

# ASX ANNOUNCEMENT

## 05 JUNE 2017

### COMPANY UPDATE



Medibio Ltd (ASX.MEB), a world-class medical technology company specializing in mental illness, is pleased to release a company update presentation, which is attached to this announcement. The presentation outlines Medibio's compelling investment case and strategy. It will be used for a series of non-deal institutional investor roadshows in the U.S. in the coming weeks.

#### INVESTMENT HIGHLIGHTS

- Medibio is at a major inflection point to deliver a **transformative system for objective mental health testing**
- Large, underserved market growing by 50% from 416 million humans affected to 615 million, which is 10 percent of the population
- **Superior value based proposition** with a quick, data driven objective non-invasive method that is easily scalable in primary care, hospital, corporate, and at home settings allowing clinicians to **get the right drug and/or therapy to the right patient at the right time**
- **Multiple applications and use cases** for primary care for screening, pharma for drug development and safety, psychiatrists/hospitals with medication management, and corporate wellness utilizing for employee healthcare.
- **Patent portfolio intact** and growing new IP each quarter
- **Regulatory approvals on track** to file CE in Q4 2017 and FDA de novo clearance in Q2 2018
- JHU Study patient enrollment and data gathering **completed**. Awaiting reporting and final data analysis.

#### BOARD AND MANAGEMENT COMMENTARY

Jack G. Cosentino, CEO and Managing Director, commented: *"Medibio is moving into a new exciting stage with enhancements to our senior leadership team, Board of Director's, strategic partnerships, and technology advancements. We are well positioned to further accelerate the company's growth. Our strategic focus is now on completing our clinical and regulatory journey and rapidly progressing to commercialization in the most significant disease state in healthcare, which previously had no objective data driven diagnosis tools until now."*

#### About Medibio Limited

Medibio (ASX: MEB), is an evidence-based medical technology company that has developed an objective testing system to assist in the diagnosis and management of depression, chronic stress and other mental health disorders. Based on research conducted over 15 years at the University of Western Australia, this test utilizes patented (and patent pending) panel circadian, sleep and autonomic system biomarkers to objectively quantify and characterize mental illness. Medibio's depression diagnostic is being validated in clinical studies undertaken by Johns Hopkins University School of Medicine and The University of Ottawa, among others. The clinical trials will support Medibio's application to become the first FDA approved, objective, and evidence based approach to the diagnosis of mental health disorders. Medibio's technology also provides an objective method for the assessment of stress and mental wellbeing that can be translated to the workplace stress/wellbeing market, wearable technology and App market.

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**Further Information:** [www.medibio.com.au](http://www.medibio.com.au)



# Investor Presentation

June 2017



# FORWARD LOOKING STATEMENTS

**The purpose of the presentation is to provide an update of the business of Medibio Limited (ASX:MEB). 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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# TRANSFORMATIVE OBJECTIVE MENTAL HEALTH TESTING



## GAME CHANGING TECHNOLOGY

The world's first objective diagnostic system to test for mental illness



## MULTIPLE APPLICATIONS AND USE CASES

**Primary care** (screening)  
**Pharma** (drug development & safety)  
**Psychiatrists/Hospitals** (medication management)  
**Corporate Wellness** (employee healthcare)



## LARGE, UNDERSERVED, GROWING MARKET

World Bank estimates that between 1990 and 2013, the number of people who have these mental health disorders has grown by nearly **50 percent**, from 416 to **615 million**, affecting **10 percent** of the population

Less than 50% of those with depression are receiving accurate diagnosis and effective treatment



## POSITIVE GLOBAL FINANCIAL BENEFIT

According to the World Bank, Depression and anxiety disorders cost the world nearly **US\$1 trillion** annually. The World Economic Forum estimated is even higher, at **US\$2.5 trillion** annually

According to the World Health Organization every **\$1 spent on mental health treatment provides a \$4 return on investment**



## SUPERIOR VALUE PROPOSITION

Quick, objective and non-invasive method easily scalable in primary care, hospital, corporate, and home settings. This allows clinicians to get **the right drug and/or therapy to the right patient at the right time**



## PATENT PROTECTED TECHNOLOGY

Based on **20 years** of clinical research



## REGULATORY APPROVALS ON TRACK

Filing for CE and FDA clearance

## COMPANY OVERVIEW

### CAPITAL STRUCTURE (ASX: MEB)

(amounts shown in AUD\$)

**Market Cap** **\$44.6M**

Share Price **\$0.30**  
*as of 2 June 2017*

Shares on Issue **148.7M**

**Market Cap (fully diluted)** **\$52.2M**

Share Price **\$0.30**  
*as of 2 June 2017*

Fully diluted shares (per March 29, 2017 Appendix 3B) **174.2M**

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**Cash Available** (includes \$4M R&D rebate in Sept '17) **\$10M**

### BOARD OF DIRECTORS

<b>Chris Indermaur</b>	<i>Chairman</i>
<b>Jack Cosentino</b>	<i>CEO &amp; Managing Director</i>
<b>Dr. Frank Prendergast</b>	<i>Non-executive Director</i>
<b>Kris Knauer</b>	<i>Non-executive Director</i>
<b>Andrew Maxwell</b>	<i>Non-executive Director</i>

### SUBSTANTIAL SHAREHOLDERS

**10.5%** 

**FIDELITY**  
Institutional holder

**7.2%** 

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

**8.1%** 

**DR. STEPHEN ADDIS**  
Held since 2015, co-founder

**55%** 

**TOP 20**

## EXPERIENCED EXECUTIVE LEADERSHIP TEAM



**JACK COSENTINO**  
CEO/Managing Director  
*Based in Minneapolis*

20 years medical technology experience as CEO and senior management including Medtronic and most recently Impedimed. Deep experience in digital health and prevention based health care delivery.



**BRIAN MOWER, CPA**  
Chief Financial Officer  
*Based in Minneapolis*

21 years experience in senior finance, including 17 years in commercializing innovative medical technologies; KPMG, lomed (AMEX: IOX), DJO, & Torax Medical (acquired by Johnson & Johnson).



**YASHAR BEHZADI, PhD**  
Chief Product Officer  
*Based in Silicon Valley*

Led the development of Proteus Digital Health's ingestible and wearable technology creating over 30 patents. Subsequently led product development and pharmaceutical collaborations.



**GREG MOON, MD, MBA**  
Chief Medical Officer  
*Based in Silicon Valley*

10 years of experience in managing Clinical Affairs and led the regulatory approval of Proteus Digital Health's solution in the US and EU.



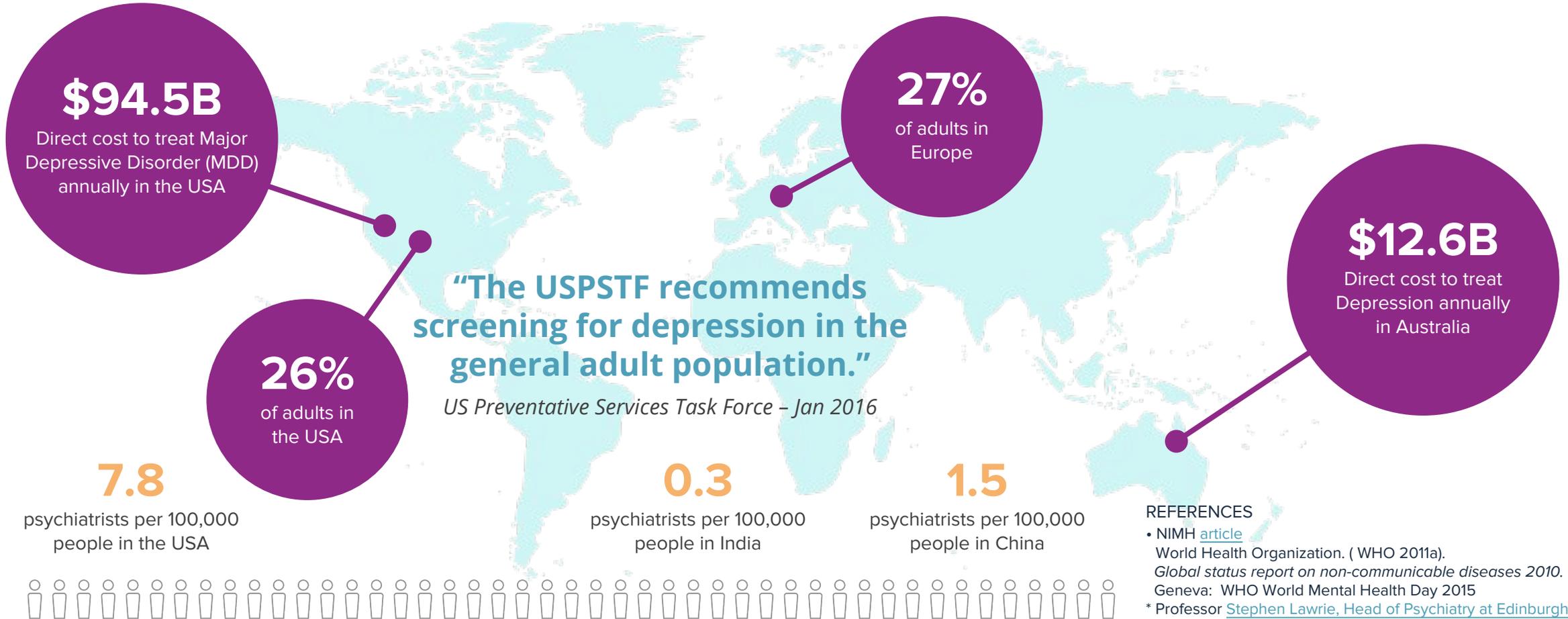
**NATHAN COWAHL**  
VP, Algorithm Development  
& Data Science  
*Based in Silicon Valley*

Research & Development Strategy Manager - Data Science and Algorithms for wearable platforms at Intel. Human physiological signal processing expert.

# “THE SINGLE GREATEST ILLNESS THAT AFFECTS MANKIND”

- 350 MILLION PEOPLE WITH DEPRESSION
- LEADING CAUSE OF DISABILITY IN US

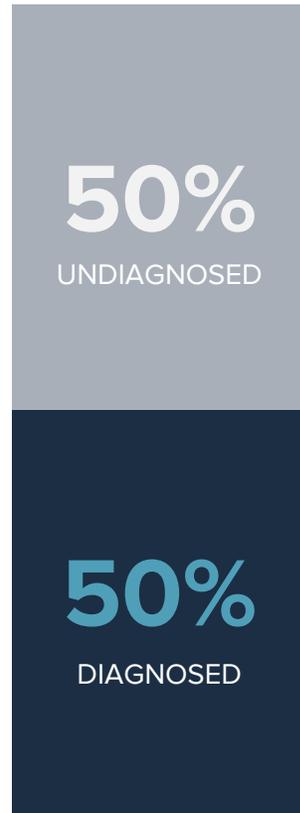
*Mental illness will result in \$6 trillion in health-care costs globally. “WHO”*



# HUGE MISALLOCATION OF RESOURCES DUE TO POOR DECISION SUPPORT

*“\$3700/person/year incremental cost for poorly managed depression in the US.”*

THERE ARE  
**350**  
MILLION  
DEPRESSED  
PEOPLE  
WORLDWIDE



(Barbui, 2006)

**SCREENING**



(Angst, 2011)

**DIAGNOSIS**



(Gonzalez, 2010)

**TREATMENT**

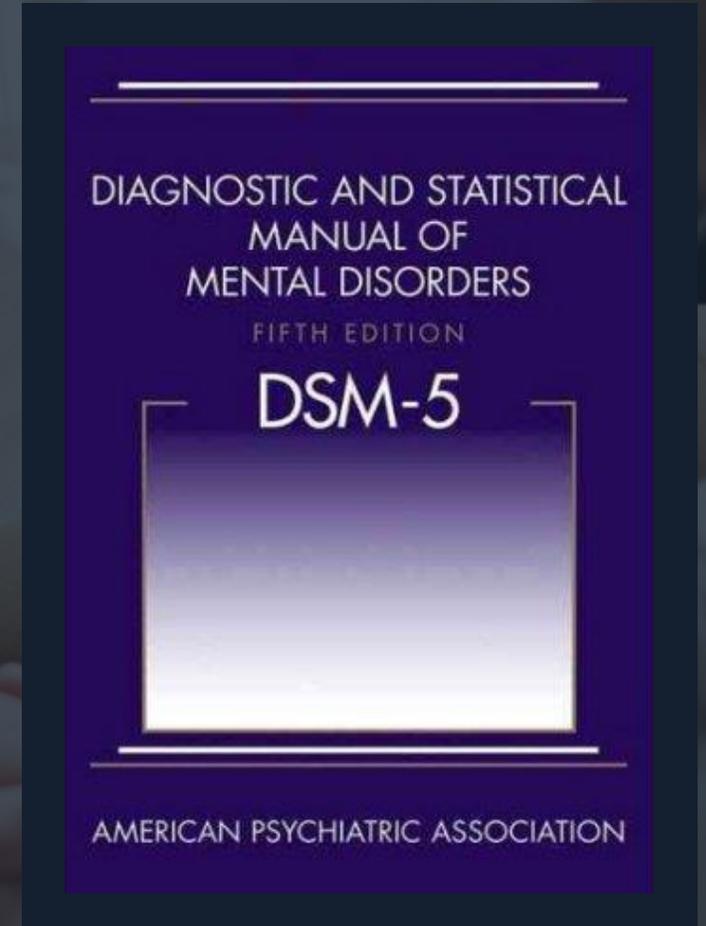
▶ **7% OF TOTAL ON OPTIMAL TREATMENT**

# WE MUST MOVE BEYOND SUBJECTIVE DIAGNOSIS

“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 quality 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



### CURRENT PAIN POINTS



Current diagnostic tests rely on clinical interviews with subjective interpretation



The standard of care is assessment by a psychiatrist > High cost & limited access



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



No objective measure of treatment effectiveness leads to long titration cycles



### MEDIBIO'S SOLUTION

**Quantitative and objective diagnostic** based on biomarkers

**Cost-effective, scalable solution** that can be administered at the primary care level > Lower cost & more accessible

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

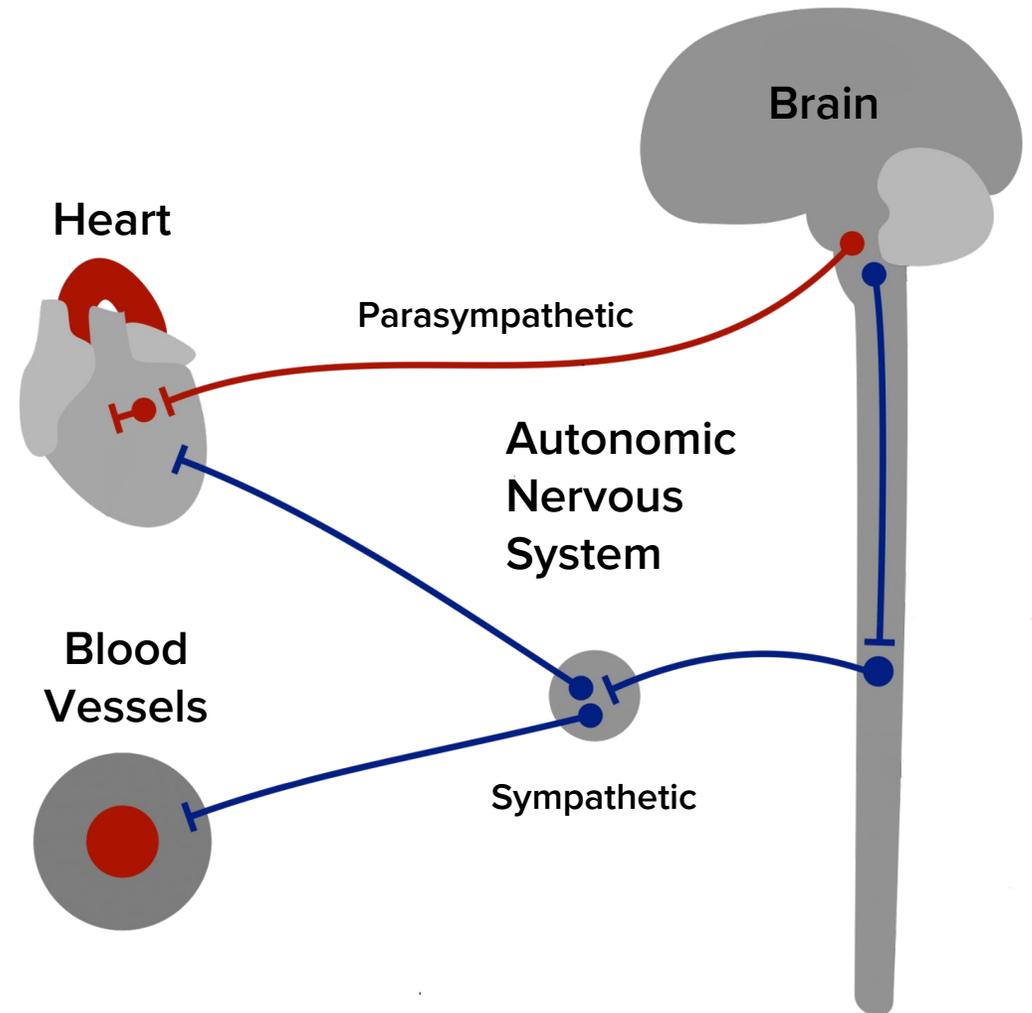
Provides **objective indication of treatment efficacy** enabling reduced time to optimal treatment

## BRAIN & HEART ARE INTIMATELY CONNECTED

The heart offers a ready window into the autonomic nervous system via a rich set of heart rate metrics focusing on Autonomic Dysnomia

Medibio solution builds on a large body of literature linking HR metrics with mental health

- Increased heart rate variability associated with greater psychological flexibility (*Geisler, 2013*)
- Decreased HRV associated with MDD and scales with severity (*Agelink, 2002; Kemp, 2010*)
- Patterns of circadian heart rate correlate specifically with multiple mental health conditions (*Stampfer, 1998, 2000, 2009, 2013; Addis, 2003*)



## SLEEP BRIDGES MANY PHYSIOLOGIC SYSTEMS

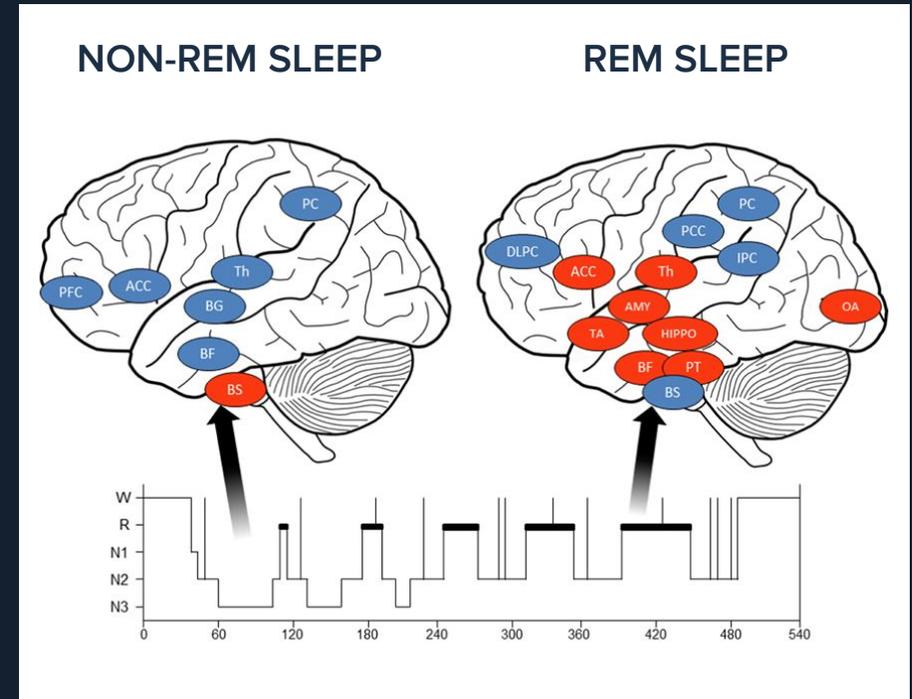
Sleep & other circadian measures provide a powerful lens into mental wellbeing

Medibio solution leverages ample science linking sleep & mental health

- 75% of MDD, 70% of bipolar, 91% of PTSD, and 80% of schizophrenia patients report sleep disturbances (Yates, 2004; Harvey, 2005; Ohayan, 2001; Cohrs, 2008)
- Short REM latency, increased REM density, decrease in slow wave activity in MDD (Horne 1992; Steiger, 2010)
- Disrupted melatonin & cortisol patterns and dyssynchrony in melatonin, sleep & body temp in MDD (Claustrat, 1984; Hasler, 2010)
- Delayed, dampened circadian phase in GAD (Coles, 2015)

EEG  
Actigraphy  
HR monitoring

HR monitoring  
Body temperature  
Skin conductance  
Serum markers



↓HR  
↓Sympathetic  
↑Parasympathetic

↑HR  
↑Sympathetic  
↓Parasympathetic

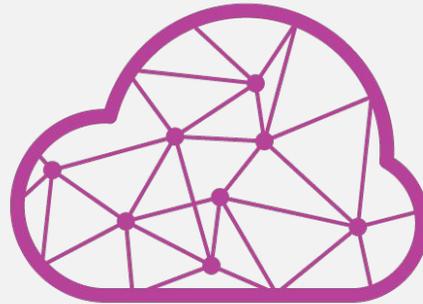
# MEDIBIO'S DIGITAL MENTAL HEALTH PLATFORM

## PHYSIOLOGICAL DATA (ECG, EEG, ACTIGRAPHY) (DEVICE AGNOSTIC APPROACH)



API

## MEDIBIO ANALYTICS CLOUD



API

## APPLICATIONS (FULL SPECTRUM MENTAL HEALTH)

- Major Depression Disorder (MDD)
- Generalized Anxiety Disorder (GAD)
- Bipolar
- Schizophrenia
- Treatment effectiveness
- Screening
- Differential Diagnosis

- Characterization of circadian, autonomic and sleep biomarkers related to psychiatric disorders
- Device agnostic platform capable of ingesting data from a multitude of devices
- Highly scalable, low cost & easy to integrate

# COMPREHENSIVE OFFERING TO ADDRESS CLINICAL NEEDS

EARLY DETECTION SCREENING

ACCURATE DIAGNOSIS

RIGHT DRUG TREATMENT

PRODUCT

MEDIBIO-ID

MEDIBIO-DX

MEDIBIO-RX

Value Proposition

**Detection of individuals** likely to have a psychiatric condition in the broad population

Objective biomarkers used to **guide diagnosis of psychiatric conditions** (MDD, Bipolar, GAD)

**Confirmation of therapy effectiveness** to drive drug selection and titration (Ketamine, SSRI's, SNRI's, TCA's, MAOI's, Antidepressants, as well as Antagonists).

Use Case

Leverages longitudinal data from available wearable devices

Leverages clinical-quality data from available medical devices over 1-30 days of monitoring

Leverages clinical-quality data from available medical devices episodically over a period of 6 weeks or monthly for patients currently being medicated

Regulatory Timelines

Q4, 2017 CE-mark of platform

Q4, 2018 FDA approval for MDD with subsequent clinical areas to follow

Q2, 2019 FDA approval for MDD treatments (Could be earlier based on multiple accelerators)

# BIOMARKER BASED OBJECTIVE DIAGNOSIS

## APPROACH

Panel of circadian, sleep and autonomic 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.

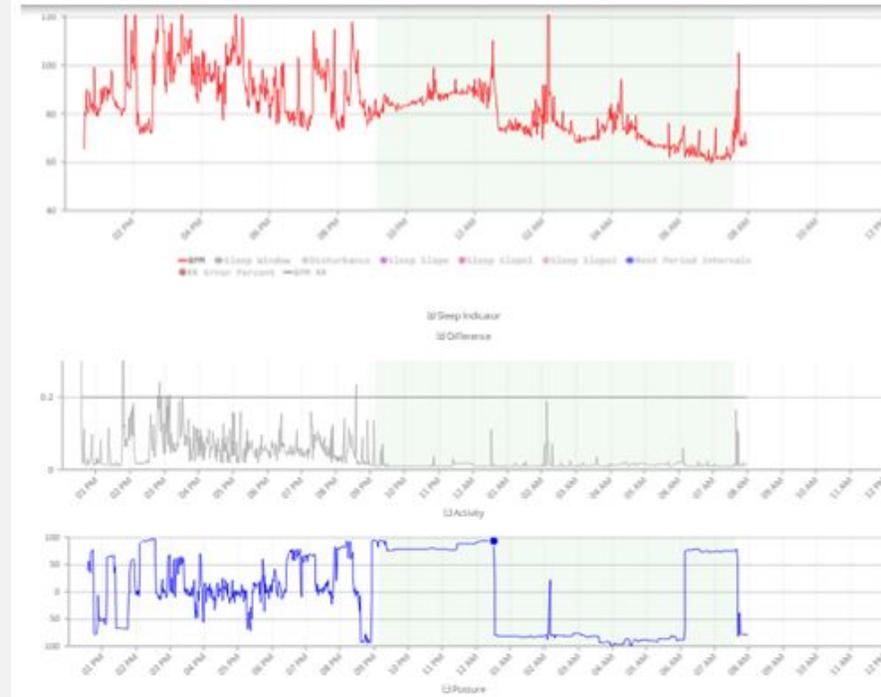
### Heart Rate

### Activity

### Posture

## PHYSIOLOGIC DATA WAVEFORMS

## PANEL OF BIOMETRICS

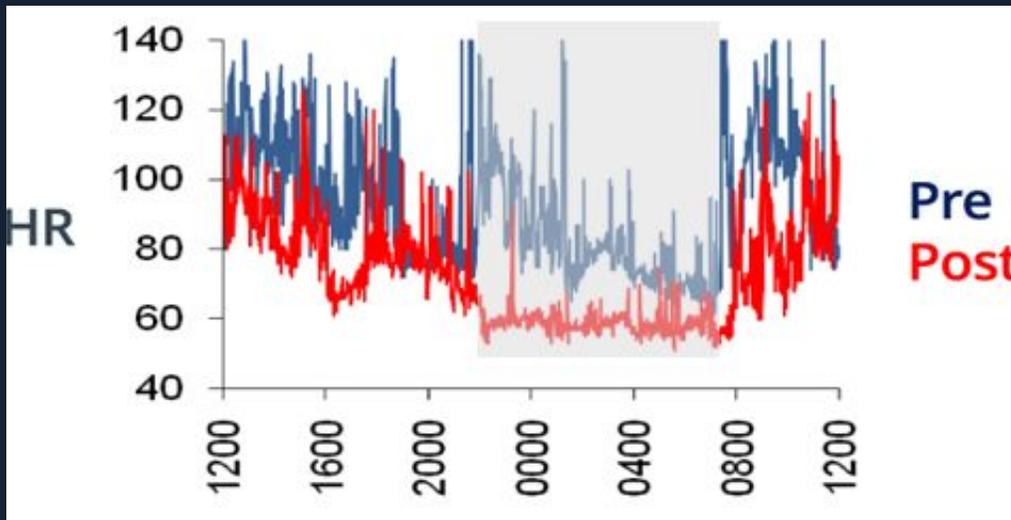


RATE	AVAIL	SCORE
Sleep Mean	78 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Awake Mean	88 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Awake Sleep Diff	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13		
Sleep Diff Mean	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
1.95		
Awake Diff Mean	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4.29		
Sleep Slope	-2.53 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sleep Slope1	-1.41 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sleep Slope2	-2.52 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sleep St Dev	9.60 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Rate Variability	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8.11		
Sleep Depth	20.00 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sleep Quality	44.52 <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

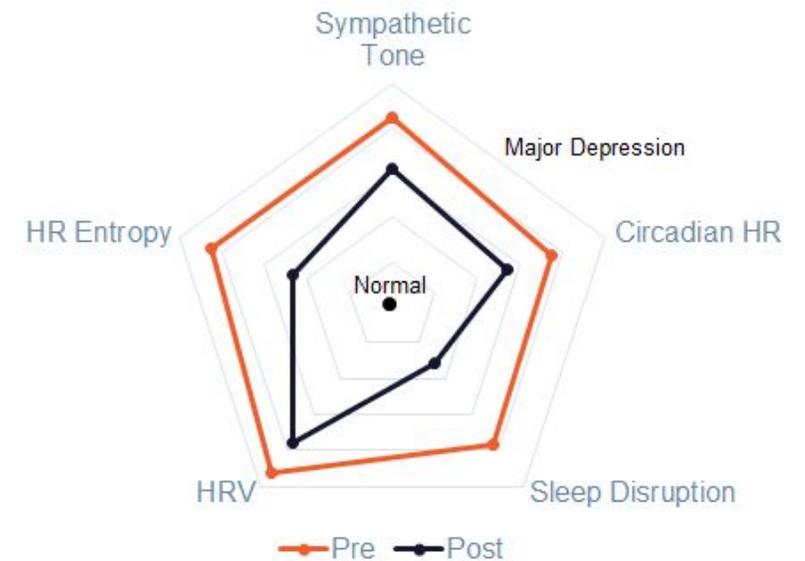
# QUANTIFYING TREATMENT RESPONSE

## Case Study 1

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



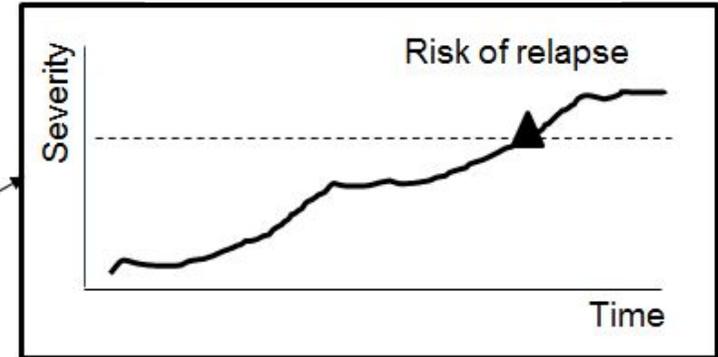
## Biometrics normalize with effective treatment



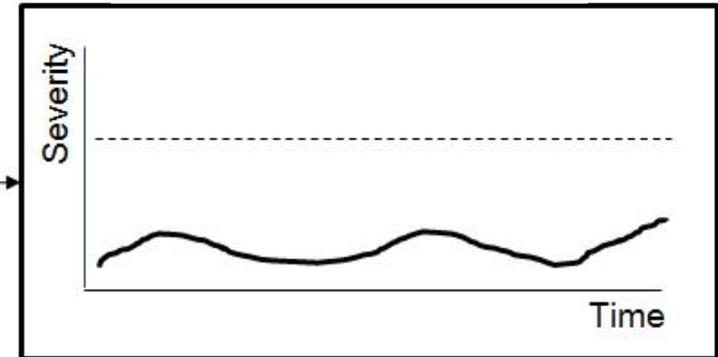
## Patient Panel Enables Early Identification of At-Risk Patients

REVIEWED	SCAN & USER ID	PARTNER	START TIME	DURATION	RESULT	ACTIONS
☆	ID: 590260196a018575256a48c User ID: 5b19f4e220109367c391950a	MED632IA2	2016-12-19 15:30:22	29:07	None	Report of Details
☆	ID: 59026a8ba018575280018e User ID: 57b423208a01a2018a01	MED632IA2	2016-08-11 10:52:21	28:48	Very Severe	Report of Details
☆	ID: 59195445250109367c397b8c User ID: 59195445250109367c397b8c	MED632DEL	2016-12-06 07:36:09	28:22	Very Severe	Report of Details
☆	ID: 59195594250109367c3017b4 User ID: 59195594250109367c3017b4	MED632DEL	2017-02-24 09:47:35	28:17	Mild	Report of Details
☆	ID: 59195201250109367c393612 User ID: 59195201250109367c393612	MED632HU	2017-03-22 16:22:01	28:05	Severe	Report of Details
☆	ID: 5919546250109367c3967f User ID: 5919546250109367c3967f	MED632DEL	2016-12-21 14:49:34	28:05	Mild	Report of Details
☆	ID: 59194d7250109367c354654 User ID: 59194d7250109367c354654	MED632HU	2017-03-08 10:37:56	27:58	Severe	Report of Details
☆	ID: 59194c6250109367c345620 User ID: 59194c6250109367c345620	MED632HU	2017-02-27 14:50:15	27:57	Mild	Report of Details
☆	ID: 59026e296a01857527e6118 User ID: 57b423208a01a2018a01	MED632IA2	2016-08-01 11:19:16	27:54	Mild	Report of Details
☆	ID: 59194d03250109367c355d9b User ID: 59194d03250109367c355d9b	MED632HU	2017-04-24 08:44:07	27:14	Mild	Report of Details

## Patient Disease Progression



## Stable Patient on Treatment



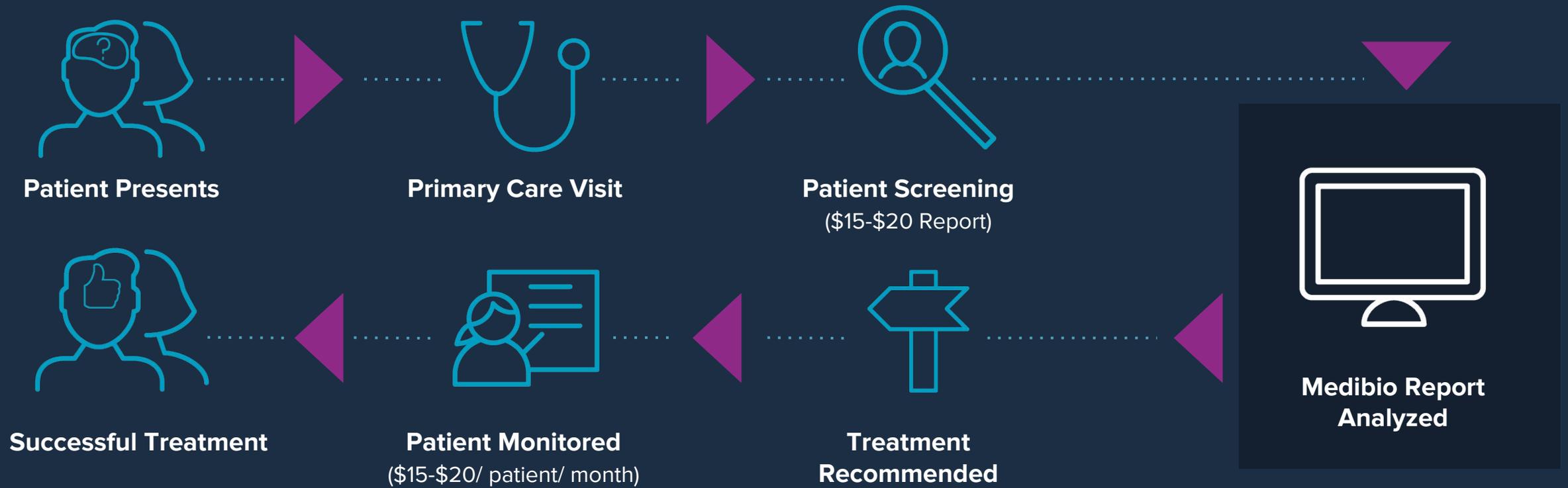
## SIGNIFICANT VALIDATION SUPPORTING TECHNOLOGY

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%	<b>Depression, anxiety disorder, schizophrenia:</b> Various historical studies (Medibio)	PEER REVIEWED
86-95%	<b>Sleep staging using ECG data:</b> 7500 patients completed 24 June 2016	JOHNS HOPKINS

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

(1) *Depression in Primary Care Vol 1: US Dept. Health*

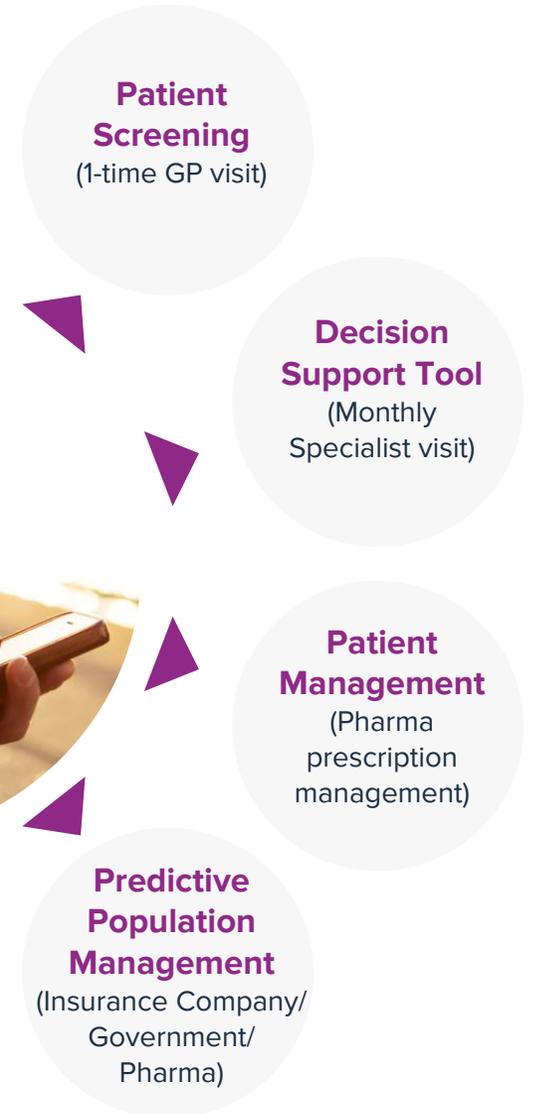
# DESIGNED TO DELIVER PATIENT SUCCESS



# REVENUE GENERATION OPPORTUNITIES



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



## 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.

EARLY DETECTION SCREENING

ACCURATE DIAGNOSIS

RIGHT DRUG TREATMENT

PRODUCT

**MEDIBIO-ID**

**MEDIBIO-DX**

**MEDIBIO-RX**

**Per Patient Revenue**

\$15-\$20 per patient screen

\$180-\$240 patient/annually

\$180 - \$240 patient/annually

**Estimated Market Size**

43.8 million U.S. adults suffer mental illness annually

21.9 million U.S. adults are diagnosed (50% rate)

15.3 million U.S. adults accurately treated (70%)

**Estimated Market Potential**

\$875 million U.S. Market

\$5.3 Billion U.S. Market

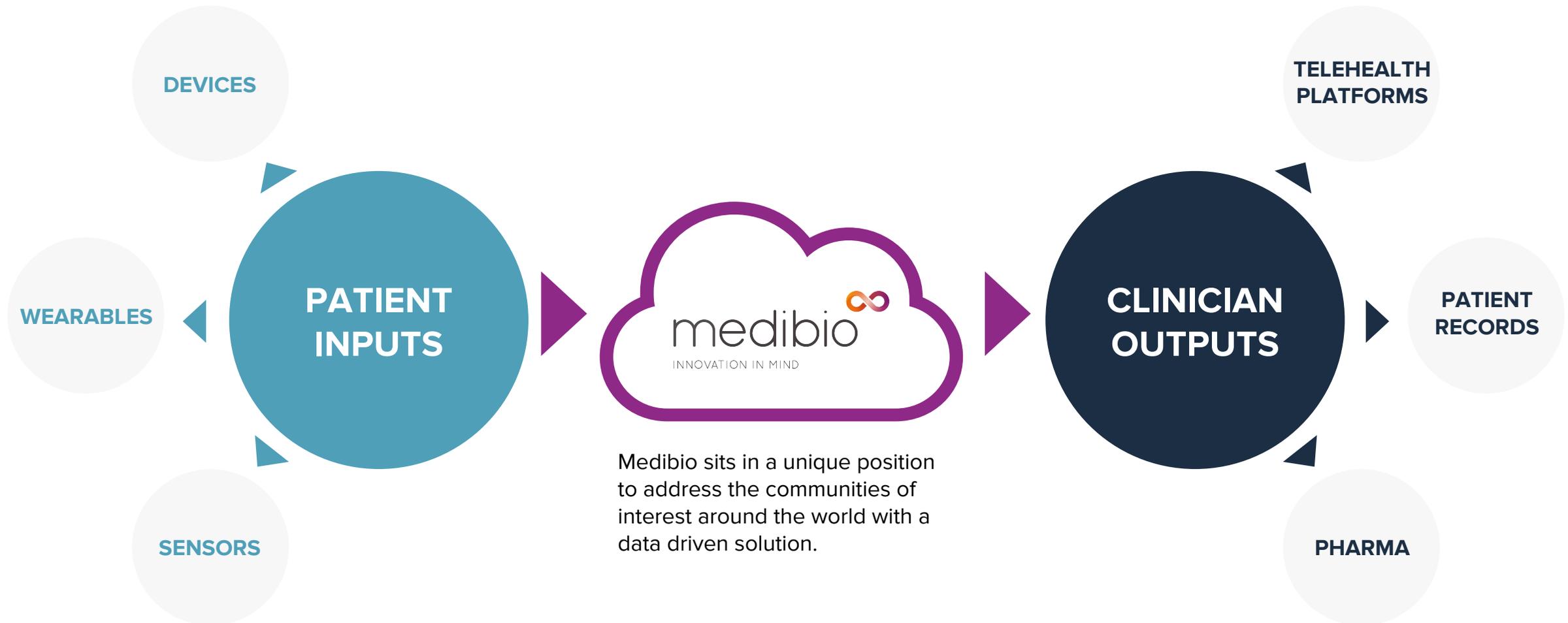
\$3.7 Billion U.S. Market

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

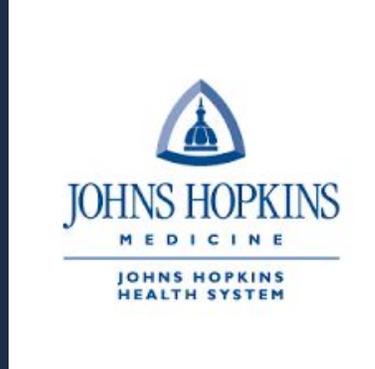
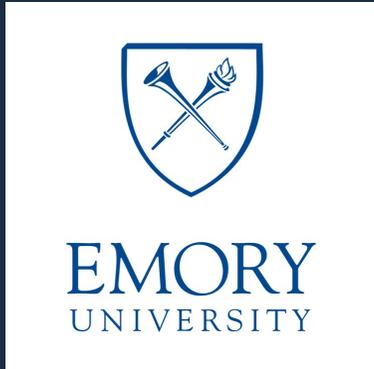
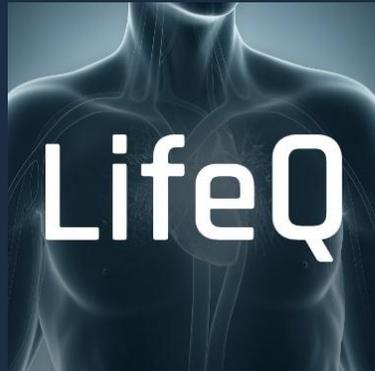
## RECENT DIGITAL HEALTHCARE COMPANY EXITS

TARGET	TECHNOLOGY	ACQUIRED BY	ACQUISITION AMOUNT
<b>Change Healthcare</b>	Revenue cycle and analytics	MCKESSON	<b>\$3.0B</b>
<b>Truven Analytics</b>	Cloud-based healthcare data, analytics & insights	IBM	<b>\$2.6B</b>
<b>eResearch Technology</b>	Patient-centric endpoint data collection	NORDIC CAPITAL	<b>\$1.8B</b>
<b>Netsmart Technologies</b>	Home health, hospice, & private duty scheduling	ALLSCRIPTS	<b>\$950M</b>
<b>Brightree</b>	Clinical software	RESMED	<b>\$800M</b>
<b>Imprivata</b>	Patient information access	THOMA BRAVO	<b>\$544M</b>
<b>Assurex</b>	Behavioral health matching	MYRIAD GENETICS	<b>\$410M</b>
<b>Cardon Outreach</b>	Eligibility solutions for healthy systems & hospitals	MED DATA	<b>\$400M</b>
<b>Sequenom</b>	Testing for genetic abnormalities	LABORATORY CORP	<b>\$371M</b>
<b>Valence Health</b>	Value-based care solution	EVOLENT HEALTH	<b>\$291M</b>

## OUR ECOSYSTEM



## OUR PARTNERS



## GROWTH THROUGH PARTNERSHIP

Medibio is small piece of the greater whole of delivery of care for Mental Health. By leveraging partnerships, we have been able to identify best-of-class organizations around the world to assist in creating a holistic solution to address the mental illness market.

## KEY COMPANY MILESTONES 2017/ 2018

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

# APPENDIX

## DEFENSIBLE POSITION BASED ON IP AND DATA ASSETS



### Comprehensive suite of patents around CHR & technology:

- Medical diagnostics including assessment of treatment efficacy
- Stress assessment



### Patent suite for medical diagnostics includes:

- Method for Diagnosing Psychiatric Disorders
- Method and System for Monitoring Stress Conditions covering the use of CHR for stress assessment
- Method and System for using CHR to Diagnose Psychiatric Disorders



### Proprietary data set required is the natural protection:

- 15,000+ 12 hour ECG files with a corresponding mental health diagnosis
- This data set would take 5 years and cost \$30 million plus to replicate
- Continuous source of new insights and clinical indications

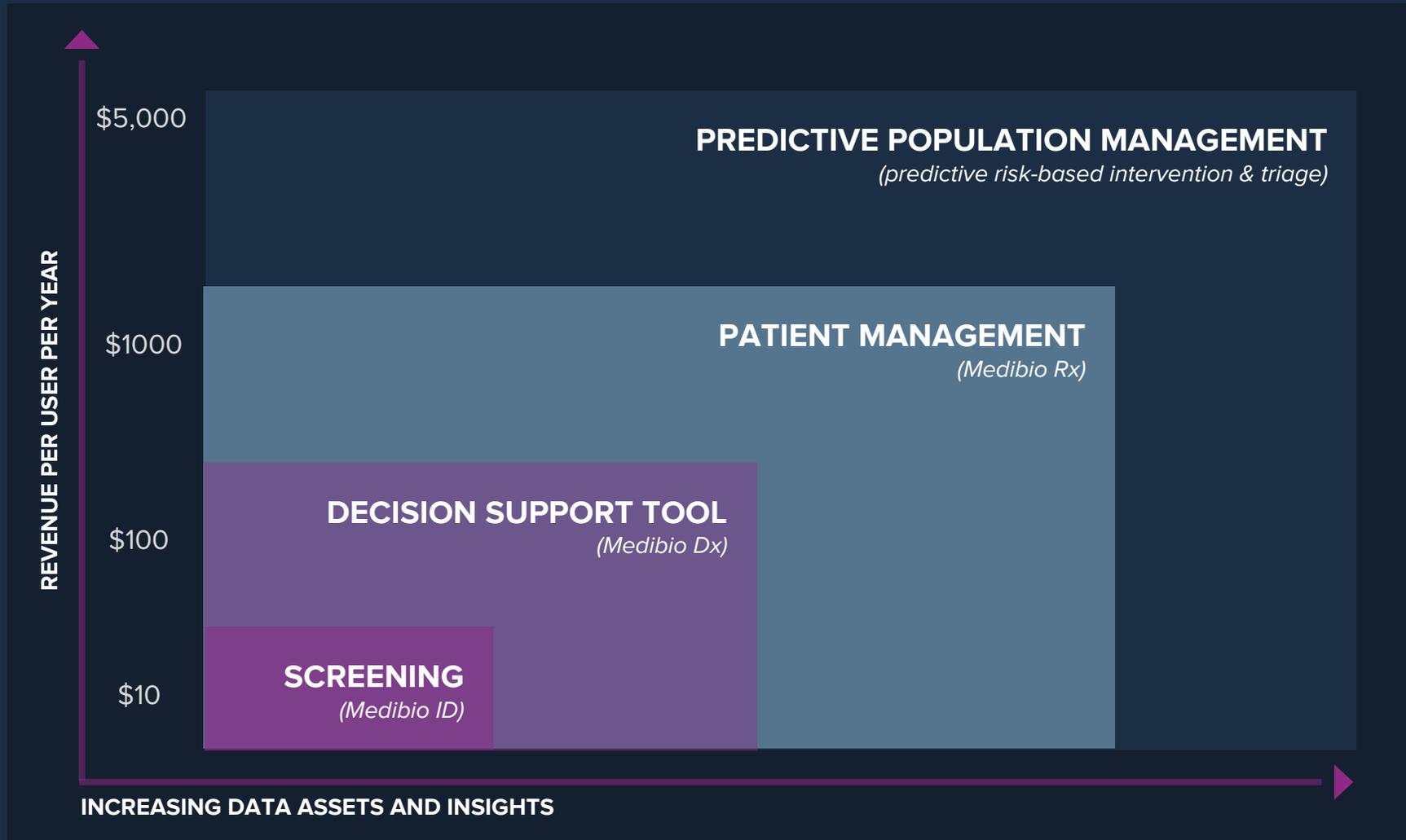
## OVERVIEW OF COMPLEMENTARY/COMPETING TECHNOLOGIES

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

## RICH PIPELINE OF PRODUCTS

FOCUS	IP	R&D	PILOT TRIAL	PIVOTAL TRIAL	CE	FDA	LAUNCH	PARTNERS
MEDIBIO ID					Q4 2017	Not required	Q1 2018	USYD
MEDIBIO DX-Depression				Q3 2017	Q4 2017	Q2 2018		OTTAWA, JHU
MEDIBIODX-Unipolar/ Bipolar Differential Diagnosis			Q4 2017					MAYO
MEDIBIO RX-MDD			Q4 2017					MAYO
Treatment MEDIBIO DX, RX-Generalized Anxiety Disorder (GAD)			Q2 2018					MAYO
MEDIBIO DX, RX-PTSD			Q3 2018					EMORY
MEDIBIO DX, RX-Schizophrenia		Q1 2019						PHARM TBD
MEDIBIO DX, RX-Bipolar		Q1 2019						PHARM TBD

## DELIVERING GREATER SHAREHOLDER VALUE OVER TIME



- Medibio has a clear path to market via the clinical route
- Medical spend is 10X with a growing appreciation of the economic burden of mental illness
- Value unlocked over time providing significant step-increase in unit economics

## SOLVING SIGNIFICANT PROBLEMS FOR PHARMA

### \$40,000

Average cost of a patient in a drug clinical trial

- Medibio can provide objective screening to ensure patients are properly diagnosed.
- 75-80% of the improvement in the drug group also occurs when people are given dummy pills. <sup>(1)</sup>
- Overall antidepressant market was valued at \$USD 11.9 Billion in 2011. <sup>(2)</sup>

### \$7,500

The annual cost of Abilify, the \$9B/ year drug, used to treat mental health conditions

- Given the high-cost of psychiatric drugs, payers are increasingly demanding demonstration of effectiveness through objective means.

### \$330

Reimbursement for companion diagnostic to determine proper therapy course

- Companion diagnostics provide 'beyond-the-pill' revenue opportunities while serving to funnel patients to specific therapies.

(1) *Antidepressants and the Placebo Effect – Kirsch I (Z Psychol. 2014; 222(3): 128–134.)*

(2) *GBI Research – Antidepressants Market to 2018 (October 2012)*

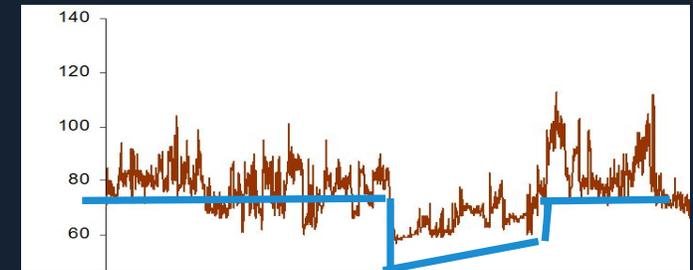
## INSIGHTS BASED ON 15 YEARS OF CLINICAL RESEARCH

- 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.

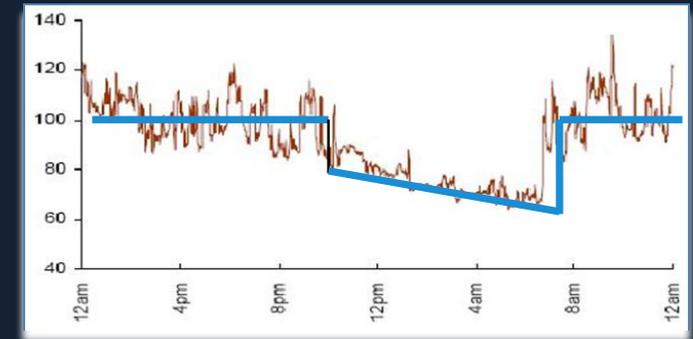
### NORMAL



### DEPRESSION



### ANXIETY



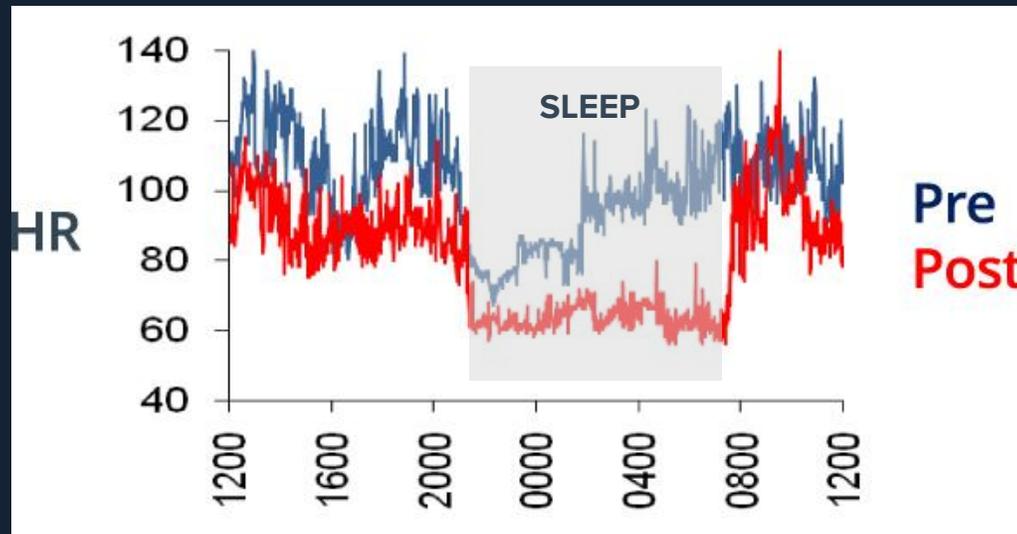
24 hour heart-rate



# OBJECTIVE ASSESSMENT OF THERAPY EFFECTIVENESS

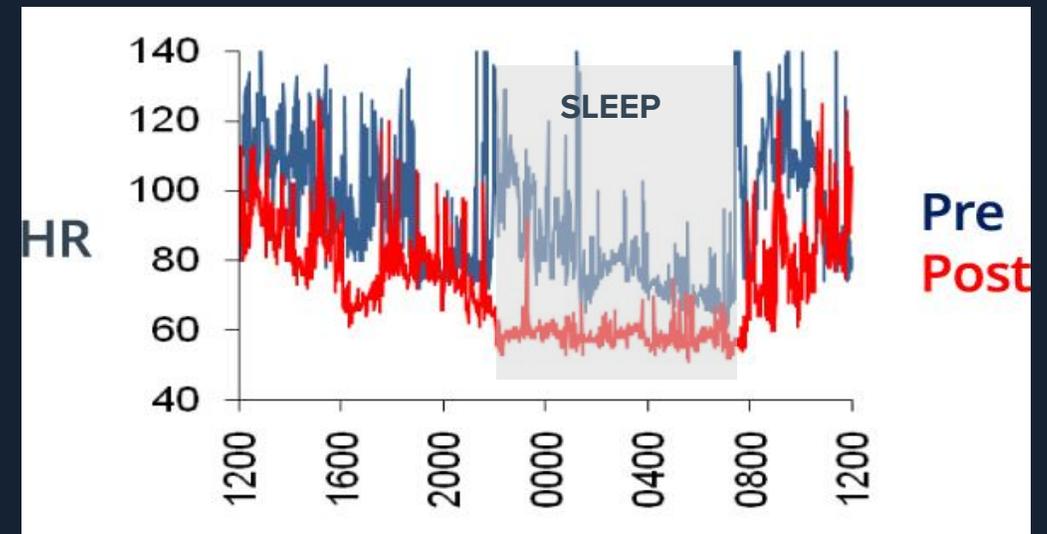
## Case Study 1

- Depressed individual upon initial diagnosis
- Treated for 18 days with:
  - Olanzapine - 10mg (night)
  - Mirtazapine - 60mg (night)



## Case Study 2

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





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