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 a panel of patented (and patent pending) 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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INNOVATION IN MIND

Investor Presentation

June 2017

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FORWARD LOOKING STATEMENTS

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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 *as of 2 June 2017*	$0.30
Shares on Issue	148.7M
Market Cap (fully diluted)	**$52.2M**
Fully diluted shares (per March 29, 2017 Appendix 3B)	174.2M
Cash Available (includes $4M R&D rebate in Sept '17)	**$10M**

BOARD OF DIRECTORS

Chris Indermaur	*Chairman*
Jack Cosentino	*CEO & Managing Director*
Dr. Frank Prendergast	*Non-executive Director*
Kris Knauer	*Non-executive Director*
Andrew Maxwell	*Non-executive Director*

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

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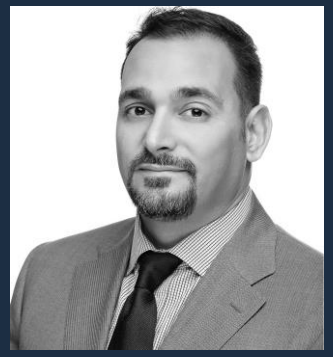
EXPERIENCED EXECUTIVE LEADERSHIP TEAM



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, Iomed (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.

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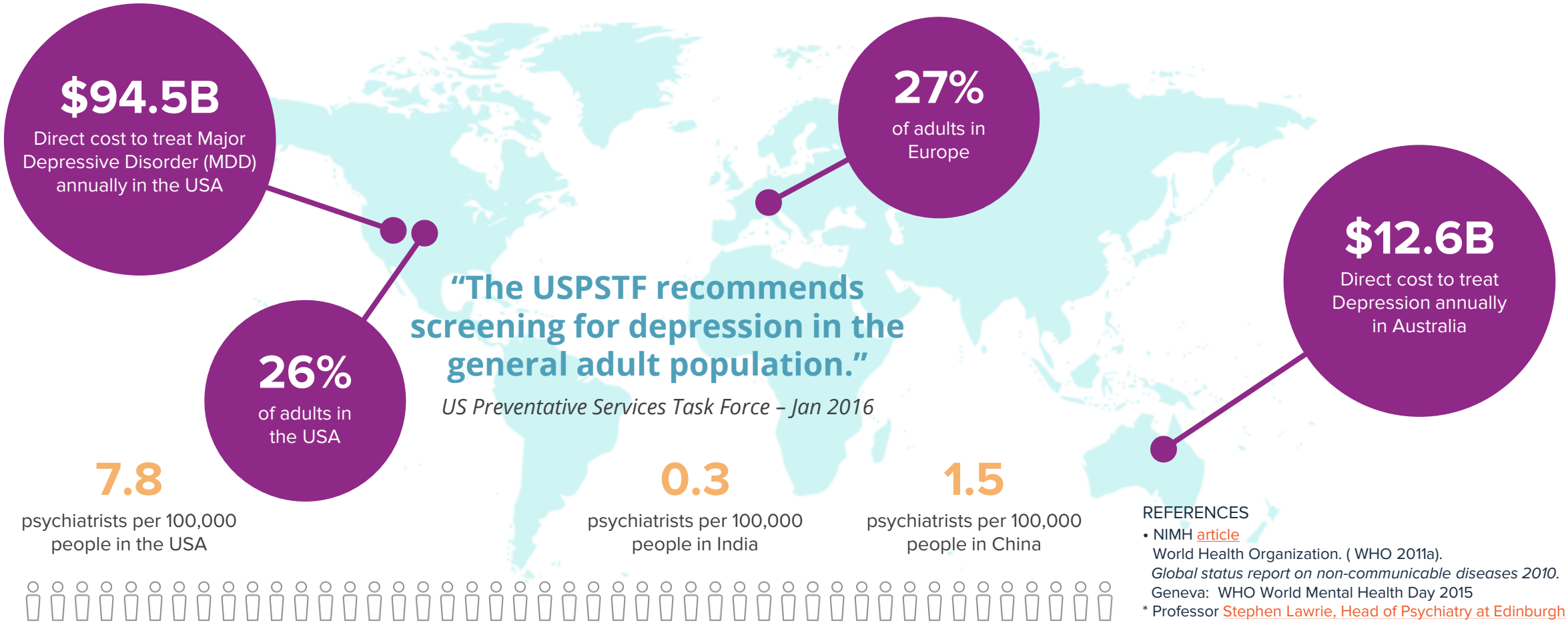
"THE SINGLE GREATEST ILLNESS THAT AFFECTS MANKIND"

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

Mental illness will result in $6 trillion in health-care costs globally. "WHO"



REFERENCES

- NIMH article
  World Health Organization. (WHO 2011a).
  Global status report on non-communicable diseases 2010.
  Geneva: WHO World Mental Health Day 2015
- Professor Stephen Lawrie, Head of Psychiatry at Edinburgh

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HUGE MISALLOCATION OF RESOURCES DUE TO POOR DECISION SUPPORT

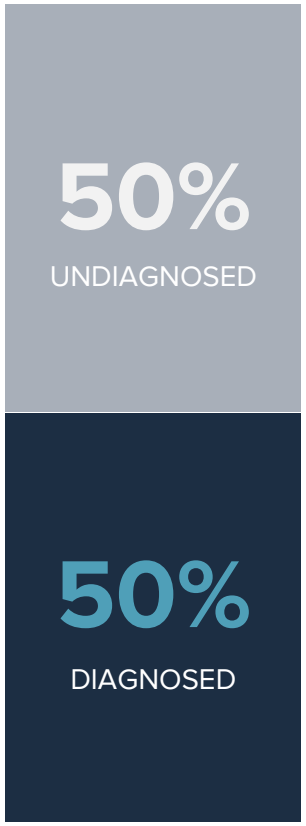
"$3700/person/year incremental cost for poorly managed depression in the US."

THERE ARE

350

MILLION

DEPRESSED PEOPLE WORLDWIDE

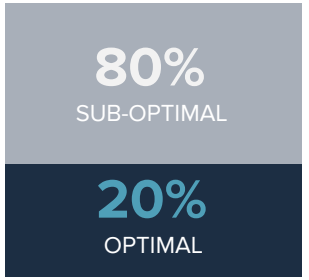


(Barbui, 2006)

SCREENING

(Angst, 2011)

DIAGNOSIS



(Gonzalez, 2010)

TREATMENT

7% OF TOTAL ON OPTIMAL TREATMENT

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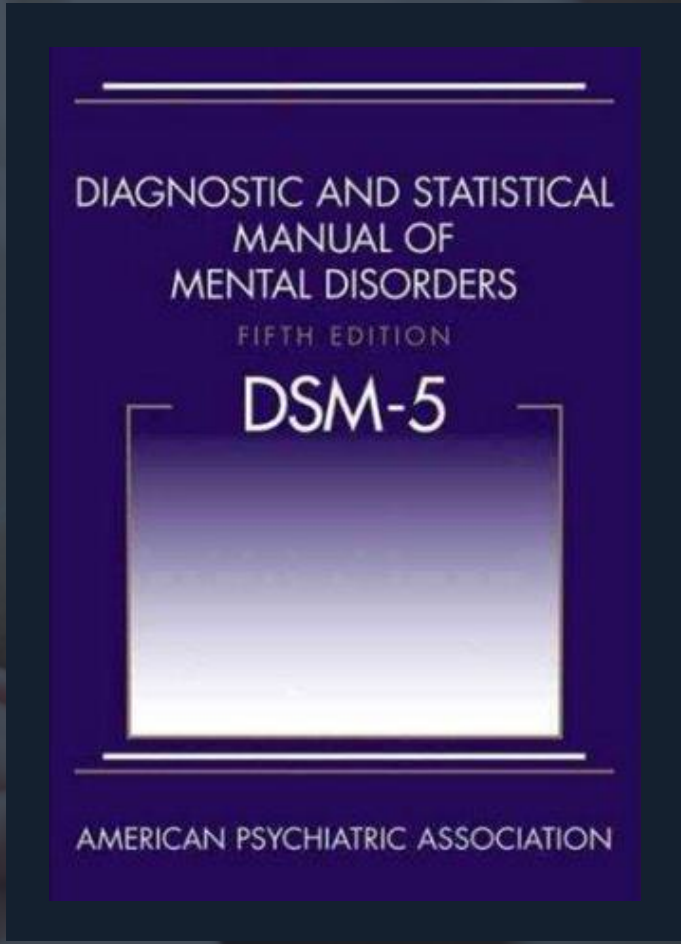
WE MUST MOVE BEYOND SUBJECTIVE DIAGNOSIS

"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



MEDIBIO SOLUTION OFFERS OBJECTIVITY & SCALABILITY

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

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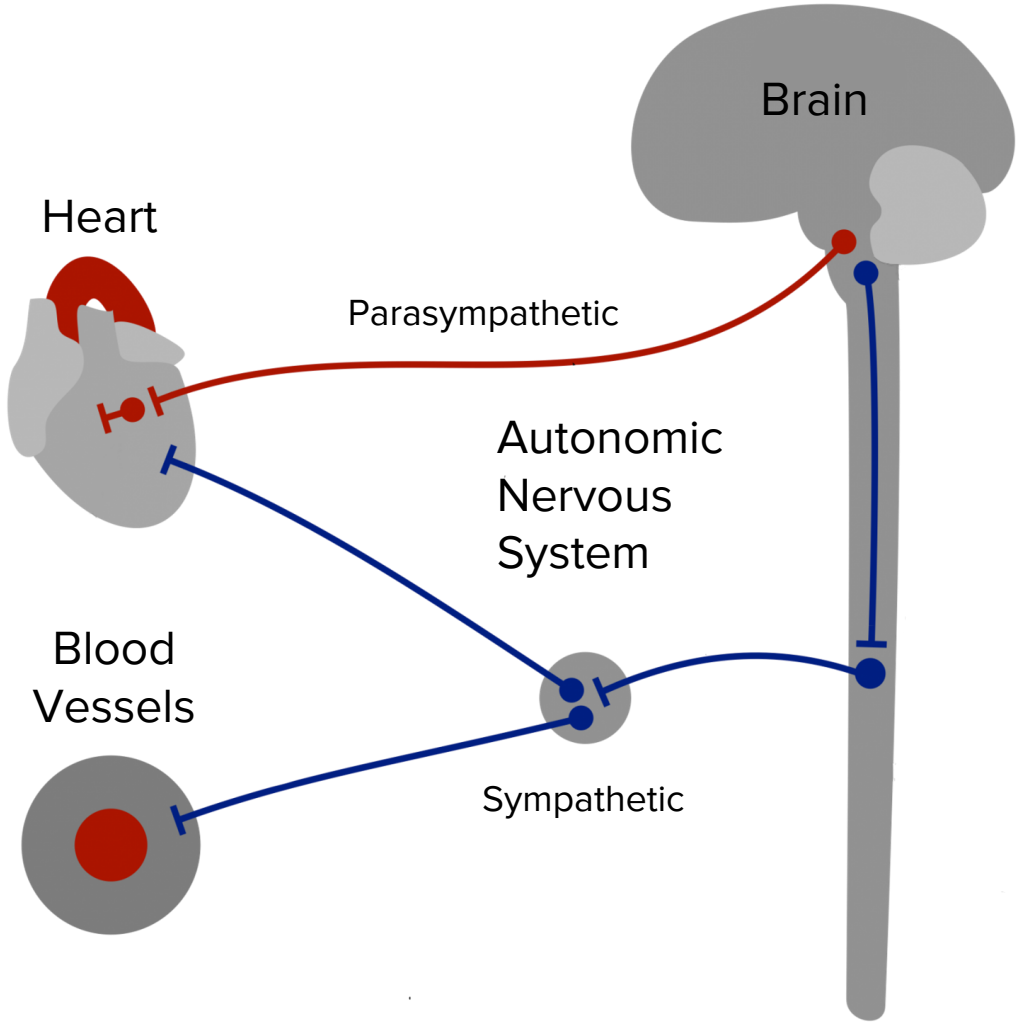
BRAIN & HEART ARE INTIMATELY CONNECTED

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)*



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SLEEP BRIDGES MANY PHYSIOLOGIC SYSTEMS

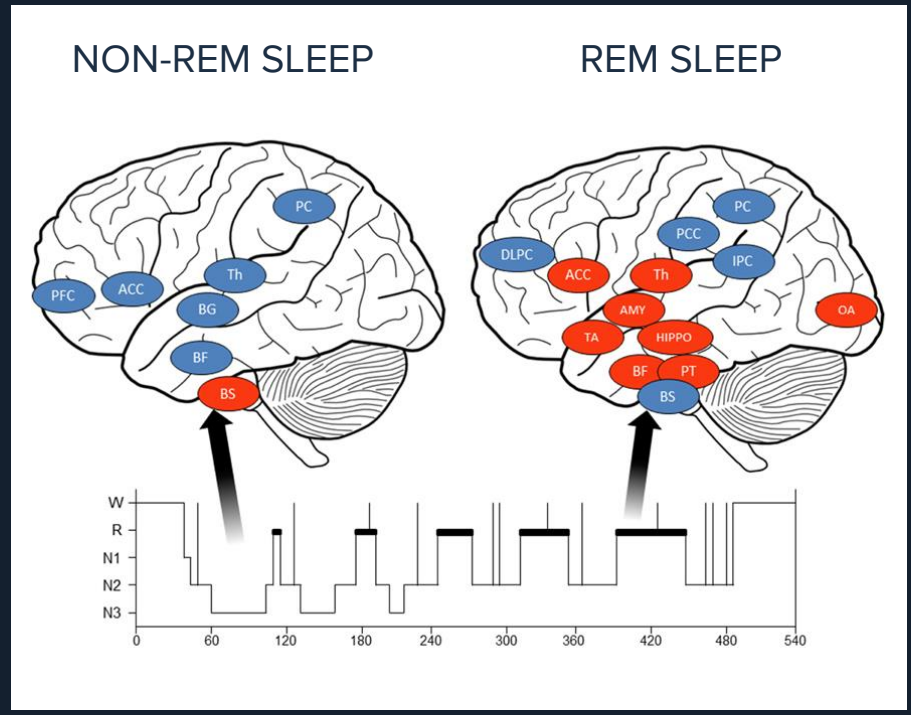
Sleep & other circadian measures provide a powerful lens into mental wellbeing

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

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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

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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)

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BIOMARKER BASED OBJECTIVE DIAGNOSIS

APPROACH

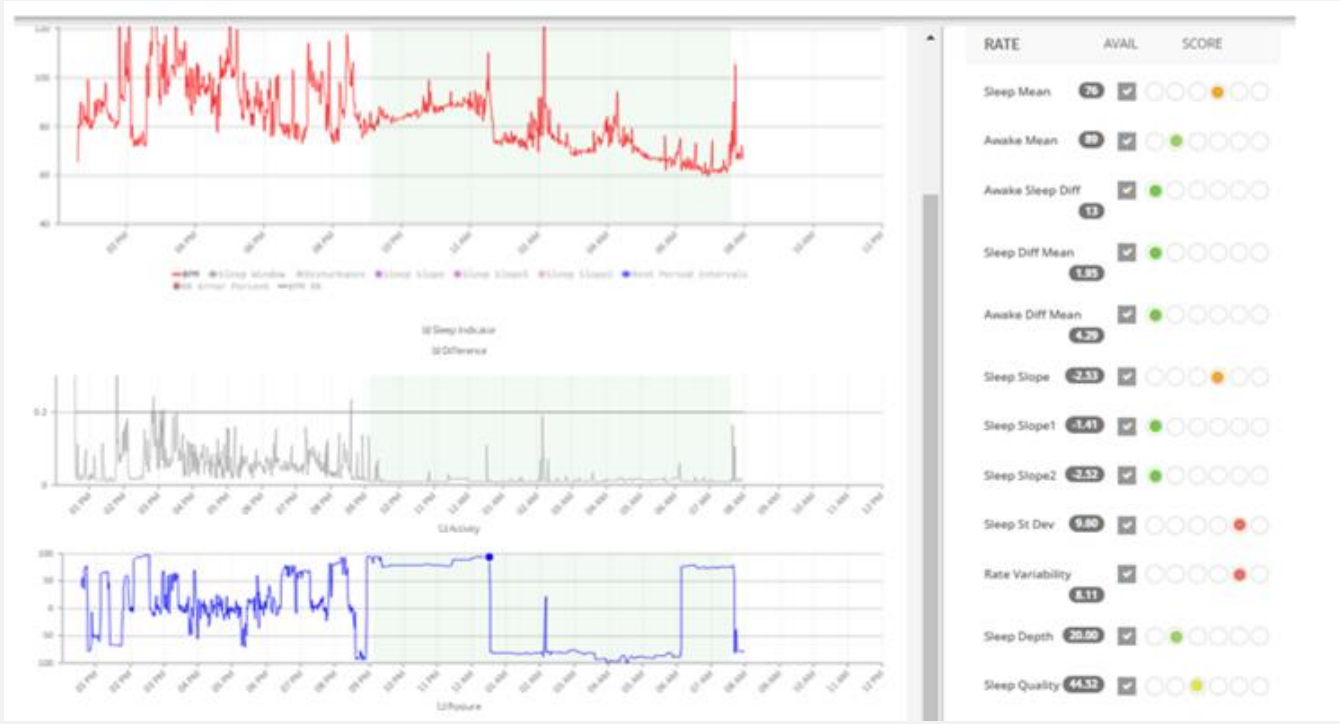
Panel of circadian, sleep and automatic system biomarkers enables automated, repeatable, and objective characterization of the impact of mental illness on physiologic state

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.

PHYSIOLOGIC DATA WAVEFORMS

PANEL OF BIOMETRICS



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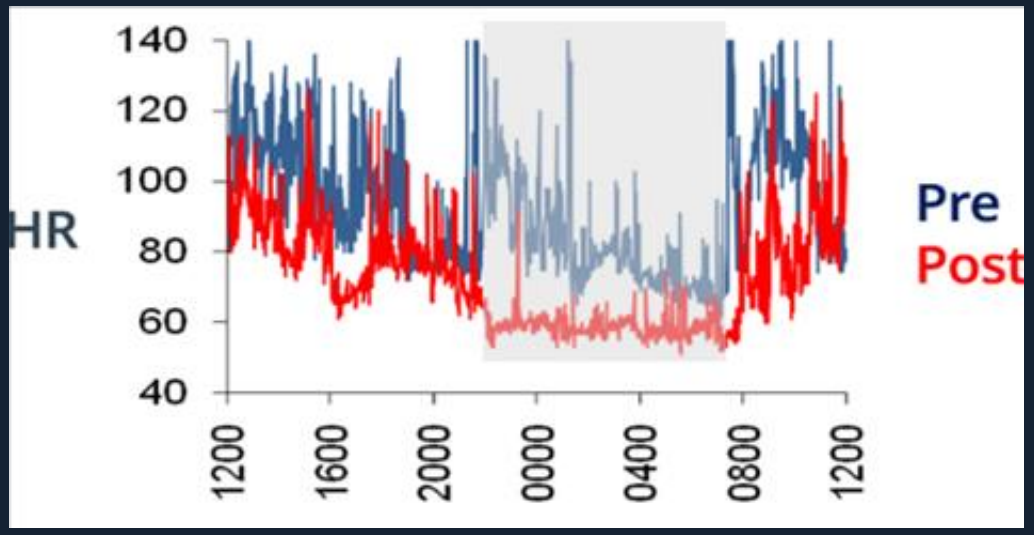
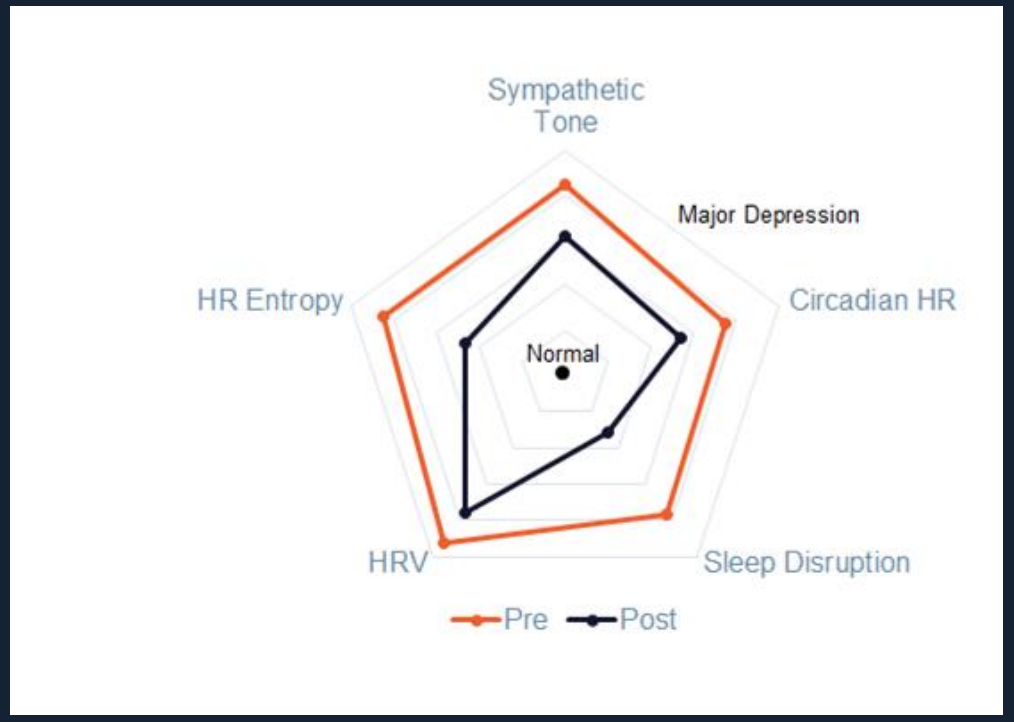
QUANTIFYING TREATMENT RESPONSE

Case Study 1

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



Biometrics normalize with effective treatment



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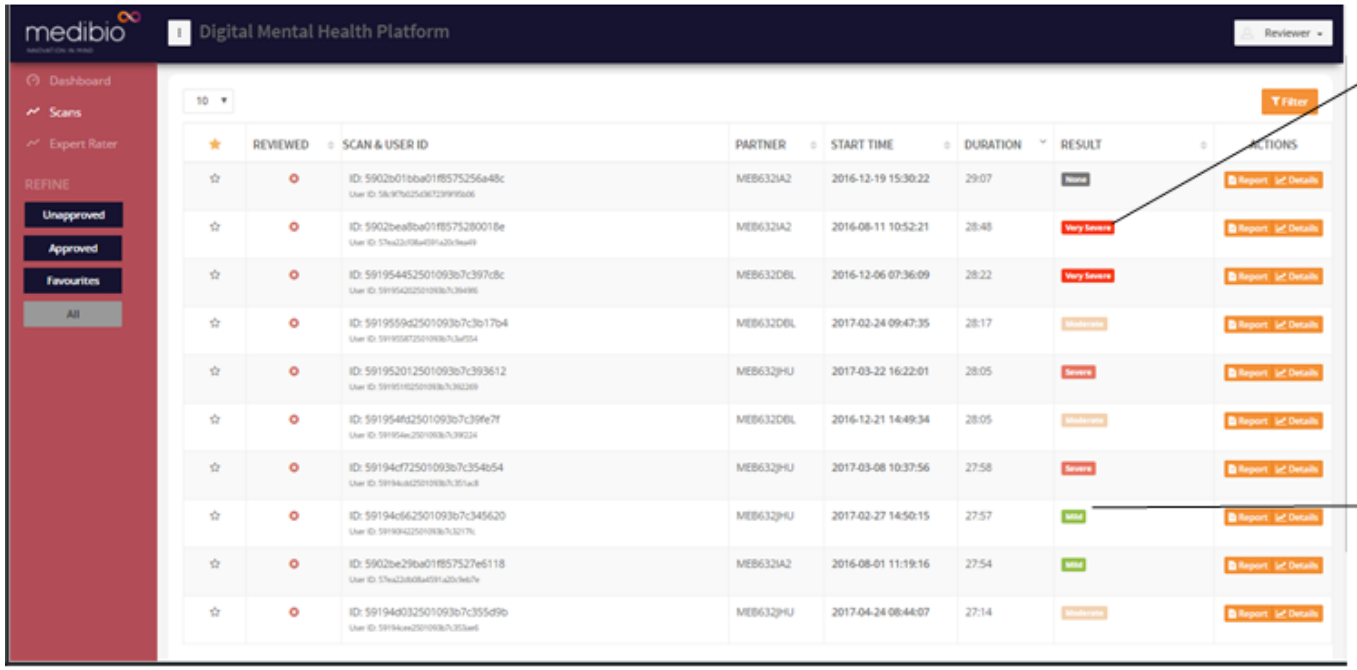
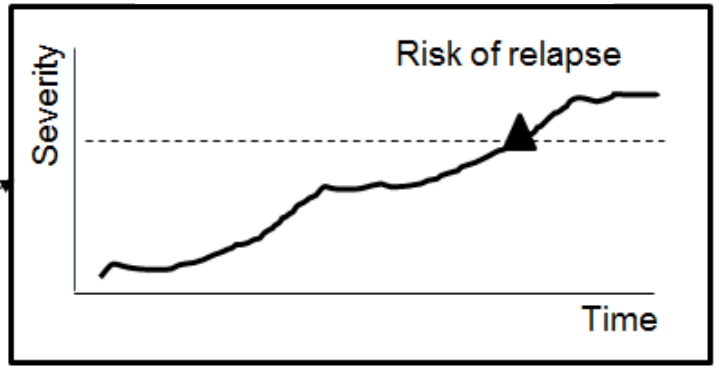
DATA-DRIVEN PATIENT MANAGEMENT

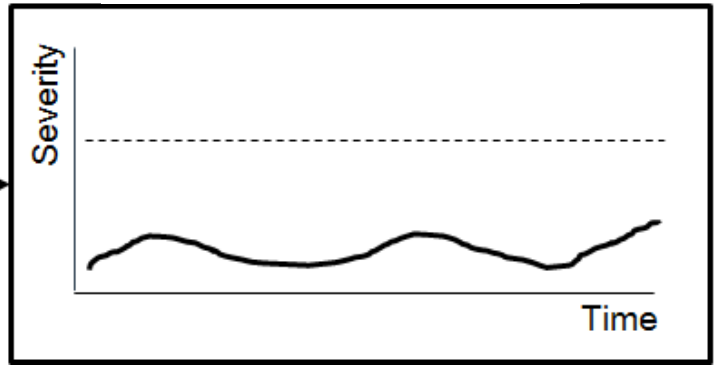
Patient Panel Enables Early Identification of At-Risk Patients



Patient Disease Progression



Stable Patient on Treatment



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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: US Dept. Health

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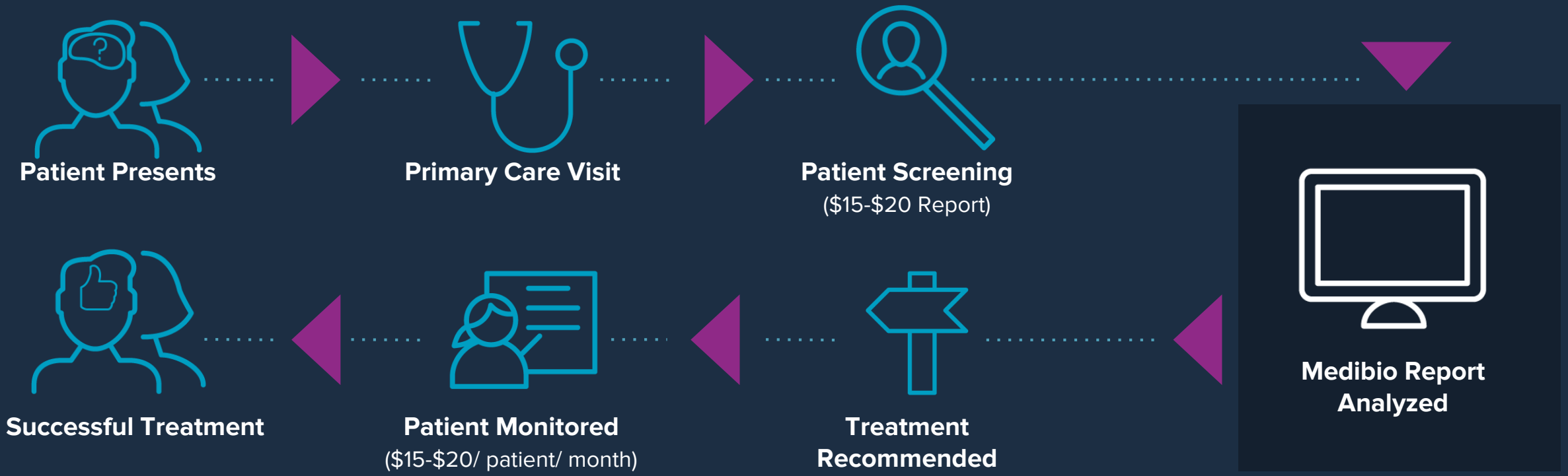
DESIGNED TO DELIVER PATIENT SUCCESS



REVENUE GENERATION OPPORTUNITIES

Report Generated
($15-$20 per report)

Patient Screening
(1-time GP visit)

Decision Support Tool
(Monthly Specialist visit)

Patient Management
(Pharma prescription management)

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.

	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.

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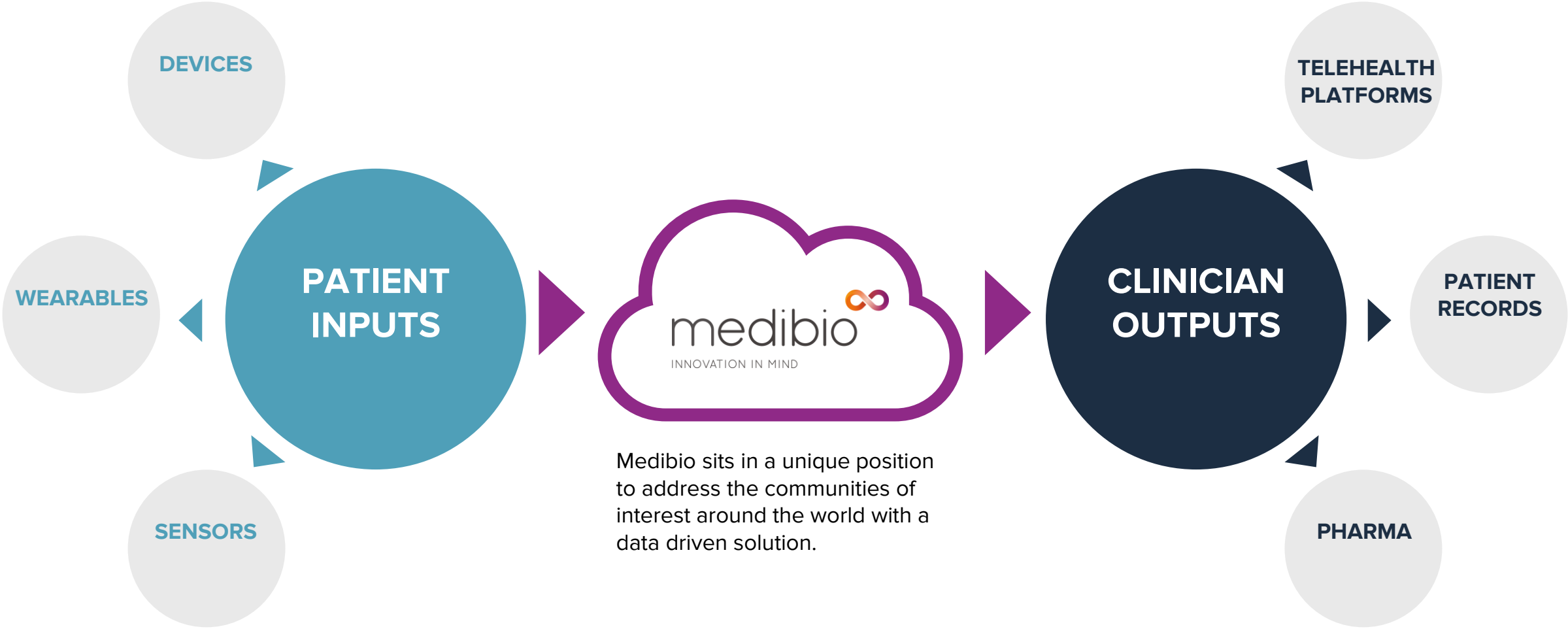
RECENT DIGITAL HEALTHCARE COMPANY EXITS

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

OUR ECOSYSTEM



Medibio sits in a unique position to address the communities of interest around the world with a data driven solution.

Medtronic

MAYO CLINIC

LifeQ

EMORY UNIVERSITY

JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTH SYSTEM

The Melbourne Clinic

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
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	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)	
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)	

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

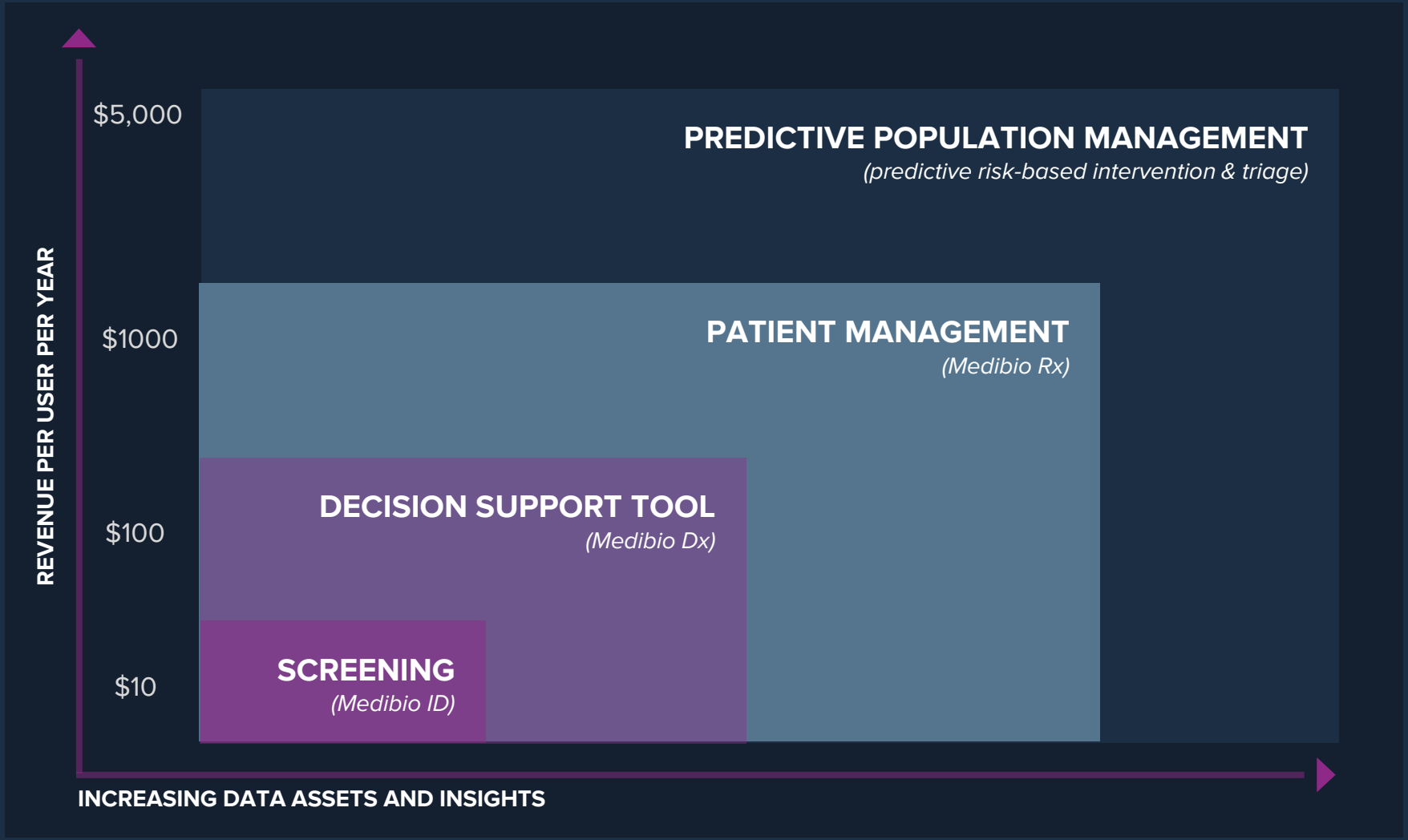
OVERVIEW OF COMPLEMENTARY/COMPETING TECHNOLOGIES

TECHNOLOGY	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIP COST	TEST COST
Medibio	*Autonomic Nervous Dysfunction, circadian and sleep biomarker-based test*	**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**

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
MEDIBIO DX-Unipolar/ Bipolar Differential Diagnosis			Q4 2017					MAYO
MEDIBIO RX-MDD Treatment			Q4 2017					MAYO
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. (1)
- Overall antidepressant market was valued at $USD 11.9 Billion in 2011. (2)

$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)

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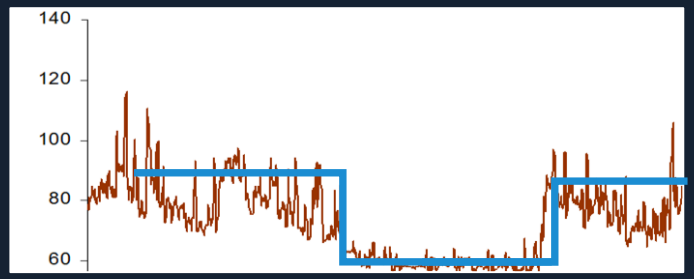
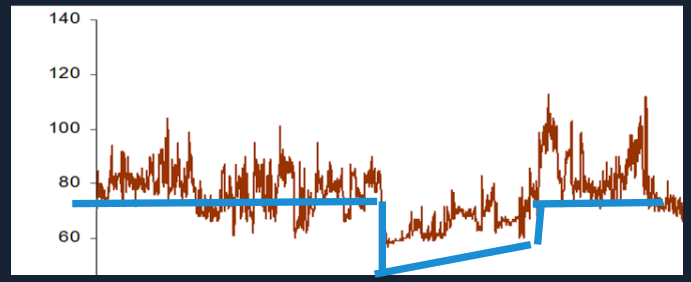
INSIGHTS BASED ON 15 YEARS OF CLINICAL RESEARCH

- 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.

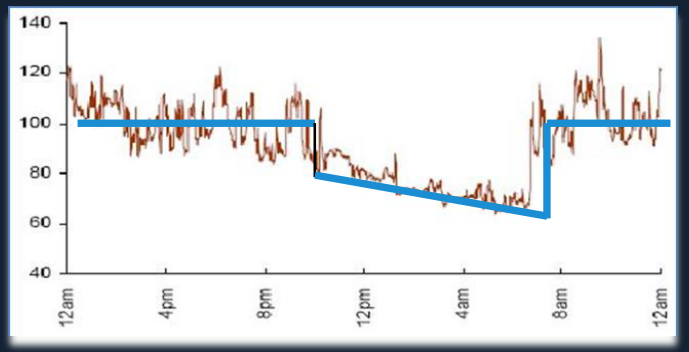
NORMAL



DEPRESSION



ANXIETY



24 hour heart-rate

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BIOMARKERS PROVIDE RICH CHARACTERIZATION OF MENTAL STATE

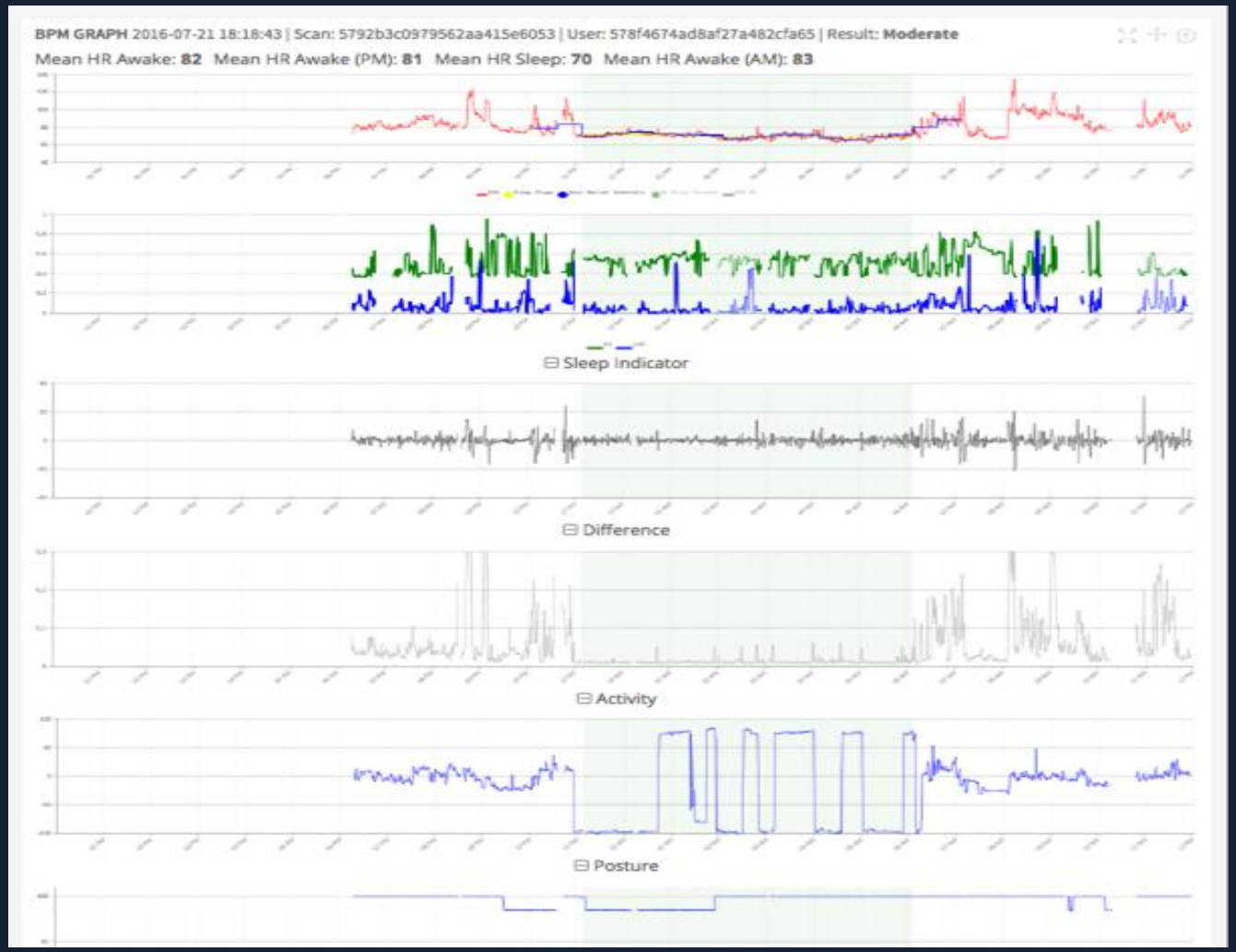
HEART-RATE

AUTONOMIC FUNCTION

ACTIVITY

SLEEP

CIRCADIAN PATTERNS



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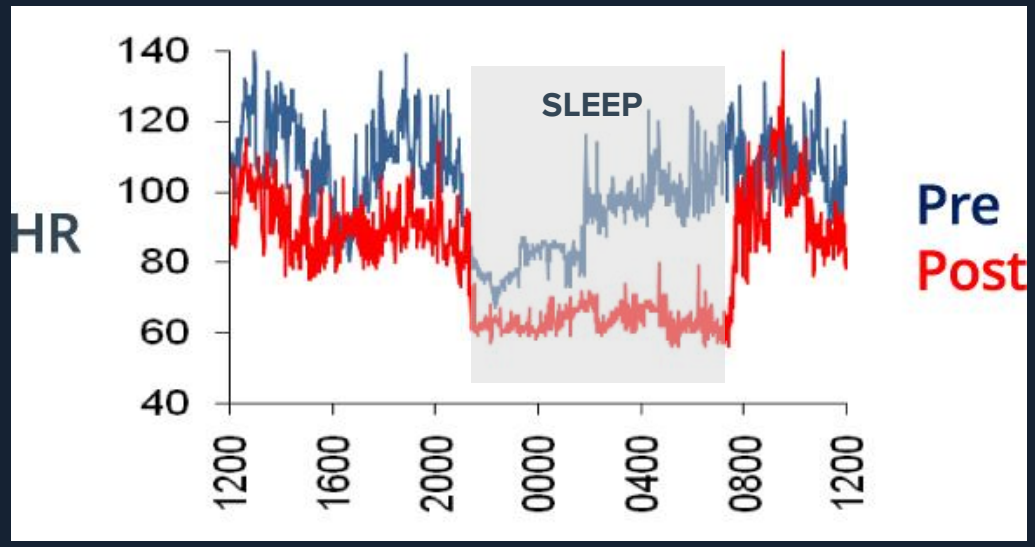
OBJECTIVE ASSESSMENT OF THERAPY EFFECTIVENESS

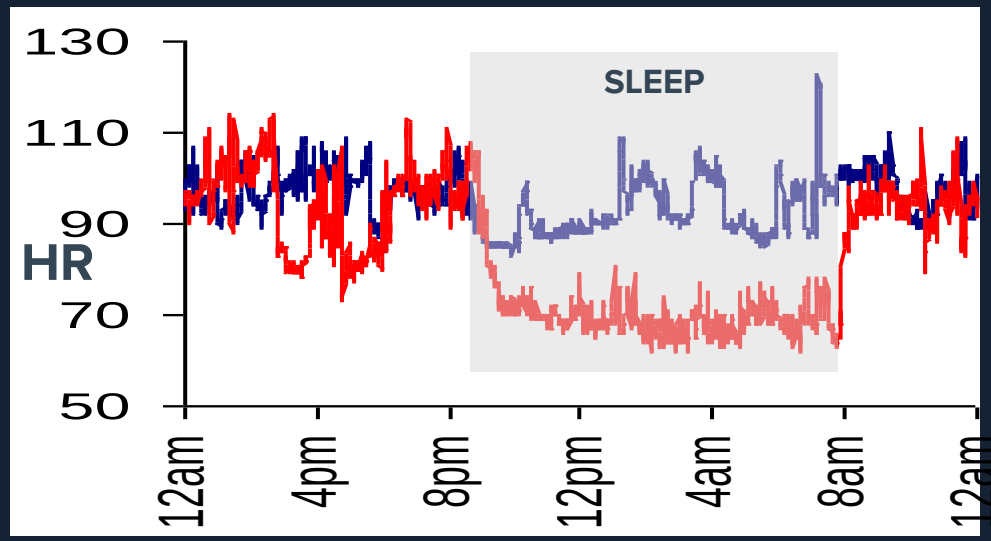
Case Study 1

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



Case Study 2

- Individual diagnosed with melancholic depression
- Series of 8 ECT treatments
- Much improved profile 2 weeks post ECT



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