



Company Summary



- Medibio has developed the first evidence based quantitative test for depression and mental health disorders, addressing the largest issue in healthcare today.
- Defensible IP/technology which has been developed based on 15 years of research into the relationship between the autonomic nervous system and depression, anxiety and stress
- Accelerating progress with US and Australian trials, FDA submission H1CY16, existing precedence for approval and reimbursement codes paves way for clinical and corporate acceptance
- “Best-of-Breed” research partners - Johns Hopkins and Black Dog Institute
- Multiple commercialisation routes - Medical, Corporate and Consumer market. Each vertical represents significant market opportunity and revenue streams
- Revenue generation to commence in Q4CY15, Corporate and Consumer market products not dependent on regulatory approval

“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 - May 2013)



Corporate Snapshot

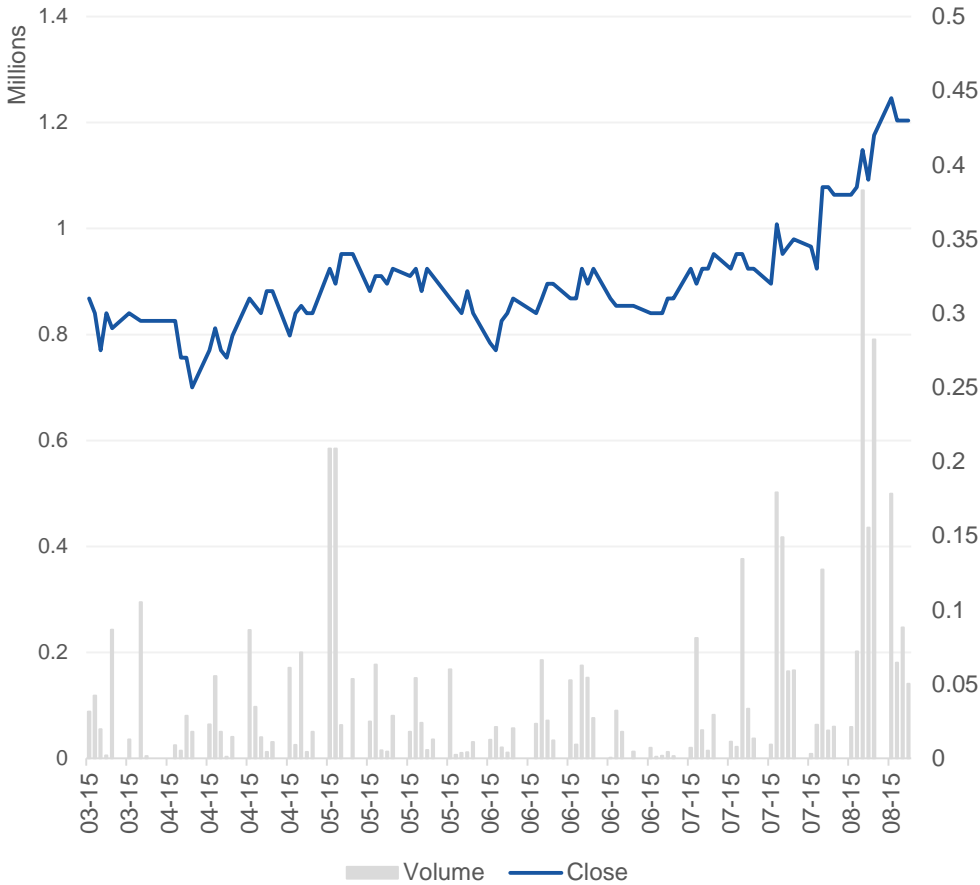


Trading Information

ASX Ticker	MEB
Shares on Issue	90.1m
Share Price	\$0.46
52-Week High	\$0.50
52-Week Low	\$0.20
Market Capitalisation	40.27m

Top 20	63,330,745	70.3%
Board and Management	38,671,470	42.9% (incl 23.9m escrowed)
Vendor Milestone 1	6,000,000	Independent Validation
Vendor Milestone 2	6,000,000	Commercial Algorithm Development
Vendor Milestone 3	6,000,000	FDA/CE Mark
Unlisted Options	21,530,009	\$0.30 (6.67M) & \$0.10 (14.86m)

Share Price Since Listing



Key Executives



Kris Knauer
Chief Executive Officer

- 20 years experience in Finance and Corporate Advisory
- Experienced CEO of ASX Listed companies
- Previous role as CEO in a group owning GP Centers and Radiology practices
- Founded and grew ASX Listed company from sub \$3 million valuation to \$300 million valuation prior to a \$1bn takeover



Dr Matt Mesnik,
Chief Medical Officer

- Healthcare Executive with 25 years of healthcare management experience
- Chief Medical Officer of Aprima Medical Software, US EMR company
- Chief Medical Officer of MinuteClinic, developed the concept of retail healthcare, the largest U.S. retail health clinic provider (>1,000 clinics with >8M annual primary care visits). Acquired by CVS Pharmacy with >7,500 stores.



Dr Michael Player
Chief Operating Officer

- Research Psychologist at the Black Dog Institute and active patient work as a Clinical Psychologist.
- Completed his PhD at the University of NSW, investigating and quantifying objective, biological markers of depression.
- Research importantly found that neuroplasticity was reduced in depression, as demonstrated by an objective test not confounded by subject effort and motivation. This provided ground-breaking support for the hypothesis of impaired neuroplasticity in MDD.



Sean Mathieson
Chief Innovation Officer

- Business Technology Executive with 25 years of Global Business Software experience
- Reputation for Technology Vision enabling Business Outcomes
- Global Leadership Team of Siebel Systems, Founding Member of SAP Australia



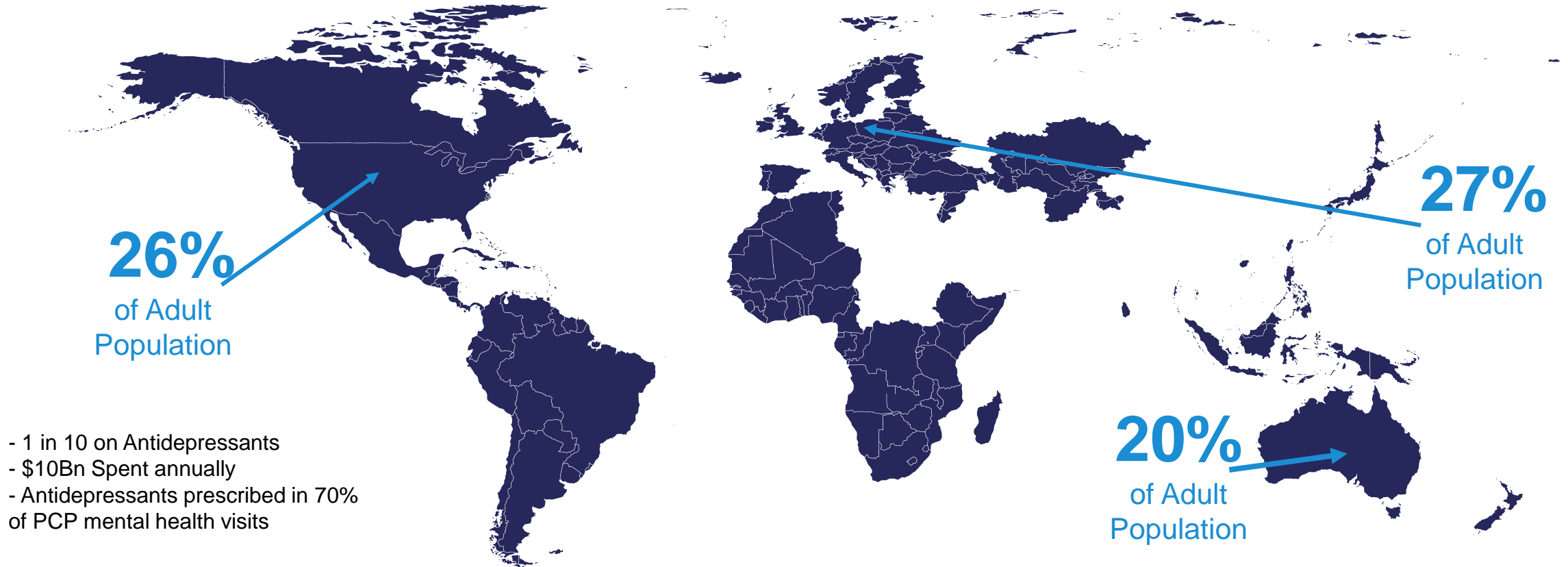
Dr Franklyn Prendergast
Advisory Board Member

- Current Director of Eli Lilly and Company and Past Chair of the Board of Governors of the Mayo Foundation
- Past Chair, Department of Biochemistry and Molecular Biology, Mayo Foundation
- Guggenheim Professor of Biochemistry and Molecular Biology, Mayo Medical School (retired-January 2015)
- Past Director, Mayo Clinic Center for Individualized Medicine and Mayo Clinic Comprehensive Cancer Center

Mental Health Landscape

350 Million Worldwide Diagnosed With Depression
1 Suicide Every 40 Seconds

1 Million Suicides Every Year



- 1 in 10 on Antidepressants
- \$10Bn Spent annually
- Antidepressants prescribed in 70% of PCP mental health visits

Global Cost \$2.5T (2030 est. \$6T) — Depression and Anxiety account for **+50%** of this burden

Most Challenging Problem in Healthcare Today



The Problem

- No objective test for mental illness
- The diagnostic “gold standard” is a clinical/expert opinion
- Diagnostic agreement between clinicians can vary considerably – concordance rates near 70%
- Current assessments are subjective and some require professional administration)
- Misdiagnosis of depression (and other mental illness) places a huge cost burden on the healthcare system and the workplace

The Solution (Medibio)

- Quantitative, objective test
- Diagnosis based on patient’s biometric data (circadian heart rate)
- Simple, safe, quick, and unobtrusive
- Provides objective indication of treatment efficacy along with medication compliance and adherence
- Savings to the health system and better patient outcomes

First Quantitative Diagnostic Test for Mental Health

Medibio's research has allowed it to develop the first evidence based quantitative diagnostic test of all the key mental health disorders including:

- Depression
- Anxiety
- Mixed Depression and Anxiety
- Panic Disorder
- Psychosis and Schizophrenia
- PTSD – Post Traumatic Stress Disorder
- Stress

Proprietary technology in which algorithms assist in the diagnosis of a number of mental health conditions utilizing the analysis of Circadian Heart Rate ("CHR") variability waveforms

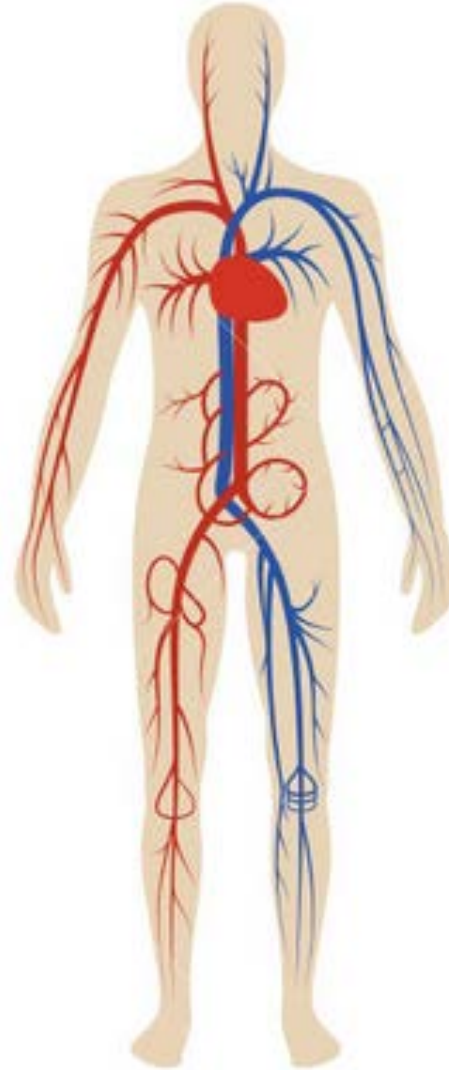
Sleep is **the key period**. It is only during sleep when external influences and distractions are absent

CHR is 'state-dependent' - a change in mental state is associated with a change in CHR waveform

Serial monitoring of patients under psychiatric treatment shows **Treatment efficacy is associated with normalisation of CHR**



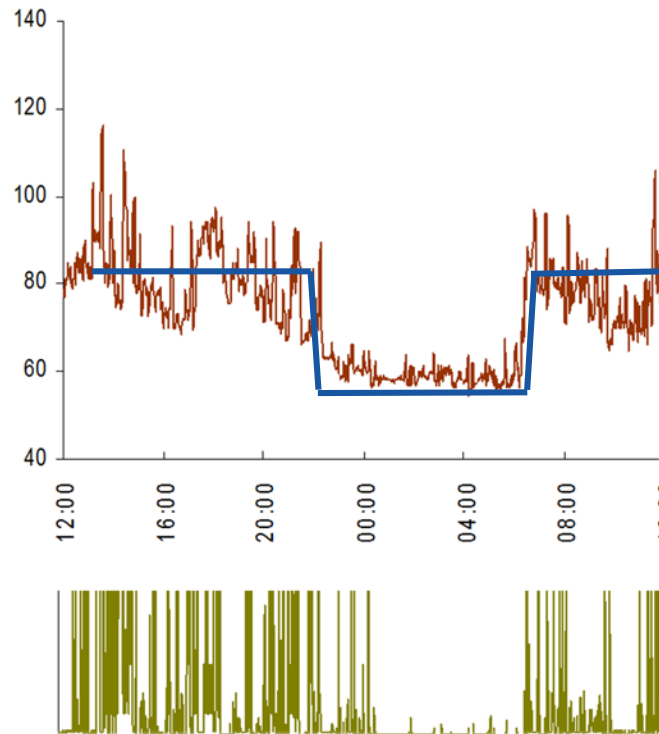
- Autonomic nervous system (ANS) plays a **key role in circadian sleep-wake regulation** of physiological activity including heart rate
- Research initiated **18 years ago** at UWA to test the theory that mental state linked ANS disturbance could be observed via the cardiovascular system
- Involved the collection of **24 hour ECG data** and corresponding clinical psychiatric diagnoses from **thousands of subjects** covering all the key psychopathologies
- Data was collected during a number of clinical studies with the **key studies peer-reviewed and published**



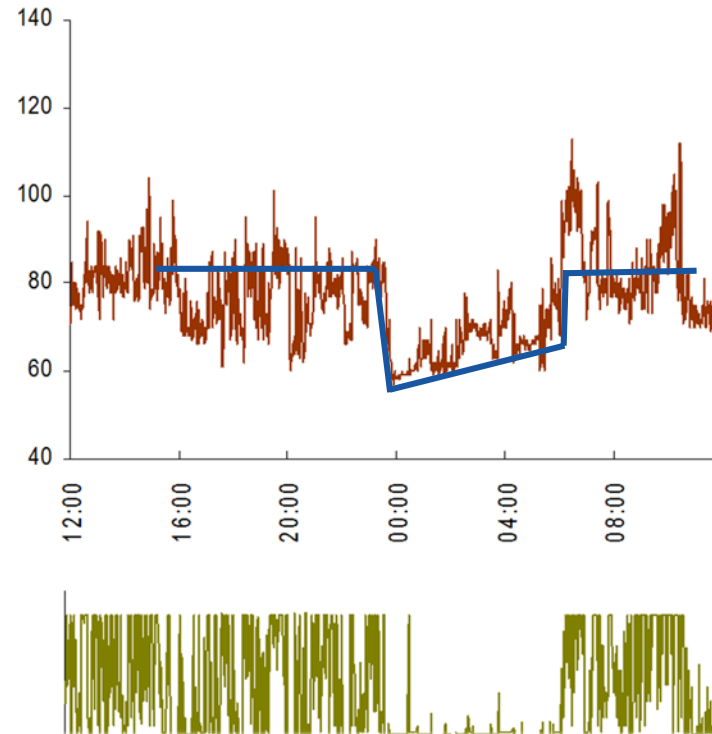
- Validated both internally and externally via blinded studies with one external blinded study peer-reviewed and published **showing 78-92% diagnostic accuracy**
- The technology was developed via the correlation over **4000 CHR waveforms** with the corresponding clinical psychiatric diagnosis
- Algorithm Development has only been possible with the introduction of **state of the art machine learning techniques**

Technology Overview

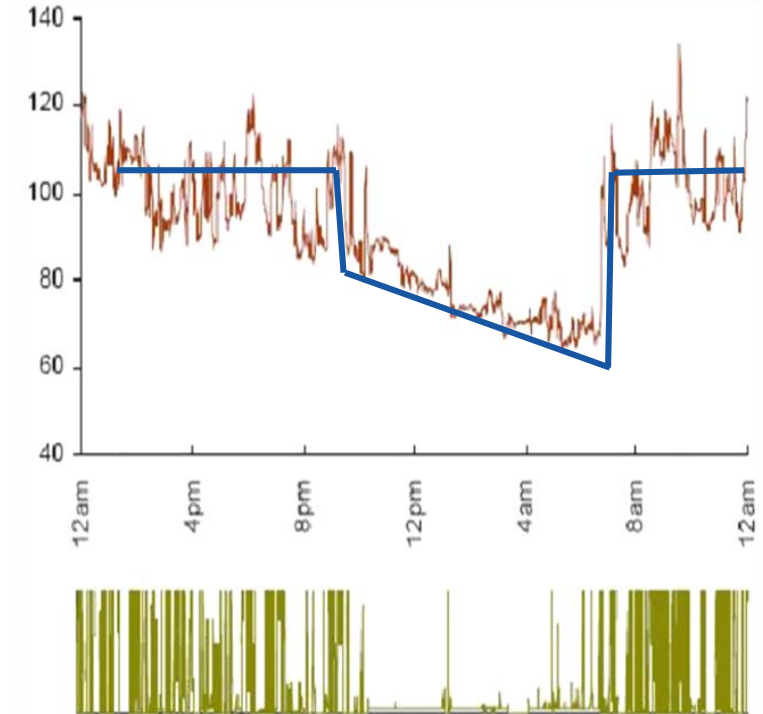
Normal Individual



Depressed Individual



Anxiety Disorder



Validation of Medibio's Technology



Study Objective & Timeline:

- Provide external validation of the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals
- Provide clinical data to support FDA certification of Medibio's proprietary depression test
- Study population 50 depressed and 50 non-depressed individuals
- Anticipated data collected by Q1 2016 with results published in Q2 2016
- Simple, quick, powered to only need 80-100 participants

Study Objective & Timeline:

- To demonstrate that CHR Technology distinguishes between melancholic and non-melancholic depression and also determine treatment response.
- Study population 30-40 with melancholic depression and 30-40 with non-melancholic depression
- Anticipated study completed in Q4 2015 with results published in Q1 2016
- Simple, quick, powered to only need 60-80 participants



BLACK DOG INSTITUTE

Defensible IP Developed over 15 years



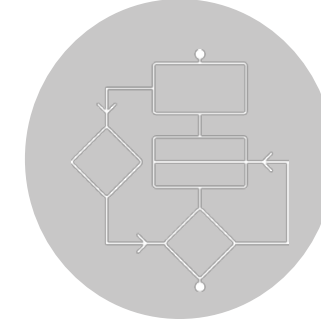
Comprehensive suite of patents covering the use of CHR technology for both:

- Medical diagnostics including assessment of treatment efficacy
- Stress assessment



Patent suite for medical diagnostics includes:

- “Method for Diagnosing Psychiatric Disorders”
- USA(US624502), Canada, Australia, New Zealand, Israel
- 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” covering new discoveries in past 18 months



Data set required for algorithm development is the natural protection:

- 10,000 +12 hour ECG files with a corresponding psychiatric diagnosis
- This data set would take 5 years and cost \$20 million to replicate

Three Clearly Defined Markets

Clinical

Medical



US\$30Bn
Industry

Primary Care Physicians
Psychiatrists
Psychologists
Therapists
Counsellors
Cardiologists

Non-Clinical

Corporate



US\$19Bn
Industry

High Risk Occupations

- Defence
- Police
- Fire/Emergency

Insurance Companies
Corporate Wellness
Professions
Elite Sports

Consumer



US\$26Bn
Industry

App Stores
Insurance Companies
Wellness
Digital Health
Companies

How it Works



Clinician orders test

CHR collected from Patient and transmitted to HIPAA compliant Cloud Storage

Pre-Processing can be conducted on the phone via the Medibio App

CHR processed by machine learning algorithms in the Cloud

Clinician has secure access to Diagnostic Reporting and Analysis – Anywhere/Anytime



Pathology model whereby the patient is referred to hospital or clinic to be fitted with an ECG Monitor

Next generation ECG monitors sync to mobile phone which transmits the data to the cloud or have a cellular chip installed sending data direct to the cloud via the cellular network

Process to verify data quality recorded

Noise removal and IBI extraction

Significant reduction in data transmission costs

Completely automated process from data collection to report generation.

No physical data handling

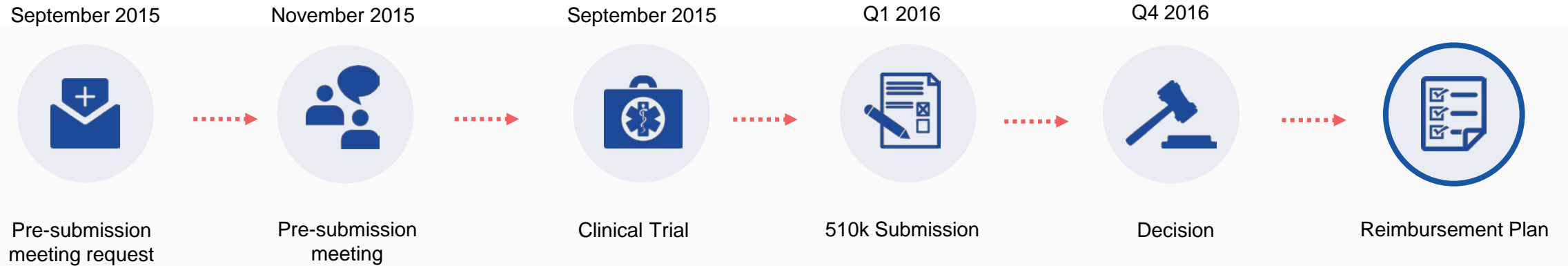
Biometric data stored in HIPAA compliant cloud

Clinician uses report as a diagnostic aid to make the diagnosis

Augmentation by device, instead of driving clinician redundancy for diagnosis

Targeting FDA Approval by Q42016

510k Premarket Notification Flow Chart



- Regulatory strategy is to obtain FDA clearance by submitting a 510(k) Premarket Notification Application
- Medibo is being advised by NAMSA who have completed over 300 successful 510k submissions
- For a novel product such as this it will be a De Novo 510k as there is no predicate device
- Anticipated that the FDA will require a clinical study to support market clearance
- Application will be submitted at completion of data collection
- Typical 510k review process takes 195 days to completion
- The depression diagnostic will then act as the predicate device for FDA approvals for anxiety, PTSD, etc.

Clinical Market Opportunity

- GP's or PCP's in the US are becoming the primary psychiatric care provider with in excess of **50% of all psychiatric diagnosis** in the US done by PCPs.
- Of the **21 million annual** PCP visits in the US which are mental health related:
 - **40%** receive only psychiatric medication
 - **30%** receive medication and are referred for therapy
 - **30%** are referred to a psychiatrist/psychologist
- The test will be marketed as a **diagnostic aid with the early adopters** to be GP's and Primary Care Physicians in the US
- Partner and Payment structure for 24hour ECG monitoring.

	Medicare	Private	Insurance	Assumption
93225	Recording (Provider)	\$26.87	\$40	
93226	Analysis with Report (Medibio)	\$37.91	\$57	\$45
93227	Physician review and Interpretation (Provider)	\$26.87	\$40	

- PCP Initial diagnostic market – **21 million annual PCP visits @ \$45 ~ \$1 billion annually**
- Ongoing monitoring - **16 million with depression in US quarterly ² @ \$22.50 ~ \$1.6 billion annually**
- **5% penetration of the US market** for depression diagnosis would generate revenue of **\$175 million annually**
- Cloud based analysis and reporting = minimal costs per report = **very high margins**

Corporate Stress Product

Using stress specific algorithms MEB has developed the first objective measure of the impact of **stress on wellbeing**

Based on the type and degree of deviation from normal CHR and the clinical significance of these deviations, individuals are classified into one of three distinct categories.

- **'green'** - normal to mild (no immediate action needed)
- **'amber'** - moderate (the impact of stress on wellbeing is approaching unhealthy levels)
- **'red'** - serious (the impact of stress may have an unhealthy impact on wellbeing (recommend lifestyle changes)

Initial target market is the **Corporate Wellness market** where Medibio provides an end to end solution for corporates

We provide the first objective measure of stress and a series of interventions tailored specifically to the employees stress level



ASSESSMENT

Enable employees to check their stress levels

Personal early warning system for people at risk

Prevention is better than cure



SUPPORT

Provide education, support, and intervention based on stress level

May recommend discussion with PCP

Provide the ability to conduct on-going monitoring to check progress



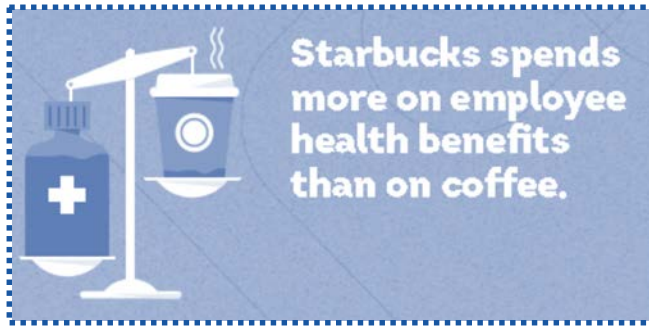
Employer Benefit

Metrics on stress levels for job classes and types

Reduced absenteeism and increased productivity

Reduced claims and pressure on the health care systems

Corporate Stress & Mental Wellness



DEMAND IN THE US DRIVEN BY MANY FACTORS

- **43%** of the adults in the US suffer adverse health effects from stress
- Stress is estimated to cost US employees **\$300** billion annually
- Over half of the **550** million working days lost annually in the U.S. from absenteeism are stress related¹⁾
- Harvard estimate **60-90%** of doctor's visits are caused by stress²
- Need to reduce health care spend
- Social responsibility/OHS Requirements

US MARKET SIZE

- **54 million** employees in the US (+1,000 staff firms³)
- **22 million** US Government employees in the US³
- **90%** of corporates have an existing wellness program
- Annual wellness spend **\$100-\$500** per employee
- **US\$4Bn** revenue potential annually

GO TO MARKET STRATEGY

- Partner with existing participants in the Corporate Wellness market
- Medibio will provide data analytics and reporting - our core competency

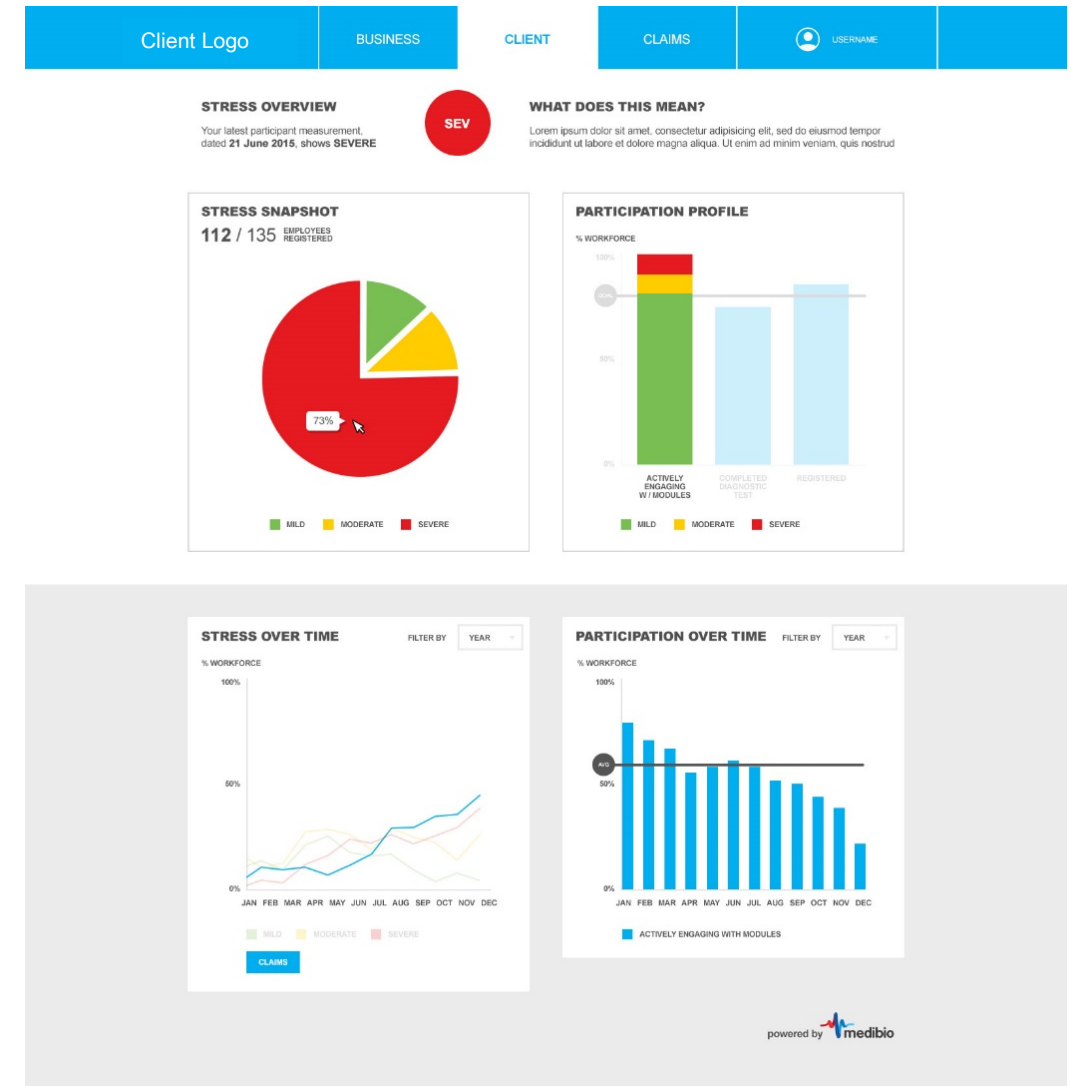
1. www.stress.org/workplace-stress.

2. www.evancarmichael.com/Work-Life/1877/Less-Stress-More-Profit--the-Value-of-Corporate-Stress-Management-Training.html

3. US Census

Corporate Stress Market Opportunity

- Price point is important
 - \$120** - executives and at risk employees only
 - <\$60/year/employee** – entire staff base
- Pricing model
 - \$25** for initial stress assessment
 - \$10** for re-test (moderate/serious category)
 - Intervention **\$2/employee/month**
- Revenue of ~ **\$52** per staff member per annum
(Ametus Group Independent Analysis)
- 5% penetration of the US market would generate \$200 million annual revenue**
(Assumptions 5% of 76 million employees @ US\$52)
- 5 year revenue target **\$100 million annual revenue**



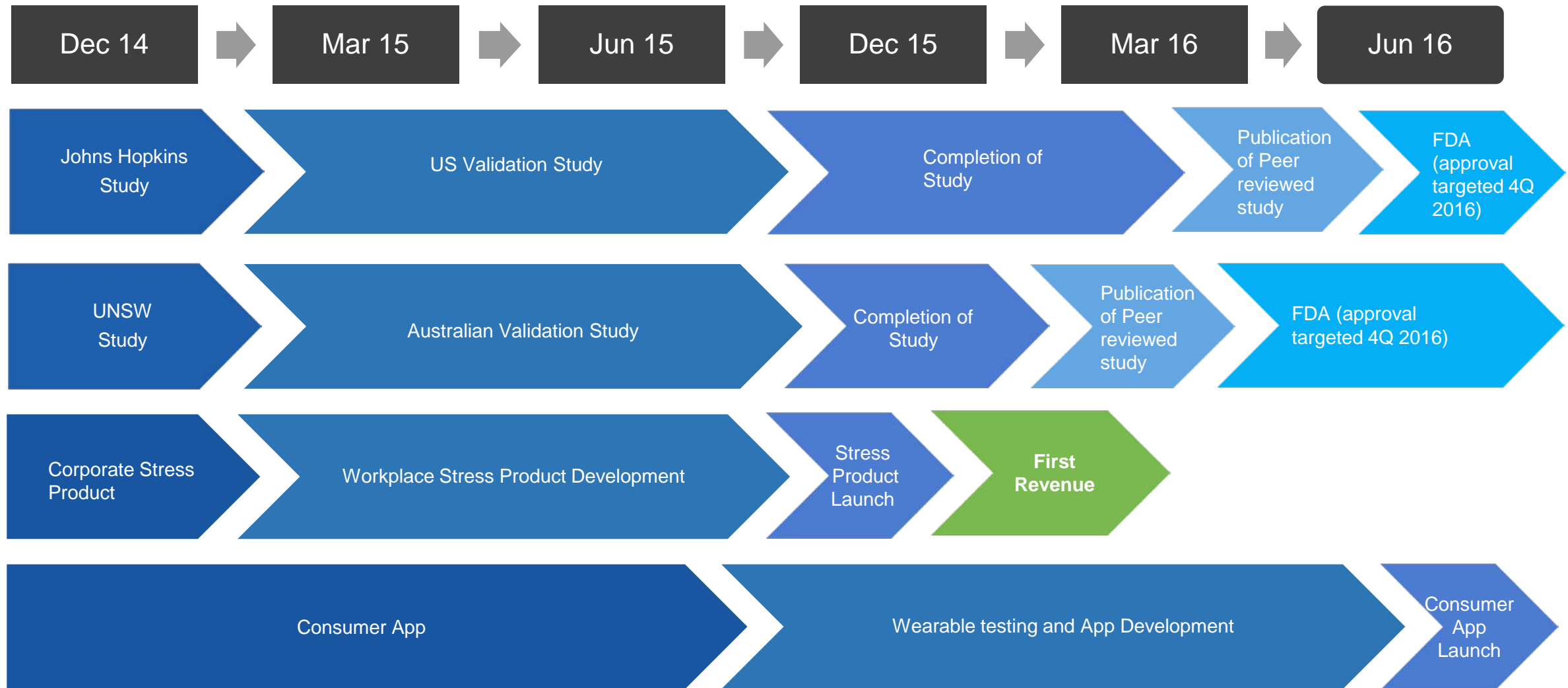
Consumer App Market Opportunity



- All Apps related to stress/mental health are:
 - based on reducing tension via breathing, yoga, and relaxing sounds
 - wellness products not stress identification and management
 - mental health Apps are based on a digitised version of the DSM
 - **none offer objective stress assessment based on extended research**
- Medibio's App:
 - Based on **15 years of medical research** which is currently being validated by **Johns Hopkins University and Black Dog Institute**
 - An objective, health sector endorsed, objective stress assessment application and management tool
 - Ability to compare this test with previous scans run to check progress
 - **Best in class** intervention tailored to your stress level
- Business Model:
 - Initial **\$5 download** gives you a month of complete usage including the stress management interventions
 - **\$10 to subscribe for a 12 month period** and have ability to retest and track your progress against yourself
 - A "Stress Doctor" penetration would generate **\$600 million** in revenue and our offering is superior



Timeline to Commercialisation



Competitor Overview

Technology	Description	FDA	Diagnostic Accuracy	Equipment Cost	Test Cost
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
MEDIBIO	CHR Waverform test based on ECG monitoring overnight	In train	80-90% - based on in excess of 4000 data points	\$250	<\$100
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

Investment Highlights



- One of the few areas in Health Care yet to be disrupted by technology
- Multiple commercialisation routes with each vertical representing a multi billion dollar market opportunity
 - Medical
 - Corporate
 - Consumer App.
- Strong lead over any potential competing technologies and exclusivity over the use of CHR – IP secured
- Significant cost advantage over any other competing technologies
- Revenue not dependent on regulatory approval – can generate income via range of applications
- Commercialising the first vertical now - 5% of the US market generates \$200 million annual revenue
- Scalable, low cost, and high margin – minimal capital outlay or operating expenditure
- The next six months will be transformational for the company



Contact Us:

Kris Knauer

Chief Executive Director

Kris.Knauer@medibio.com.au

