



General Meeting Presentation March 6 2015

Medibio Limited - Snapshot

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Mission: - To introduce the first FDA approved evidence-based test for depression/anxiety

- Present an objective test for evaluating the efficacy of treatment for mental illness

Vision: - Early entrant in the transformation of Healthcare by technology (Digital Health)

Strategic - Johns Hopkins University and the Black Dog Institute

Partners: - World leaders in mental health research





Market: - Depression diagnostic alone is a US\$16bn revenue opportunity – "large"

Timeline: - First revenue via corporate stress-test products targeted mid 2015

- Johns Hopkins validation study completed in 8-10 months

- Targeting FDA Approval within 12 months from completion of study

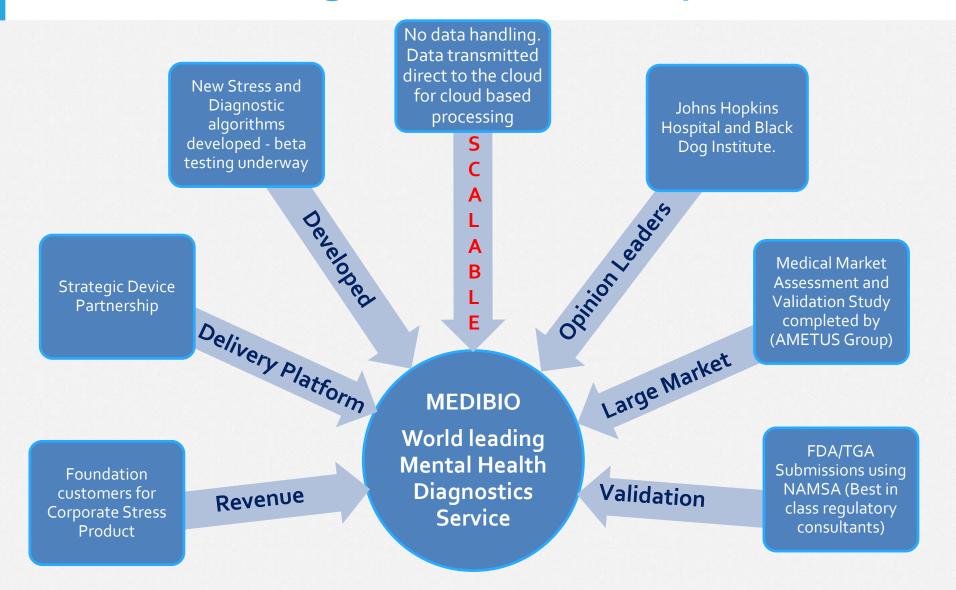
Market - Capitalisation \$25m (1) with \$3m in cash post completion (Appendix 1)

Cap:



The building blocks are now in place



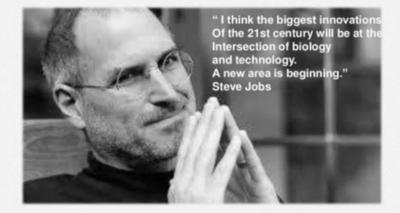




Long Term Vision – MedTech for Mental Health (9)



- World's first Digital Health Diagnostics Platform specialising in the analytics of ECG data focused on Stress and Mental Health
- Digital Health: Hardware agnostic for the collection of ECG Data
- Allowing for global access to all payers in the Health, Occupational Health, Wellbeing, and E-Health space
- Monetise each segment of the market and diversify the potential client base:
 - Medical Diagnostics
 - Remote Patient Monitoring
 - Corporate Wellness/Elite Sports
 - Wearables/Consumer Apps
- Hardware is not our core business



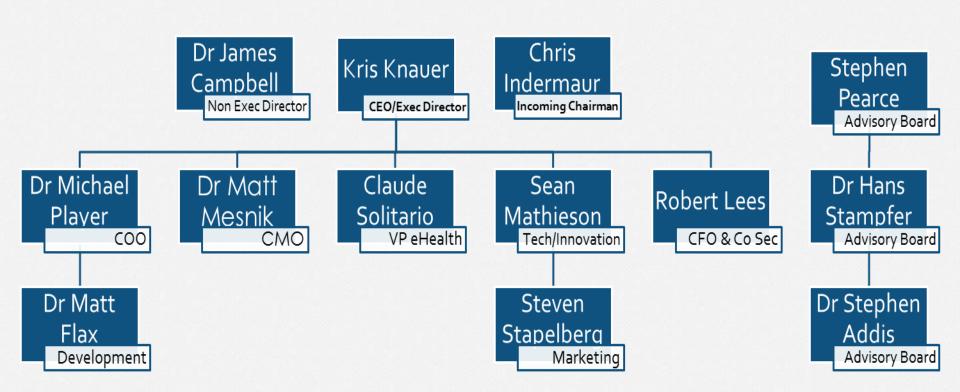
Become a data play which adds value based on a secure HIPAA protected analytics platform with the largest collection of clean ECG data sets worldwide



Key Company Milestones

Timing	Milestone	Status	
Q4 2014	Australian and US validation studies (BDI & JHU)	✓	
Q1 2015	Delivery of Commercialisation Study (AMETUS)	✓	
	Strategic device partner		
	Pre-submission package delivered to the FDA		
	Complete beta testing of new Stress Algorithms		
Q2 2015	Formal Announcement of foundation customers		
	Complete beta testing of new Diagnostic Algorithms		
	Commercial partnership with U.S. strategic partner		
Q3 2015	Commercial launch of Corporate Stress product		
	Completion U.S. and Australian validation studies		
Q4 2015	Results from U.S./Australian validation studies published		
	FDA Submission		

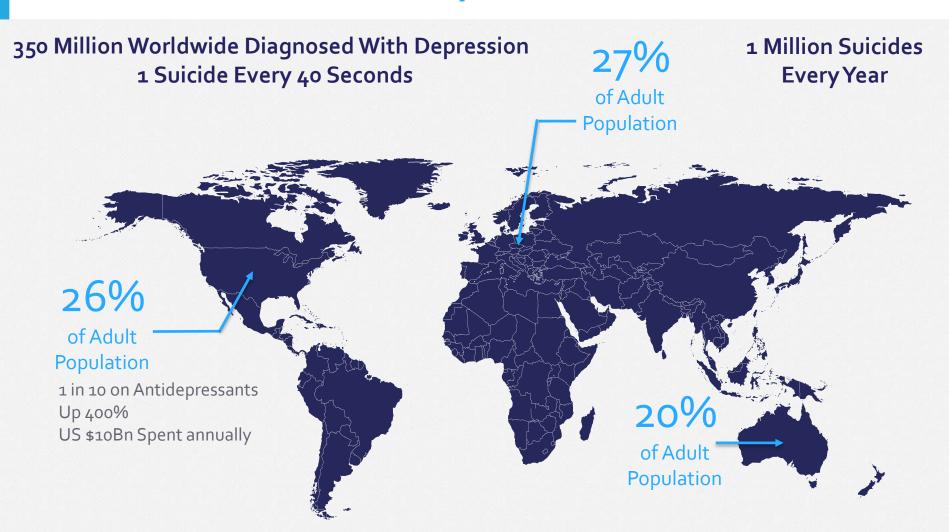






Mental Health Landscape





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



- There is no objective test for mental illness
- The diagnostic "gold standard" is a clinical/expert opinion
- Diagnostic agreement between clinicians can vary considerably even for high prevalence disorders like depression and anxiety
- Circadian Heart Rate (CHR) analysis adds an objective dimension to the diagnosis of depression/anxiety and the evaluation of treatment
- The late, under/over, and misdiagnosis of depression (and other mental illness) places a huge cost burden on the healthcare system and the workplace
- CHR can add an objective dimension to screening for depression and anxiety

"The need for screening for and early detection of depression in primary care services is unarguable"

(World Federation for Mental Health)



- The 'gold standard' clinical diagnosis is based on criteria defined in one of two diagnostic manuals used in Psychiatry, namely,ICD-10 and DSM-5
- However according to the National Institute of Mental Health in the U.S.A.

"We will no longer endorse DSM5, as it has fundamental flaws and we are actively seeking a diagnostic system that is evidence based"

"It is critical to realise that we cannot succeed if we use DSM categories as the gold standard" -

"We need a <u>quantitative</u> method for diagnosing depression"

(U.S. National Institute of Mental Health - May 2013)



Our Solution



- Quantitative, objective test
- Diagnosis based on biological data (circadian heart rate)
- Simple, safe and unobtrusive
- Gives objective indication of therapeutic effectiveness
- Earlier diagnosis enables earlier intervention
- o Improved monitoring helps to optimize effective treatment
- Savings to the health system from earlier diagnosis



The Hypothesis Behind the Technology

- The autonomic nervous system (ANS) plays a key role in circadian sleep-wake regulation of physiological activity including heart rate
- It is well known that mental illness is associated with disturbances in ANS/circadian regulation
- Mental state-linked ANS disturbance is observed via the cardiovascular system, particularly during sleep when external influences are absent
- Therefore an analysis of CHR gives objective indications of 'core' physiological differences between broadly different forms of mental illness such as anxiety and depression





Research Findings



- Based on over 15 years of research
- Different forms of mental illness such as 'anxiety' and 'depression' are associated with distinctly different patterns of CHR
- Distinct 'biomarkers' in heart rate data for depression and certain other mental illnesses have been identified
- Normal people (not attending GP/mental health professional) often show minor changes in CHR
- o CHR is 'state-dependent' a change in clinical status is associated with a change in CHR
- Serial monitoring of patients under treatment has shown that:
 - effective treatment is associated with normalisation of CHR
 - ineffective treatment does not show normalisation
 - "a tool for determining the effectiveness of treatment"



US Validation Study – Johns Hopkins University

- Study Objective
 - To validate the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals
 - Designed to provide clinical data to support FDA certification of Medibio's proprietary depression test
- Study Timeline
 - Anticipated results published in Q4 2015
- Johns Hopkins University (JHU)
 - \$7 billion integrated global health enterprise established in 1889
 - Ranked number one in the U.S. by US News & World Report for
 22 years of the survey's 25-year history
- Principal Researcher Dr Naresh Punjabi
 - Presents clinical instruction at JHU School of Medicine and Bloomberg School of Public Health
 - Dr Punjabi has published more than 100 research papers



SCHOOL OF MEDICINE



Australian Validation Study – Black Dog Institute



Study Objective

- To demonstrate that Medibio's CHR Technology can distinguish between melancholic and non-melancholic depression.
- A positive outcome in the BDI study would make a significant impact on the treatment of depression and improved patient outcomes. Why?
- Melancholic Depression
 - Type of Major Depressive Disorder (MDD)
 - Biological condition

will respond to medication and/or ECT

- Non Melancholic Depression
 - Psychosocial condition
 - will respond better to Psychotherapy
 - ~ 50% of cases do not respond to antidepressants. Medications do not change the precipitating event/stress, nor the inwards coping style, but may lessen the symptoms
 - High rate of spontaneous remission (treatment response can be difficult)





Medical

- ✓ Primary Care Physicians
- ✓ Psychiatrists
- ✓ Psychologists
- √ Therapists
- ✓ Counsellors

Corporate



- ✓ High Risk Occupations
- ✓ Insurance Companies
- ✓ Corporate Wellness
- ✓ Professions
- ✓ Elite Sports

Consumer



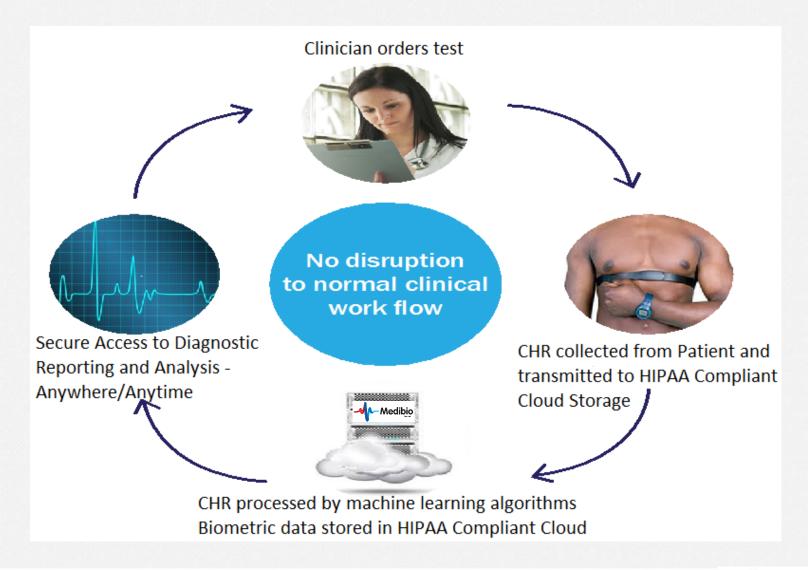
- ✓ Direct to Consumer
- ✓ Ideal for wearables

Pay per report/Licensing arrangements



1. Medical Diagnostic Market







Medical Diagnostic market in the US



- Size of the Market in the US \$2.35bn annually (Depression Only)
 - Untreated market (initial diagnosis)
 - 60 million annual visits (50% to PCP's) with mental health diagnosis @ US\$45
 - US\$1.35bn revenue opportunity based on PCP's
 - Treated market (ongoing monitoring)
 - 3.5% population @ US\$22.50 per report quarterly monitoring
 - US\$1bn revenue opportunity
- US Market Research undertaken as part of the market validation study showed
 - Clear majority of mental health clinicians (+90%) would use this test as a diagnostic once clinically proven and reimbursable
 - Confirmed two primary markets for the use of the technology
 - Initial diagnosis
 - Monitoring to gauge therapeutic intervention effectiveness
 - PCP's likely first adopters of the technology as a diagnostic tool
 - Mental health clinicians would use it as an adjunct tool



Reimbursement Analysis for the US market

o Identified a series of existing CPT™ codes and payment structures which are supportive of, and can be leveraged for, MEB's business plan in the US

	Medicare	Private	Insurance	Assumption
93225	Recoding (Provider)	\$26.87	\$40	
93226	Analysis with Report (Medibio)	\$37.97	\$57	\$45
93227	Physician review & Interpretation (Provider)	\$26.87	\$40	

- Reimbursement Assessments focuses on three fundamental, independent variables:
 - Coding Is there a CPT code that clinicians can use to bill professional services to government and private insurers - YES
 - Payment Are the current payment amounts sufficient for clinicians to adopt, and not too expensive that payers will balk at covering - YES
 - Coverage Do government and private insurers provider coverage for the services for the specific clinical indication?
- The use of CHR for the diagnosis of mental health conditions should only confront one of the three common barriers that challenge new technologies
- Full reimbursement possible as early as 2 years post FDA Approval based on strategy of leveraging off existing CPT Codes



2. Corporate Stress and Mental Wellness Product



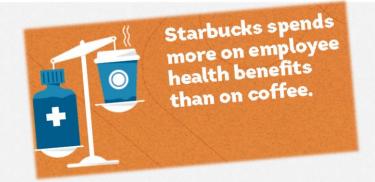
- Does not require regulatory approval thus can be done pre-validation
- Our unique selling position is that our product is based on 15 years of medical research and validation studies of the technology are currently under way
- Only test based on the analysis of high quality extended ECG readings rather than a short term snap shot of non ECG quality data or questionnaire based
- No evidence-based competing products
- Concept of how far is the CHR pattern away from a normal signature:
 - Normal, mild, moderate or severe or a score out of 10
 - Provides a diagnostic measure of how the impact of life stressors have affected your mental health and wellbeing



Corporate Wellness



- US Market
 - 40 million in the US (+5,000 staff firms²)
 - 21.3 million US Government positions
- US\$2.2Bn revenue potential annually
- Demand in the US driven by many factors
 - Need to reduce health care spend
 - Social responsibility/OHS Requirements
 - Absenteeism, presenteeism (In a 3-month period, patients with depression miss an average of 4.8 workdays and suffer 11.5 days of reduced productivity¹)
- Three distinct channels to market
 - Full service turn-key solution
 - Licensing/sale and data analytics model
 - White label









3. mHealth Consumer App Market

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- o 500 million smartphone owners using a healthcare app in 2015
- 1.7 Billion smartphone/tablet owners will have downloaded mobile health applications by 2018¹
- Currently 44,000 medical apps on the App Store
- The market for mobile health applications and associated devices will grow at a compound annual growth rate of 61% to reach \$26 billion in revenue by 2017, according to a new report from Research and Markets.
- Apple/Mayo Clinic partnership with IOS8. The Goal?
 IPhone/Apple Watch that makes you healthier!
- NHS (and US Institutions) predict that by 2030 self diagnosis and medication will be a necessity to alleviate pressure from the health care system resulting in only the critically ill being admitted to a medical institution.







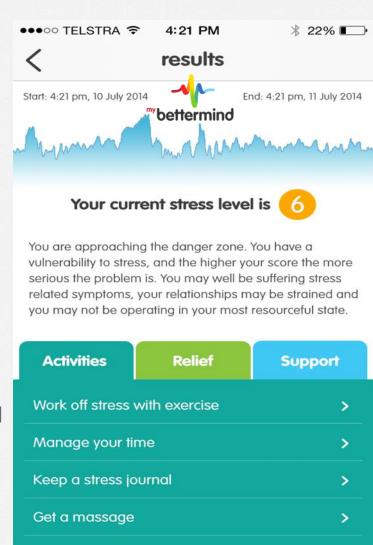
^{2.} Accenture Digital Consumer Tech Survey 2014



Consumer App - Mental Health Category



- 10% of the 44,000 Health Apps are related to stress/mental health:
 - 2538 results in the search for stress
 - 628 results for depression
 - 854 results for anxiety
 - 475 results for mental health
- Most Stress Apps are based on reducing tension via breathing, yoga, and relaxing sounds.
- All are more of a wellness product than stress identification and mental health management
- Mental health and depression Apps are mostly based on subjective DSM5 method
- None offer objective stress assessment based on extended research

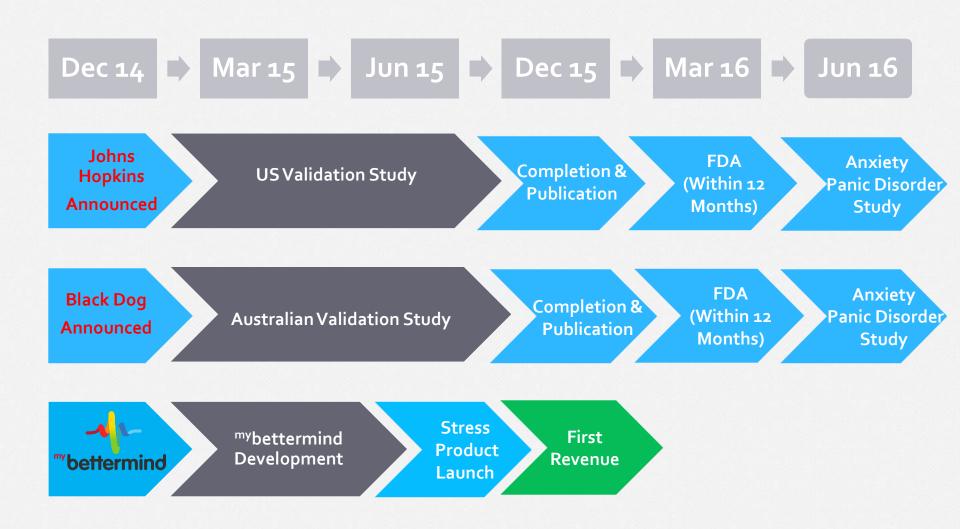


- 1. Source Technology News.com.au
- 2. Accenture Digital Consumer Tech Survey 2014



Timeline to Commercialisation







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Appendix 1 - Capital Structure



	Existing Capital Structure	Post Consolidation 100:1	
		Shares	Options
Existing shareholders	3,506,522,703	35,065,227	-
Existing Convertible Notes	30 series "A" x \$50,000 @ 0.1¢ 40 series "B" x \$25,000 @ 0.3¢	15,000,000 3,333,333	15,000,000
\$2.5 million Capital Raising #		8,333,333	-
Invatec Vendors		25,537,500	4,000,000
TOTAL ON ISSUE AT COMPLETION		87.2 million	19.0 million
Heartlink Patents		10,346,803	
Vendor Milestone 1	(VALIDATION)	6,000,000	
Vendor Milestone 2	(ALGORITHIM)	6,000,000	
Vendor Milestone 3	(FDA/TGA)	6,000,000	
ALL MILESTONES ACHIEVED		115.6 million	19.0 million

[#] to be confirmed

