

INNOVATION IN MIND

# Investor Presentation

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### We believe individuals, families and carers affected by mental health can live full, happy & healthy lives.

Redefining mental health by making the intangible, tangible.



## **Company Summary**

- Medibio's mission is to transform the assessment and management of mental health through the application of advanced AI
- Defensible IP/technology based on 15 years of research into the relationship between the autonomic nervous system and mental health
- Support of notable research partners: Johns Hopkins University, Mayo Clinic, Emory University, Ottawa University, BMRI
- World's largest database of ECG data with corresponding mental health assessment driving new insights and clinical indications
- Endorsement from corporate partners: Medtronic, Preventice, others
- Multiple commercialisation routes: Clinical, Pharma, B2B and B2C represent multi-billion dollar market opportunities

"The economic costs of mental illness will be more than cancer, diabetes, and respiratory ailments put together."

> Dr Thomas Insel, MD, the former Director of the US National Institute of Mental Health)

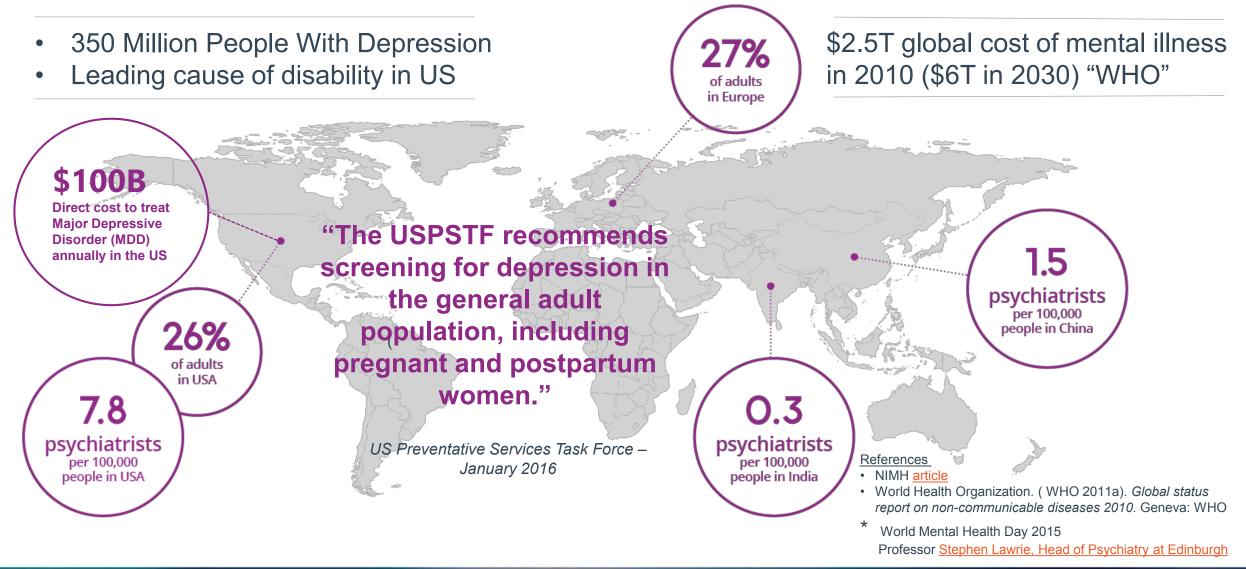


## **Key Executives**

	Kris Knauer Chief Executive Officer	<ul> <li>20 years experience in Finance and Corporate Advisory</li> <li>Experienced CEO of ASX Listed companies</li> <li>Previous role as CEO in a group owning GP Centers and Radiology practices</li> <li>Founded and grew ASX Listed company from sub \$3 million valuation to \$300 million valuation prior to a \$1bn takeover</li> </ul>
Contraction of the second seco	Sean Mathieson Chief Operating Officer	<ul> <li>Business Technology Executive with 25 years of Global Business Software experience</li> <li>Reputation for Technology Vision enabling Business Outcomes</li> <li>Global Leadership Team of Siebel Systems, Founding Member of SAP Asia/Pacific, Founding Member of Ariba Asia/Pacific</li> <li>Experience in start-up through multi-billion valuations</li> </ul>
-	Yashar Behzadi, PhD <b>Head of US Operations</b> (Based in Silicon Valley)	<ul> <li>Digital Health expert with 10 years experience building disruptive technology platforms and business models</li> <li>Previously head of product, applications and data sciences at Proteus Digital Health, a health-tech unicorn</li> <li>20 issued patents across medical device, wearables, software &amp; algorithms</li> <li>Technology advisory board member at Accenture</li> </ul>
	Greg Moon MD MBA Head of Clinical Affairs (Based in Silicon Valley)	<ul> <li>Digital Health expert with 15 years of experience in managing Clinical Affairs</li> <li>Led the commercial launch of Proteus Digital Health's first digital medicine solution in the US market</li> <li>Gained Proteus' first FDA clearance (Proteus Personal Monitor)</li> <li>Represented Proteus on the World Economic Forum's Workplace Wellness Alliance (WWA) leadership board</li> </ul>
	Dr Franklyn Prendergast <b>Board Member</b> (US based)	<ul> <li>Current Director of Eli Lilly and Company and Past Chair of the Board of Governors of the Mayo Foundation</li> <li>Past Chair, Department of Biochemistry and Molecular Biology, Mayo Foundation</li> <li>Guggenheim Professor of Biochemistry and Molecular Biology, Mayo Medical School (retired-January 2015)</li> <li>Past Director, Mayo Clinic Centre for Individualized Medicine and Mayo Clinic Comprehensive Cancer Centre</li> </ul>



# "The Single Greatest Illness that Affects Mankind" \*





### **Snowball Effect of Depression**



medibio

# The Need for Objectivity and Scalability

"It is critical to realise that we cannot succeed if we use DSM categories as the gold standard. We need a quantitative method for diagnosing depression." (U.S. National Institute of

Mental Health - 2013)

### **Current Pain Points**

- No objective test for mental illness.
- The standard of care is a clinical/expert opinion which has limited access and availability
- Diagnostic agreement between clinicians can vary considerably concordance rates near 70%.
- Current assessments are subjective which can lead to inadequate or incorrect diagnosis.
- Misdiagnosis of depression (and other mental illness) places a huge cost burden on the healthcare system and the workplace.

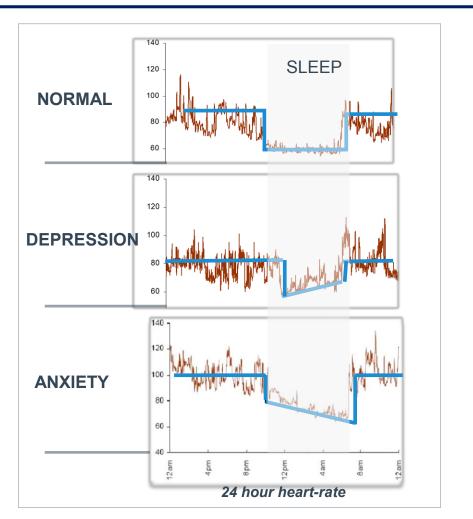
### Medibio's Solution

- Quantitative, scalable, and non-invasive objective test.
- Diagnosis based on patient's biometric data (circadian heart rate waveform).
- Repeatable, reliable test with classification accuracy of >80%.
- Provides objective indication of treatment efficacy along with medication compliance and adherence.
- Savings to the health system and better patient outcomes.



# **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 linked ANS disturbance could be observed via the cardiovascular system.
- Mental state-linked ANS disturbance is observed via the cardiovascular system during sleep when external influences are absent.
- Morphologic analysis of circadian heart rate waveforms (CHR) gives objective indications of 'core' physiological differences between different forms of mental illness such as anxiety, depression, and stress.
- Distinctly different patterns are evident during sleep when confounding influences on heart rate are minimal
- All serious mental illness (SMI) are associated with ANS and wider neuroendocrine dysregulation (especially affective disorders) and abnormalities in circadian regulation.
- Effective treatment is indicated by normalisation of CHR

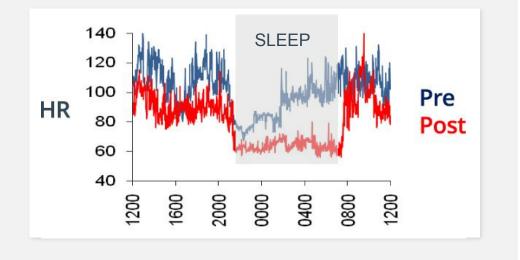




### **Objective Assessment of Therapy Effectiveness**

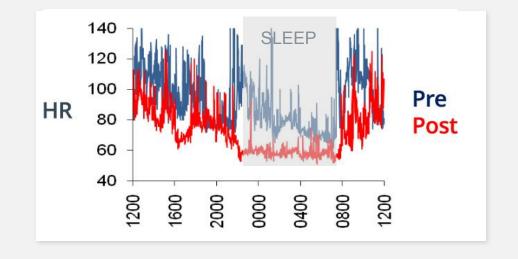
#### **Case Study 1**

- Depressed individual upon initial diagnosis
- Treated for 18 days with antidepressants



#### **Case Study 2**

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





# Significant Validation Supporting Technology

CLASSIFICATION ACCURACY	STUDY OUTLINE	REFERENCE
98%	32 controls (normals) and 28 with either an affective disorder or a psychotic disorder	International Congress on Schizophrenia – 2003
78%	50 across the mental health continuum	Psychiatric Quarterly, Vol. 73, No. 3, Fall 2002 (2002)
<b>80%</b> 98 patients, mixed psychopathology and normals		Diligence by independent University researchers
82%	200 patients (30 normals, 30 depression, 30 GAD,110 other mixed psychopathologies)	Australian & New Zealand Journal of Psychiatry 1998; 32; 187-198



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

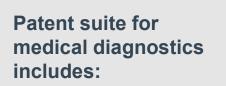


### **Defensible Position Based on IP and Data Assets**

Comprehensive suite of patents around CHR & technology:

- Medical diagnostics including assessment of treatment efficacy
- Stress assessment

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- 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



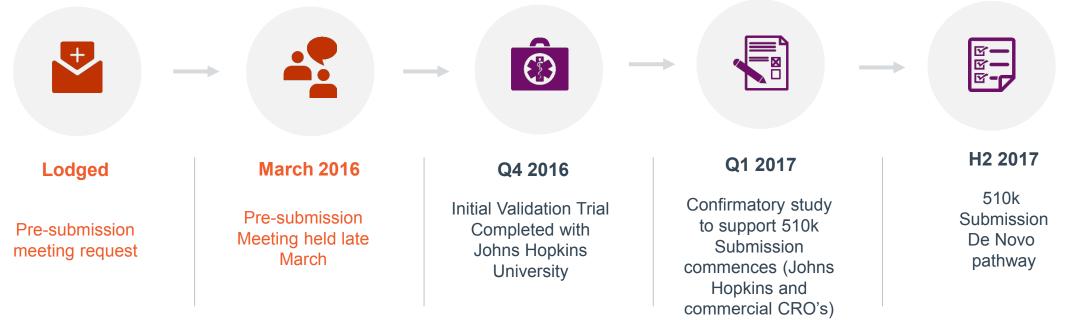
### **Opportunities in Multiple Broad Markets**





## **Targeting First FDA Submission 2017**

### 510k Premarket Notification Flow Chart



#### Positive FDA meeting confirming:

- 1. de novo classification and regulatory pathway
- 2. Indications for use
- 3. Proposed software level of concern



## **Clinical Study with Johns Hopkins University**

**Study Objective** 

To validate the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals



- Anticipated data collection completed Q4 2016
- Simple, quick, powered to only need 60 participants
- 30 subjects with MDD, 30 Normal Controls

Johns Hopkins University (JHU) Ranked #1 in the U.S. by US News & World Report for 22 years of the survey's 25 year history

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 Behavioural Sciences and Director of the Mood Disorders Clinic, where he leads a team of clinicians specializing in the care of persons with mood disorders.





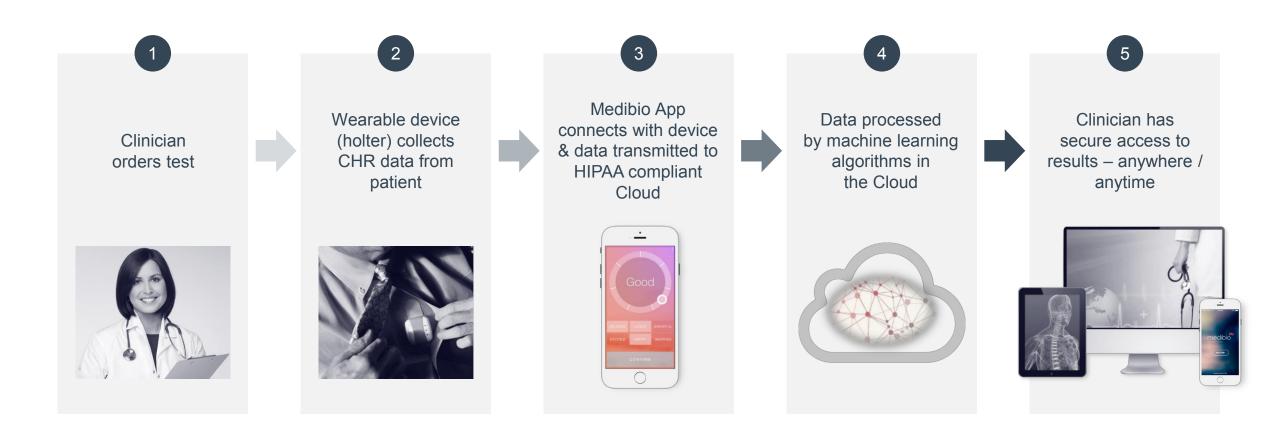
Dr Naresh Punjabi



Dr Frank Mondimore



### **Clinical Work Flow in Primary Care Setting**





### Initial Clinical Market Opportunity – Primary Care Setting

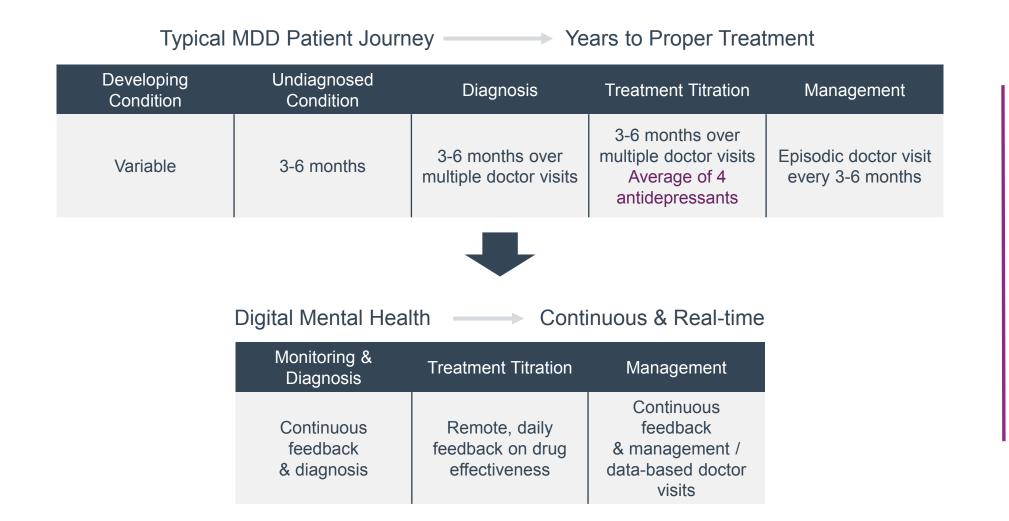
- Will be marketed as a diagnostic aid with the early adopter PCPs
- PCP's in the US are becoming the primary psychiatric care provider with in excess of **50% of all psychiatric diagnosis**
- 21 million annual PCP visits in the US which are mental health related
- 150 million PCP visits annually where mental health is a factor
- Model based on the current structure for ambulatory ECG monitoring

CPT CODE	DESCRIPTION	MEDICARE	PRIVATE	AVG
93225	Recording (Provider)	\$26.87	\$40	\$33.44
93226	Analysis with Report (Medibio)	\$37.91	\$57	\$47.46
93227	Physician review and Interpretation (Provider)	\$26.87	\$40	\$33.44

- PCP Initial diagnostic market –
   21 million annual PCP visits @ \$45
   \$1 billion annually (TAM)
- Ongoing monitoring 16 million with depression in US quarterly @ \$22.50
   \$1.6 billion annually (TAM)
- 5% penetration of the US market would generate revenue of \$130 million annually
- Cloud based analysis and reporting = minimal costs per report = very high margins



# **Cost Savings Drives Payer Adoption**



\$3,000/yr.
 50% cost saving in annual direct costs between managed and

unmanaged

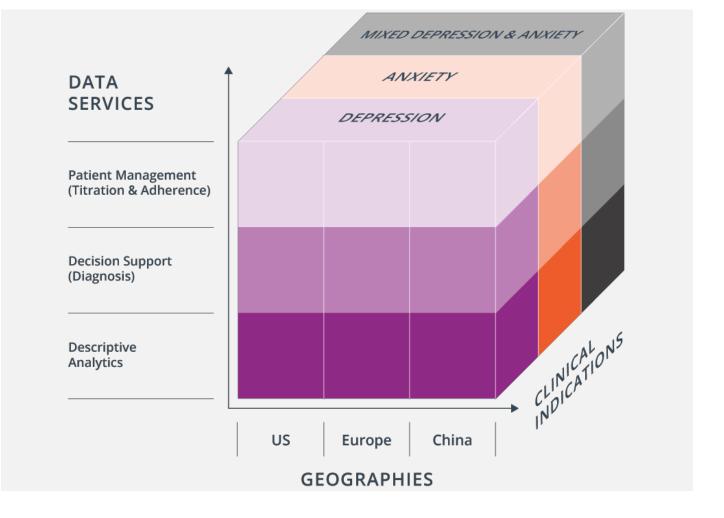
depression.

\$6,000/yr.

medibio

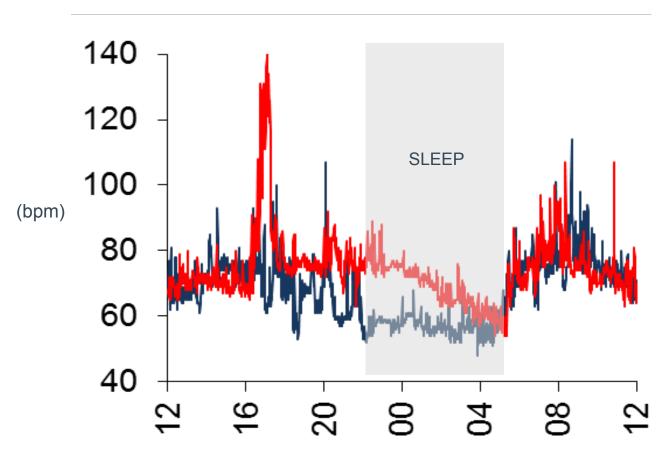
### **Highly Scalable Unit Economic Model**

- 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





### **Chronic Stress - Serial Changes**



#### **Profile**

- Middle Aged Man
- Senior Executive Position (high-stress)

	24 Hour Mean	Sleep Mean
Pre Senior Position	67	57
6 months after Senior management role	74	65

Before promotion to senior executive role6 months after promotion to senior executive role



# **Corporate Wellness is a Large & Growing Market**

#### **Value Proposition**

- 43% of the adults in the US suffer adverse health effects from stress
- Stress is estimated to cost US employees **\$300 billion** annually as a result of:
  - Accidents
  - Absenteeism half of the 550 million working days lost annually in the US
  - Employee turnover 30% of staff turnover stress related
  - Diminished productivity
  - Direct medical, legal, and insurance costs

#### **US Market Size**

- **54 million** employees in the US (+1,000 staff firms<sup>3</sup>)
- 90% of corporates have an existing wellness program
- Annual wellness spend \$100-\$500 per employee, US\$4BN revenue potential

#### Go to market strategy

- Partner with existing participants in the Corporate Wellness market
- Service delivery model through Wellness Channel partners
- Medibio will provide data analytics and reporting our core competency
  - 1. <u>www.stress.org/workplace-stress</u>
  - 2. www.evancarmichael.com/Work-Life/1877/Less-Stress-More-Profit--the-Value-of-Corporate-Stress-Management-Training.html
  - 3. US Census



Starbucks spends more on employee benefits than on coffee.



Of chief financial officers cited healthcare costs as their main financial concern.



SOLUTION \$1 spent on health promotion & disease prevention = \$5 decrease

in overall medical costs.



### **B2B Stress Product**

	Digital Mental Health Platform					Scan Report towards, wy statisticity	
<ul> <li>Dashboard</li> </ul>		g all statistics			▼ Filter		mandmastacke merende
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Report	STRESS SNAPSHOT		PARTICIPATION PROFILE			<text></text>	mundy.
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- Stress rating and trends
- Sleep analysis
- Longitudinal comparisons

#### **Group Dashboard**

- Aggregate View Client
- Participation Profile
- Organization risk summary

- Australian National Wellness Partner (Health Services Provider): (~6,000 Australian employees). Existing Corporate Wellness clients have in excess of 500,000 Australian staff.
- Vital Conversations (WA based wellness partner): Pilot Program completed, potential of 5,000 Australian staff (200,000 staff internationally). Number of additional clients
- WellNovation: Discussions with a client with 360,000 participants in the Middle East.



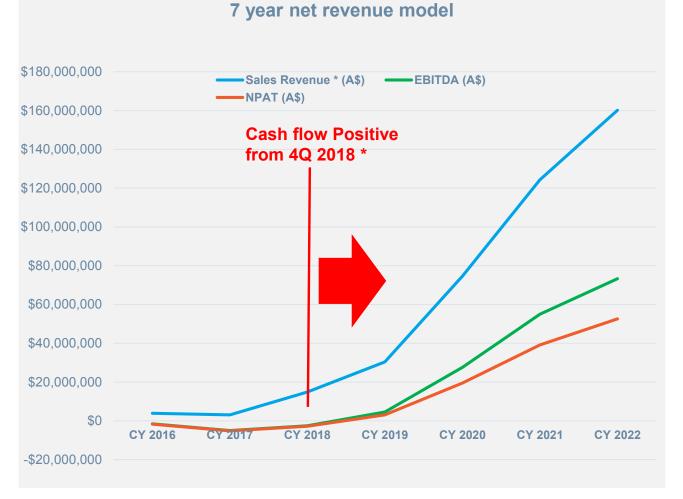


#### Clinical 'Moderate' Model

Diagnosis:	\$45/test
Monitoring:	\$22.50/patient
# of tests in 2020:	800K (~1.1% of TAM)

#### B2B 'Moderate' Assumptions

Initial Assessment:	\$60/test
Retest program:	\$10/test
# of tests in 2020:	500K (~1% of TAM)



\* Assumes a \$10m capital raise H1 2017



### **Corporate Snapshot**

ASX TICKER	MEB
Shares on Issue	105M
Warrants (\$0.10 – Expire April 2018)	15M
Warrants (\$0.30-\$0.80 - Expire Apr 2017)	12.7M
Last Trading Price	A\$0.31
Valuation (Existing Capital)	US\$24.1M
Milestone Shares*	20M
Debenture (convertible 2020 @ \$0.31)	US\$2.5M
VALUATION (FULLY DILUTED)	US\$33.6M

Available Cash – \$2.2M (plus ~ \$2.5M from R&D Rebate in Sept 2016)

Board & Management	38,671,470	43%
Milestone 1*	6,666,667	Independent Validation
Milestone 2*	6,666,667	Commercial Algorithm Development
Milestone 3*	6,666,667	FDA or CE Mark

Medibio's analytics platform will transform the assessment and management of mental health

- Enabling access to care
- Providing objective, quantifiable diagnosis
- Confirming the effectiveness of therapies
- Driving optimal disease management



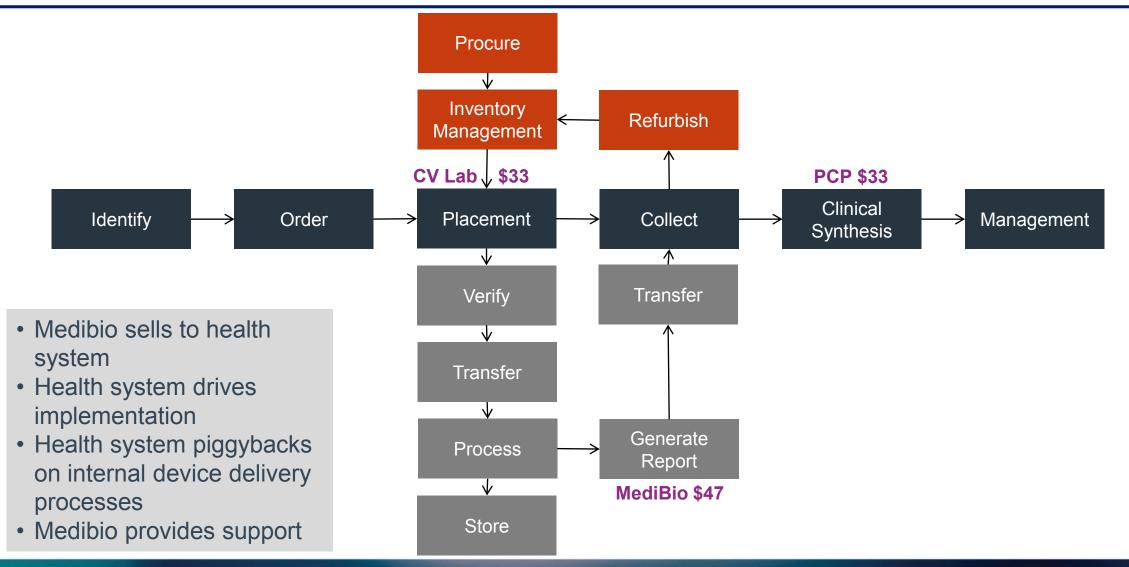
# Appendices



### **Competitor Overview**

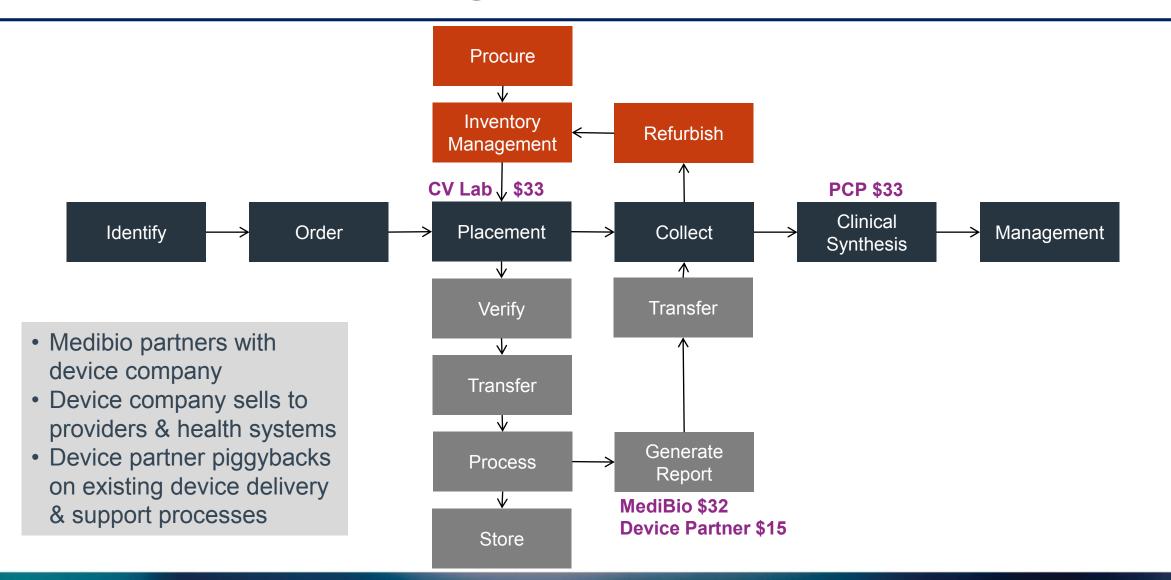
TECHNOLOGY	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIPMENT COST	TEST COST
Medibio	CHR Waverform test based on ECG monitoring overnight	Under way	80-90% - based on in excess of 4000 data points	\$30	<\$100
Blood test	Ridge Diagnostics offer an MDD score of 1 to 10 based on the analysis of 9 blood markers	No	80-90% - based on a pilot study with 79 participants	n/a	\$800
EEG	Johns Hopkins research using 3 hour resting 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

### **Clinical Workflow Integration: Health System Partner**



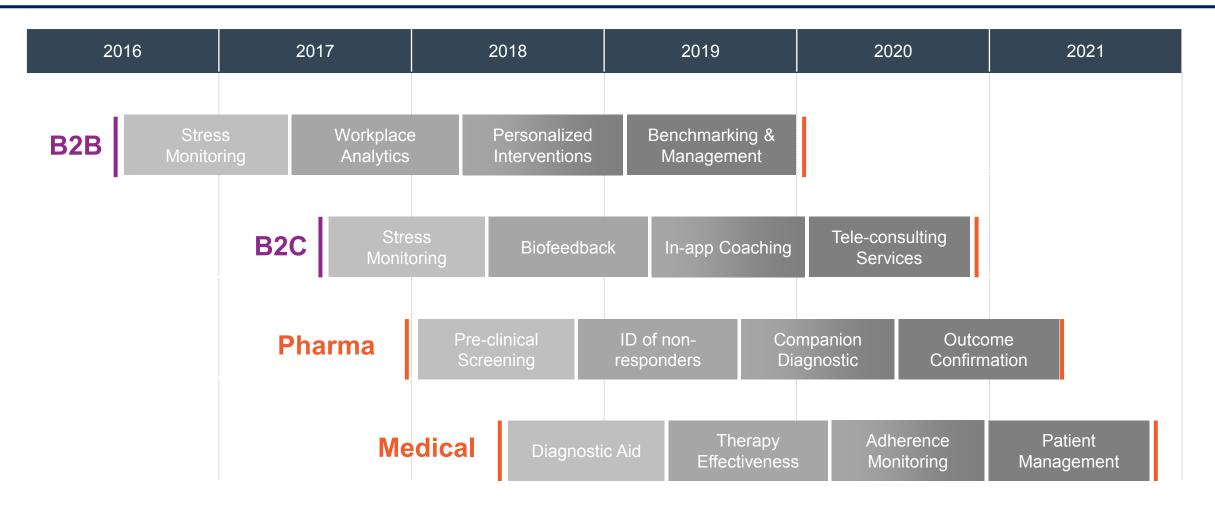


### **Clinical Workflow Integration: Device Partner**



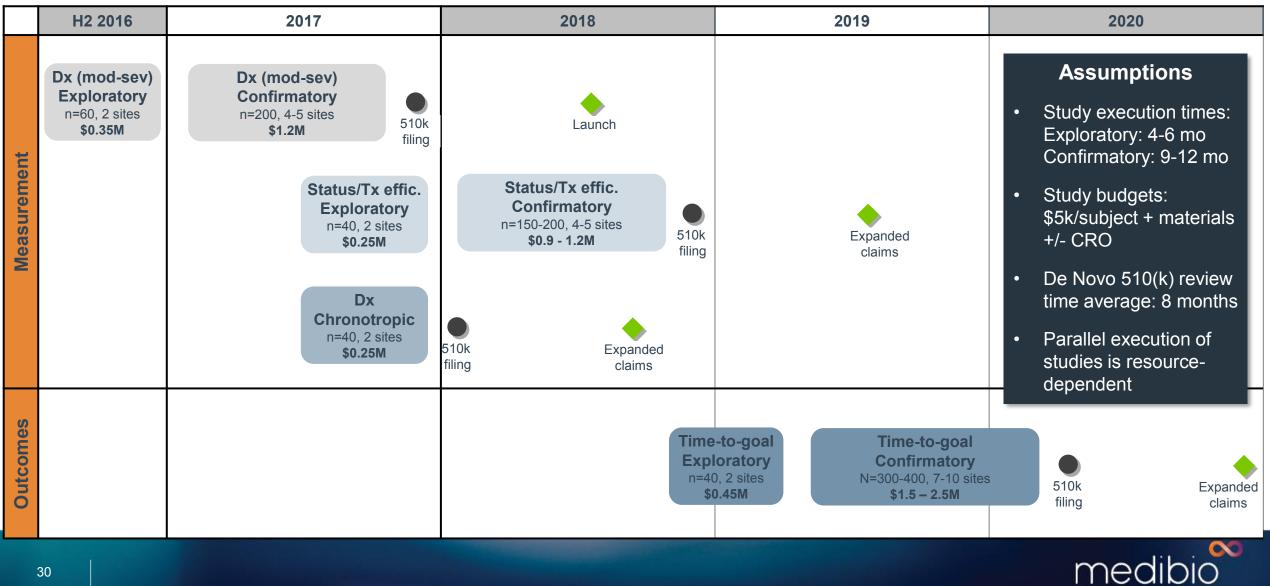


### **Robust Roadmap into Multi-billion \$ Verticals**





### **Depression Study Series (Exemplar)**



## **B2C Market Opportunity**

All Apps related to stress/mental health are:

- based on reducing tension via breathing, yoga, and relaxing sounds
- mental health Apps are based on a digitised version of the DSM
- none offer objective stress assessment based on extended research

#### Medibio's App

- An health sector endorsed, objective stress assessment application and management tool
- Integration testing with popular wearable devices underway as a precursor to commercial launch decision

#### **Business Model**

- Initial download cost gives you a month of complete usage including the stress management interventions
- Subscription based model for a 12 month
- Nearest competitor is "Stress Doctor" which has generated 60+ million iOS downloads
  - Current Price US\$7.99





# **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)





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