

Overview Presentation

March 2017



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“Caring for the mind is as important and crucial as caring for the body. In fact, one cannot be healthy without the other.

*From the book “Approaching the Natural: a Health Manifesto” by Sid Garza-Hillman

Medibio will radically change mental health care delivery through objective, data-driven assessment & management.

Medibio Overview

Who are we?

Developers of the world's first objective test for the diagnosis of depression and other mental health disorders.

What are we doing?

On track to commercialise our platform technology, the Digital Mental Health Platform which is based on a patented biomarkers from the autonomic nervous system.

The problem

Depression is a global epidemic with insufficient psychiatrists, where GPs become the front liners for mental health diagnosis which is often inefficient

The solution

Medibio's technology will provide a diagnostic aid to assist GPs and mental health clinicians

Why invest in us?

- **Disruptive technology** – the potential to be the world's first objective test for the diagnosis of a largely intangible health epidemic
- **Targeting a large market** - Depression is estimated to cost US economy US\$210 billion a year with the cost in Australia estimated at \$12.6 billion annually.
- **Superior value proposition** – Quick, objective and non-intrusive method which enables early identification, confirms treatment efficacy and enables data-driven patient management
- **Validation studies with leading researchers in the industry** - Johns Hopkins, Mayo Clinic, Emory University, Ottawa University, BMRI
- **Global partnerships with notable players in the market:** Medtronic, Preventice, Zephyr Biopatch, and currently rolling out our Corporate Stress Product with Wellness Channel partners.
- **Patent protected technology** – based on 15 years of research
- **Regulatory approvals underway** – Plans to file for FDA approval and CE Mark approval

Corporate Snapshot

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ASX TICKER	MEB
Shares on Issue	148.5M
Warrants (\$0.10 – Expire April 2018)	9M
Warrants (\$0.30-\$0.80)	18.8M
Last Trading Price	\$0.35
Valuation (Existing Capital)	\$54.0M
Milestone Shares (to Inventors)	20M
Performance Rights (Key Management vest over 3 yrs.)	13M
VALUATION (FULLY DILUTED)	\$65.5M

Available Cash – \$11M (includes \$3M R&D Rebate in Sept 17)

Strategic plan funded into 2019

Top 10 Shareholders

1. Fidelity
2. Dr Stephen Robert Desmond Addis
3. Mr Claude Solitario
4. Mr Kris Knauer
5. Regal Funds Management
6. L1 Holdings
7. Paragon Funds Management
8. Metavone Ltd
9. Thorney Investment Group
10. Mr Josh Slattery

Acceleration in 2017: Revamped Strategy, Team & Focus

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- Newly appointed, highly experienced med-tech executives team to drive new phase of business
- Cohesive product strategy implemented to address serious clinical pain-points with a robust product roadmap
- Optimized development and regulatory pathway combining valuable retrospective data assets and prospective studies
- Investment in extending world-class algorithm and data science capability

"The Single Greatest Illness that Affects Mankind" *

- 350 Million People With Depression
- Leading cause of disability in US

\$2.5T global cost of mental illness in 2010 (\$6T in 2030) "WHO"

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"The USPSTF recommends screening for depression in the general adult population."

US Preventative Services Task Force – Jan 2016

\$94.5B

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

26%

of adults in the USA

7.8

psychiatrists per 100,000 people in the USA

27%

of adults in Europe

1.5

psychiatrists per 100,000 people in China

\$12.6B

Direct cost to treat Depression annually in Australia

0.3

psychiatrists per 100,000 people in India

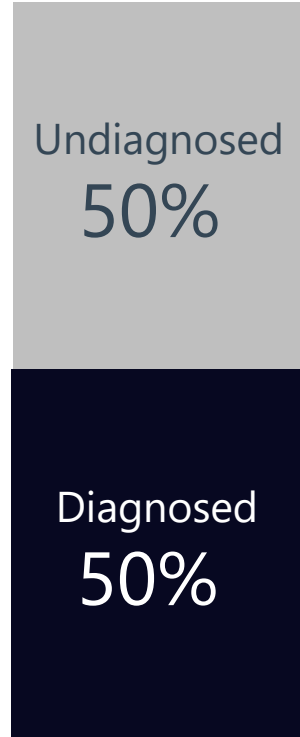
References

- 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](#)

Huge Misallocation of Resources Due to Poor Decision Support

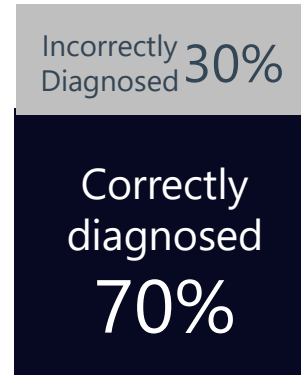
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There are
350 million
depressed
people
worldwide



(Barbui, 2006)

SCREENING



(Angst, 2011)

DIAGNOSIS

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



(Gonzalez, 2010)

TREATMENT

→ 7% of total on optimal treatment

The Need for Objectivity Over Subjectivity

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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 aid 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%.

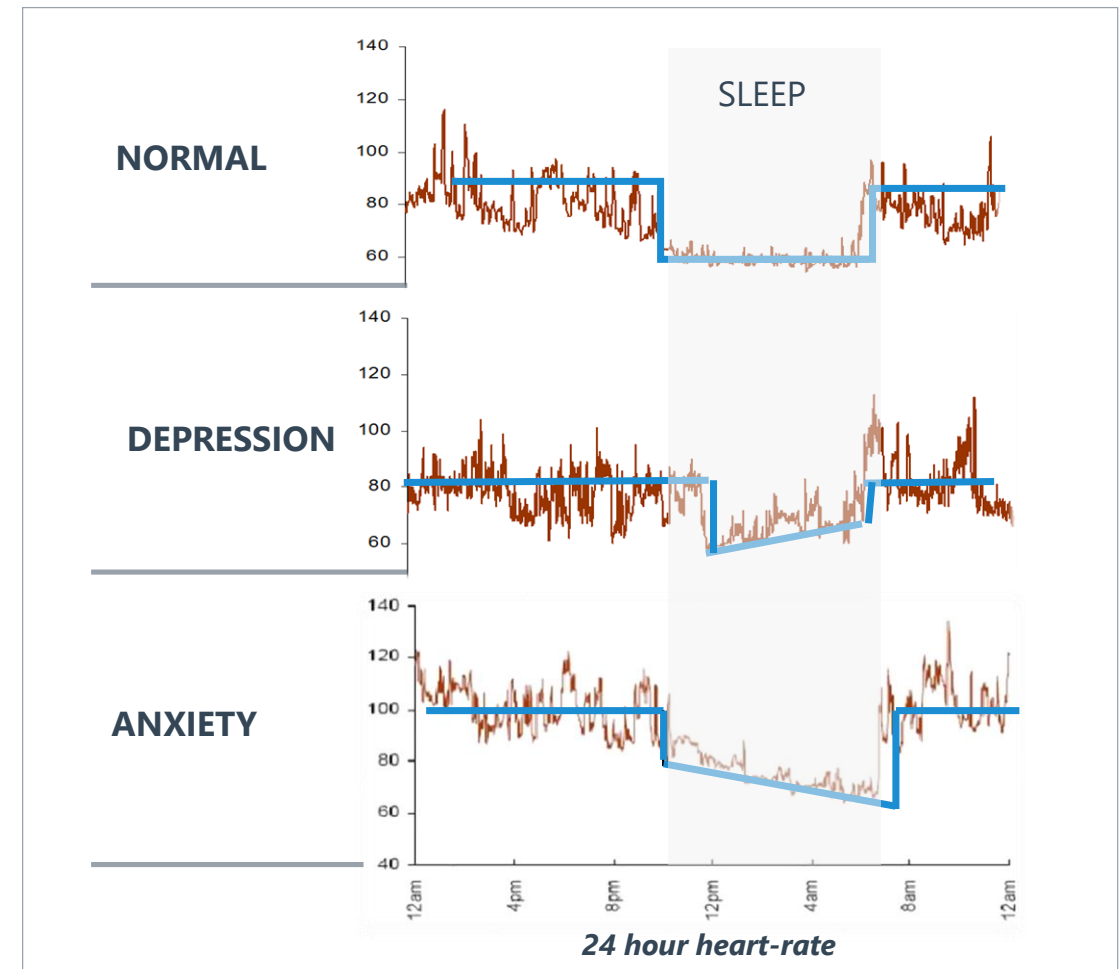
Provides **objective indication of treatment efficacy** enabling reduced time to optimal treatment

Scientific & Clinical Foundation

Insights Based on 15 years of Clinical Research

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- 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.



Significant Validation Supporting Technology

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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

Defensible Position Based on IP and Data Assets

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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

Clinical & Regulatory

Clinical Demand for Medibio Solution

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Voice of Customer Study Key Findings

- Majority (91%) of clinicians are likely to consider using the device as a diagnostic aid
- Majority (82%) of clinicians would use the device to monitor effectiveness of therapy
- Majority (63%) would use the device to monitor patients every 1-3 months
- Primary care physicians (PCP) and psychiatrists are likely first users as they are more likely to see patients first before referring them to therapists

Opinion Leader Comments

"I see tremendous value in a tool to help diagnose depression in the real-world population, where mixed and overlapping conditions are the norm."

- Mark Frye MD, Mayo Clinic

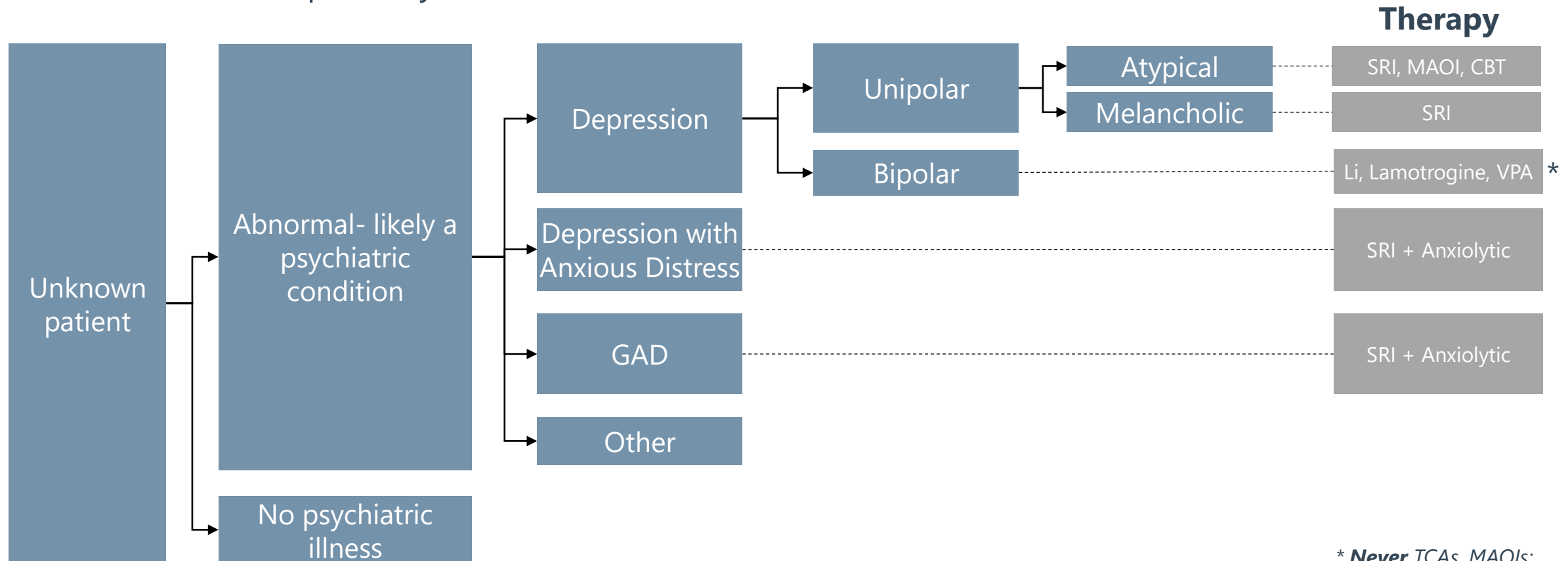
"What would be helpful for clinicians is a biomarker test with results that would convert to those seen in a normal control as the patient improves or, even better, convert before the changes are clinically noticeable in the depressed patient."

- Anthony Rothschild MD, UMass

Speed and Accuracy of Diagnosis will Improve Treatment



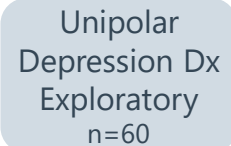
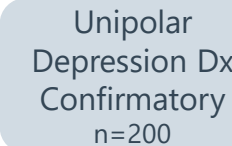


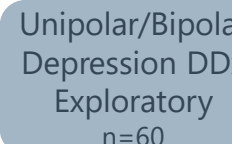
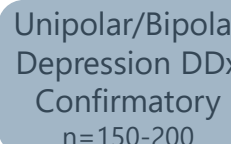



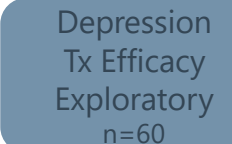
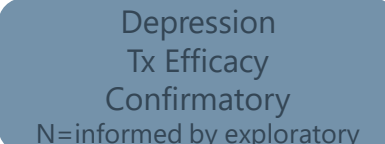



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Precise diagnosis is key to clinical and health-economic outcomes, especially when linked to different treatment pathways



* **Never** TCAs, MAOIs;
caution SRIs -> mania

Clinical and Regulatory Timelines for First Clinical Indication

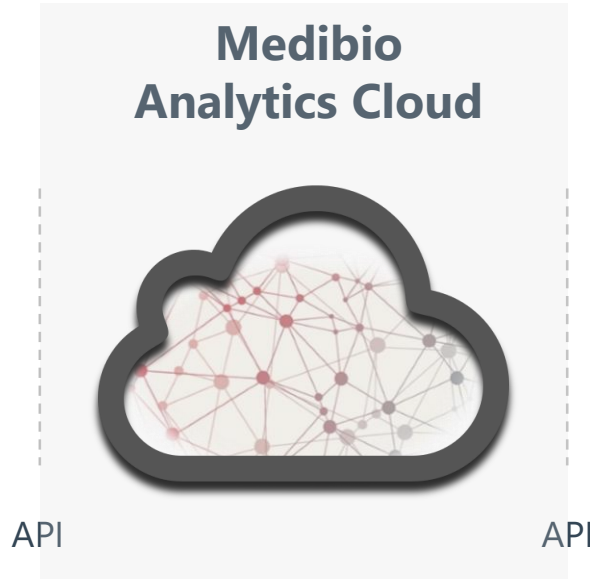
	2017	2018	2019	2020
Platform & Depression Screening	Platform Refinement & Validation with Existing Dataset	 CE Mark Certification  EU Market Testing		
Unipolar Depression Diagnosis	 Unipolar Depression Dx Exploratory n=60  Unipolar Depression Dx Confirmatory n=200	 510(k) Submission  US Launch		
Depression Differential Diagnosis	 Unipolar/Bipolar Depression DDx Exploratory n=60	 Unipolar/Bipolar Depression DDx Confirmatory n=150-200  CE & 510k filings	 Expanded product claims	 Reimbursement CPT Code
Depression Treatment Efficacy	 Depression Tx Efficacy Exploratory n=60	 Depression Tx Efficacy Confirmatory N=informed by exploratory  CE & 510k filings	 Expanded Product claims	 Reimbursement CPT Code

Platform & Product Roadmap

Medibio's Digital Mental Health Platform

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**Physiological Data (ECG, EEG, actigraphy)
(Device agnostic approach)**



**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

Biomarkers Provide Rich Characterization of Mental State

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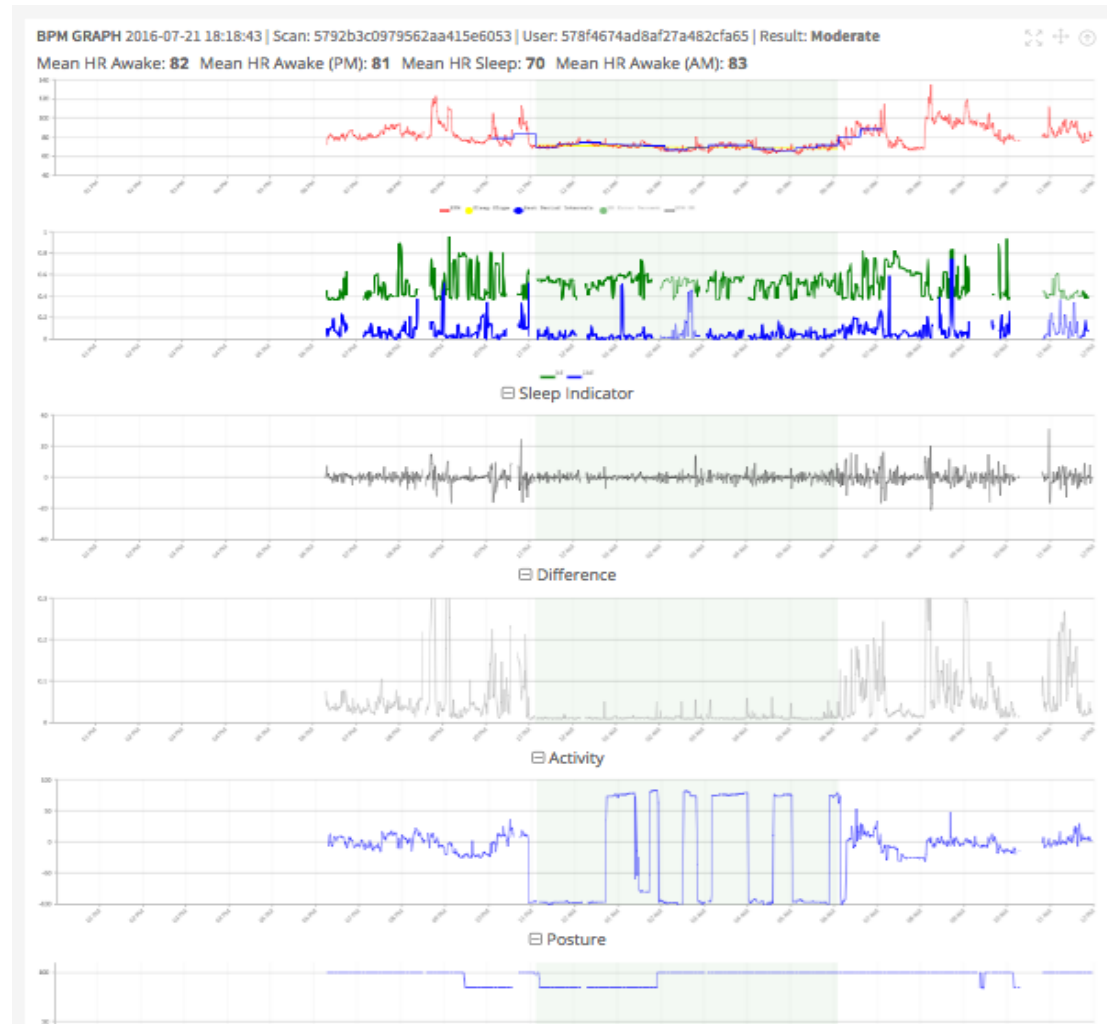
Heart-rate

Autonomic Function

Activity

Sleep

Circadian Patterns



Comprehensive Offering to Address Clinical Needs

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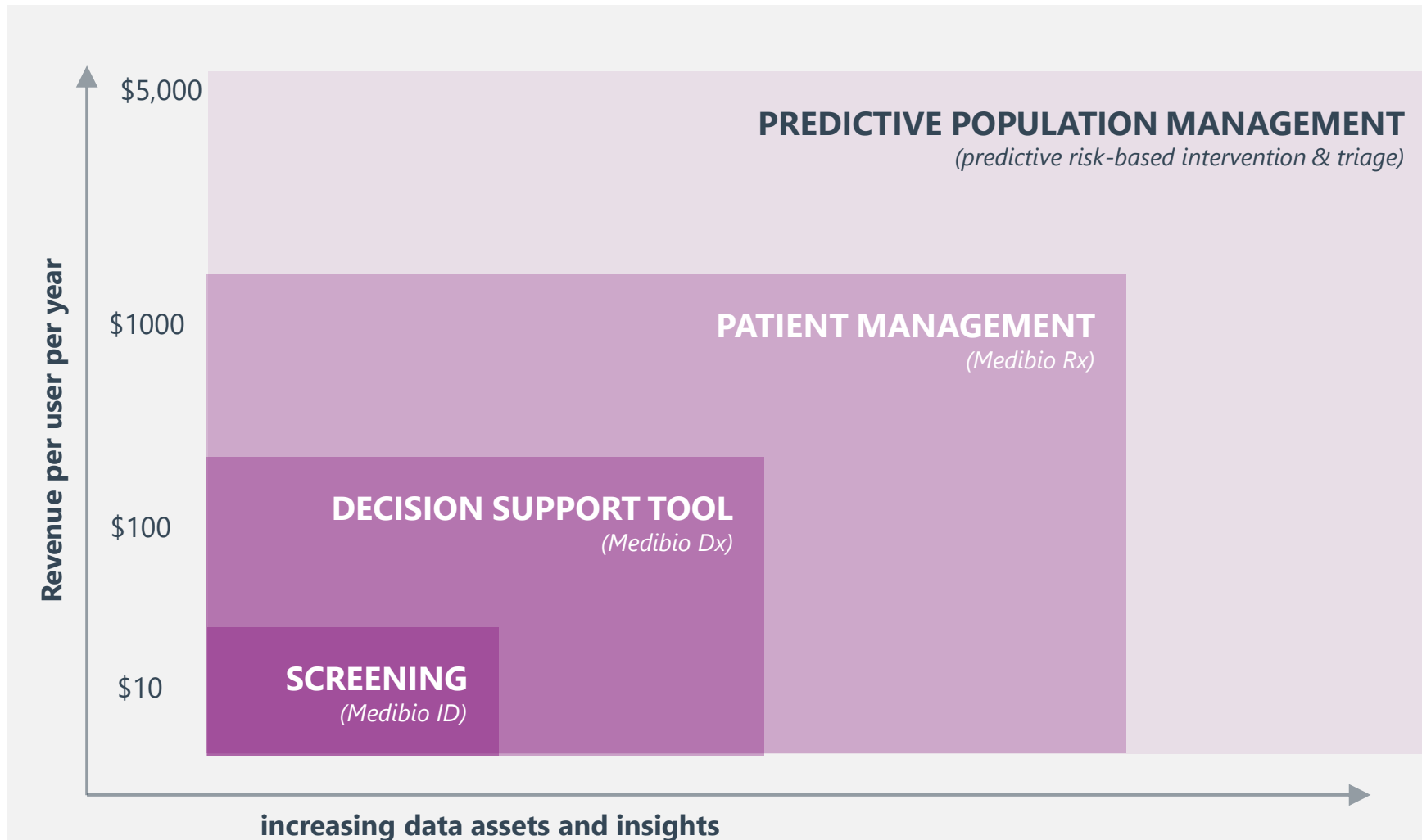
	Early Detection	Accurate Diagnosis	Right Drug
Product	Medibio-ID	Medibio-DX	Medibio-RX
Value Proposition	Detection of individuals likely to have a psychiatric condition in the broad population	Objective biomarkers used to guide diagnosis of psychiatric conditions (MDD, Bipolar, GAD)	Confirmation of therapy effectiveness to drive drug selection and titration
Use-case	Leverages longitudinal data from available wearable devices	Leverages clinical-quality data from available medical devices over 1-3	Leverages clinical-quality data from available medical devices episodically used over a period of 6 weeks
Regulatory Timelines	CE-mark of platform Q4,2017	FDA approval in H2, 2018 for MDD with subsequent clinical areas to follow	FDA approval in H1, 2019 for MDD treatments

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

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- 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

5 Year Targets & Near-Term Milestones

Medibio's Journey to Commercialization

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Technology Validation Phase 2016

- Development of analytics infrastructure and platform
- Leverage large retrospective datasets to validate technical approach

Clin/Reg Validation Phase 2017-2018

- ISO 13485:2016
- Development of Internal Systems and Process
- CE Mark – Q4, 2017
- FDA Clearance

Customer Validation Phase 2017-2018

- Marketed system use and VOC
- Strategic Partnerships
- HEOR and coding

Global Commercialization 2019

- ROW Plan
- Go-to market Partnerships
- US Launch

5-Year Strategic Targets

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	1 year – end 2017	3 year - 2020	5 year - 2022
Product use	100 patients (pilot)	10,000 patients	100,000 patients
Product attributes	<ul style="list-style-type: none"> • Identification of high-risk individuals • Characterization of circadian, autonomic & sleep biomarkers • Classification of MDD vs normal 	<ul style="list-style-type: none"> • Differential diagnostics for normal, MDD (unipolar, bipolar), GAD and mixed GAD/MDD. • Confirmation of therapy effectiveness • Screening within integrated payer/providers 	<ul style="list-style-type: none"> • Addition of PTSD, schizophrenia & bipolar clinical indications
Reimbursement	n/a	<ul style="list-style-type: none"> • Depression. Stretch goal: Diff Depression & therapy (likely 2021) 	<ul style="list-style-type: none"> • PTSD, bipolar, schizophrenia
Regulatory	<ul style="list-style-type: none"> • CE mark for platform • CE mark for MDD classification 	<ul style="list-style-type: none"> • FDA - MDD v normal & GAD • FDA - Diff Depression • FDA - Therapy effectiveness 	<ul style="list-style-type: none"> • FDA for PTSD • FDA for schizophrenia • FDA for Bipolar
Clinical	<ul style="list-style-type: none"> • FDA confirmatory for MDD completed • Differential diagnosis & treatment response exploratory completed 	<ul style="list-style-type: none"> • Registry for HEOR and reimbursement • Confirmatory studies completed for Diff Dx and therapy effectiveness 	<ul style="list-style-type: none"> • Expanded registry and HEOR
Partnerships	<ul style="list-style-type: none"> • Collaboration with Pharma partner • Device partner/s secured 	<ul style="list-style-type: none"> • Therapy partner secured (pharm, CBT) • Pharma partnerships secured 	<ul style="list-style-type: none"> • Telehealth partner in private & government

Key Company Milestones - 2017

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TIMING	MILESTONE	STATUS
Q4 2016	Pilot Study Validation results – 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)	
	Agreement with FDA on subject numbers required for depression confirmatory study	
Q3, 2017	Commencement of Confirmatory Study to provide data for FDA Submission (n = 200)	
	Publishing of Peer-reviewed paper – University of Ottawa (Major Depressive)	
	Publishing of John Hopkins University Validation 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

Experienced Leadership Team

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MANAGEMENT



Jack Cosentino
CEO/Managing Director
(US based)

20 years medical technology experience as CEO and senior management including Medtronic and most recently Impedimed



Yashar Behzadi PhD
Chief Product Officer
(Based in Silicon Valley)

Led the development of Proteus Digital Health's ingestible & 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

BOARD



Chris Indermaur
Chairman

Over 30 years of experience in Engineering, Business Development and Commercial roles. Previously the General Manager of Strategy and Development at Alinta Ltd



Kris Knauer
Director

A key shareholder of the Company. A consultant to Medibio in the due diligence process, and provides corporate and strategic advice



Dr Franklyn
Prendergast
Head Advisory Board
(US based)

Current Director of Eli Lilly and Company and Past Chair of the Board of Governors of the Mayo Foundation



Andrew Maxwell
Director

Medical device expert. Commercialised a research project emanating from the Florey Institute of Neuroscience and Mental Health and created a global medical device company

Overview of Competing Technologies

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TECHNOLOGY	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIPMENT COST	TEST COST
Medibio	Autonomic, 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 specially 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

Cost Savings Drives Payer Adoption

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Typical MDD Patient Journey  Years to Proper Treatment

Developing Condition	Undiagnosed Condition	Diagnosis	Treatment Titration	Management
Variable	3-6 months	3-6 months over multiple doctor visits	3-6 months over multiple doctor visits Average of 4 antidepressants	Episodic doctor visit every 3-6 months



Digital Mental Health  Continuous & Real-time

Monitoring & Diagnosis	Treatment Titration	Management
Continuous feedback & diagnosis	Remote, daily feedback on drug effectiveness	Continuous feedback & management / data-based doctor visits

\$6,000/yr.



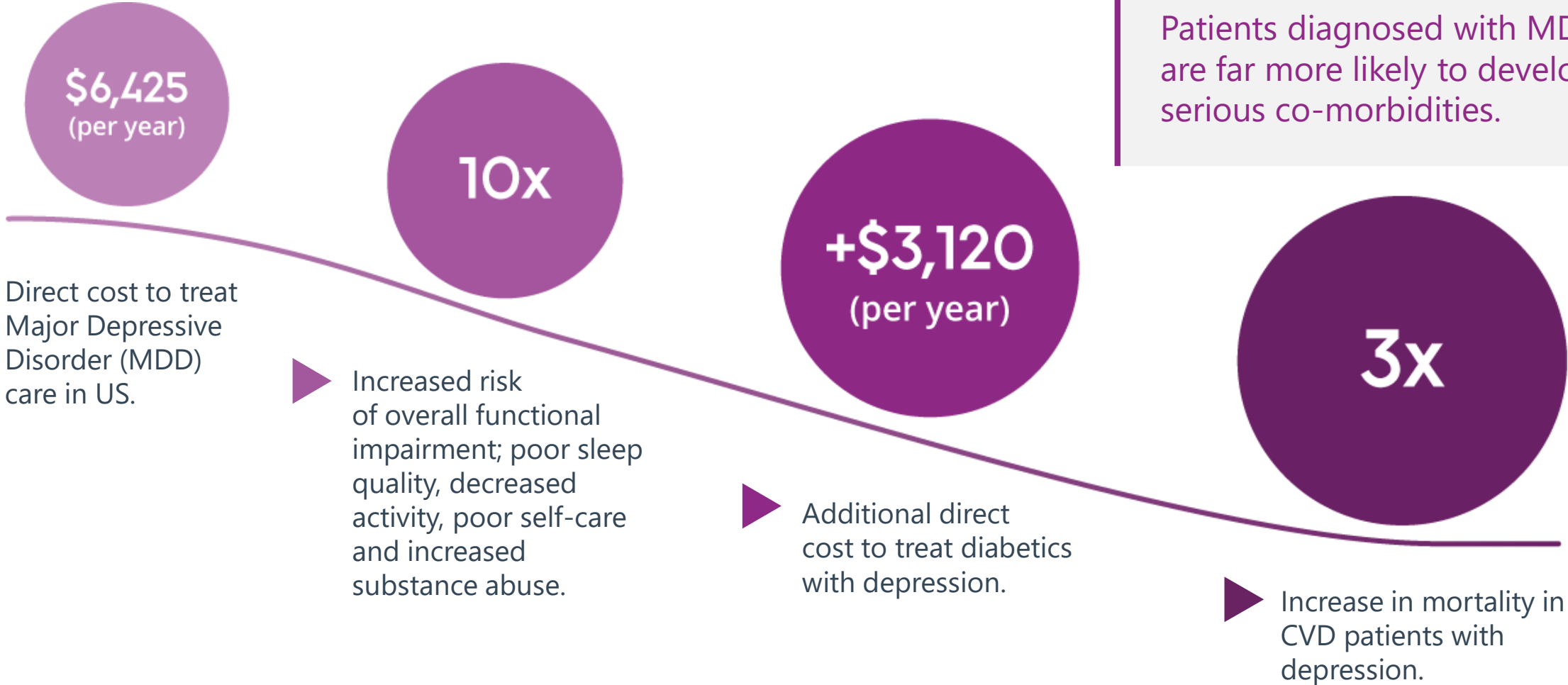
\$3,000/yr.

50% cost saving in annual direct costs between managed and unmanaged depression.

The Clinical & Economic “Snowball Effect” of Depression

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Patients diagnosed with MDD are far more likely to develop serious co-morbidities.

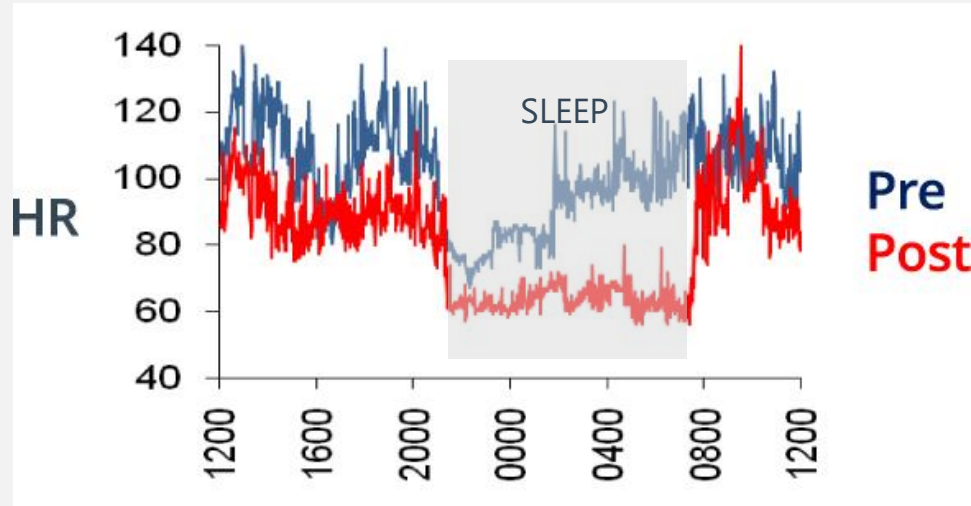


Objective Assessment of Therapy Effectiveness

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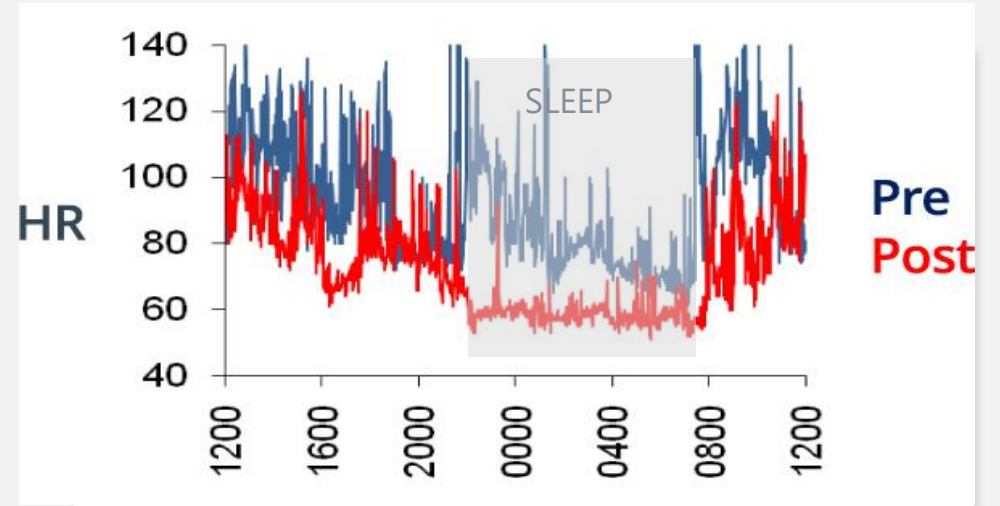
Case Study 1

- 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



Voice of Customer Survey

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Key Findings

- Majority (91%) of clinicians are likely to consider using the device as a supportive diagnostic tool.
- Primary care physicians (PCP) and psychiatrists are likely first users as they are more likely to see patients first before referring them to therapists.
- Primary care physicians are also more likely to be largest users for this device as a diagnostic tool followed closely by psychiatrists/CNS as most patients with mental health issues are likely to meet a PCP/psychiatrist or CNS before referral to a therapist
- Majority (82%) of clinicians would use the device to monitor effectiveness of therapy
 - 63% of the clinicians surveyed would use the device for monitoring patients every 1 – 3 months
 - 18% would use it at least once every 4 – 6 months

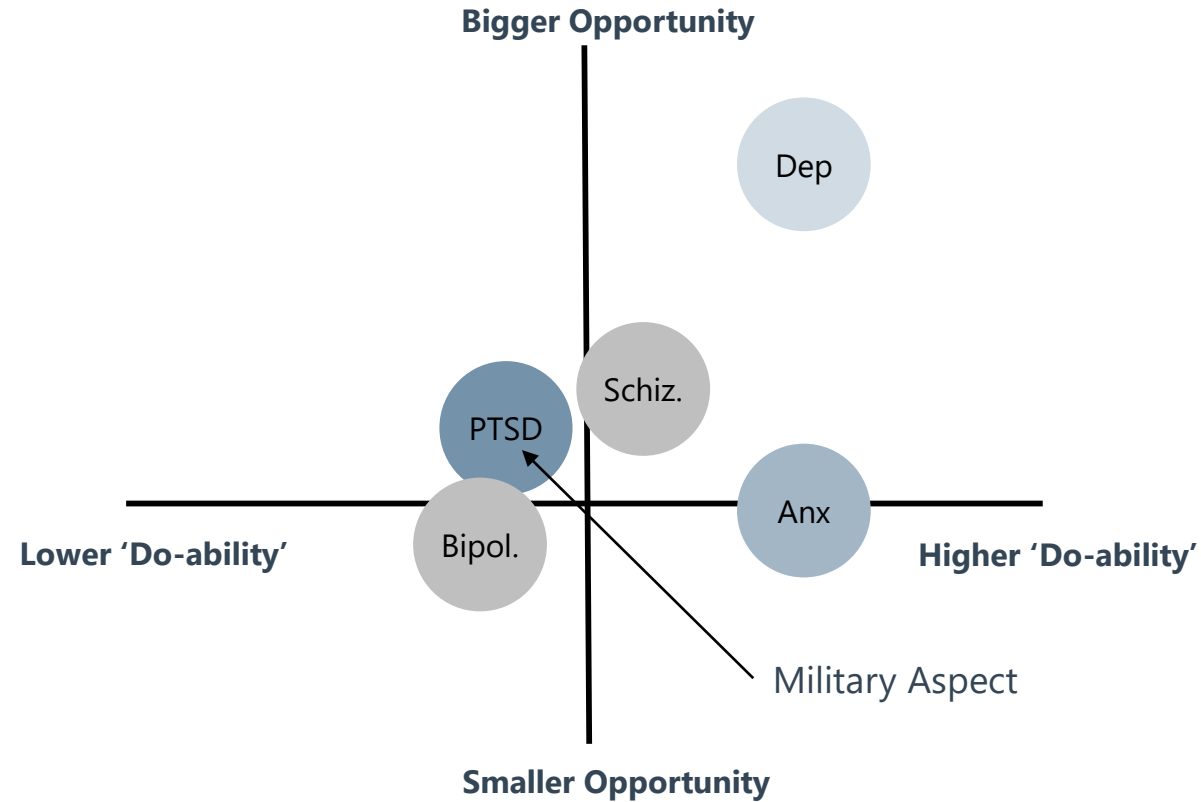
Factors influencing decision to use

- Insurance coverage (reimbursement) was the most significant factor influencing clinicians' decision to use the device
- Ease of use, price and clinical evidence were the next most important factors influencing use
- Diagnostic accuracy, reliability and validity of the device also ranked high in the clinical use decision
- Other factors included availability / accessibility of diagnostic procedure, client consent, comfort and compliance and ease of ordering diagnostic test

Opportunity by Disease

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Disease	US 12-month Prevalence	US # Affected	US Cost Per Year
Depression	6.7%	15.7M	\$210B (total) <i>Greenberg, 2015</i>
Anxiety	3.1%	7.3M	\$42B (total) <i>Greenberg, 1999</i>
PTSD	3.5%	8.2M	\$48B <i>extrapolate data from VHA study, 2012</i>
Bipolar	2.6%	6.1M	\$24-45B (total) <i>Kleinman, 2003</i>
Schizophrenia	1.1%	2.6M	\$63B (total) <i>Wu, 2005</i>



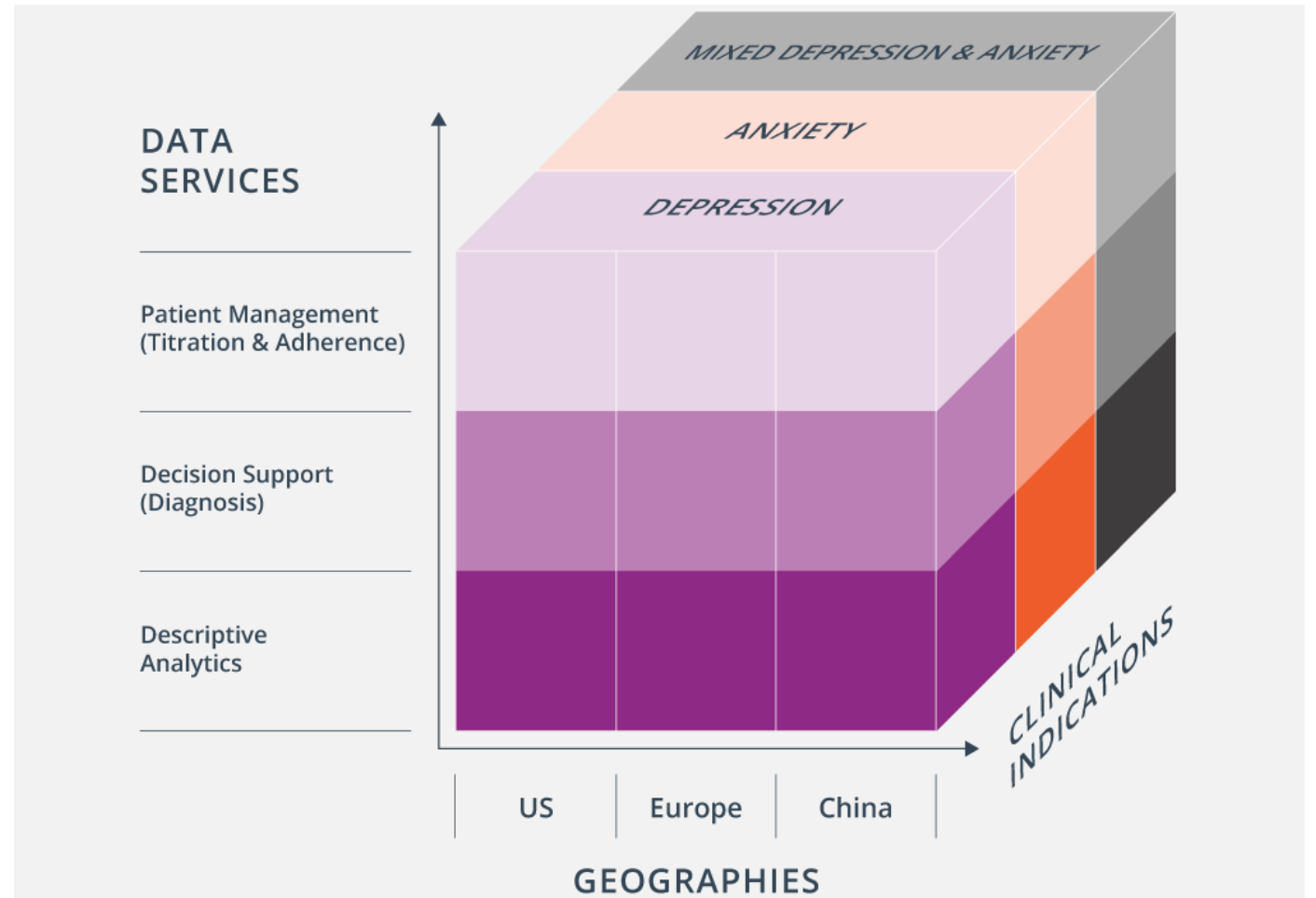
'Do-ability' = $f(\text{ease of evidence building, patient characteristics})$

Opportunity = $f(\text{TAM, societal/payer economic impact})$

Highly Scalable Unit Economic Model

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- Ability to step into adjacent and new clinical indications
- Higher value extracted over time through data services at marginal increased cost of acquisition
- Comprehensive suite of mental health services over time



Solving Significant Problems for Pharma

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\$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.

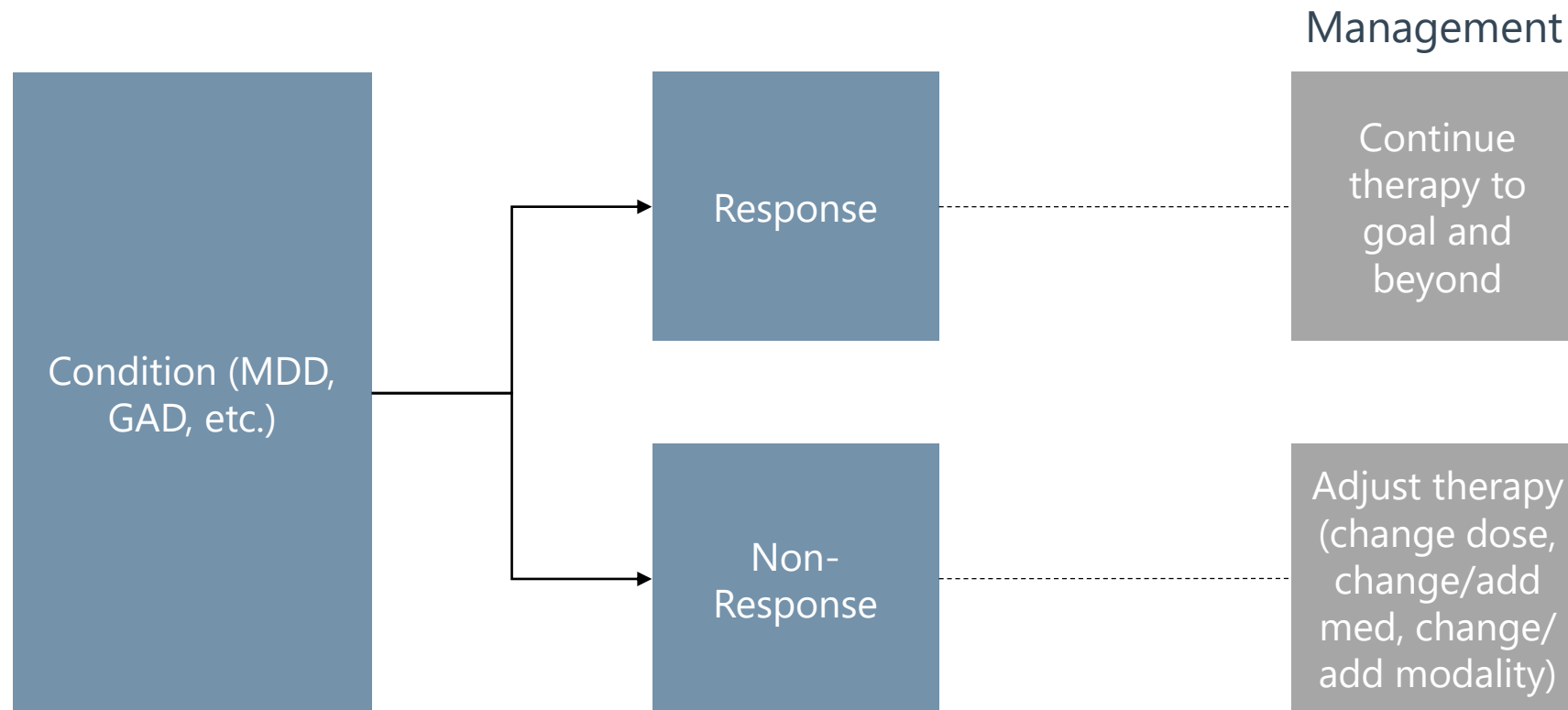
(1) *Antidepressants and the Placebo Effect* – Kirsch I (*Z Psychol.* 2014; 222(3): 128–134.)

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

Timing is Critical to Improving Treatment Outcomes

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- Monitoring response to therapy is key to clinical and health-economic outcomes, since proper therapy should lead to faster attainment of the therapeutic goal, reduced complications, and reduced iatrogenesis (serial measurements)



Current Exploratory Study with Johns Hopkins University

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Study Objective

- To validate the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals
- Designed to provide data to power the confirmatory phase of the study which will support FDA certification of Medibio's proprietary depression test

Study Description

- Powered to only need 60 participants from the primary care setting
- 30 subjects with MDD, 30 Normal Controls

Current Status

- Completion of data collection imminent
- Data from the initial 30 participants has been reviewed

Principal Investigators

Dr Naresh Punjabi

Professor of Medicine and Epidemiology at JHU. Published more than 100 research papers.

Dr Francis M. Mondimore, M.D.

Associate Professor in the Department of Psychiatry and Behavioral Sciences and Director of the Mood Disorders Clinic, where he leads a team of clinicians specializing in the care of persons with mood disorders.



Dr Naresh Punjabi



Dr Frank Mondimore

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