Medibio Limited

# General Meeting Presentation
# March 6 2015

ASX: MEB

# Medibio Limited - Snapshot



**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 Partners:**
- Johns Hopkins University and the Black Dog Institute
- World leaders in mental health research

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

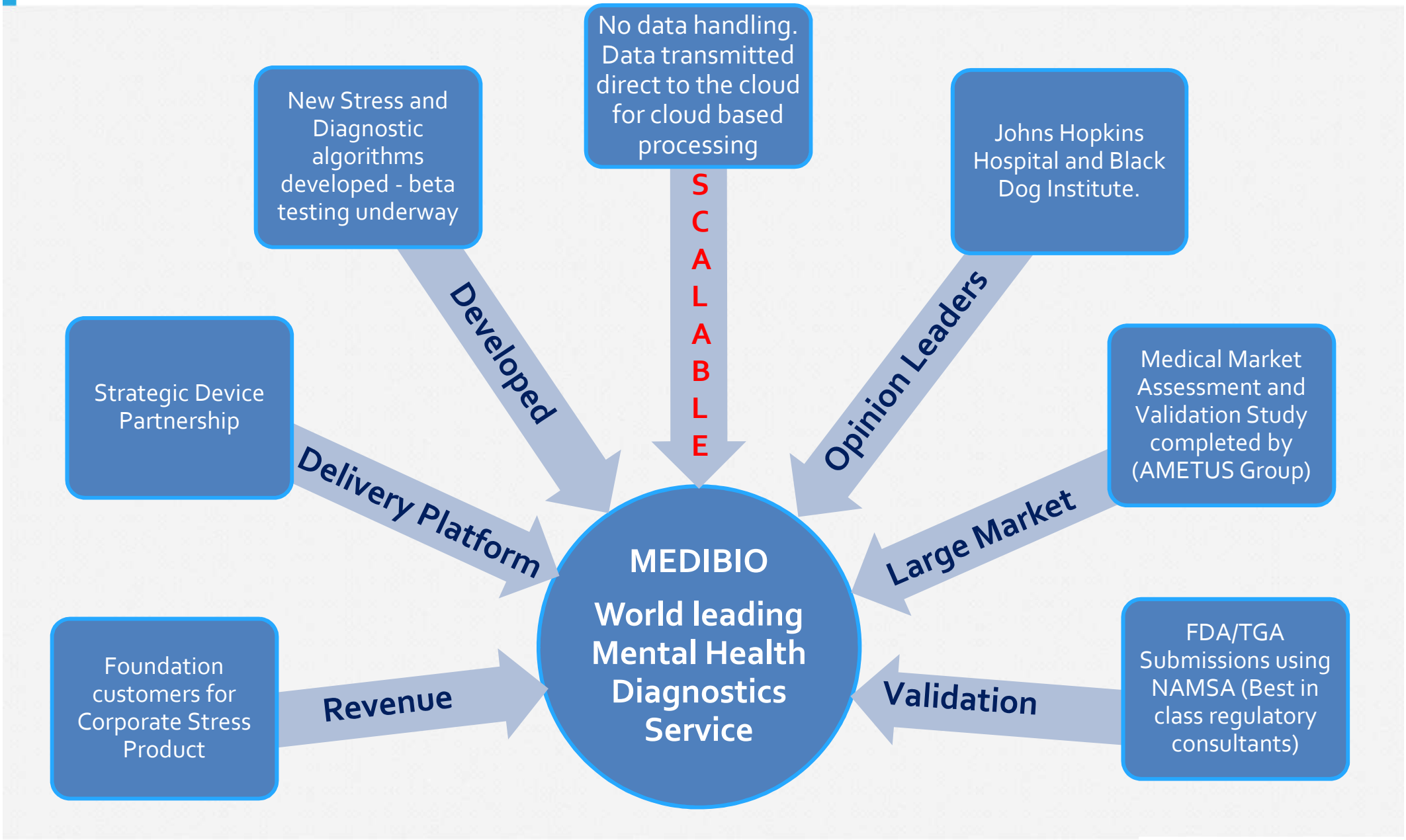
**Timeline:**
- First revenue via corporate stress-test products targeted mid 2015
- Johns Hopkins validation study completed in 8-10 months
- Targeting FDA Approval within 12 months from completion of study

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

(1) upon completion of acquisition of 100% of Invatec and $2.5m capital raise at capital raise price

# The building blocks are now in place



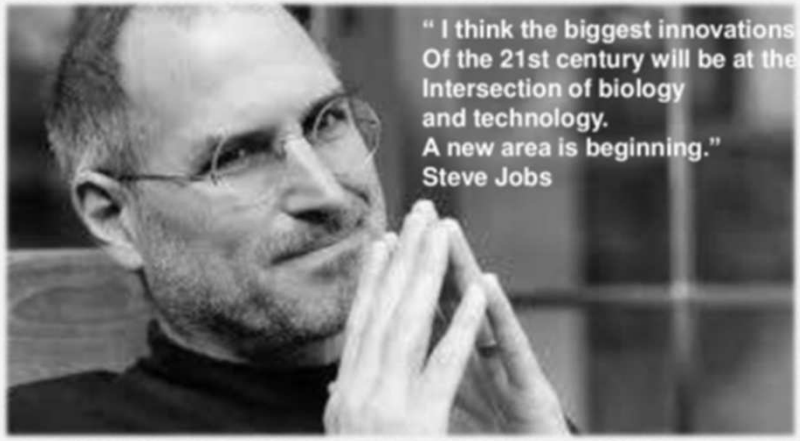



Medibio Limited

# Long Term Vision – MedTech for Mental Health



- 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

Medibio Limited

# Key Company Milestones



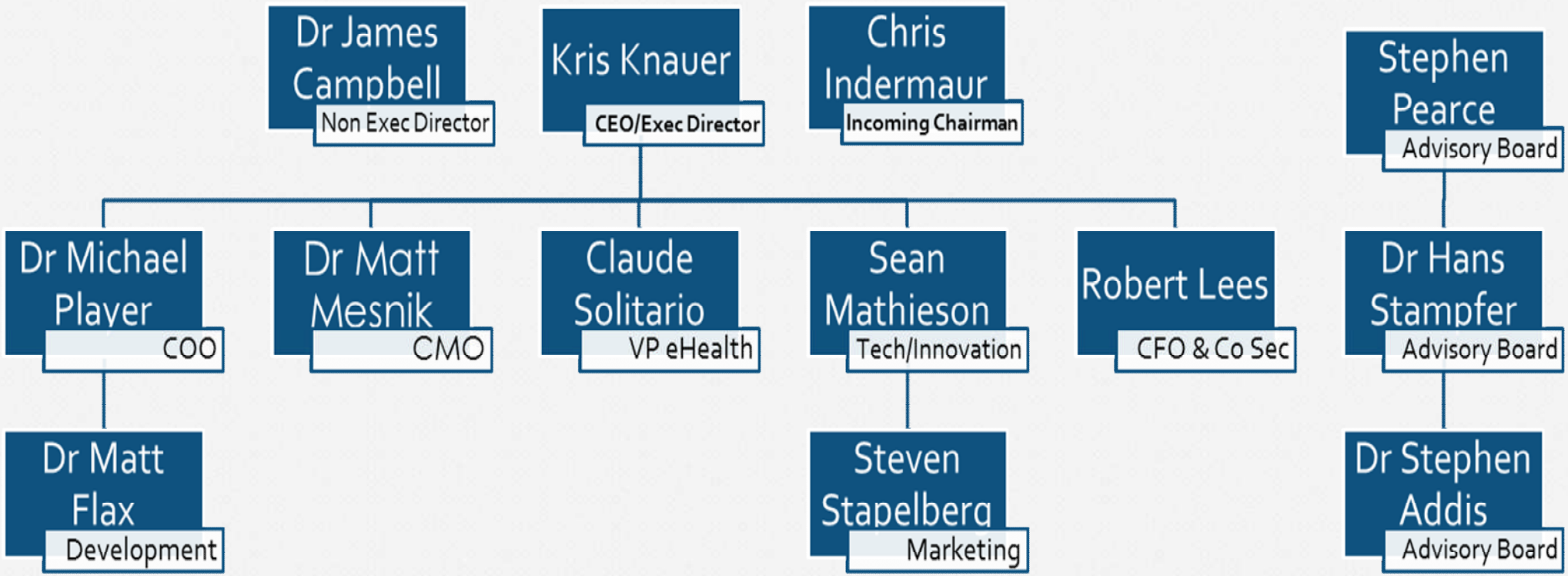
| Timing | Milestone | Status |
|---|---|---|
| Q4 2014 | Australian and US validation studies (BDI & JHU) | ✓ |
| Q1 2015 | Delivery of Commercialisation Study (AMETUS) | ✓ |
| | Strategic device partner | |
| | Pre-submission package delivered to the FDA | |
| | Complete beta testing of new Stress 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 | |

* Based on the company's best estimates

Medibio Limited

# Organizational Chart





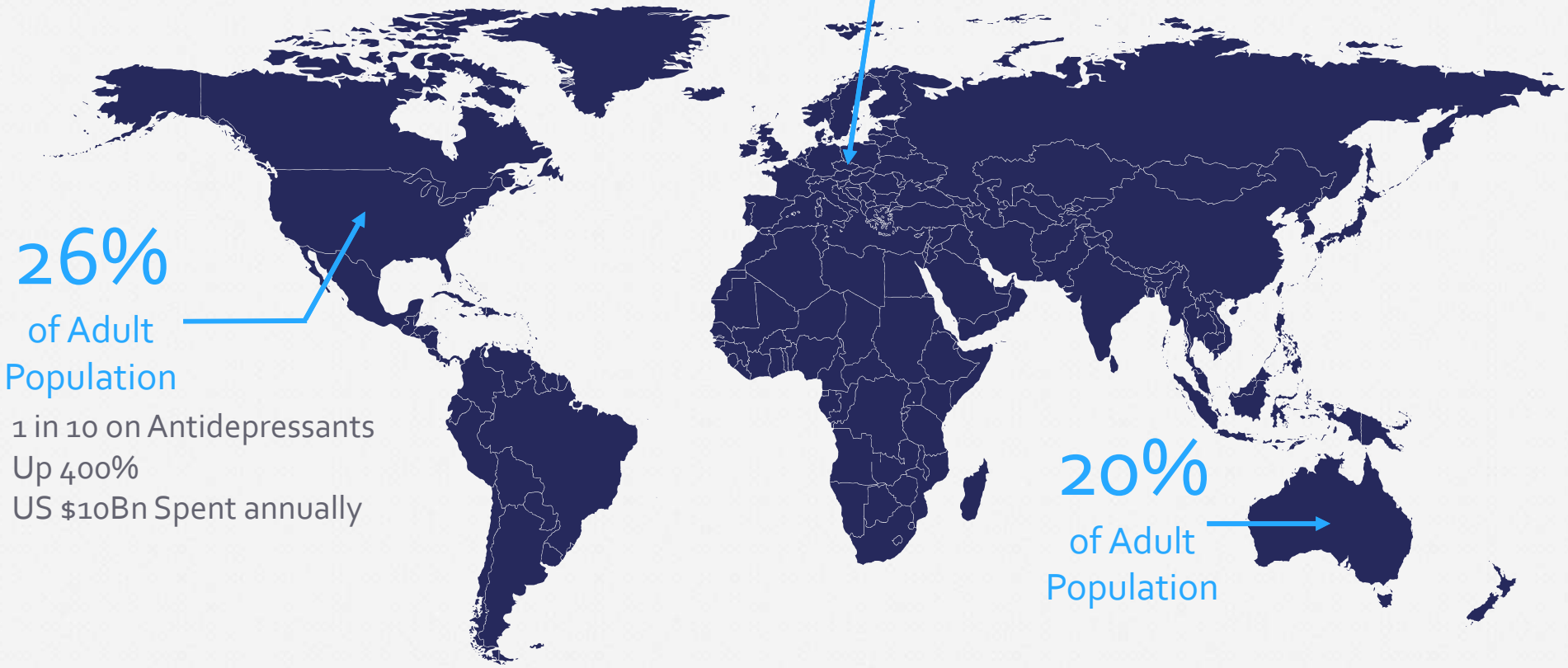
# Mental Health Landscape



**350 Million Worldwide Diagnosed With Depression**
**1 Suicide Every 40 Seconds**

**1 Million Suicides Every Year**

27% of Adult Population



26% of Adult Population

1 in 10 on Antidepressants
Up 400%
US $10Bn Spent annually

20% of Adult Population

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

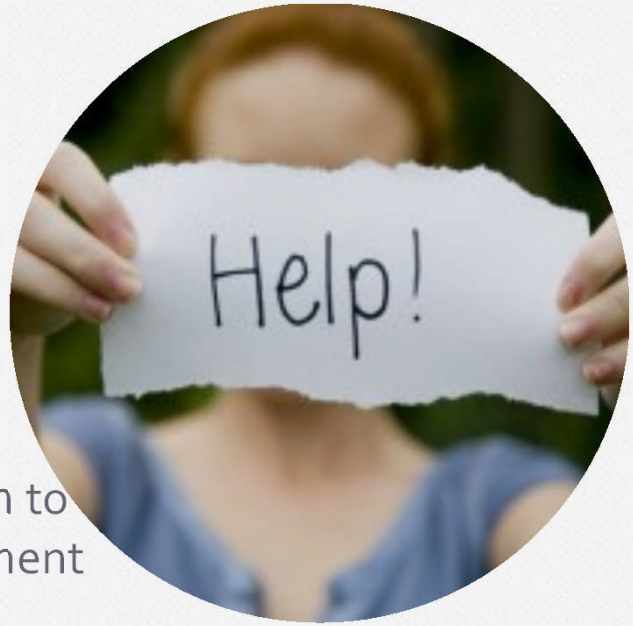
http://www3.weforum.org/docs
WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf

Medibio Limited

# 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
- 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)

Medibio Limited

# 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)

Medibio Limited

# 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

Medibio Limited

# 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

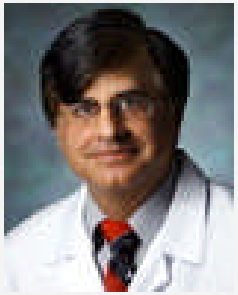


- Based on over 15 years of research
- Different forms of mental illness such as 'anxiety' and 'depression' are associated with distinctly different patterns of CHR
- Distinct 'biomarkers' in heart rate data for depression and certain other mental illnesses have been identified
- Normal people (not attending GP/mental health professional) often show minor changes in CHR
- 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



# 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)

Medibio Limited

# Three Clearly Defined Target Markets



## Medical

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

## Corporate

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

## Consumer

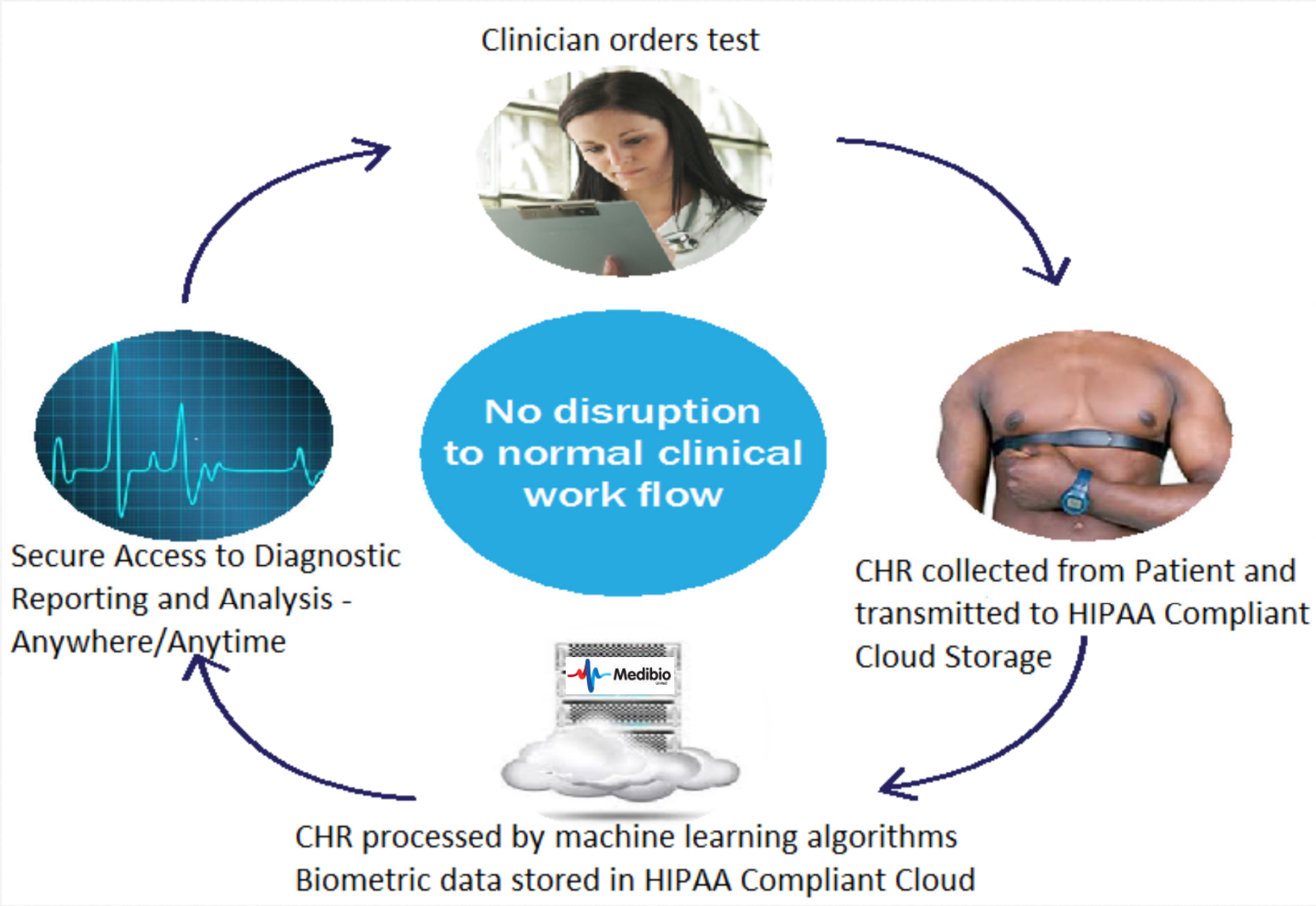
- ✓ Direct to Consumer
- ✓ Ideal for wearables

**Pay per report/Licensing arrangements**

Medibio Limited

# 1. Medical Diagnostic Market






Medibio Limited

# 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



- 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

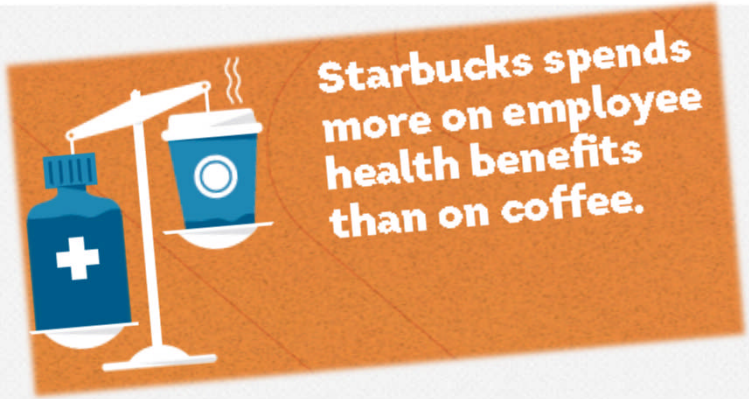


- Does not require regulatory approval thus can be done pre-validation
- Our unique selling position is that our product is based on 15 years of medical research and validation studies of the technology are currently under way
- Only test based on the analysis of high quality extended ECG readings rather 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 firms[2])
  - 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 productivity[1])
- Three distinct channels to market
  - Full service turn-key solution
  - Licensing/sale and data analytics model
  - White label





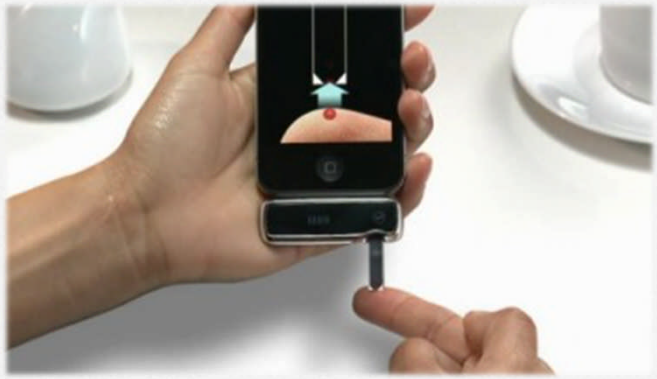

1. US CDC
2. US Census

Medibio Limited

# 3. mHealth Consumer App Market



- 500 million smartphone owners using a healthcare app in 2015
- 1.7 Billion smartphone/tablet owners will have downloaded mobile health applications by 2018[1]
- 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.

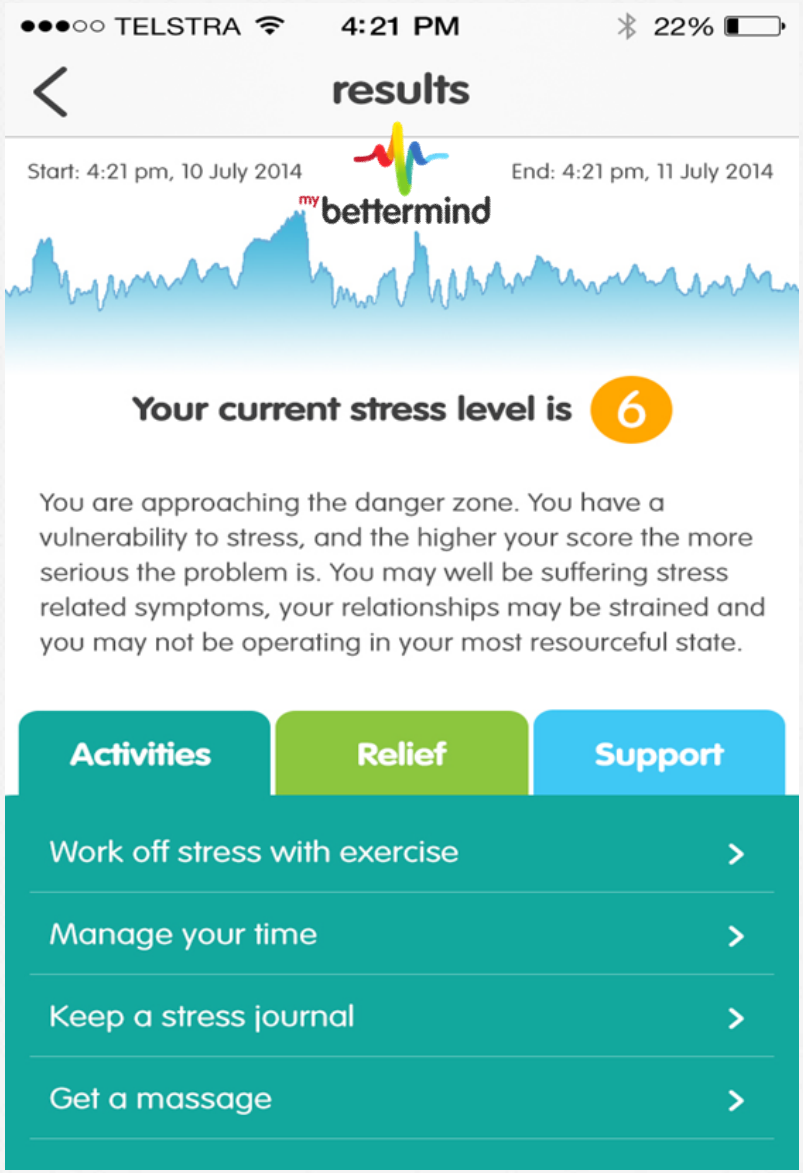
1. Source – Technology News.com.au
2. Accenture Digital Consumer Tech Survey 2014

Medibio Limited

# 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

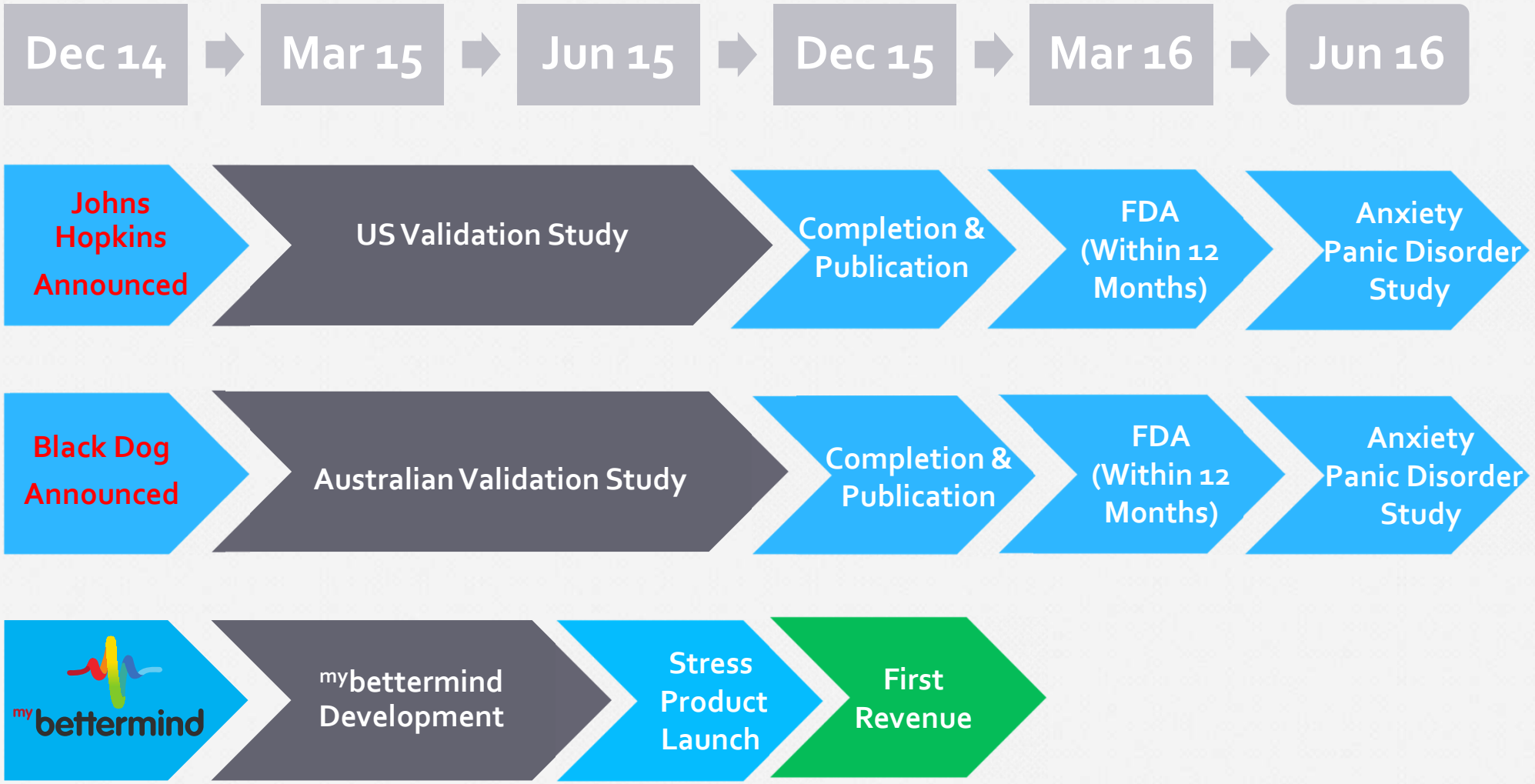



1. Source – Technology News.com.au
2. Accenture Digital Consumer Tech Survey 2014

Medibio Limited

# Timeline to Commercialisation






Medibio Limited

# Disclaimer



This presentation does not constitute, or form part of, an offer to sell or the solicitation of an offer to subscribe for or buy any securities, nor the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issue or transfer of the securities referred to in this presentation in any jurisdiction in contravention of applicable law. Persons needing advice should consult their stockbroker, bank manager, solicitor, accountant or other independent financial advisor.

Certain statements made in this presentation are forward-looking statements. These forward looking statements are not historical facts but rather are based on Medibio Limited's current expectations, estimates and projections about the industry in which Medibio operates, and its beliefs and assumptions.

Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements and should be considered at-risk statements. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services.

These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Medibio, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements.

Medibio cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Medibio only as of the date of this presentation. The forward-looking statements made in this presentation relate only to events as of the date on which the statements are made.

Medibio will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

# 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¢<br>40 series "B" x $25,000 @ 0.3¢ | 15,000,000<br>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

Subject to relevant Shareholder approvals – anticipated on March 6 2015

Medibio Limited