Medibio Limited

Investor Presentation December 2014

ASX: MEB

Medibio Limited - Snapshot

Our Aim:
- To introduce the first FDA approved evidence-based test for depression/anxiety
- To present an objective test for evaluating the effectiveness of treatment for mental illness

Research Partners:
- Johns Hopkins and the Black Dog Institute - world leaders in mental health research

Market:
- Depression diagnostic alone is a US$16bn revenue opportunity

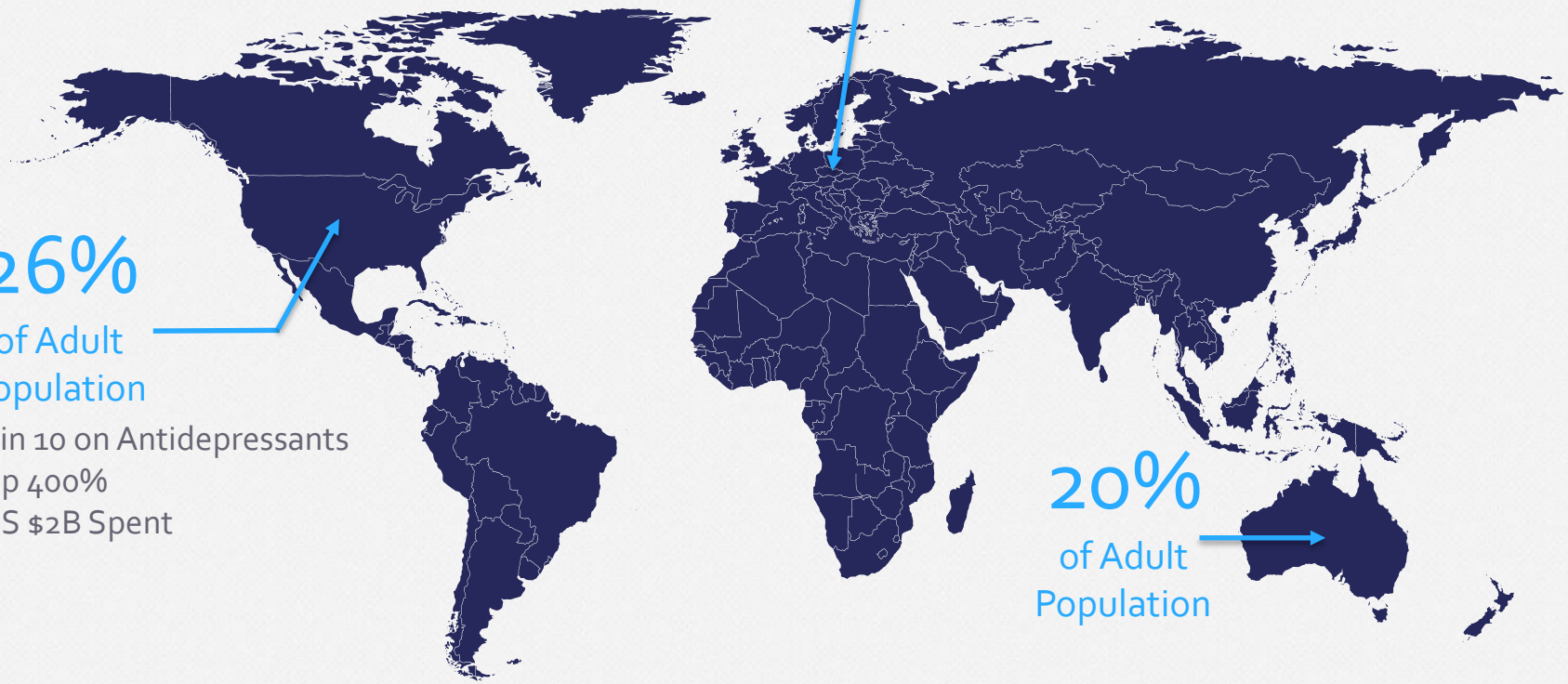
Timeline:
- First revenue via corporate and consumer stress-test products mid 2015
- Johns Hopkins validation study completed in 12 months
- FDA Approval within 12 months from completion of study

Valuation:
- Capitalisation $25m with $3m in cash post completion (Appendix 1)

Mental Health Landscape

350 Million Worldwide Diagnosed With Depression
1 Suicide Every 40 Seconds

1 Million Suicides Every Year



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

http://www3.weforum.org/docs
WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf

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Board and Management Team

Board of Directors

- Chris Indermaur (Incoming Chairman)
- Vince Fayad (Chairman retiring)
- Dr James Campbell (Non Executive Director)
- Kris Knauer (Executive Director)

Management

- Dr Matt Mesnik (CMO) US Based with 20 years Medical Executive experience
- Dr Michael Player (COO) Research Psychologist at Black Dog Institute
- Claude Solitario (Head Consumer Division) Founder
- Stephen Stapelberg (Head Marketing)

Advisory Board

- Stephen Pearce (Chairman Lions Eye Institute and CFO Fortescue Metals)
- Dr Hans Stampfer (Inventor - Professor Psychiatry at UWA and Head Psychiatry Joondalup Teaching Hospital)
- Dr Stephen Addis – (Founder and Head Psychiatry Fremantle Hospital)

The Problem

- 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
- CHR adds an objective dimension to the diagnosis of depression and 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)

Game Changer

- 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 quantitative method for diagnosing depression"

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

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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
- Improved monitoring helps to optimize effective treatment
- Savings to the health system from earlier diagnosis

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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 'markers' 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
- 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

How it Works

Clinician orders test

24 Hour Heart rate data captured and sent to cloud server

Heart rate data analysed by algorithms

Diagnostic report sent to clinician

No disruption to normal clinical work flow

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US Validation Study – Johns Hopkins University

- Study Objective
  - To validate the use of our 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 3/4Q 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 & Bloomberg School of Public Health.
  - Dr Punjabi has published well over 100 research papers

JOHNS HOPKINS MEDICINE SCHOOL OF MEDICINE

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Australian Validation Study – Black Dog Institute

- What is the Study Objective?
  - To demonstrate that our Circadian Heart Rate Technology can distinguish between melancholic and non-melancholic depression.
- Who is the Black Dog Institute (BDI)?
  - Australia's preeminent mental health research organisation.
  - Over 150 research and clinical staff
  - Independent not-for-profit organisation
  - Focus on the rapid translation of mental health research into improved clinical practice
- Who is the Principal Researcher?
  - Professor Gordon Parker
  - The founder of the Black Dog Institute and Officer of the Order of Australia
  - One of the world's leading authorities on depression and bipolar disorder

BLACK DOG INSTITUTE
Because everyone deserves peace of mind

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Background to the Study – A Major Breakthrough

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)

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Target Markets

Medical

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

Corporate

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

Consumer

- ✓ Direct to Consumer
- ✓ Ideal for wearables

Pay per report/Licensing arrangements

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Early Revenue Opportunity (Pre-validation)

Consumer App/Corporate Product
(Chronic Stress)

my bettermind

E-Health Consumer Market

- 500 million smartphone owners using a healthcare app
- 1.7 Billion by 2018[1]
- 52% interested in buying wearable devices that measure their health[2]
- Apple/Mayo Clinic partnership with IOS8. The Goal? IPhone/Apple Watch that makes you healthier!
- Other stress apps on the market have achieved 25 million downloads and we are confident our offering is superior

- ***8,500 downloads achieves break even on the my bettermind capital costs***

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

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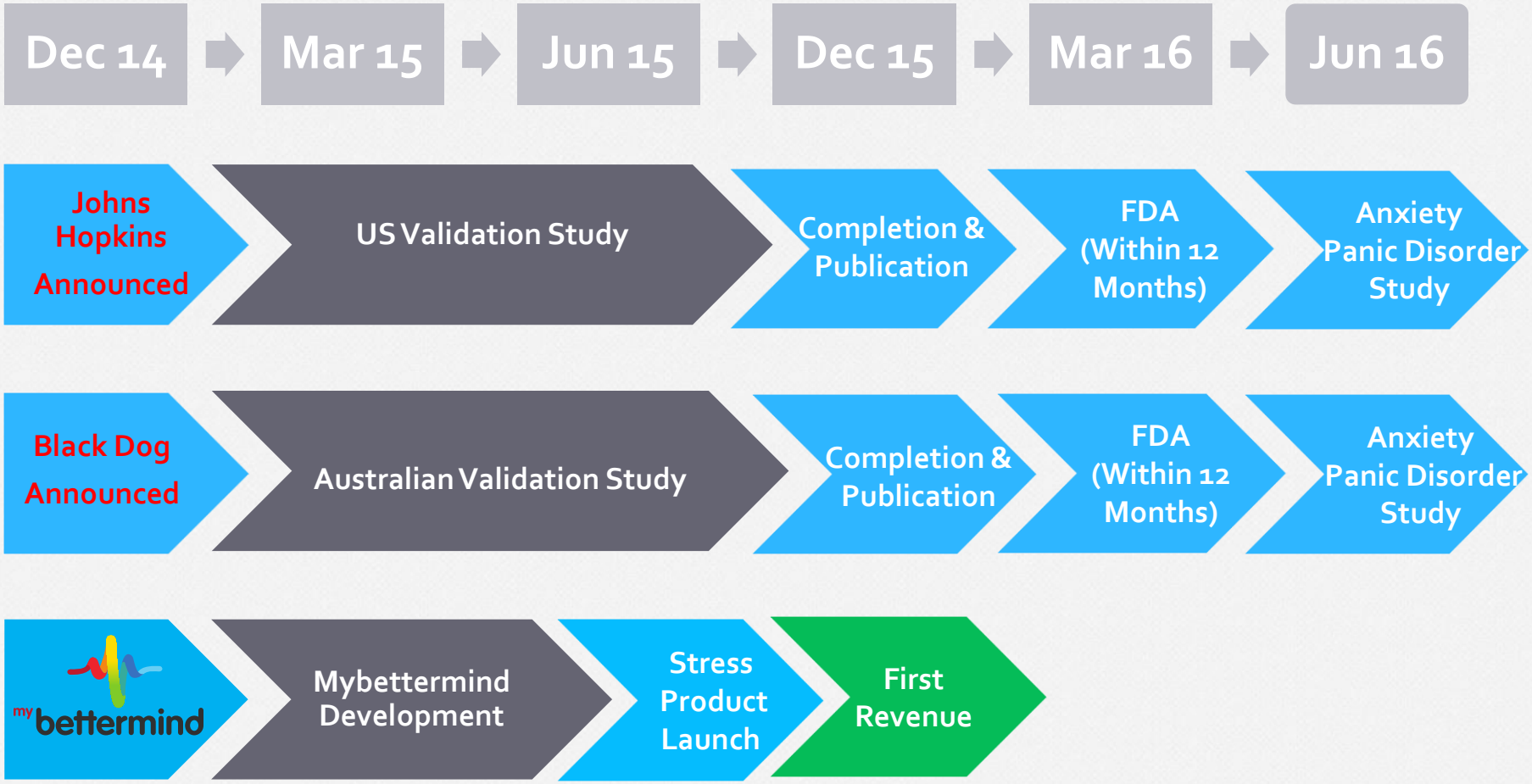
Timeline to Commercialisation



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Key Company Milestones

Timing	Milestone	Status
Q4 2014	Australian validation site confirmed	✓
Q4 2014	U.S. validation site confirmed	✓
Q4 2014	Appointment of U.S. CRO	✓
Q4 2014	Delivery of Commercialisation Study	
Q1 2015	Initiate discussions with FDA	
Q1 2015	Initiate U.S. and Australian validation studies	
Q1 2015	Confirm strategic partner for portable device	
Q1 2015	Complete development of product	
Q2 2015	Commercial launch of product	
Q3 2015	Commercial partnership with U.S. strategic partner	
Q4 2015	Results from U.S. and Australian validation studies	
Q4 2015	Submission to FDA	

Medibio in 12 months - December 2015

Australian & US Validation Trials Complete

Trial Results Published

First Revenue

FDA Application (Est 12 Months)

Stress App Launch

December 2015

New Australian & US Trials

- General Anxiety Disorder
- Panic Disorder

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Summary

- ✓ **Ground-breaking quantitative test for mental illness**
  - Based on analysis of circadian heart data
  - No cost effective competing technologies
  - Protected by patents and know how
  - No existing FDA approved quantitative test

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- ✓ **Multiple global market sectors – all large**
  - Depression diagnostic alone is a $16 billion revenue opportunity
- ✓ **Supported by over 10 years of research**

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- ✓ **Validation trials to commence in both:**
  - U.S.A.
  - Australia
- ✓ **Early revenue opportunity–chronic stress product (pre-validation)**

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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**

Subject to relevant Shareholder approvals–anticipated in November 2014

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Appendix 2 – US Revenue Potential (Depression)

"Appears the existing CPT & ICD9 codes for cardiac rhythm monitoring devices may be leveraged"

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

1. **Untreated market (initial diagnosis)**
   - 3.5% population @ $45 per report to Medibio
   - US$507m revenue opportunity

2. **Treated market (ongoing monitoring)**
   - 3.5% population @ US$22.50 per report – quarterly monitoring
   - US$1014m revenue opportunity

"Given the capital expense of the equipment, proprietary software algorithms, and the work associated with the testing, the current payment levels should be sufficient for clinician adoption"

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