



Investor Presentation

April 2016

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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 digital mental health platform will transform the assessment and management of mental health
- Defensible IP/technology based on 20 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
- Endorsement from corporate partners: Medtronic, Preventice, others
- FDA submission this year and existing reimbursement codes to pave the way for clinical and corporate acceptance
- Multiple commercialisation routes: Clinical, Pharma, B2B and B2C represent multi-billion dollar market opportunities
- B2B product (stress) on market now and in use with key strategic partners

“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)

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



Sean Mathieson
Chief Operating 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 Asia/Pacific, Founding Member of Ariba Asia/Pacific
- Experience in start-up through multi-billion valuations



Dr Matt Mesnik
Chief Medical Officer
(US Based)

- 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.



Yashar Behzadi, PhD
Head US
(Based in Silicon Valley)

- Digital health expert with 10 years experience building disruptive technology platforms and business models
- Previously head of product, applications and data sciences at Proteus Digital Health, a health-tech unicorn
- 20 issued patents across medical device, wearables, software & algorithms
- Technology advisory board member at Accenture



Dr Franklyn Prendergast
Board Member
(US based)

- 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 Centre for Individualized Medicine and Mayo Clinic Comprehensive Cancer Centre

Corporate Snapshot

| | |
|--|----------------|
| ASX TICKER | MEB |
| Shares on Issue | 101M |
| Warrants (\$0.10 – Expire April 2018) | 15M |
| Warrants (\$0.30-\$0.80 - Expire Apr 2017) | 12.7M |
| Last Trading Price | \$0.23 |
| Valuation (Existing Capital) | \$23.2M |
| Milestone Shares* | 20M |
| Debenture (convertible 2020 @ \$0.31) | US\$2.5M |
| VALUATION (FULLY DILUTED) | \$33.8M |

Available Cash – \$2.5M (plus ~ \$2.3M 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/CE Mark |

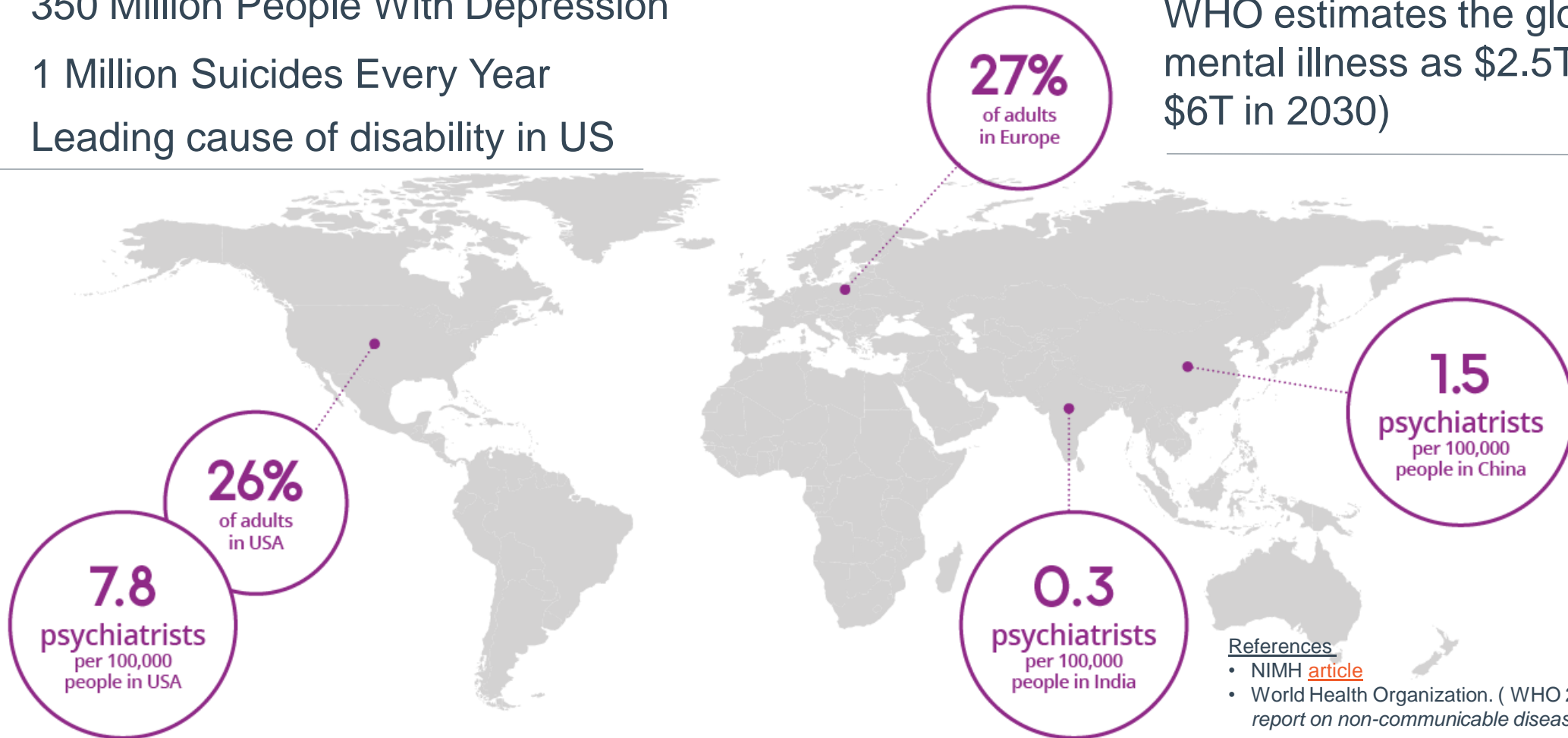
**Medibio's
Digital Mental Health Platform
will transform the assessment
and management of mental
health by:**

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

“The Single Greatest Illness that Affects Mankind” *

- 350 Million People With Depression
- 1 Million Suicides Every Year
- Leading cause of disability in US

WHO estimates the global cost of mental illness as \$2.5T in 2010 (est. \$6T in 2030)



References

- NIMH [article](#)
- World Health Organization. (WHO 2011a). *Global status report on non-communicable diseases 2010*. Geneva: WHO

* World Mental Health Day 2015
Professor [Stephen Lawrie, Head of Psychiatry at Edinburgh](#)

Snowball Effect of Depression

Patients diagnosed with MDD are far more likely to develop serious co-morbidities.



The Need for Objectivity

“The economic costs of mental illness will be more than cancer, diabetes & respiratory ailments put together.”

Thomas Insel, MD – Former Director National Institute of Mental Health

Current Pain Points

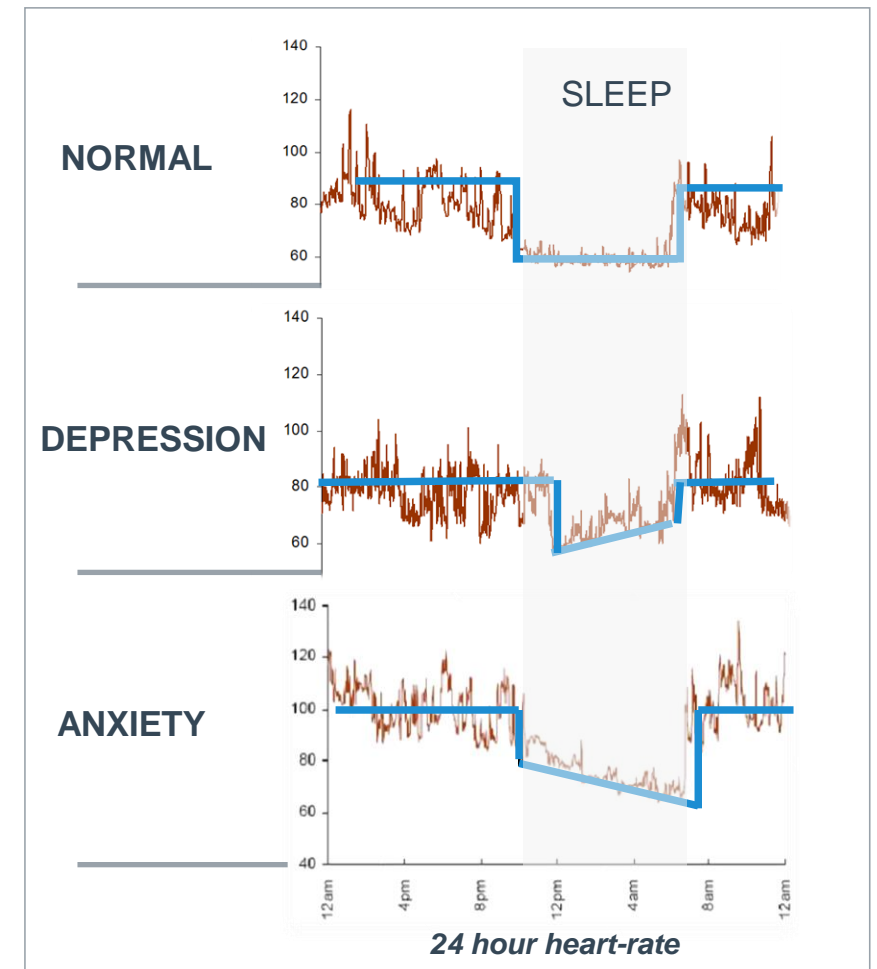
- No objective test for mental illness.
- The diagnostic “gold standard” is a clinical/expert opinion.
- Diagnostic agreement between clinicians can vary considerably – concordance rates near 70%.
- Current assessments are subjective which can lead to inadequate or incorrect diagnosis.
- Misdiagnosis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

Medibio’s Solution

- Quantitative, 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 20 years of Clinical Research

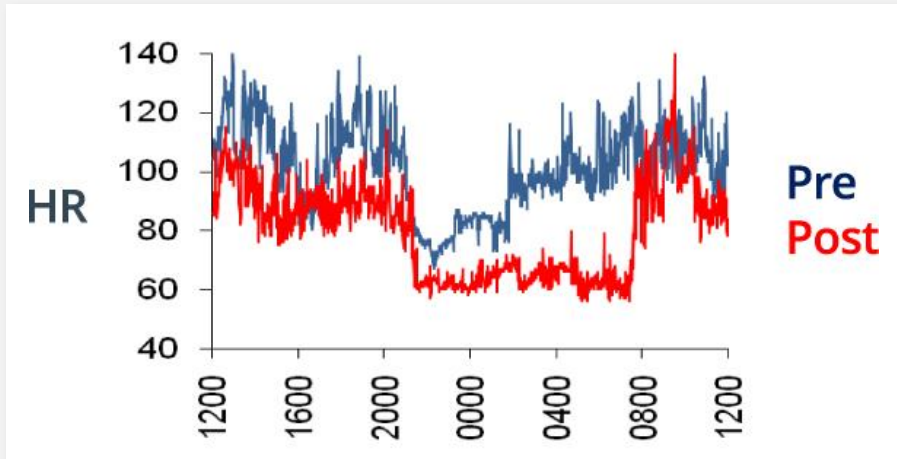
- Research initiated 20 years ago at University of Western Australia to test the theory that mental state linked ANS disturbance could be observed via the cardiovascular system.
- Mental state-linked ANS disturbance is observed via the cardiovascular system during sleep when external influences are absent.
- 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

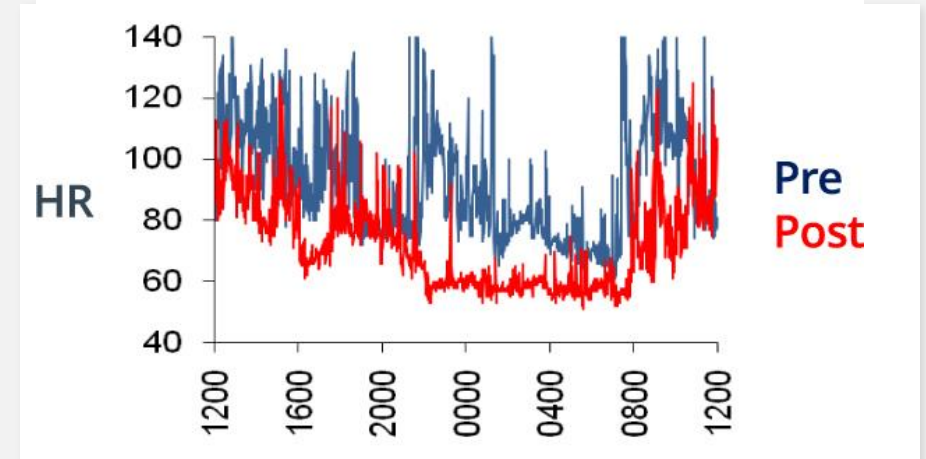
Case Study 1

- Depressed individual upon initial diagnosis
- Treated for 18 days with:
 - Olanzapine – 10mg (daily)
 - Mirtazapine – 60mg (daily)

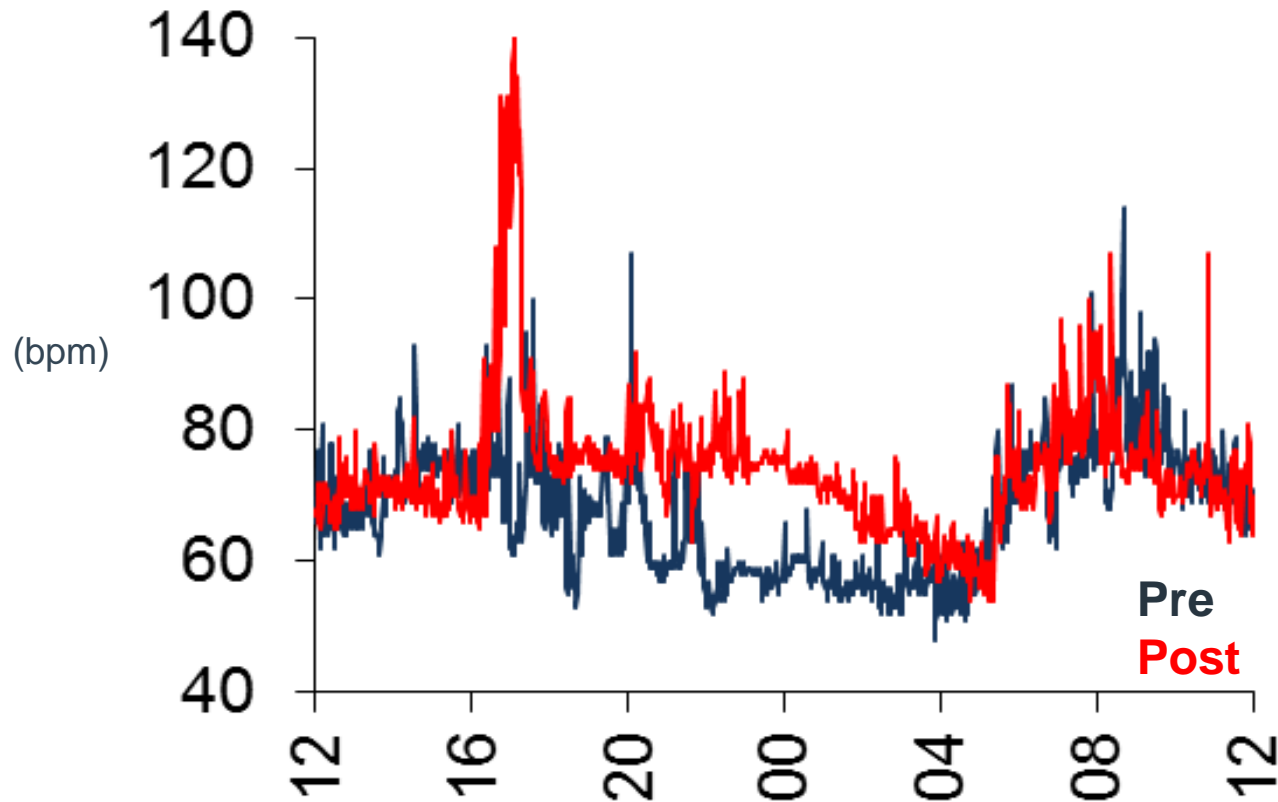


Case Study 2

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



Chronic Stress - Serial Changes



Patient Profile

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

| | 24 Hour Mean | Sleep Mean |
|--|--------------|------------|
| Prior to Senior Position | 67 | 57 |
| 6 months with treatment for Blood Pressure | 74 | 65 |

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) |
| 80% | 98 patients, mixed psychopathology and normals | Diligence by UNSW and Newcastle University independent researchers |
| 82% | 200 patients, 30 normals, 30 depression, 30 GAD, 110 other mixed psychopathologies | Australian & New Zealand Journal of Psychiatry 1998; 32; 187-198 |

Defensible Position Based on Decades of Research



Comprehensive suite of patents around CHR & technology:

- Medical diagnostics including assessment of treatment efficacy
- Stress assessment



Patent suite for medical diagnostics includes:

- 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:


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

Opportunities in Multiple Broad Markets

REGULATED

UNREGULATED

MEDICAL
US \$30Bn Industry



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

PHARMA
US \$76Bn Industry



- Global Pharma companies
- Clinical trial organizations
- Companion diagnostics

B2B
US \$19Bn Industry



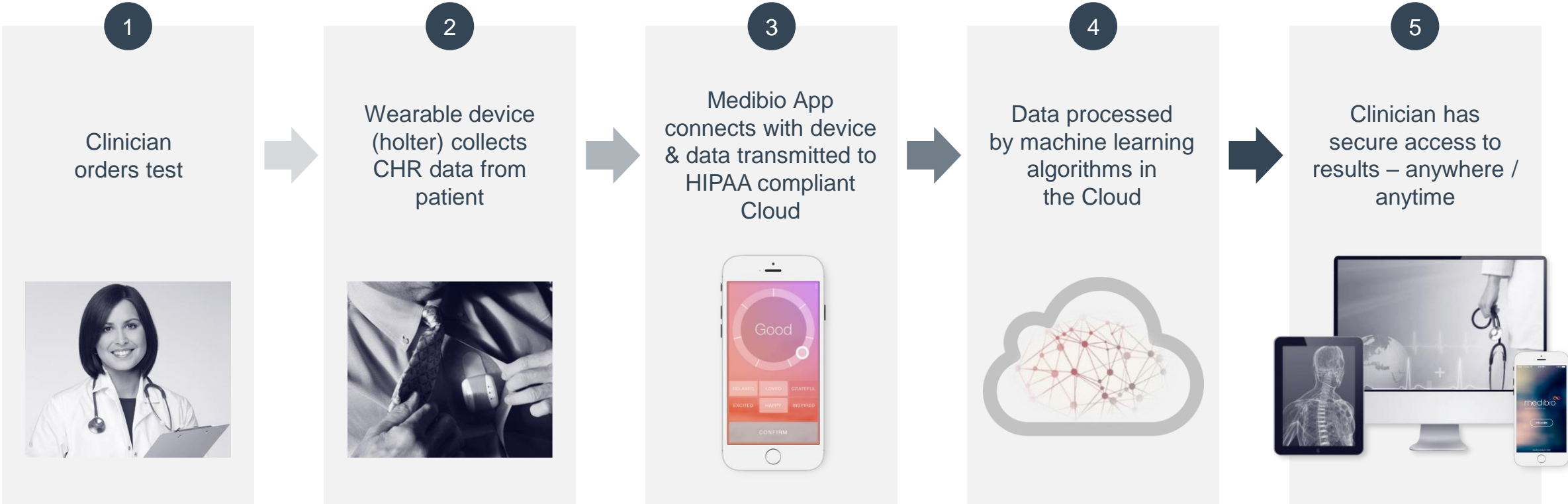
- High Risk Occupations
 - Defence
 - Police/Fire/Emergency
- Govt / Corporate Wellness
- SME Health and Wellbeing
- Elite Sports

B2C
US \$26Bn Industry



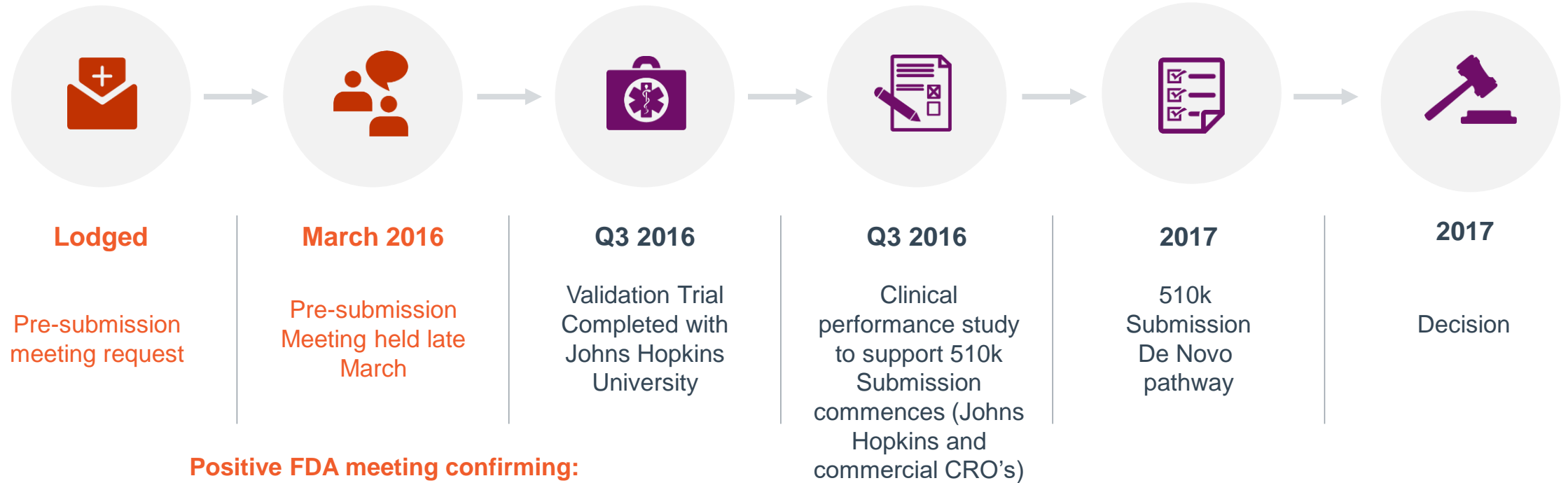
- Direct to Consumer
- Insurance Companies
- Wellness Providers
- Digital Health Companies

Clinical Work Flow



Targeting First FDA Approval in 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

Validation Trial with Johns Hopkins University

Study Objective

- Exploratory Study 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 data collection completed Q3 2016
- Simple, quick, powered to only need 50-60 participants
- subjects with MDD and Normal Controls

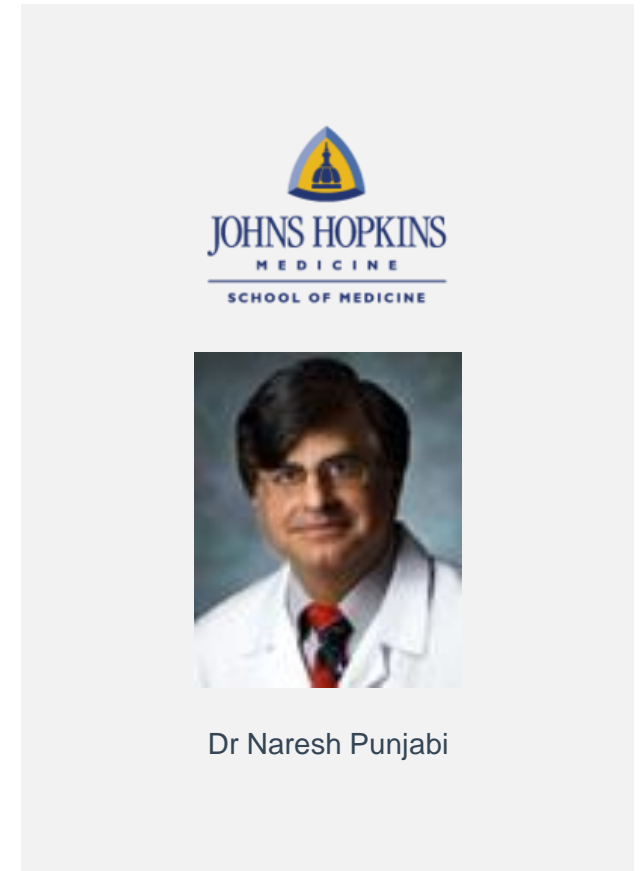
Johns Hopkins University (JHU)

- Ranked number one in the U.S. by US News & World Report for 22 years of the survey's 25 year history

Principal Investigator

Dr Naresh Punjabi

Professor of Medicine and Epidemiology in the Division of Pulmonary and Critical Care Medicine Associate Director of Graduate Training Program in Clinical Investigation at JHU. Published more than 100 research papers.



Clinical Market Opportunity

- PCP's in the US are becoming the primary psychiatric care provider with in excess of **50% of all psychiatric diagnosis**
- 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 given some therapy
 - **30%** are referred to a psychiatrist/psychologist
- Will be marketed as a **diagnostic aid with the early adopter PCPs**
- Model based on the current structure for ambulatory ECG monitoring

| CPT CODE | MEDICARE | PRIVATE | INSURANCE |
|----------|--|---------|-----------|
| 93225 | Recording (Provider) | \$26.87 | \$40 |
| 93226 | Analysis with Report (Medibio) | \$37.91 | \$57 |
| 93227 | Physician review and Interpretation (Provider) | \$26.87 | \$40 |

- 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** for depression diagnosis would generate revenue of **\$175 million annually**
- Cloud based analysis and reporting = minimal costs per report = **very high margins**

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
 - Workers' compensation awards as well as tort and FELA judgments

US Market Size

- **54 million** employees in the US (+1,000 staff firms³)
- **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. 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



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

Using stress specific algorithms Medibio's technology provides objective indications of the stress. Based on an extensive number of indicators and measures from the CHR waveform, individuals are classified into one of six distinct categories:

1. **Normal** – No indication of stress, no action required
2. **Slight** – Some signs of stress, no action required
3. **Mild** – Some signs of stress, action required to prevent escalation
4. **Moderate** – Multiple signs of stress, action recommended
5. **Severe** – Signs of significant stress, action required to prevent development of long term mental health problems
6. **Very Severe** – Signs of extreme stress, immediate action required to prevent development of mental health problems

We provide the first objective measure of stress, a series of user and corporate dashboards, and can plug into wellness partner interventions.

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/types
- Reduced absenteeism and increased productivity
- Reduced claims and pressure on the health care systems

B2B Market - Existing Commercial Relationships

- Covidien (subsidiary of Medtronic) platform integration agreement as part of a strategic collaboration with Medtronic.



- Vital Conversations (WA based wellness partner): 50 person Pilot Program underway, potential of 5,000 Australian staff (200,000 staff internationally). Number of additional clients waiting on completion of the Pilot Program



- ASX Top 100 Company: 150 person Pilot Program starts in Q2 2016, 10,000 staff roll-out contingent on Pilot Results.

- Australian National Wellness Partner (Health Services Provider): 100 person Pilot Program underway via internal staff wellness program (~6,000 Australian employees). National Partner's existing Corporate Wellness clients have in excess of 500,000 Australian staff.

- WellNovation: Preliminary discussions with a client with 360,000 participants in the Middle East.



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. ⁽¹⁾
- Overall antidepressant market was valued at \$USD 11.9 Billion in 2011. ⁽²⁾

\$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)*

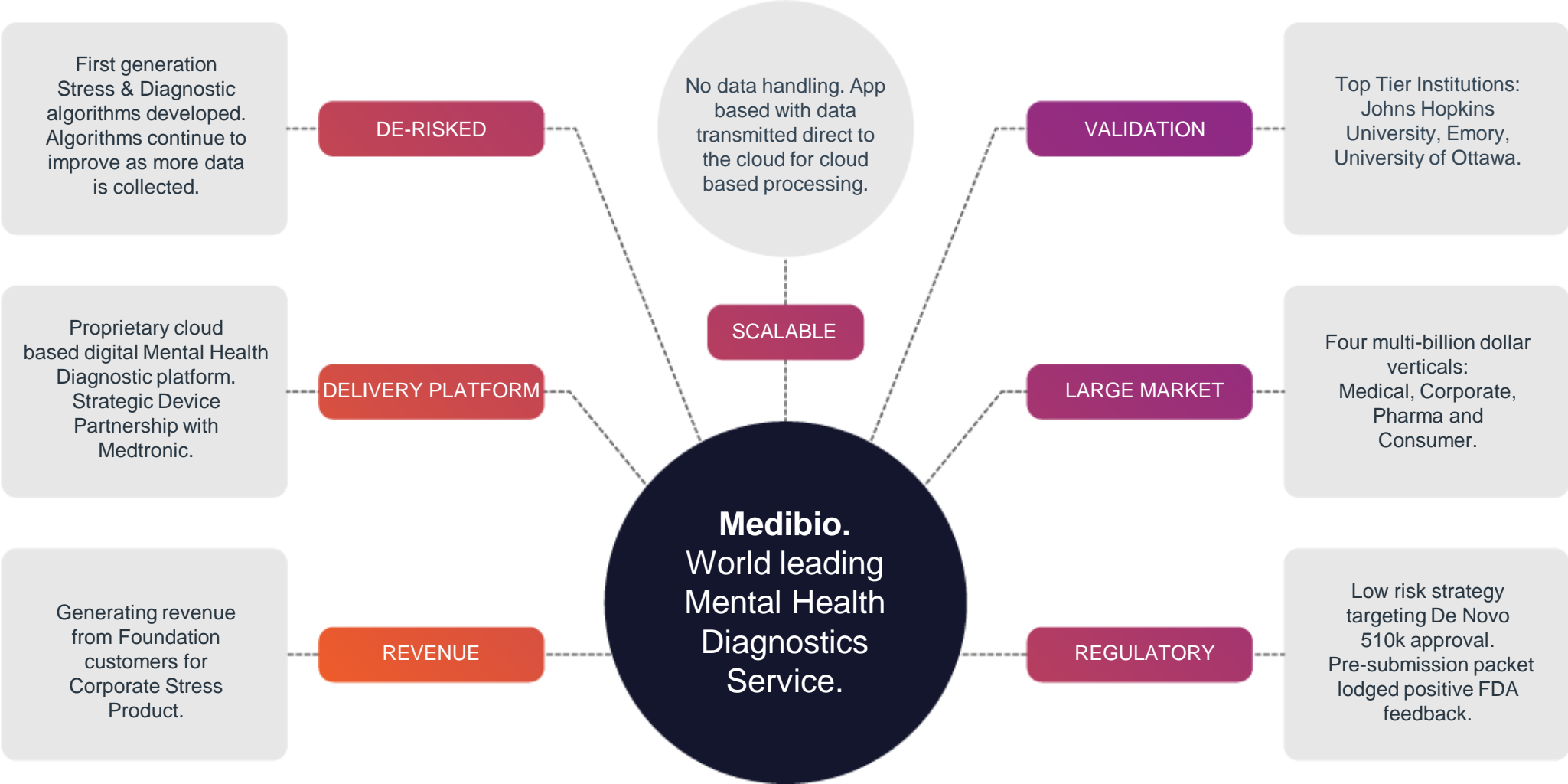
Key Company Milestones

| TIMING | MILESTONE | STATUS |
|---------|--|--------|
| Q1 2016 | FDA Feedback on Pre-submission package – confirmed proposed regulatory pathway | ✓ |
| | Completion of wearable testing program with NTICA – confirmed suitability of Apple Watch and Fitbit | ✓ |
| Q2 2016 | Completion of commercial stress pilots (2 separate pilots) | |
| | Announcement of Foundation Partner for Australian Corporate Stress Rollout | |
| | Completion of stand alone sleep staging algorithm (5 stages of sleep) using ECG data | |
| Q3 2016 | Completion of first phase of clinical study to provide stress validation | |
| | Binding Commercial Agreement with Medtronic | |
| | Decision on launch of Consumer Stress App | |
| Q4 2016 | Announcement of second Regional Foundation Partner | |
| | Completion of John Hopkins University Validation Study on depression | |
| | Completion of Independent Validation Study Corporate Stress product | |
| | Lodgement of FDA Application (Depression Diagnostic) | |

Competitor Overview

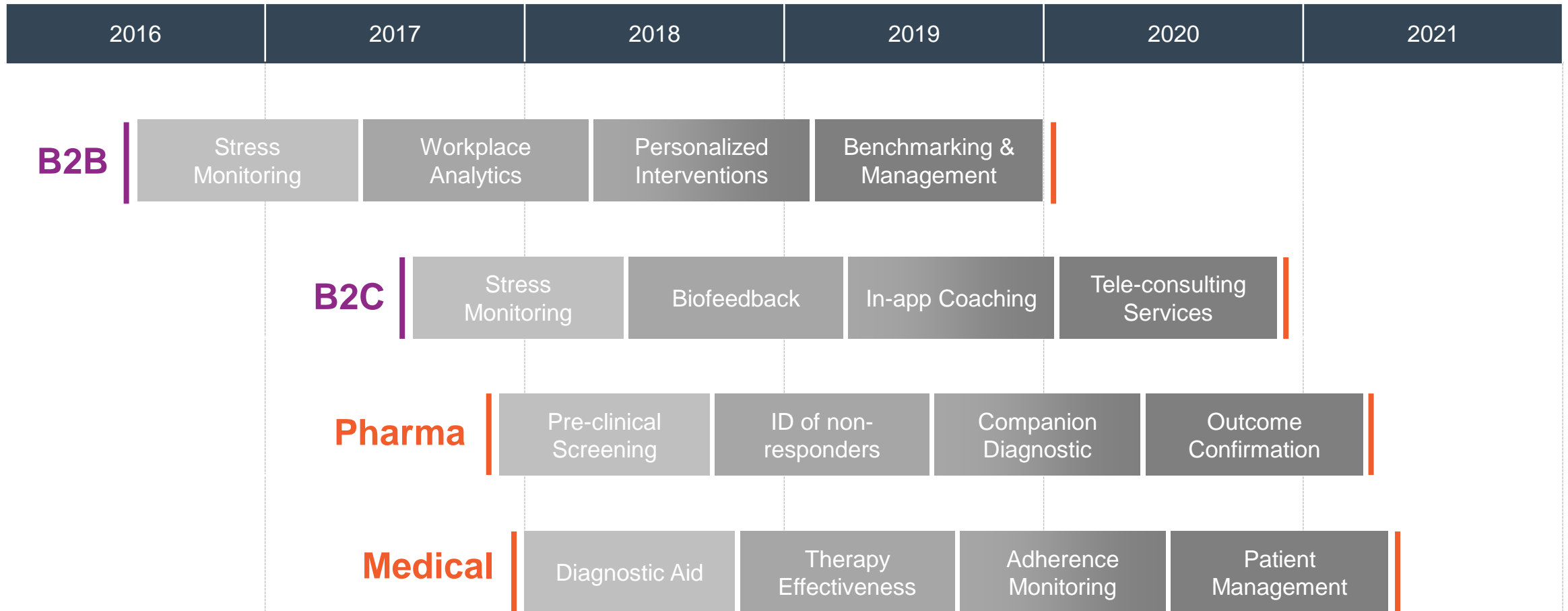
| TECHNOLOGY | DESCRIPTION | FDA | DIAGNOSTIC ACCURACY | EQUIPMENT COST | TEST COST |
|--------------------------------|--|-----------|--|-------------------|-----------|
| Medibio | CHR Waverform test based on ECG monitoring overnight | Under way | 80-90% - based on in excess of 4000 data points | \$30 | <\$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 |

All the Building Blocks Are Now in Place:



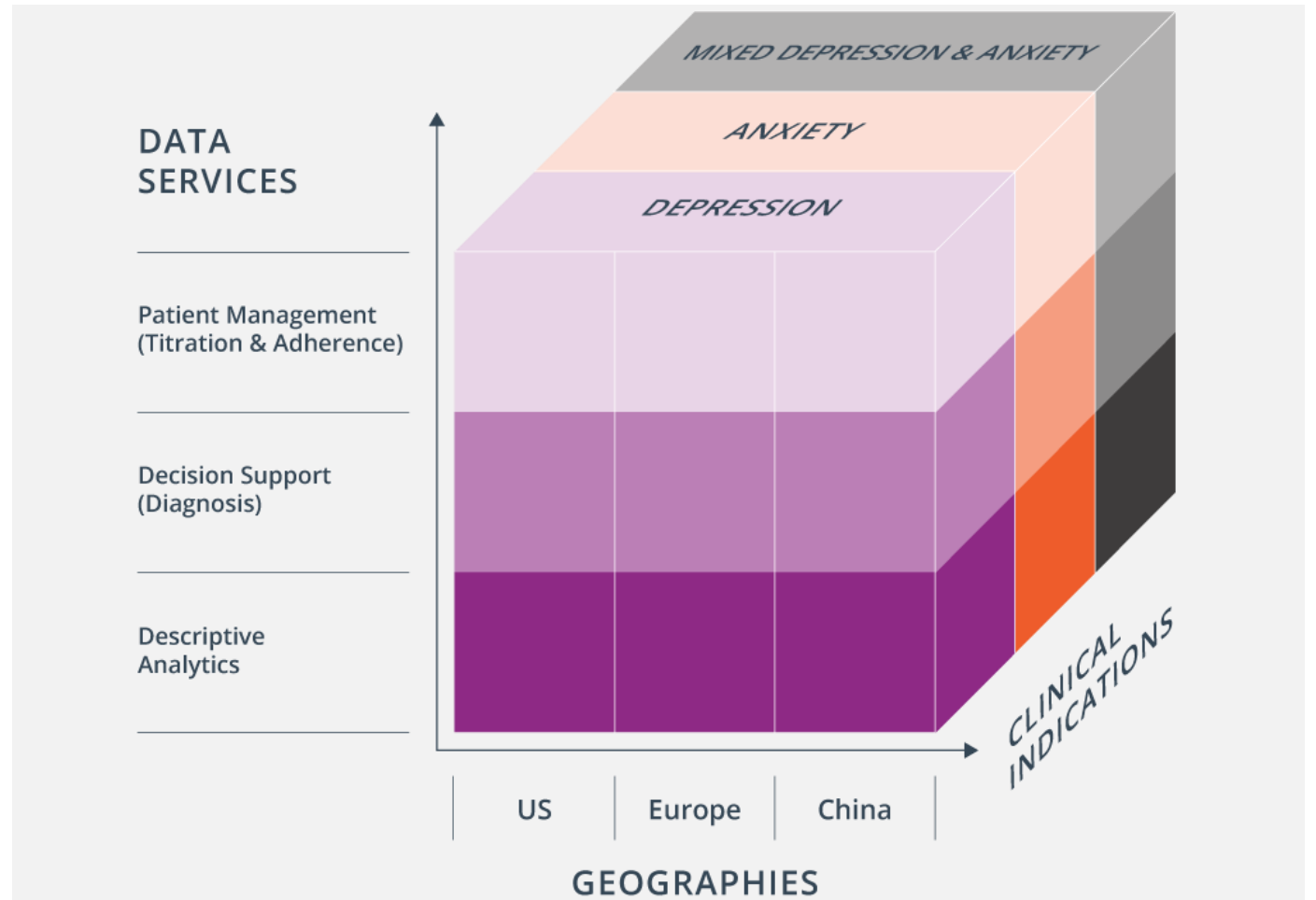
Appendices

Robust Roadmap into Multi-billion \$ Verticals



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



medibio 

INNOVATION IN MIND

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