**

Mental Health in the Workplace

Only **3.5**\*

of employees will utilize their employee assistance program, at an approximate cost of





of employees in severe ranges will be untreated



Hours per year of lost productivity



of employees meet the diagnostic criteria for depression



return on investment through early and effective targeted interventions

## In Society

Stigma and lack of access are prevalent globally

21 million suicide attempts from mental illness

Of those, nearly 1 million are successful

In 2015, suicide was the leading cause of death among 15 to 29 year-olds globally

suffer from depression





## In the **Health Care System**

Only 1 psychiatrist per 100,000 people in over half the countries in the world

40% of countries have less than one hospital bed reserved for mental disorders per 10,000 people

Out of 350 million patients globally < 7% receive optimal treatment



are never



are incorrectly diagnosed



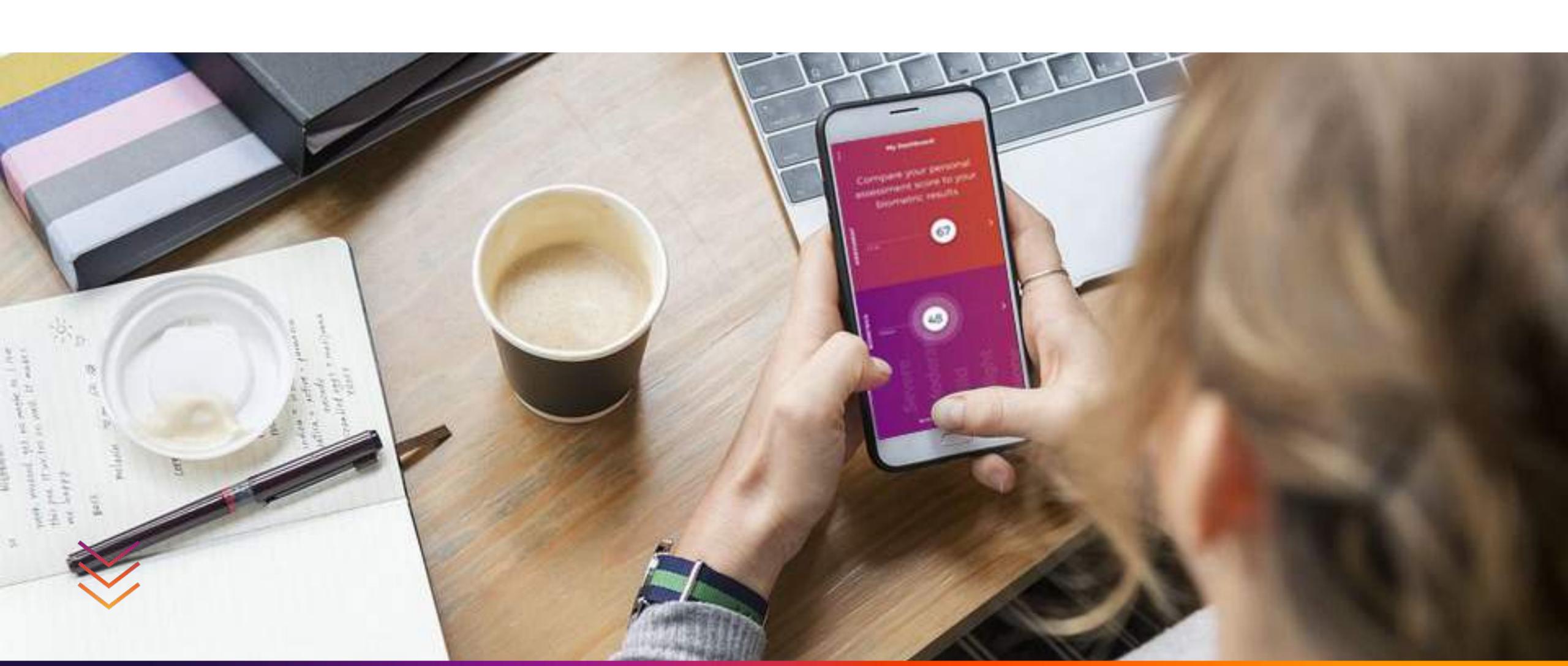
direct cost to treat Major Depressive Disorder (MDD) annually in the USA



direct cost to treat depression annually in Australia

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# The Solution



## THREE UNIQUE VERTICALS

ADDRESS THE CHALLENGE

### 20 Million Covered Lives By 2020

## **Vertical 1:** CORPORATE HEALTH

Personalised solutions in employee and organizational mental health.

Launched May 2018 ~64 million lives<sup>1</sup>

## **Vertical 2:** CONSUMER **HEALTH**

Empowering consumers to track and manage mental health.

## **Vertical 3: INTEGRATED** HEALTH

Clinical decision support systems, enabling clinicians to monitor and manage their patient populations.

**Launching Q2 FY19** ~266 million lives<sup>2</sup>

~450 million lives<sup>3</sup>

**Launching Q3 FY19** 

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Based on employment in USA and Australia Based on adult population in USA and Australia

Based on people in the world currently suffering from a mental health condition

### MEDIBIO CORPORATE HEALTH & INSURANCE

PRODUCT LINE

Medibio Inform
CORPORATE HEALTH



**Entry Level** 

A mental health assessment + biometric snapshot into your organizations' mental health.

\$5 per capita/per person for a 4 week program

Illuminate + IlluminateExecutive
CORPORATE HEALTH



**Subscription Based** 

End to end mental health program from proactive, high performance and executive, to telepsych support and triage.

\$68 per capita per annum \$1500 per executive per annum Incentify INSURANCE



White Labelled

Real time monitoring & management for policyholders. Prospective and retrospective data analytics from your population.

**Custom pricing** 

medio

The world's most advanced combined psychological and biometric technology platform.

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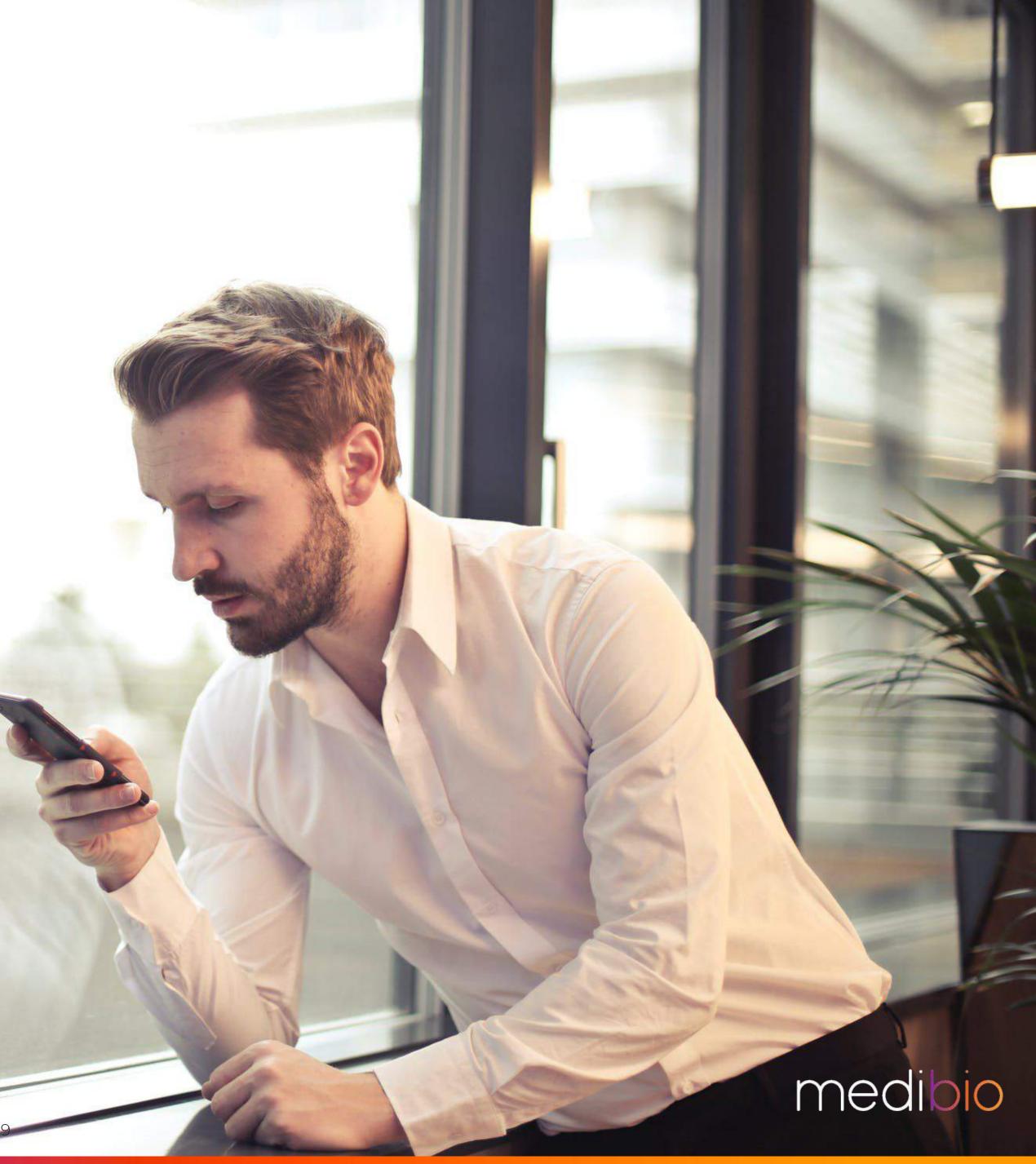
### **CORPORATE HEALTH**

Providing objective analysis and mental health services to the employee, paid for by their employer.

- Confidential Major and Mini mental health checks
- Personalized strategies direct to employee's smartphone
- Daily biometric tracking
- Telepsych debriefing of results
- Proactive strategies to reduce and protect against risk
- Optional system tracking and notifications when scores escalate
- Elevated scores reviewed by qualified psychologists
- Executive Program
- Unprecedented, real time dashboard into workforce mental health and targeted strategies for change

Clients include:

JACOBS PWC Wesfarmers



# CONSUMER OFFERING TRANSFORMING MENTAL HEALTH OUTCOMES

# Empowering individuals to monitor mental health and wellbeing like never before.

Insights is the mobile mental health system combining digital biomarkers from wearables and subjective monitoring, to put personalized mental health in the palm of the consumers hand.

- Wearable driven Mental Health scoring that allows the user to baseline and manage their Mental Health journey with biometric feedback
- Interactive mood tracking and journaling that enables users to proactively manage episodes of mental illness
- Integrates with all heart rate enabled devices from Garmin, Apple & Fitbit
- Compatible with most smartphones & tablets on Android & iOS
- Upgrade to Insights Pro to get deeper biometric insights, unlimited history and storage of your mental health readings, plus data sharing capabilities via the Logics professional portal with caregivers and clinicians
- To be available for purchase at \$9.99 per month or \$99 per year



#### INTEGRATED HEALTH



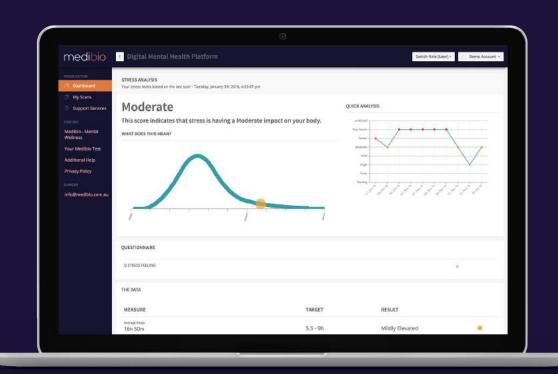
Index is a regulated medical device software for Apple and Android mobile platforms to allow the collection of high-fidelity biomarkers.

iOS and Android apps empower mental health patients and their practitioners with a concentrated, highly personalized, objective understanding of mental health, complemented by management tools to ensure better quality of life.

Featuring the Index biometric reporting, the app includes the functionality Of the Insights app plus:

- Regulated data collection device and software platform
- Integration with regulated, skin worn ECG patch medical devices
- Diagnosis aide for mental health indications
- Compliance and feedback tracking
- Monitoring of mental health indications
- Depression Episodes
- Longitudinal data integration on Medibio portal
- Mental Health Care Plans





Logics Professional Portal is a cloud-based, HIPAA-compliant platform allowing providers to gather, interpret and manage near real-time mental health patient data.

The platform will provide a longitudinal view into both Insights and Index data, including information on risk stratification, early detection, monitoring and intervention, treatment response and efficacy, along with tools to program and provide proactive patient care.

#### Features include:

- •Longitudinal view of data points heart rate, sleep, mood tracking, medication adherence, therapy engagement
- •Engagement with Insight scoring and utilization of platform features for wellness management
- •High resolution Index mental health biometric data analytics



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## **EMERGING DIVISION**

DIGITAL THERAPEUTICS



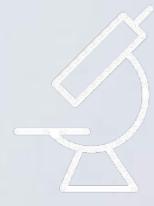
Therapy
Adherence and
Effectiveness



Future
Formulation
and Tracking



CRO Support



Technology for clinical trials, academic research

Current Partnerships and Projects in Process



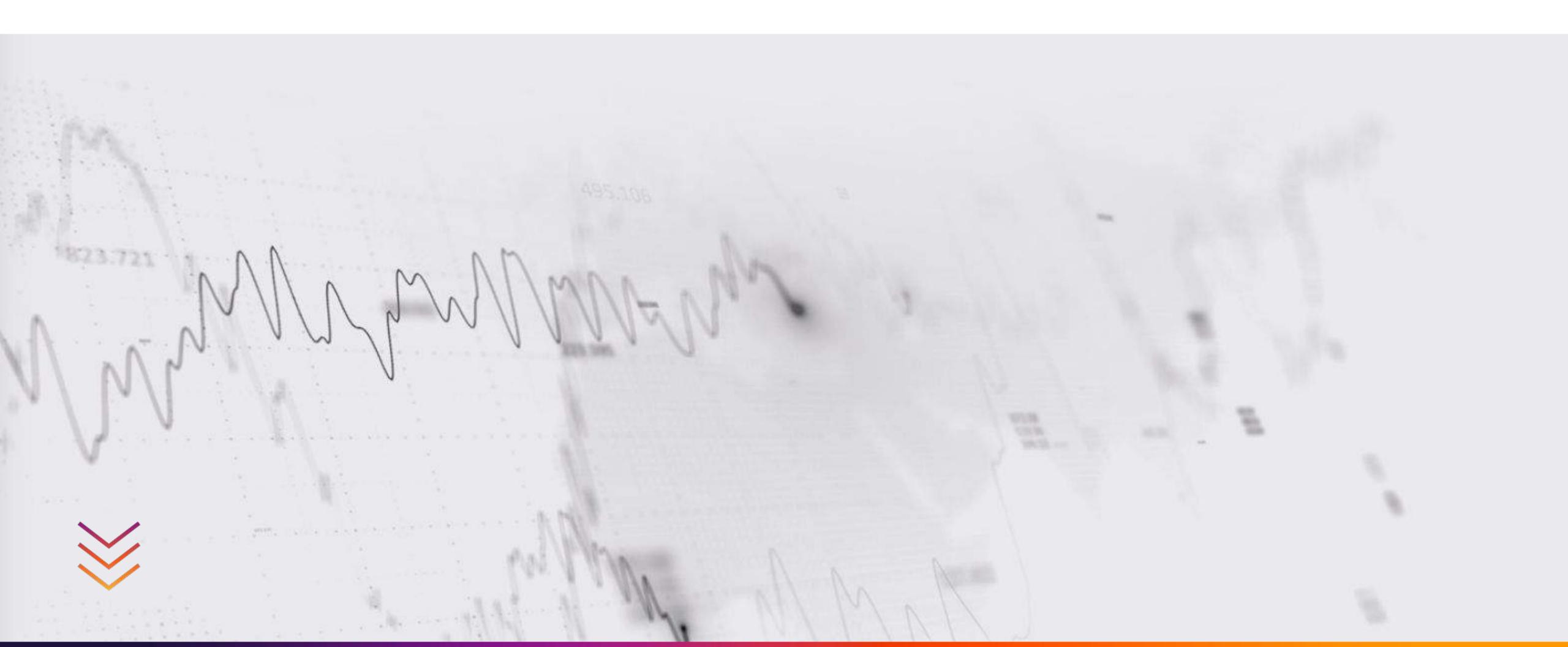


- Ketamine Titration and Effectiveness
- Differential Diagnosis



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# The Science





# Physiology

Our approach exploits features of cardiovascular physiology influenced directly by the autonomic nervous system and susceptible to disruption during sleep, as a source of biometrics that correlate with onset and existence of mental dysfunction.

20 plus years\* of data collected

## **Data Science**

Our approach focuses on using Artificial Intelligence to monitor mental illness types (such as depression, anxiety and stress) and potential physiological metrics, so we can predict irregularity and future recurrent episodes.

A comprehensive patent suite CHR, technology, and diagnostics

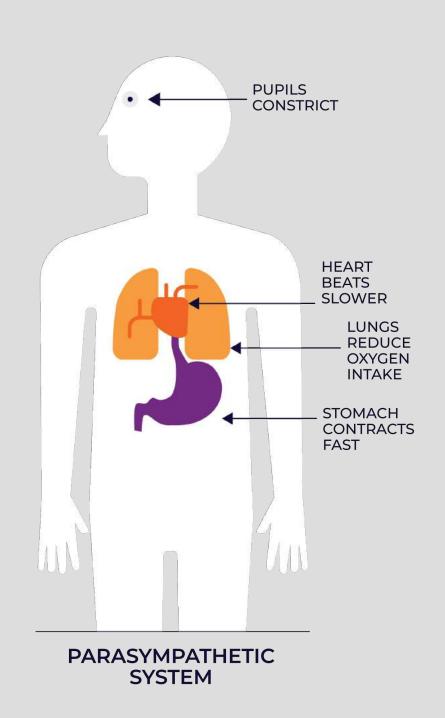
The relationship between psychiatric illness and the circadian pattern of heart rate. Hans G . Stampfer, Australian and New Zealand Journal of Psychiatry 1998; 32:187-198.

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#### PHYSIOLOGICAL SCIENCE

### THE CIRCADIAN CARDIAC AND SLEEP RELATIONSHIP

## The autonomic nervous system (ANS) is comprised of two arms:



# PARASYMPATHETIC SYSTEM (PS)

Plays a key role in growth, **restorative processes,** anabolic activities, conservation of bodily energy and resting of vital organs

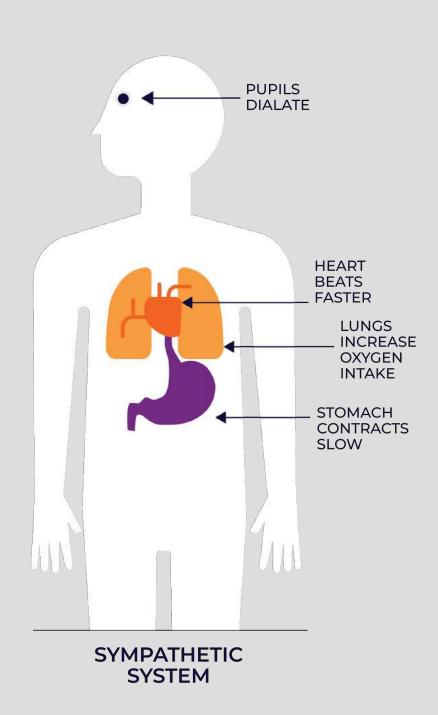
Modulation controls physiological stability

Activity is recessive (night-time)

# SYMPATHETIC SYSTEM (SS)

Prepares us for the fight or flight situations, keeping the body in a constant state of alert

Activity is predominant (day-time)

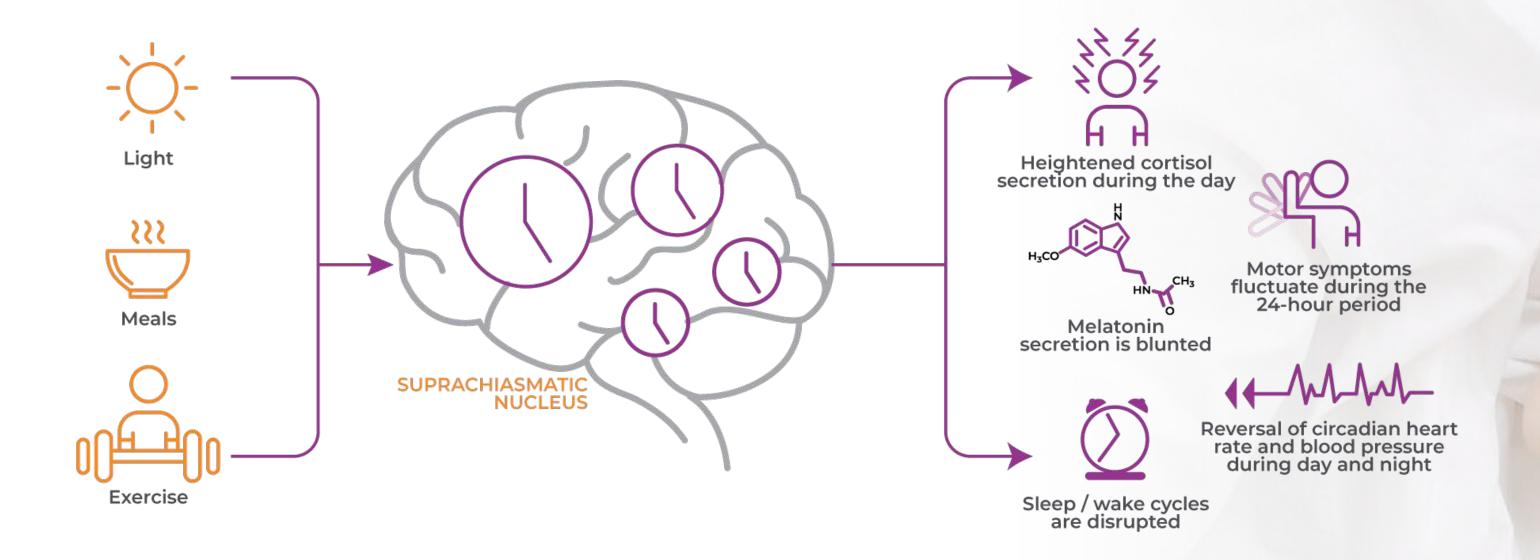


The ANS is continuously seeking balance of these two major components



### PHYSIOLOGICAL SCIENCE

Altered Circadian Cardiac and Sleep ANS Function in Mental Illness



- There are physiological changes observed in both cardiovascular regulation and sleep patterns associated with mental illness.
- The normal parasympathetic modulation seems to be dominating during sleep and sympathetic activity awake-time are completely transformed.
- Pathophysiological alterations are likely to alter heart rate dynamics during sleep, thereby providing a relevant window to observe multi-systemic characteristic of depression and anxiety.



# PHYSIOLOGICAL SCIENCE IBI-HRV

## **Heart Rate Variability:**

a reliable indicator of ANS function

HRV is a quantitative, non-invasive, highly reproducible index of cardiac autonomic function and an important indicator of the balance of sympathetic and parasympathetic tone

HRV analysis is typically based on Time and Frequency – Power Spectral domains Reduction in HRV is altered in individuals with psychiatric disorders including depression, anxiety, bipolar I and II, schizophrenia, and substance dependence

The use of HRV as a transdiagnostic marker has become a novel tool in the psychiatry armamentarium for determination of SS activity, PS modulation and sympathovagal imbalance

High LF domain index combined with low HF index in the presence of an elevated LF-HF power ratio is indicative of parasympathetic dysfunction until proven otherwise



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#### SCIENTIFIC ADVISORY BOARD

### External Advisors:

#### Martin Chapman, MBBS FRANZCP

Psychiatrist and Fellow of the **Royal Australian and New Zealand College of Psychiatrists**. As a medical administrator he has worked in both hospital and community settings in private and government sectors. His clinical practice is in the area of treatment resistant mood and anxiety disorders. He has taught in undergraduate and postgraduate Psychiatry with a focus in assisting primary care physicians in their management of mental health conditions. He has an interest in mental health system development and the role of new technologies in streamlining and providing clinical decision support.

#### Joel R. Ehrenkranz, M.D.

Endocrinologist on the faculty of the **University of Colorado School of Medicine** and a biotech entrepreneur in Salt Lake City, Utah. Dr. Ehrenkranz received his M.D. degree from Stanford and trained in internal medicine at Columbia University, neurology at Memorial Sloan Kettering Cancer Center, and endocrinology at the National Institutes of Health.

#### Mark A. Frye, M.D.

Chair of the Department of Psychiatry and Psychology at **Mayo Clinic**. He also serves as director of the Mayo Clinic Depression Center. Dr. Frye received his M.D. from the University of Minnesota and completed his psychiatric training at the Semel Institute for Neuroscience and Human Behavior at the David Geffen School of Medicine at UCLA. He subsequently completed a fellowship at the National Institute of Mental Health in Bethesda, Maryland with a research focus on the neurobiology of treatment resistant depression and bipolar disorder.

#### Lawrence Hunter, Ph.D.

Professor at the **University of Colorado** and directs the Computational Bioscience Program. He earned his degrees from Yale University, including B.A. in Psychology (cum laude); M.S. and M. Phil. and Ph.D. in Computer Science.

#### Wallace Mendelson, M.D.

Psychiatrist and author, and was formerly **Professor of Psychiatry and Clinical Pharmacology**, and director of the **Sleep Research Laboratory**, at the **University of Chicago**. Dr. Mendelson earned an MD degree from Washington University School of Medicine in St. Louis and completed a residency in psychiatry there as well. He has held professorships at Ohio State University and the State University of New York at Stony Brook, was Chief of the Section on Sleep Studies at the National Institute of Mental Health in Bethesda, MD, and Director of the Sleep Disorders Center at the Cleveland Clinic.

#### Marie Casey Olseth, M.D.

Currently in private practice as a Board Certified Adult Psychiatrist in the group practice that she owns. She earned her of Medicine degree from the University of Minnesota Medical School and completed her residency in General Psychiatry at the University of Minnesota and University of Wisconsin, Madison.

#### Giampaolo Perna, M.D., Ph.D.

Currently Chair of the Department of Clinical Neurosciences at **San Benedetto Menni Hospital of the Hermanas Hospitalarias (Como Lake)** and Academic Coordinator of Mental Health and Adjunct Professor at **Humanitas University (Milan)**, in Italy. He earned his degree in Medicine and Surgery at the State University of Milan, followed by Ph.D. and completed a residency in Psychiatry there as well. He is the Chair of WPA section on personalized psychiatry and Co-editor in chief of the Elsevier Journal "Personalized Medicine in Psychiatry".

### Internal Advisors:

#### Archie Defillo, M.D.

Currently the Chief Medical Officer at **Medibio Limited**. He has over 25 years of clinical experience with neurological diseases. For the past 13 years his efforts have been focused in neurological research. His research interests include cerebrovascular, stroke, neuro-trauma, brain oxygenation, metabolism and autonomic dysfunction.

#### Peta Slocombe, M.S.

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Registered Psychologist, member of the Australian Psychological Society and a registered National Health Practitioner with over 20 years' experience. She is currently Senior Vice President, Corporate Health with **Medibio Limited**.

#### Franklyn Prendergast, M.D., Ph.D.

Currently a director on the **Medibio Limited** board and chair of the Scientific Advisory Board. Previously, he was the Emeritus Edmond and Marion Guggenheim Professor of Biochemistry and Molecular Biology and Emeritus Professor of Molecular Pharmacology and Experimental Therapeutics, Mayo Medical School, to its Physician Advisory Board.

Dr. Prendergast earned his medical degree with honors from the University of West Indies. He attended Oxford University as a Rhodes Scholar, where he earned his masters degree in Physiology. After completing residency in Internal medicine at The Mayo Clinic in Rochester, Minnesota he earned a doctorate degree Biochemistry from the University of Minnesota/Mayo Graduate School.

Positions held: Chair, Department of Biochemistry and Molecular Biology; Director for Research Mayo Clinic (Rochester) (1989-1992). Board of Governors Mayo Clinic in Rochester; Mayo Clinic Board of Trustees (1992-2009); Mayo Clinic Board of Governors (1999-2006). Mayo Distinguished Investigator; Emeritus Director, Mayo Clinic Comprehensive Cancer Center and Mayo Center for Individualized Medicine.

In addition to his current role as a director on the Medibio board and chair of the Scientific Advisory Board, Dr. Prendergast holds numerous appointments with Industry and Extramural academic affiliations. He has extensive interactions over many years with National Institutes of Health (NIH): Board of Advisors for the Division of Research Grants; National Advisory General Medical Sciences Council; Board of Scientific Advisors of the National Cancer Institute; and the National Cancer Advisory Board.



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#### **MAJOR STUDIES**

PAST / PRESENT STUDIES

**PARTNERS** 

PLANNED STUDIES

#### **PARTNERS**

#### **DEPRESSION**

Retrospective Study, 889 patients November 2016



Retrospective Study, 26 patients December 2016

DEPRESSION, ANXIETY DISORDER, SCHIZOPHRENIA

Various studies

SLEEP STAGING USING ECG DATA

7500 patients June 2016

#### **DEPRESSION**

220 patients
Diagnostic aid supporting
De Novo FDA submission
Complete Q4 '18

#### **PTSD**

48 patients May 2017

Versus 33-50% – Diagnostic accuracy in the Primary Care Setting<sup>1</sup>
(1) Depression in Primary Care Vol 1: U.S. Department of Health





**PEER REVIEWED** 



**MULTIPLE SITES** 



#### **OPIOIDS**

FDA extended a formal invitation for breakthrough technology

#### **PTSD**

Monitoring with multi-day patch and wearable usage to support 510K Initiate Q2 '19

#### **PANIC ATTACK**

Comparison study between anxiety and panic disorder to identify differences in chronobiology with Humanitas University Milan Initiate Q1 '19

#### **UNIPOLAR & BIPOLAR DEPRESSION TREATMENT**

Response monitoring to look at differences in cohorts and changes during treatment.
Currently enrolling patients with Mayo Clinic.
Initiated Q1 '18
Ongoing





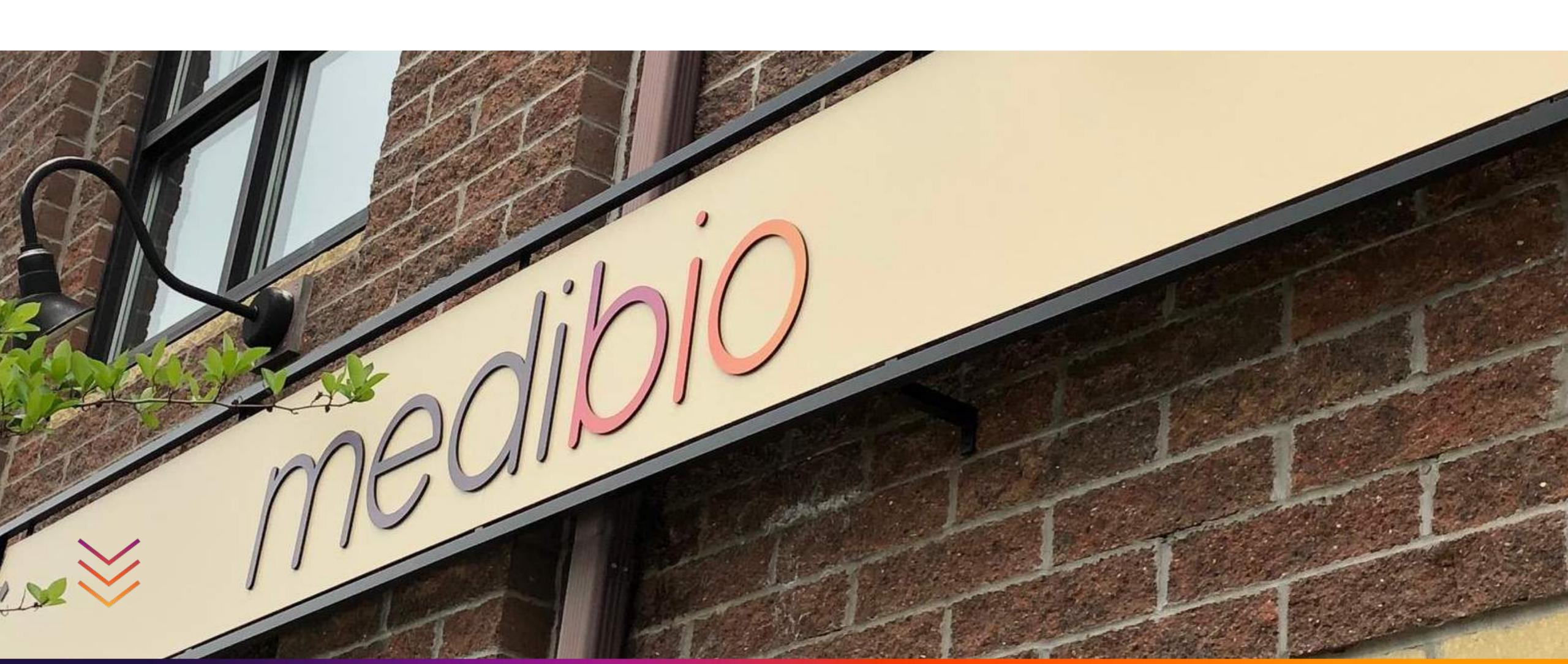




### MEDIBIO TECHNOLOGY ARCHITECTURE

GATEWAYS / DATA COLLECTION MEDIBIO PORTAL + SENSORS AND MEDIBIO CLOUD MOBILE APPLICATIONS **DATA SOURCES** INTEGRATION + SERVICES LOGICS CORE SERVICES WELLNESS GARMIN. API **PAYER** Medibio **Inform** SERVICES Mental Health Check-in™ UNREGULATED DEVICES (API) **PHARMA PROVIDER** API Health Kit DATA PROCESSING ... - fitbit API Mental Logics Professional Portal™ Medibio **Insights**™ A clinical decision support and An **uregulated** data analysis platform. ₩ medibio product for self-managing mental illness CORPORATE WELLNESS ASSESMENTS CLINICIAN **CAREGIVER** DATA ANALYSIS + MACHINE LEARNING **ED** DEVICES Medibio **Index**™ CONSUMER medibio A **regulated** product for monitoring Patch mental illness REGULAT DATA ANALYSIS MACHINE LEARNING LOGICS DATA WAREHOUSE

# The Company



### MEDIBIO BY THE NUMBERS



32
patents
and provisional
patents in our
portfolio

53 employees

25,000+ current covered lives

54%

of total budget invested in R&D Years of Patient Data Collected

200+

years of combined professional psychological experience



2 certifications

### **CORPORATE STRUCTURE**

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

Market Cap	AU\$35N
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Share Price as of 30 May 2018 AU\$0.17

Shares on Issue 203M

Cash Available

AU\$13.5M

- 1. Cash balance of \$11.6M at March 31, 2018 plus anticipated inflows from option purchases, partly paid share, and grants
- 2. Percentage of shares on issue
- 3. Percentages based on available information, including share registry, options listing, ASX filings, and other reported data
- 4. Includes shares on issue and options

## Significant Institutional Investors

- FIDELITY 9.1%
- REGAL FUNDS MANAGEMENT 7.0%
- IFM INVESTORS 4.9%

## Shareholder Mix3

- PRIVATE HOLDERS 46%
- INSTITUTIONAL HOLDERS 43%
- BOARD AND MANAGEMENT 11%4



# BOARD OF DIRECTORS



CHRIS INDERMAUR
Chairman



JACK COSENTINO
CEO/Managing Director



PETER CARLISLE

Managing Director, Olympics &
Action Sports, Octagon Worldwide



PATRICK KENNEDY
Former US Congressman
Founder, Kennedy Forum
Non Executive Director



DR FRANKLYN G PRENDERGAST

Former member board of Trustee

and Board of Governors

Mayo Clinic and Medibio

Non Executive Board Member



MICHAEL PHELPS

Non Executive Director



ANDREW MAXWELL

Non Executive Director



BRIAN MOWER
Chief Financial Officer



### **EXECUTIVE TEAM**



JACK COSENTINO
CEO & Managing Director



BRIAN MOWER
Chief Financial Officer



ARCHIE DEFILLO
Chief Medical Officer



PETA SLOCOMBE SVP, Corporate Health



JEREMY SCHROETTER
Chief Technology Officer



SONJA GRUNLAND
VP, Human Resources



PATRICK MIDDEN
Chief Privacy Officer

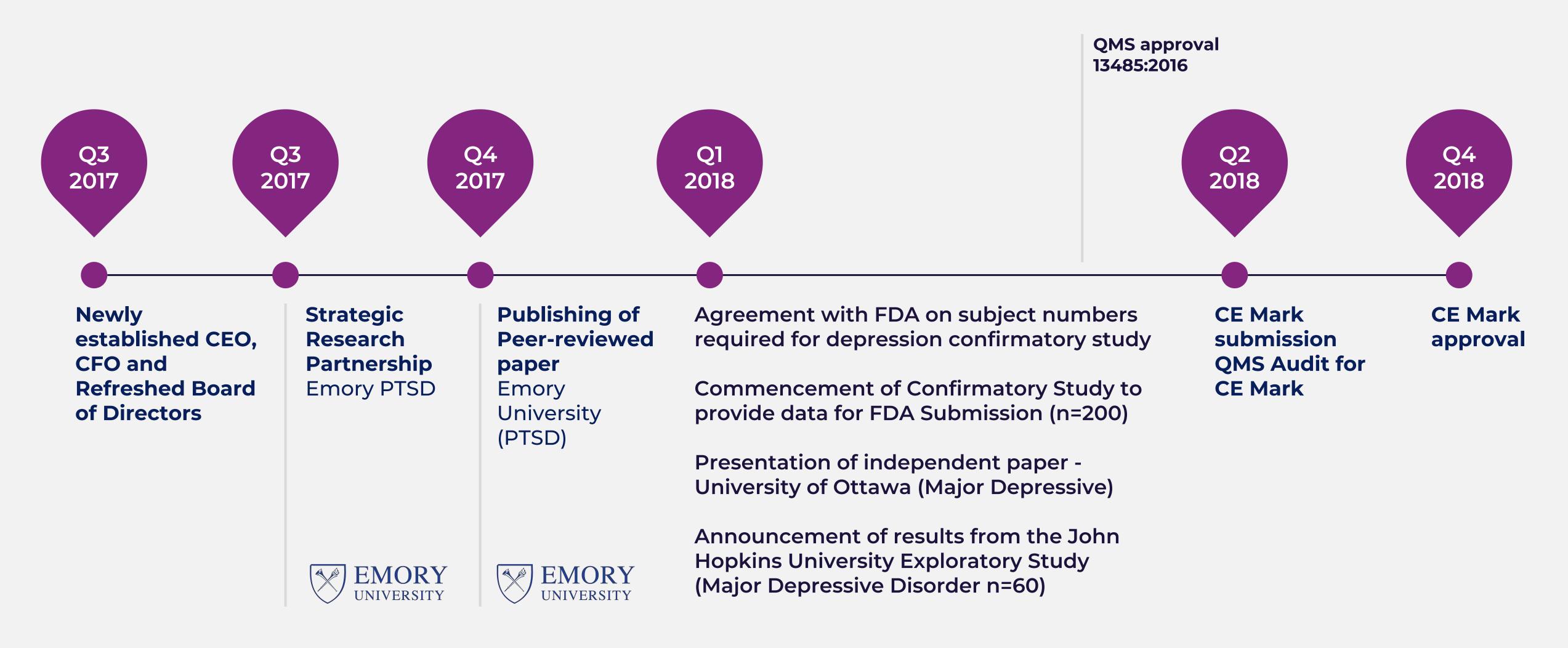


**TONY JOHNSON**Director, Quality & Regulatory



#### **RECENT MILESTONES**

TIMING NOTED IS FY





### **FUTURE MILESTONES**

TIMING NOTED IS FY





21 million suicide attempts from mental illness. Of those, nearly 1 million are successful

End to end solutions for mental healthcare

20+ years of scientific rigor

Well structured and ready to capture the total addressable market

## **Corporate Health**

Estimated Addressable
Market: **64 million**employees
(US and Australia)

### **Consumer Market**

Estimated Addressable Market: **85 million**+

\*based on ¼ of adult population in US and Australia

## **Integrated Health**

Market Size: **66 million**US mental health visits
per year

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## **APPENDIX**

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### **SECURITY AND PRIVACY**

## **Cybersecurity Statement**

At Medibio we take data privacy and protection very seriously and we know that you take data protection just as seriously. That is why we have implemented a multi-tier security program to protect the personal data of our users.

We have technical, administrative, and physical security measures surrounding our data stores and data processing facilities to protect the confidentiality, integrity, and availability of our user data. We also have security measures and additional precautions designed to protect the integrity and viability of our user-facing products, that extends security beyond the perimeter of our own networks, and into the hands of our users.

- Patrick Midden, Chief Privacy Officer



## MEDIBIO'S POTENTIAL BUSINESS GROWTH

## REGULATED MARKET

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6	Phase 6
Mental Health	Sleep Disturbances	Neurology	Cardiology	Endocrinology	Pulmonology	Internal Medicine
<ul> <li>Euthymia</li> <li>Unipolar and Bipolar disorder</li> <li>Mood disorders</li> </ul>	Shift work sleep disorder Advanced sleep phase disorder Delayed sleep phase disorder Irregular sleep–wake rhythm Non-24	307.4 Sleep Disorders Manifestations of thiamine deficiency 332 Paralysis agitans 333 Parkinsonism & Huntington's chorea Other degenerative diseases of the basal ganglia & Olivopontocerebellar degeneration 333.9 Extrapyramidal disease & abn. movement disorders (incl., Stiff-man syndrome) Cerebellar degeneration, Spinocerebellar & Amyotrophic diseases, Syringomylia & Syringobulbia 336 Diseases of the spinal cord 337 Severe neuropathy	401-405.99 Hypertension 412 Post-MI 413 Angina 414 Atherosclerosis 424 Mitral Valve Prolapse Syndrome 425.4 Cardiomyopathy 427 Cardiac Dysrhythmias 428 Congestive Heart Failure Endocrinology 244 Acquired Hyperthyroidism 246 Thyroid disorders 250-250.8 Diabetes 256.3 Premature Menopausal Symptoms 627 Menopausal Symptoms  Heart transplant recipients, there is a loss of HRV. Individuals with high hostility scores and patients with anxiety or depressive disorders have low HRV and may be at risk for cardiovascular death associated with coronary heart disease and arrhythmias.	244 Acquired Hypothyroidism 246 Thyroid Disorders 250.0-250.8 Diabetes 256.3 Premature Menopausal Symptoms 627 Menopausal Symptoms	780.51, 780.53, 780.57 Sleep Apnea 493.90-493.93 Asthma 493.2 COPD	278.01 Morbid Obesity 279.3 AIDS 296 Depression or Bipolar Disease 300 Anxiety 309.81 Post-traumatic Stress Syndrome 314.0 Attention Deficit Disorder 729.1 Fibromyalgia

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# OVERVIEW OF COMPLEMENTARY/ COMPETING TECHNOLOGIES

	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIP COST	TEST COST
Medibio	Autonomic Nervous Dysfunction, circadian and sleep biomarker-based test and platform	In Process	80-90% - based on in excess of 4000 data points	\$30	<\$100
Blood Test	Ridge Diagnostics offer an MDD score of 1 to 10 based on the analysis of 9 blood markers	No	80-90% - based on a pilot study with 79 participants	n/a	\$800
EEG	Johns Hopkins research using full EEG's to discriminate between depressed and non-depressed	No	80% based on a pilot study with 30 participants	\$30,000	\$600
EVG	ElectroVestibuloGraphy measurement of the inner ear taken in a specialty designed tilt chair	No	77-87% - based on a pilot study with 74 participants	\$10,000	>\$300
Saliva and Hormone Tests	Cortisol and hormone tests mainly aimed at stress	No	For stress only	n/a	\$100-300
Clinical Psychiatric Diagnosis	1-3 hour consult done by a trained clinician (psychiatrist/psychologist) using a structured instrument	Yes	70% concordance on the common disorders such as depression and anxiety	12 years of study	\$300-500



## THANK YOU

#### Jack Cosentino

CEO and Managing Director

Jack.Cosentino@Medibio.com.au

8696 Eagle Creek Circle, Savage, MN 55378 USA