

Medibio AGM Presentation

29 November 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.

Medibio Overview

- Medibio has developed the first evidence based quantitative test for depression and other mental health disorders, addressing the largest issue in healthcare.
- Defensible IP/technology based on 15 years of research into the relationship between the autonomic nervous system and mental health
- Support of notable research collaborators:
Johns Hopkins, Mayo Clinic, Ottawa University, Sydney University/BMC
- World's largest database of ECG data with corresponding mental health assessment driving new insights and clinical indications
- Endorsement from corporates via commercial agreements: Medtronic, Preventice, HBF, others
- Four verticals with each representing a multi billion dollar opportunity

"The economic costs of mental illness will be more than cancer, diabetes, and respiratory ailments put together."

Dr Thomas Insel, MD, the former
Director of the US National Institute
of Mental Health)

Regulatory Approval required

1.

Clinical

2.

Pharma

Regulatory Approval not required

3.

B2B

4.

Consumer

Medibio in perspective

Direct Medical Costs

- Annual cost of cancer in the US \$88.7B ⁽¹⁾
- Annual cost of depression in the US \$94.5B ⁽²⁾

Medibio's Objective Test

- Diagnosis ✓
- Treatment Efficacy ✓
- Patient Management ✓

CLASSIFICATION ACCURACY	SETTING	REFERENCE
83-86%	Medibio and University of Ottawa (440 depression and 449 controls)	Medibio : 2 November 2016
70%	Accuracy between psychiatrists – “the current standard of care”	DSM-IV mood disorders field trial. Keller et al : Am J Psychiatry 1995 Jun
33-50%	Diagnosis of depression in the US Primary Care setting (GP equivalent)	Depression in Primary Care Vol 1: US Dept. Health

1. Agency for Healthcare research and Quality (AHRQ)

2. The economic burden of adults with major depressive disorder in the United States (2005 and 2010). J Clinical Psychiatry 2015

Key achievements over the past 12 months and what they mean for shareholders

Key Achievements over the past 12 months

- ✓ FDA Pre-submission meeting
- ✓ Successful Commercial Pilots (stress)
- ✓ First Validation of Technology - Ottawa University (Depression)
- ✓ Sleep Staging Algorithm
- ✓ Vital Conversations Partnership
- ✓ WellNovation Agreement
- ✓ Sydney University Validation (stress)
- ✓ Monash University Partnership
- ✓ Data Sharing Research Program
- ✓ Australia's Biggest Mental Health Check-In
- ✓ HBF Partnership
- ✓ Binding agreement Medtronic
- ✓ Assembled a world class team
- ✓ Company now fully funded

Key validation efforts in 2016 significantly de-risk the technology

Established ecosystem of partners will help drive market adoption in 2017

Clinical – A paradigm shift over the past 12 months

FDA Pre-submission meeting

- approval as a device not a drug
- agreed on regulatory pathway with the FDA
- **we know what we have to do to gain FDA approval - 73.5% accuracy**

First Validation of our technology – Ottawa University Depression

- ~ 900 participants 50% depressed and 50% normal controls
- double blind psychiatric screening
- 86% accuracy distinguishing depressed from non depressed
- **number participants 5-10 times what we will require for FDA and CE Mark**

Sleep Staging Algorithm – 86-95% ~ 7500 patients

- using ECG data only to determine sleep stages
- never been done before with previous best ~70% accuracy
- **new metrics to enable better diagnosis of mental health conditions**
- **potential new business opportunity and good fit with our Workplace Stress Solution**

Day 1: FDA receives 510(k) submission.



By Day 7

FDA sends **Acknowledgement Letter**.
OR
FDA sends **Hold Letter** if unresolved issues with User Fee and/or eCopy.



By Day 15

FDA conducts **Acceptance Review**.

FDA informs submitter if 510(k) is accepted for **Substantive Review** or placed on **RTA Hold**.



By Day 60

FDA conducts **Substantive Review**.

FDA communicates via a **Substantive Interaction** to inform the submitter that the FDA will either proceed with **Interactive Review** or that the 510(k) will be placed on hold and **Additional Information** is required.



By Day 90

FDA sends final **MDUFA Decision** on 510(k).



By Day 100

If MDUFA Decision is not reached by Day 100, FDA provides **Missed MDUFA Decision Communication** that identifies outstanding review issues.

Workplace Wellness – from concept to launch in the past year

Successful Commercial Pilot – workplace Mental Wellness Solution (Stress)

- 66 participants in a pilot with an international service firm
- identified at risk cases where the traditional self-reports failed
- good agreement with traditional self-report 86% correlation
- **the first external validation of our workplace stress product**

Sydney University Validation Study (Workplace Wellness)

- clinical study comparing self-reports, psychiatric evaluation, and CHR in the workplace
- first 150 of 300 participants completed
- **validation of our stress product by a leading institution will open significant markets**

Internal Stress Study

- designed to collect data to calibrate and validate our stress algorithms
- collecting self-reports, psychiatric evaluation, and CHR
- 300 of 600 participants completed
- **data set required to convert interest from insurers/payers into commercial agreements**



Starbucks spends more on employee benefits than on coffee.

60%

Of chief financial officers cited healthcare costs as their main financial concern.



ROI

SOLUTION

\$1 spent on health promotion & disease prevention =
\$5 decrease in overall medical costs.

Moving past “technology risk” aiming to de-risk execution

University Data Sharing and Research Collaboration program

- initiated with four leading US universities and expanding rapidly
- in excess of 10,000 overnight physiological (ECG, EEG and other biometrics) data files
- **joint development with world leading institutions into various mental health conditions**
- **allows more advanced machine learning techniques expanding the commercial offering**

Commercial agreements

- numerous agreements over the past 12 months
- **5 major corporates participating in Australia’s biggest mental health check-in**

Assembled a world class team to execute your company’s business plan

- Yashar Behzadi (Head USA/Algorithm)
 - Greg Moon (Head Clinical/Regulatory)
 - Platform/Algorithm Team (Palo Alto and Melbourne - 7 world class resources)
- Ex Proteus Digital Health, a start-up now valued at +\$2 billion**

Company fully funded - \$13.5 million raised @ \$0.40 November 2016

- **now the hard work begins**

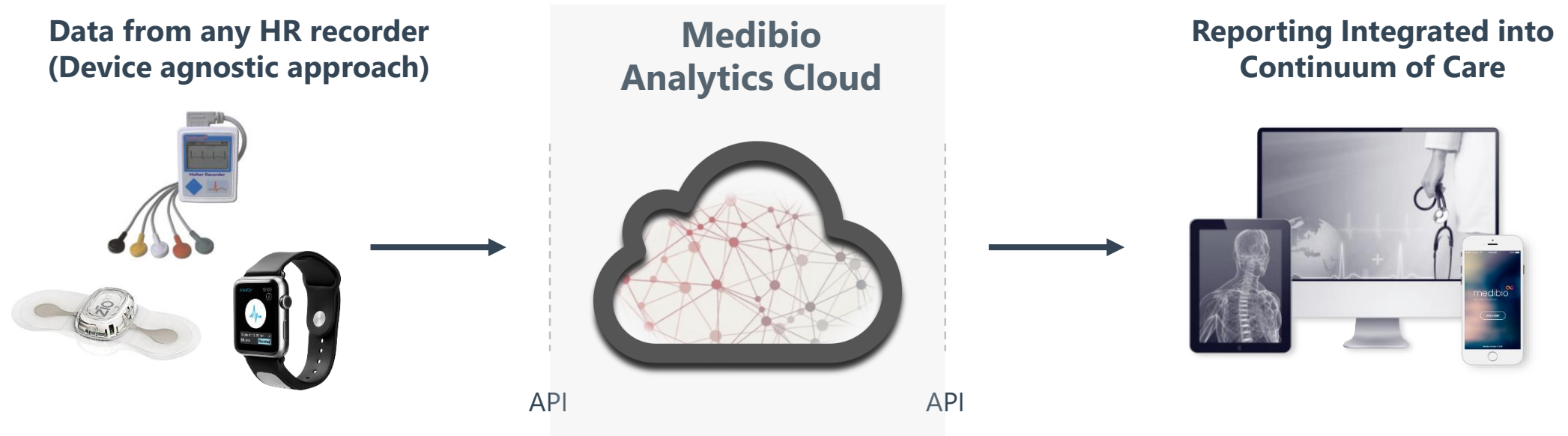


**Medtronic – ASX
Release 24 Nov 16**

**Numerous other
commercial
discussions on foot**

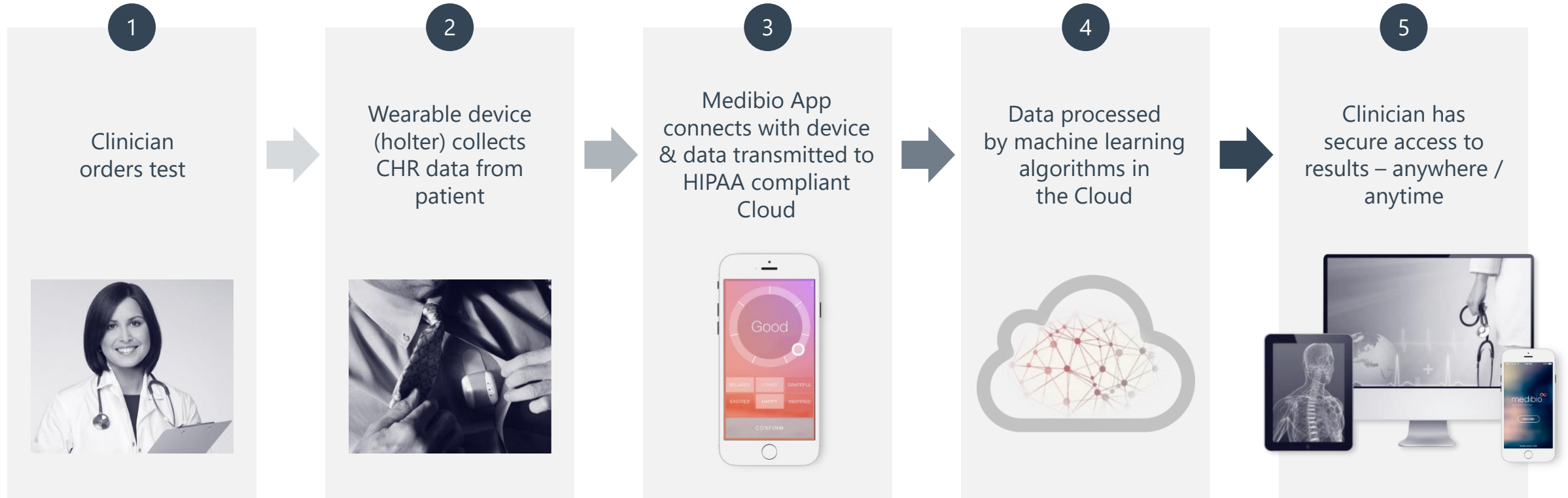
Business Overview (a refresher)

Business Model : Analytics-as-a-Service Offering



- **Device agnostic -> works with any HR or ECG monitor**
- **Highly scalable, low cost & easy to integrate**
- **Build once and monetize across vertical segments & geographies**
- **Data from partners is stored allowing for the creation of valuable data assets**

Clinical Work Flow in Primary Care (GP) Setting



Initial Clinical Market Opportunity – US Primary Care Setting

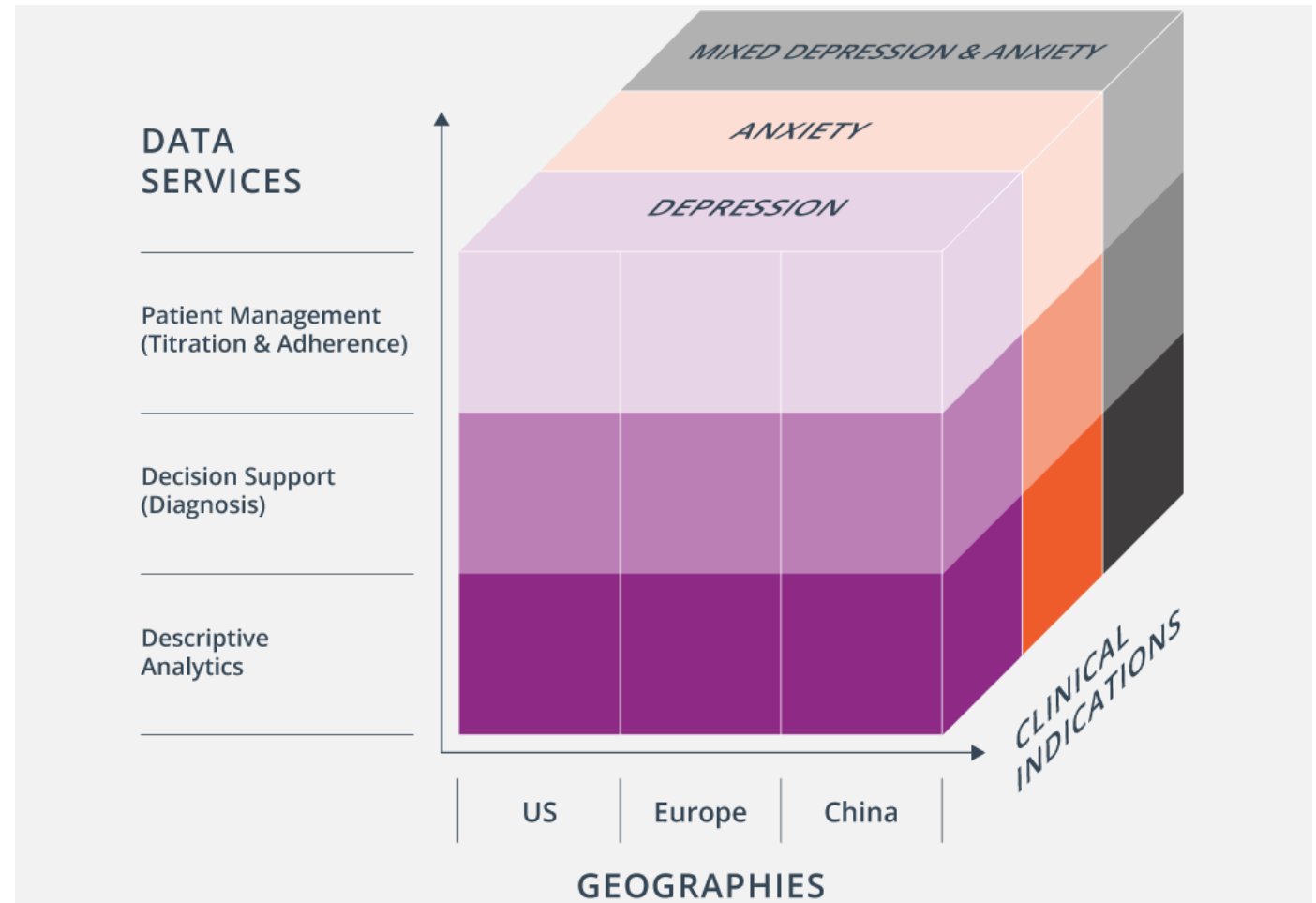
- Will be marketed as a **diagnostic aid with the early adopter** PCPs
- PCP's in the US are becoming the primary psychiatric care provider with in excess of **50% of all psychiatric diagnosis**
- 21 million annual PCP visits in the US which are mental health related
- 150 million PCP visits annually where mental health is a factor
- Model based on the current structure for ambulatory ECG monitoring

CPT CODE	DESCRIPTION	MEDICARE	PRIVATE	AVG
93225	Recording (Provider)	\$26.87	\$40	\$33.44
93226	Analysis with Report (Medibio)	\$37.91	\$57	\$47.46
93227	Physician review and Interpretation (Provider)	\$26.87	\$40	\$33.44

- 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** would generate revenue **of \$130 million annually**
- Cloud based analysis and reporting = minimal costs per report =
very high margins

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's Corporate Mental Wellness Solution

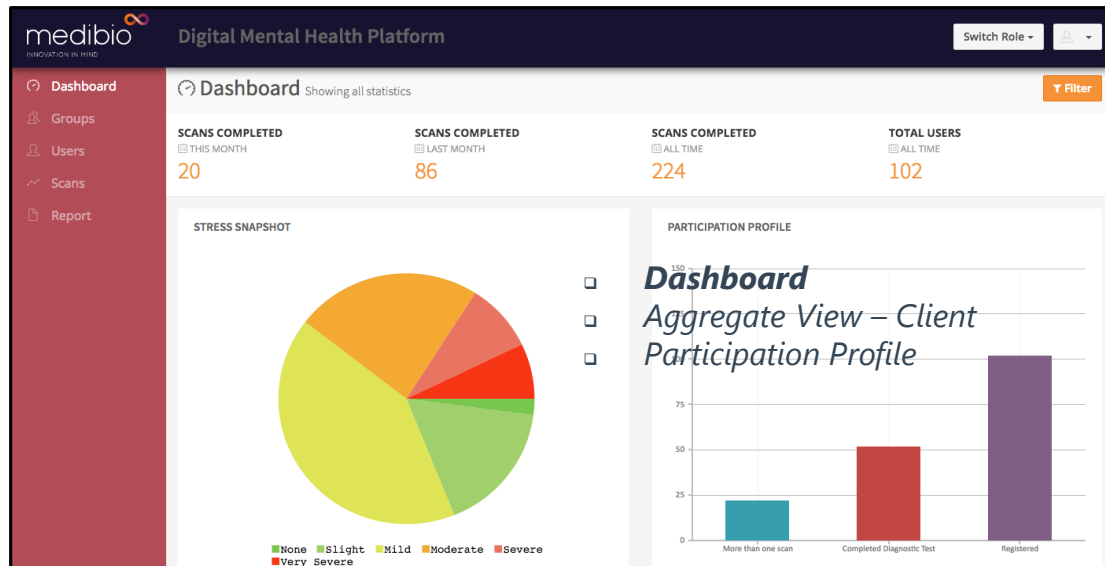
Using stress specific algorithms Medibio's technology provides objective indications of the stress. Based on an extensive number of indicators and measures from the CHR waveform, individuals are classified into one of six distinct categories:

1. *None* – No indication of stress
2. *Slight* – Minor markers of stress, ongoing monitoring
3. *Mild* – Specific indications, action to prevent escalation
4. *At Risk – Lvl 1* – Multiple signs of stress, action recommended
5. *At Risk – Lvl 2* – Signs of significant stress, action required
6. *At Risk – Lvl 3* – Signs of extreme stress, immediate action required

"at risk"

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



The screenshot displays the 'Scans' list view of the Medibio Digital Mental Health Platform. It features a sidebar with navigation links: Dashboard, Groups, Users, Scans, and Report. The main content area shows 'List of all the scans' with a 'Filter' button. A table lists scans with columns: START TIME, DURATION, RESULT, and ACTIONS. The results are categorized as 'Very Severe' (red) or 'Severe' (orange). The actions column includes 'Report' and 'Details' buttons. The title 'List View – Client Stress Test Ratings Escalation' is overlaid on the table.

	START TIME	DURATION	RESULT	ACTIONS
4	2016-04-19 03:15 PM	16:06	Very Severe	Report Details
8	2016-03-28 02:11 PM	04:52	Very Severe	Report Details
1	2016-05-19 11:01 PM	09:17	Severe	Report Details
2	2016-04-17 04:13 PM	15:41	Severe	Report Details
3	2016-04-17 04:13 PM		Severe	Report Details

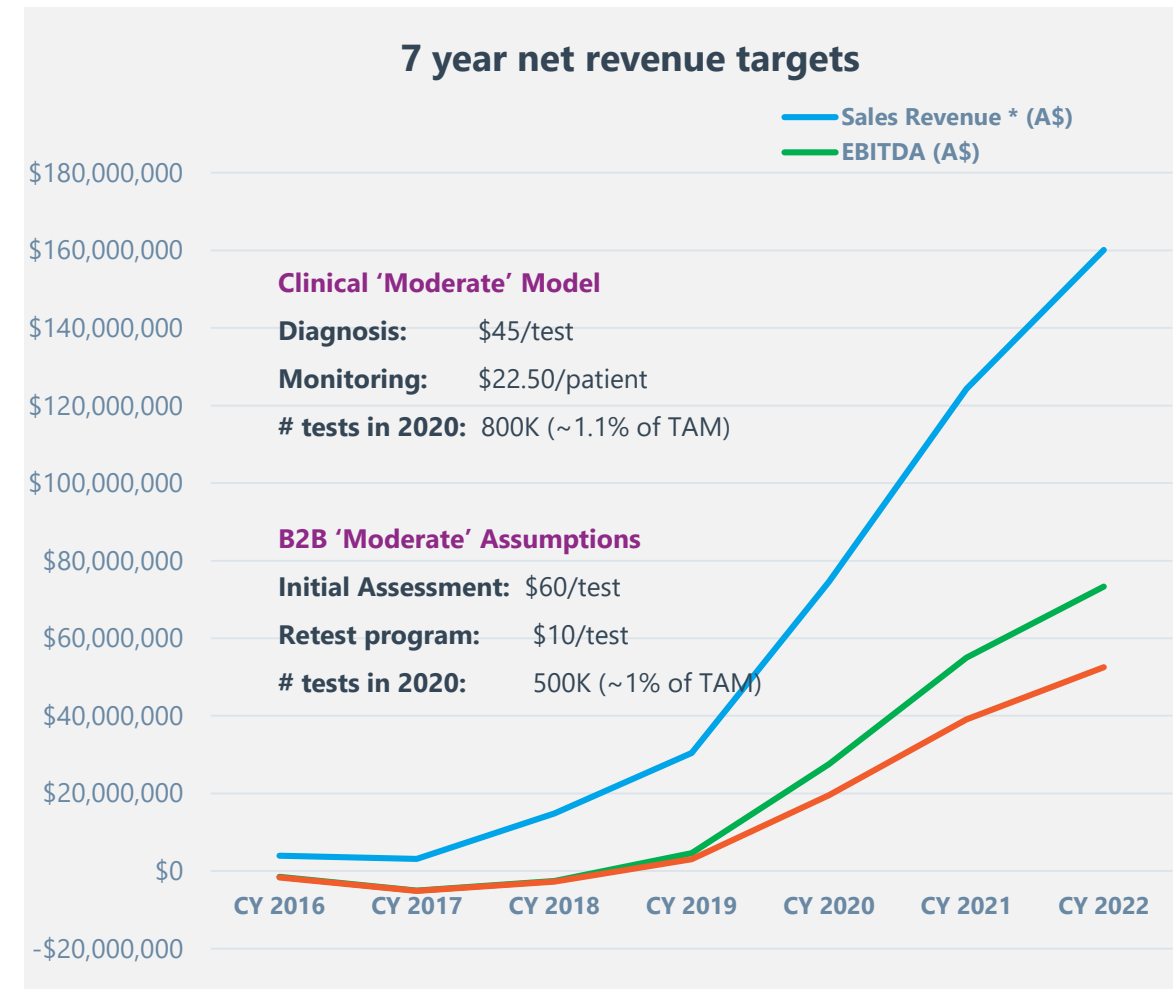
The next 12 months

Corporate Snapshot as we start 2017 and our long term goals

ASX TICKER	MEB
Shares on Issue (post completion \$13.5M raise)	147.9M
Warrants (\$0.10 – Expire April 2018)	9M
Warrants (\$0.30 - Expire Apr 2017)	5.8M
Last Trading Price	\$0.43
Valuation (Existing Capital)	\$67.30M
Milestone Shares*	20M
Debenture (convertible 2020 @ \$0.31)	US\$2.5M
ENTERPRISE VALUE (FULLY DILUTED)	\$63.9M

Available Cash – \$15.5M + \$2-3m R&D rebate Sept 2017

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 or CE Mark



Pivotal Clinical Validation already nearing completion

ACCURACY	STUDY OUTLINE	PARTNER
86%	Stress : 66 subjects completed 30 May 2016	Vital Conversations
86-95%	sleep staging using ECG data : 7500 patients completed 24 June 2016	Johns Hopkins
83%	depression : 326 patients (168 with depression and 158 controls) 8 Aug 2016	Ottawa University
	depression : Johns Hopkins Validation Study Pilot Phase (20 depressed/controls)	Johns Hopkins
	stress : 600 subjects Medibio clinical study	internal
86%	depression : 889 patients Medibio and The University of Ottawa	Ottawa University
	stress : 300 subjects in the workplace setting	University Sydney
	depression : Johns Hopkins Validation Study (30 depressed 30 normal)	Johns Hopkins
78-98%	depression, anxiety disorder, schizophrenia - various historical studies (Medibio)	Peer Reviewed

New 2017 initiatives post funding

Clinical – expanded 2017 program

Depression Treatment Efficacy

- study with leading US institution to demonstrate Medibo's as a tool to determine the effectiveness of treatment
- aim to provide data to support and FDA approval as a tool for depression treatment efficacy

Gradation of depression

- algorithm work underway
- anticipate a clinical study will commence in 2017
- aim to provide data to support an FDA approval

Anxiety Disorder

- algorithm work to begin in H1 2017
- leading to a study targeted to commence in H2 2017
- aim to achieve FDA approval for as a diagnostic for Anxiety Disorder

Other Mental Health Conditions

- Post Traumatic Stress Disorder
- depression diagnostics in heart attack sufferers

Regulatory/Medical Affairs – 2017 program

Increased Engagement with leading US based payers

- positive discussions held with a number of the leading US payers in Q4 2016 (coverage of in excess of 100 million lives)
- first step will be a program of retrospective claims analysis with these leading payers
- programmed to begin in Q1 2017 and roll out across 2017
- this will frame the economic studies required for reimbursement and use

Expansion of Regulatory Approvals Program

- expansion of regulatory program to include CE Mark for depression diagnosis
- preliminary work indicates the ability to gain approval using retrospective data
- currently engaging with Notified Bodies and undertaking review of Quality Systems Requirements
- Medibio will undertake CE Mark process in concert with FDA process for new indications

Sleep

- active program to source PSG data and collaborate with Sleep Centre Operators with multiple focus areas
- provide increased metrics for mental health diagnostics
- explore clinical opportunities around sleep staging
- expand the our Workplace Wellness sleep offering as sleep is emerging as a focus in Corporate Wellness

Corporate Mental Wellness Solution/Consumer App - 2017

Now ready for commercial launch providing the first objective assessment of stress

- both Android and IOS Apps available for download

Wellness partners view data collection via the leading wearables as a key milestone:

- a working prototype has been developed for the Apple Watch
- currently integrating other leading wearables including Fitbit, Garmin, Philips, Samsung

Imagine if in addition to objectively assessing stress we could also:

- provide a series of digital interventions tailored to your stress level – (developed now and being validated)
- provide an accurate assessment of sleep time and quality - (currently being incorporated into the solution)
- benchmark based on various physical measures – (Johns Hopkins SHHS data base provides a tremendous opportunity)
- screen for heart issues such as arrhythmias – (we are currently collecting the data required to do this)
- screen for sleep apnoea – (longer term project with data collection initiated)
- provide more detailed sleep analysis including sleep staging (ASX Release 24 June 2016)

Soft Launch of consumer App in one test market which has already been identified

Completion of development of digital interventions leading to stand alone commercial launch

B2C Market Opportunity will be pursued post funding

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
- Built for purpose digital intervention package currently being validated to allow an integrated offering
- Education, support, and intervention based on stress level

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



Key Company Milestones - 2017

TIMING	MILESTONE	STATUS
Q4 2016	Pilot Study Validation results – Johns Hopkins University (Major Depressive Disorder n = 20)	
	Completion of European Regulatory Pathway (CE Mark) Timetable	
	Initial Strategic Research Partnership	
Q1 2017	Publishing of Peer-reviewed paper – University of Ottawa (Major Depressive Disorder n = 300)	
	Commencement of Confirmatory Study to provide data for FDA Submission (n = 120)	
	Completion of Internal Stress Study (n = 600)	
	Publishing of John Hopkins University Validation Study (Major Depressive Disorder n = 60)	
Q2 2017	Commercial Agreements with Wellness Channel Partners covering rollout of Mental Wellness Solution	
	Publishing of Peer-reviewed paper - Sydney University Independent Validation Study Corporate Stress (n = 300)	
H2 2017	FDA submission (Major Depressive Disorder diagnostic)	
	Soft launch of Consumer App in test market	
	CE Mark (Major Depressive Disorder diagnostic)	



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