

ASX Announcement

Medibio Limited – 11 SEPTEMBER 2017



COMPANY UPDATE

Sydney, Australia and Minneapolis, MN – 11 September 2017: Medibio Limited (MEB or the Company)(ASX: MEB)(OTCQB: MDBIF), a digital health company that has developed an objective testing system to assist in the screening, diagnosis, and treatment effectiveness of depression and other mental health disorders, is pleased to release a company update presentation, which is attached to this announcement. The presentation will be used in upcoming investor road show meetings and in meetings with prospective customer partners and government entities, including multiple Departments of Veterans Affairs agencies.

INVESTMENT HIGHLIGHTS

- Large, Underserved Markets in Mental Health
- Superior Solutions to Care by Delivering Objective Data
- Completed Clinical Validation Studies
- FDA Confirmatory Study in Progress
- Patented Panel of Biomarkers
- New Executive Leadership and Board
- Multiple Applications in Large Market Verticals

About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a digital health company that has pioneered the use of objective biometrics to assist in the diagnosis and treatment of depression and other mental health disorders. Medibio's proprietary Digital Mental Health Platform uses advanced, cloud-based analytics to enable GPs and mental health clinicians to cost-effectively screen, precisely diagnose, and objectively confirm treatment effectiveness to better manage patients. Medibio's technology also provides an objective method for the assessment of stress and mental well-being that can be translated to the non-medical workplace stress/well-being, wearable technology, and app markets. The company was founded in Australia, with offices located in Melbourne (Vic), and U.S. offices in Minneapolis, MN and Palo Alto, CA. Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market www.otcmarkets.com and www.asx.com.au.

To learn more about Medibio visit www.Medibio.com.au

– ENDS –

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Investor Presentation

September 2017

ASX: MEB
OTCQB: MDBIF

DISCLAIMER



FORWARD LOOKING STATEMENTS

The purpose of the presentation is to provide an update of the business of Medibio Limited (**ASX:MEB**) (**OTCQB: MDBIF**). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification.

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COMPANY VISION & OVERVIEW

We **envision** a world where everyone is empowered to be mentally well.

Medibio is a **Digital Mental Health Pioneer** that has developed a proprietary objective system for screening, diagnosing, monitoring and management of depression and other mental health disorders

COMPANY HIGHLIGHTS

3 Clinical Studies Completed
(Depression/ PTSD)

FDA Confirmatory Study in Progress
(Depression)

New Executive Leadership & Board

Commercialization Pathway
Consumer & Medical Markets

**Australia's Biggest Mental Health
Check-In Campaign**
Annual Program - Vital Conversations

**Developing Industry's First Standardized
Mental Health Score**

WHY INVEST

DEPRESSION IS A GLOBAL EPIDEMIC AFFECTING 350M

Less than 10% of patients receive optimal care

SUBJECTIVE DATA DRIVING UNDER DIAGNOSIS

Nearly 70% of diagnosis are made by under-qualified GPs

PERSONAL MAXIMIZATION MEGA-TREND IN HEALTHCARE

69.1M wearable health and fitness trackers were sold in 2016

PIONEERING CARE BY DELIVERING OBJECTIVE DATA

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

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 - cost-effective delivering information to any healthcare provider or consumer anywhere

WHY INVEST NOW?

SUPERIOR VALUE PROPOSITION - Objective diagnosis, treatment efficacy confirmation and data-driven patient management

CLINICAL VALIDATION STUDIES WITH LEADING RESEARCH INSTITUTIONS

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

REGULATORY APPROVALS UNDERWAY

- FDA clearance and CE Mark approved

PARTNERS ACROSS VERTICALS WITH HIGH INTEREST TO COMMERCIALIZE

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

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

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

LEVERAGING PERSONAL MAXIMIZATION OF THE MEGA-TREND IN WELLNESS & HEALTHCARE

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 PRODUCT

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

HEALTHCARE PROVIDER *Diagnostic Aid*



PATIENT *Monitoring & Scoring*



CONSUMER
INNOVATION

BIOMETRIC DATA

(Wearable Device)



Wearable Device Agnostic approach



**MENTAL WELLNESS
MONITORING**



WELL

DISTRESSED

MEDICAL INNOVATION

BIOMETRIC DATA (ECG, EEG, ACTIGRAPHY)



Medical Device Agnostic approach



CONDITIONS

← Cover Mental Health Spectrum →

Major Depression Disorder (MDD)

Generalized Anxiety Disorder (GAD)

Post Traumatic Stress Disorder (PTSD)

Schizophrenia Disorder

Bipolar/Unipolar Disorder

STATE OF THE ARCHAIC NOT STATE OF THE ART

Today's Approach *Subjective Measures*

Symptom-based Diagnosis Screeners:

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

THE WEAKNESS IS SUBJECTIVITY

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ DATE: _____

How often have you been
troubled by these problems?

	Not at all	Several days	More than half the days	Nearly every day
1	0	1	2	3
2	0	1	2	3
3	0	1	2	3
4	0	1	2	3
5	0	1	2	3
6		1	2	3
7		1	2	3
8		1	2	3
9	1	2	3	

Subscales: _____ + _____ + _____

TOTAL: _____

Not difficult at all _____

Somewhat difficult _____

Very difficult _____

Extremely difficult _____

BRINGING OBJECTIVITY TO MENTAL HEALTH

Today's Approach *Subjective Measures*

Symptom Based Diagnosis Screeners:

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

Medibio Data

Objective Measures

Biometric Markers:

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

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***

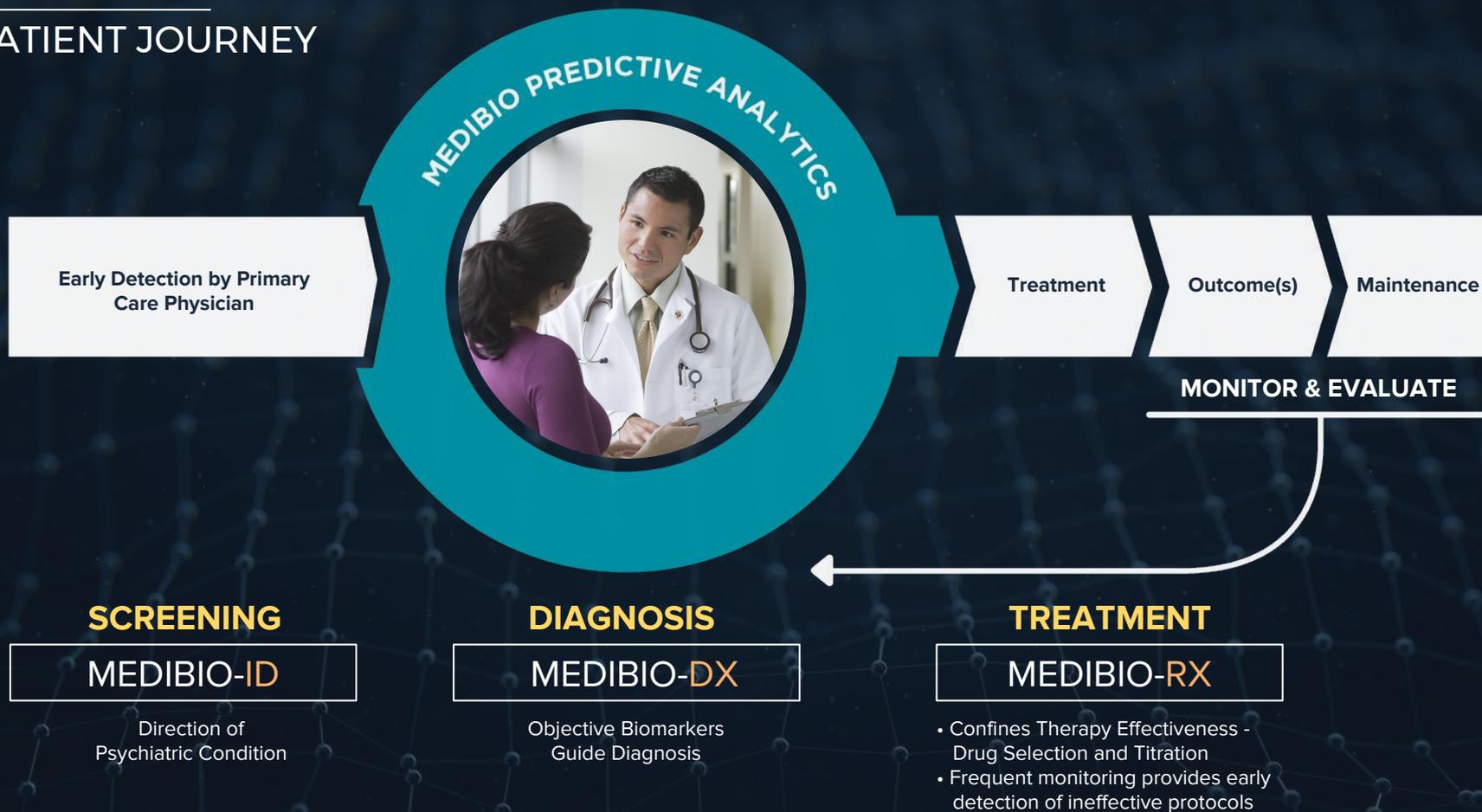
Medibio Data

Objective Measures

Biometric Markers:

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

PATIENT JOURNEY



MARKET VERTICALS*

PRIVATE INSURANCE & CORPORATE WELLNESS

133.6M Covered Lives
\$8.0B Wellness Spending

WOMEN'S HEALTH

97.7M Adult Women
1 in 8 Suffer Depression
1 in 9 Suffer Anxiety

PRO & COLLEGE ATHLETES

3M Active & Retired
24% Females - MH Issues
18% Males - MH Issues

AGING HEALTH

46M Age 65+
20% Suffer Mental Disorders
11% Suffer Anxiety



VETERANS ADMINISTRATION

9.1M Covered Lives
20.0% Suffer MDD/PTSD

ADOLESCENT'S HEALTH

41.7M Age 12-17
31.9% Suffer Anxiety
13.8 Considered Suicide

ACTIVE MILITARY DEPT OF DEFENSE

1.4M Active Enlisted
25% MH Issues
11% Multiple Diagnosed Conditions

PRIMARY CARE & PSYCHIATRY PHYSICIANS

44.2M Annual Physicals
20.0% Suffer Mental Disorders
11% Suffer Anxiety

REVENUE OPPORTUNITIES



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



Patient Screening

Risk Stratification

MEDIBIO-ID



Decision Support Tool

Monthly Specialist Visit

MEDIBIO-DX



Patient Management

Pharma prescription management

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.

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

OUR MILESTONES

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 approval (Platform, Major Depressive Disorder diagnostic aid)	
Q2, 2018	FDA submission (Major Depressive Disorder diagnostic aid)	

CORPORATE STRUCTURE

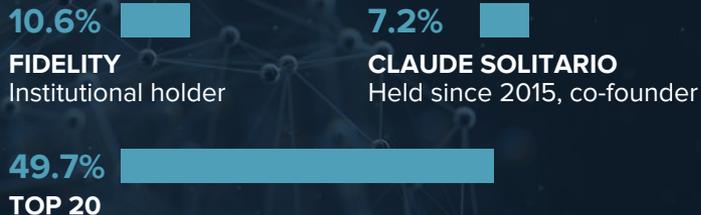
CAPITAL STRUCTURE (ASX:MEB)(OTCQB:MDBIF)

(amounts shown in AUD\$)

Market Cap	\$53.7M
Share Price <i>as of 31 August 2017</i>	\$0.36
Shares on Issue	149.0M
Market Cap (fully diluted)	\$62.5M
Share Price <i>as of 31 August 2017</i>	\$0.36
Fully diluted shares (per August 29, 2017 Appendix 3B)	173.7M
Cash Available	\$10M

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

SUBSTANTIAL SHAREHOLDERS



COMPANY
OUR BOARD



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*



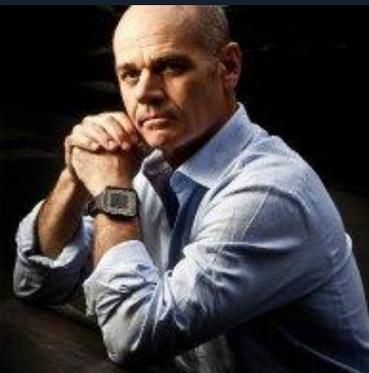
PATRICK KENNEDY

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

Addendum

medibio 
INNOVATION IN MIND

PAIN POINT



Current diagnostic tests rely on **clinical interviews with subjective interpretation**



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



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**



OUR SOLUTION

Quantitative and objective diagnostic based on biomarkers



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



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

Wearables

*Fitbit, Garmin, Medtronic,
Apple Watch, etc.*

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

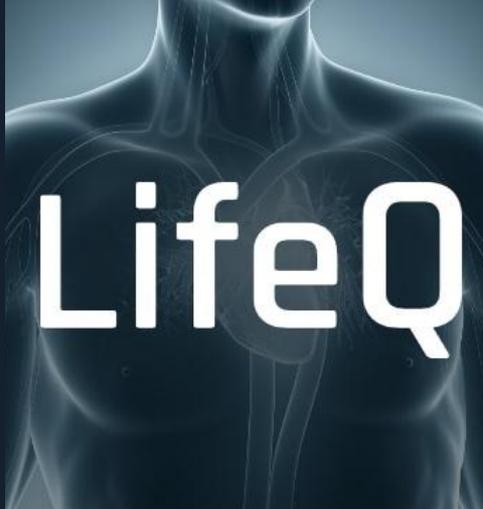
Home Test &
Medication
Management

Payers

Reimbursement for
Improved Health Score



PARTNERS IN
GROWTH



Medtronic



EMORY
UNIVERSITY

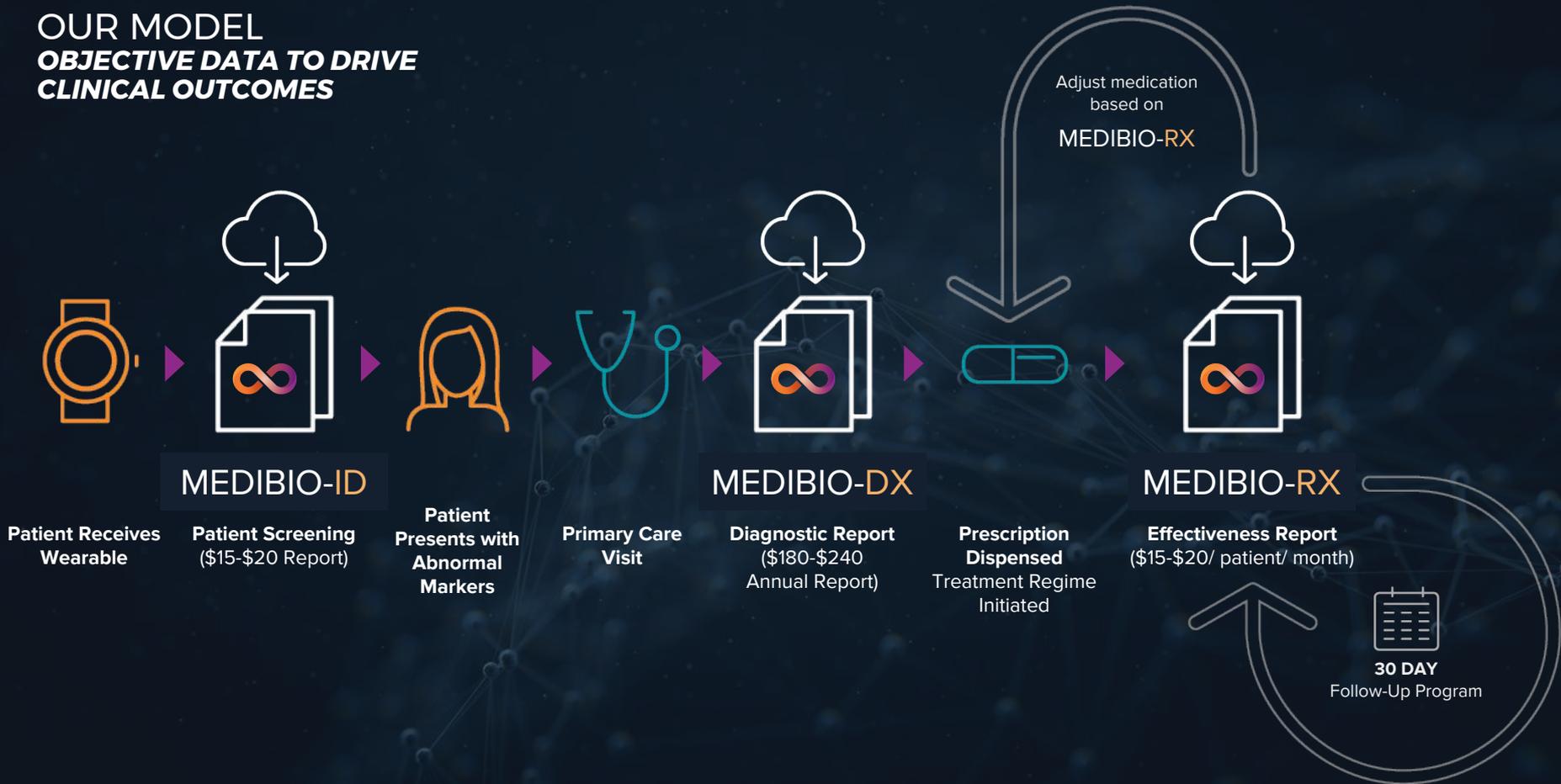
MAYO
CLINIC



JOHNS HOPKINS
MEDICINE
JOHNS HOPKINS
HEALTH SYSTEM

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⁽¹⁾

(1) Depression in Primary Care Vol. 1: U.S. Department of Health

BIOMARKER BASED ON OBJECTIVE DIAGNOSIS

APPROACH

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

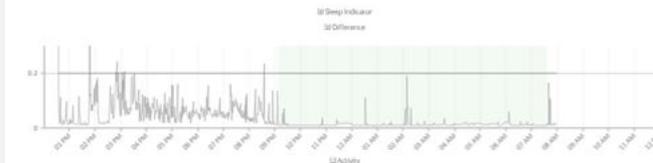
Johns Hopkins University Case Study: Patient with MDD

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

Heart Rate



Activity



Posture



PHYSIOLOGIC DATA WAVEFORMS

PANEL OF BIOMETRICS

RATE	AVAIL	SCORE
Sleep Mean	70 ✓	○○○●○○
Awake Mean	69 ✓	○○○●○○
Awake Sleep Diff	13 ✓	○○○●○○
Sleep Diff Mean	1.95 ✓	○○○●○○
Awake Diff Mean	4.29 ✓	○○○●○○
Sleep Slope	-2.33 ✓	○○○●○○
Sleep Slope1	-1.41 ✓	○○○●○○
Sleep Slope2	-2.32 ✓	○○○●○○
Sleep St Dev	9.50 ✓	○○○●○○
Rate Variability	8.11 ✓	○○○●○○
Sleep Depth	20.00 ✓	○○○●○○
Sleep Quality	44.52 ✓	○○○●○○

DATA DRIVEN PATIENT MANAGEMENT

Patient Panel Enables Early Identification of At-Risk Patients

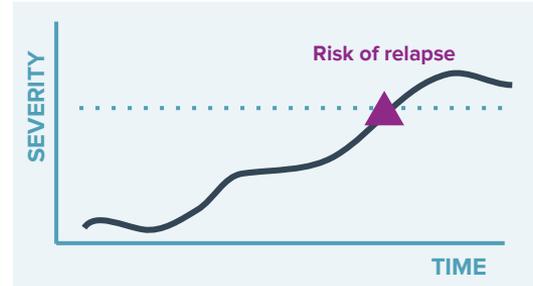
medibio Digital Mental Health Platform

Dashboard Scans Expert Rater

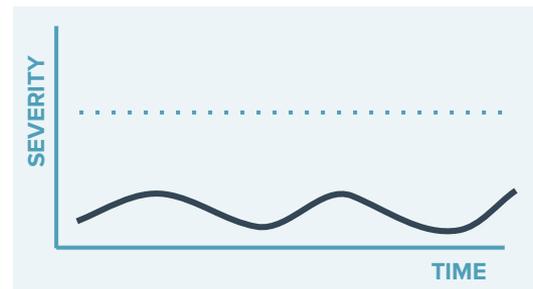
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☆	ID: 59026e8fa0718575280018e User ID: 57a033b0a0718575280018e	MEB632A2	2016-08-11 10:52:21	20:48	Very Severe	Report SF Details
☆	ID: 591954452501093b7c3978c User ID: 591954452501093b7c3978c	MEB632DBL	2016-12-06 07:36:09	28:22	Very Severe	Report SF Details
☆	ID: 59195942501093b7c3b17b4 User ID: 59195942501093b7c3b17b4	MEB632DBL	2017-02-24 09:47:35	28:17	Stable	Report SF Details
☆	ID: 591952012501093b7c393612 User ID: 591952012501093b7c393612	MEB632HU	2017-03-22 16:22:01	28:05	Stable	Report SF Details
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Patient Disease Progression



Stable Patient on Treatment



OVERVIEW OF COMPLEMENTARY/ COMPETING TECHNOLOGIES

TECHNOLOGY	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIP COST	TEST COST
Medibio	<i>Autonomic Nervous Dysfunction, circadian and sleep biomarker-based test</i>	Under Way	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

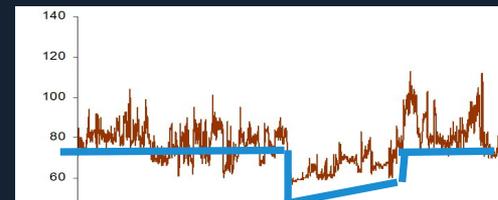
INSIGHTS BASED ON 15 YEARS OF CLINICAL RESEARCH

- Research initiated 15 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.

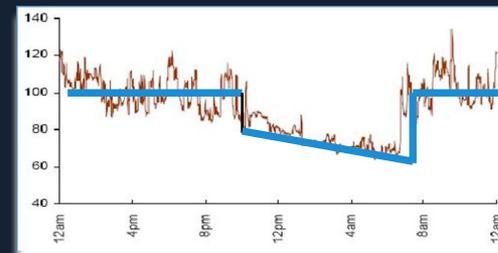
NORMAL



DEPRESSION



ANXIETY



24 hour heart-rate

BIOMARKERS PROVIDE RICH CHARACTERIZATION OF MENTAL STATE

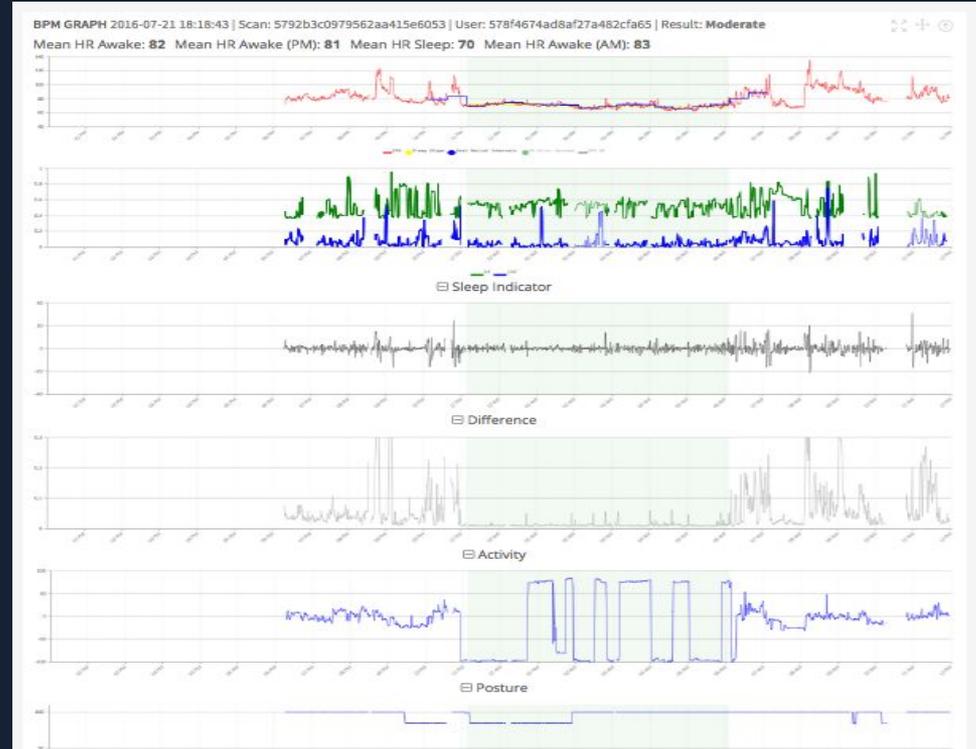
HEART-RATE

AUTONOMIC FUNCTION

ACTIVITY

SLEEP

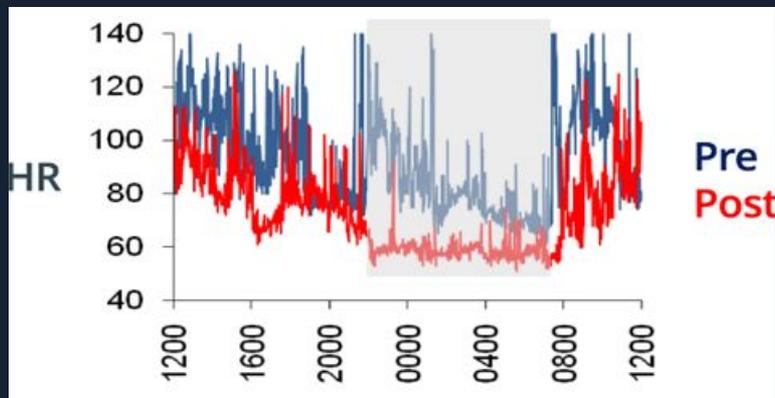
CIRCADIAN PATTERNS



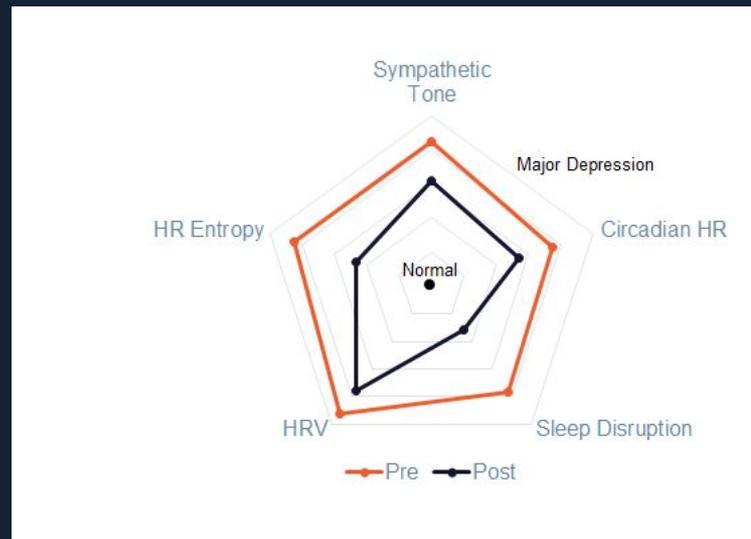
OBJECTIVE ASSESSMENT OF THERAPY EFFECTIVENESS

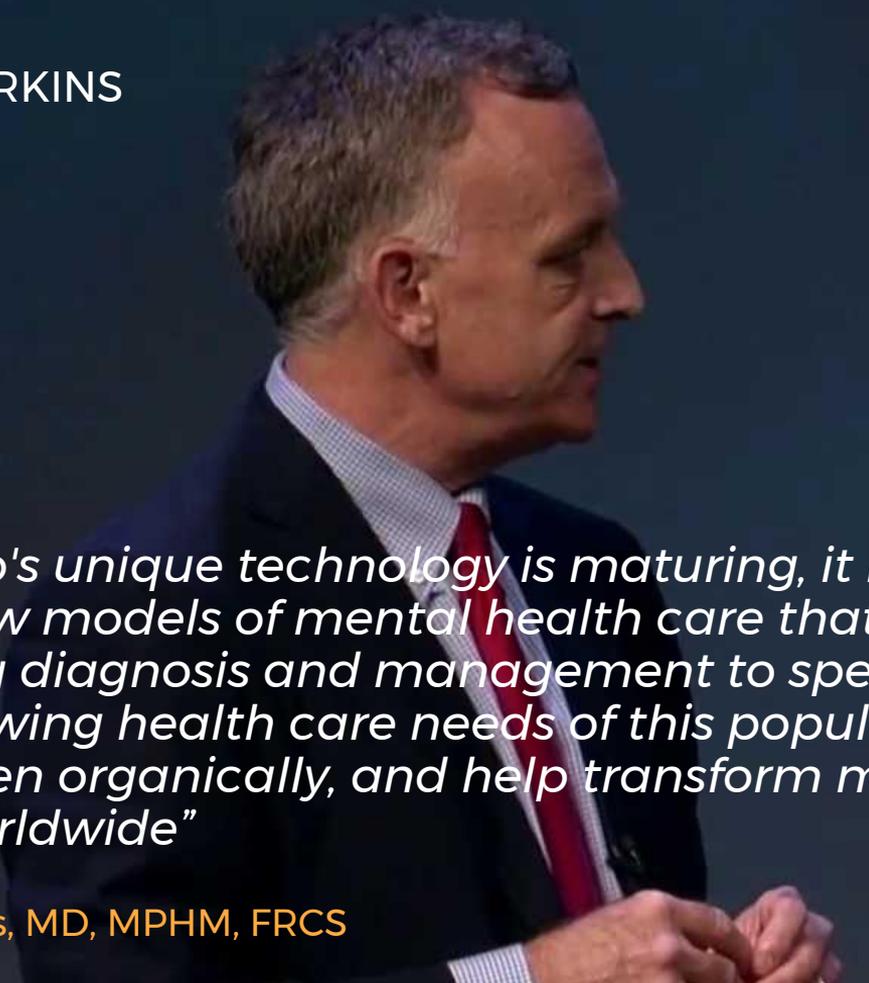
Case Study 1

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



Biometrics normalize with effective treatment



DR. ADAM DARKINSA man with short, light-colored hair, wearing a dark suit jacket, a light-colored patterned shirt, and a red tie, is shown in profile from the chest up. He is looking to the right and appears to be speaking. His hands are clasped in front of him.

“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, MPH, 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

A photograph of Michael Phelps swimming freestyle in a pool. He is wearing a white swim cap with "NBAC" and an American flag, and blue goggles. He is in a streamlined position, with his arms extended forward and his head above water. The background is a blurred pool lane with blue lane lines.

"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

PATRICK KENNEDY

A photograph of Patrick Kennedy, a man with short brown hair, wearing a light blue zip-up sweater over a blue polo shirt. He is leaning on a wooden railing with his hands clasped, looking directly at the camera with a serious expression. The background is a blurred outdoor setting with trees and a building.

“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