



Investor Presentation

July 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 mission is to transform the assessment and management of mental health through the application of advanced AI (Artificial Intelligence)
- Defensible IP/technology based on 15 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
- World's largest database of ECG data with corresponding mental health assessment driving new insights and clinical indications
- Endorsement from corporate partners: Medtronic, Preventice, others
- Multiple commercialisation routes: Clinical, Pharma, B2B and B2C represent multi-billion dollar market opportunities

"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)

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



Yashar Behzadi, PhD
Head of US Operations
(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



Greg Moon MD MBA
Head of Clinical Affairs
(Based in Silicon Valley)

- Digital Health expert with 15 years of experience in managing Clinical Affairs
- Led the commercial launch of Proteus Digital Health's first digital medicine solution in the US market
- Gained Proteus' first FDA clearance (Proteus Personal Monitor)
- Represented Proteus on the World Economic Forum's Workplace Wellness Alliance (WWA) leadership board



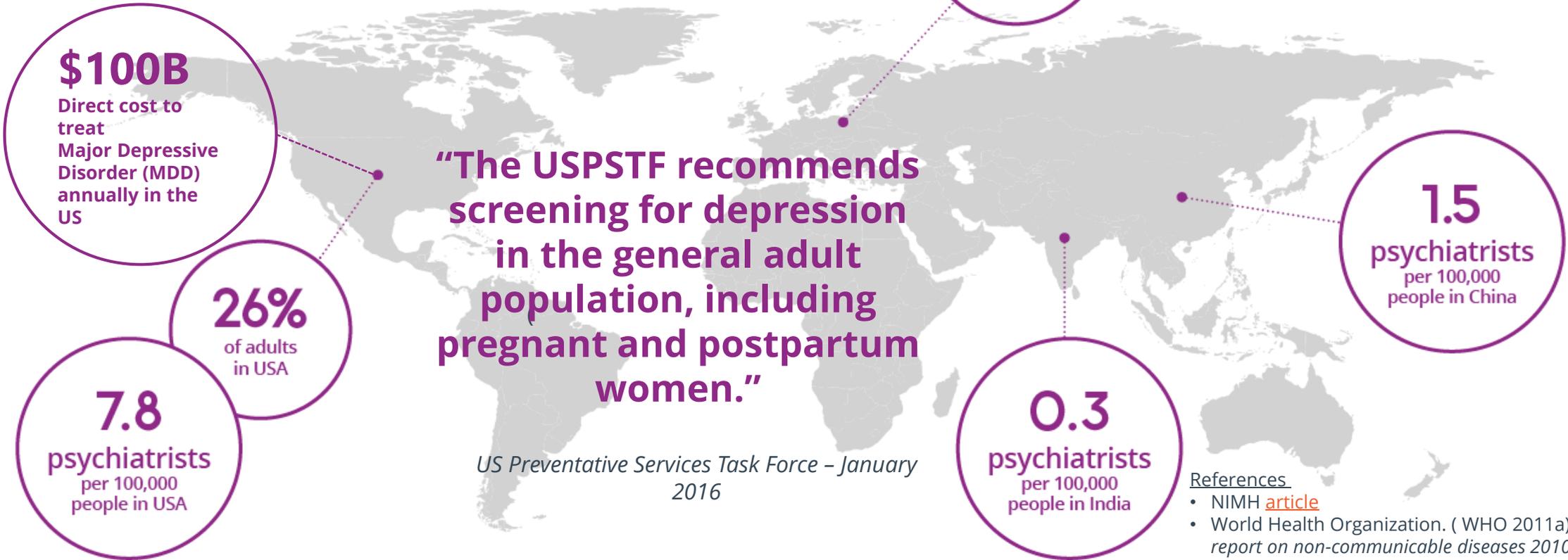
Dr Franklyn Prendergast
Board Member
(US based)

- 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

“The Single Greatest Illness that Affects Mankind” *

- 350 Million People With Depression
- Leading cause of disability in US

\$2.5T global cost of mental illness in 2010 (\$6T in 2030) “WHO”



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



The Need for Objectivity and Scalability

“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)

Current Pain Points

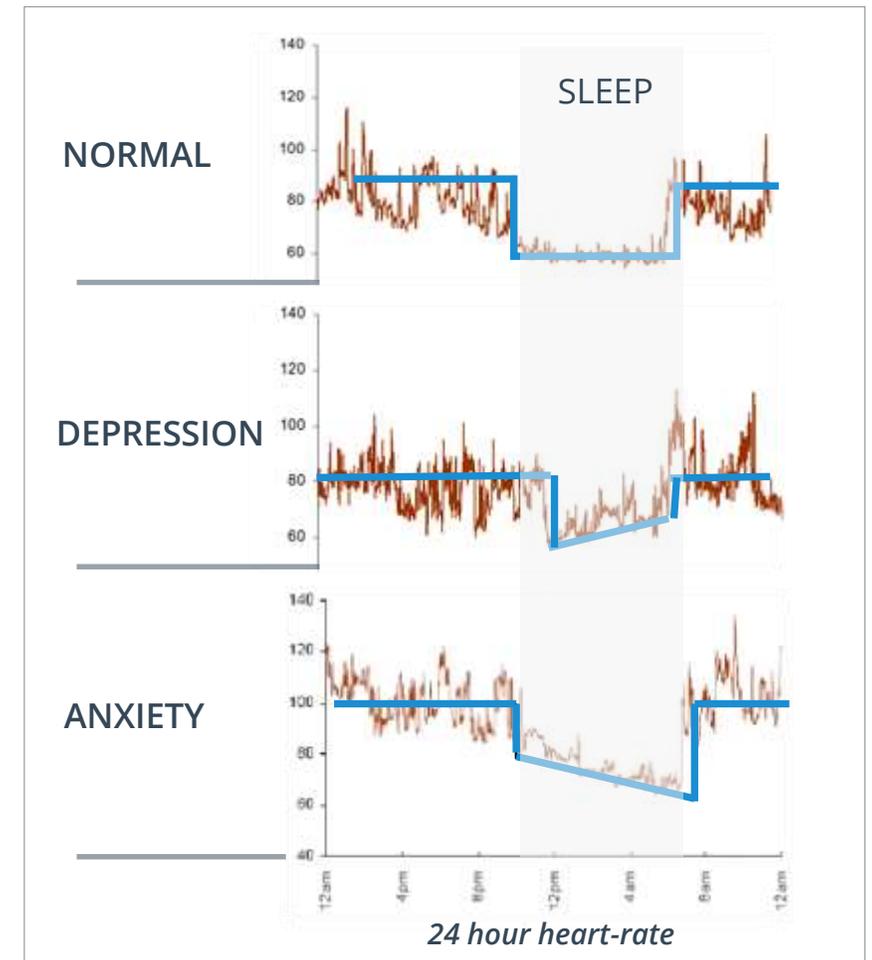
- No objective test for mental illness.
- The standard of care is a clinical/expert opinion which has limited access and availability
- Diagnostic agreement between clinicians can vary considerably – concordance rates near 70%.
- Current assessments are subjective which can lead to inadequate or incorrect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

Medibio's Solution

- Quantitative, scalable, and non-invasive 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 15 years of Clinical Research

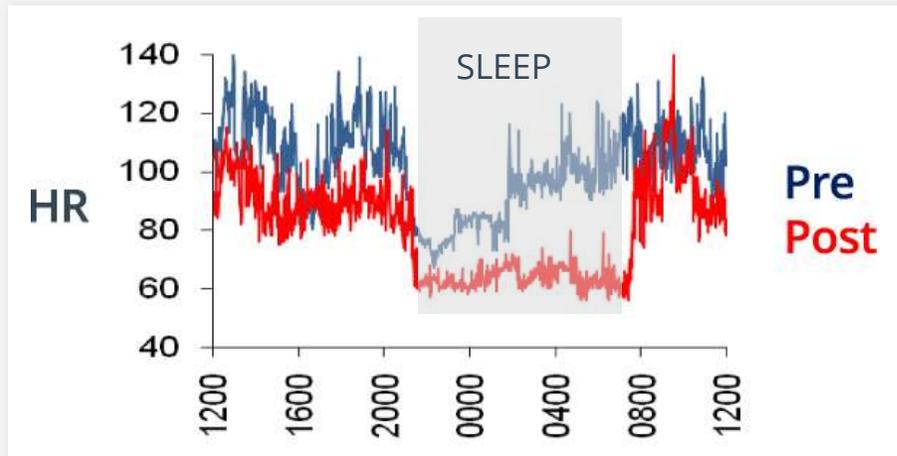
- Research initiated 15 years ago at University of Western Australia to test the theory that mental state linked ANS disturbance could be observed via the cardiovascular system.
- Mental state-linked ANS disturbance is observed via the cardiovascular system during sleep when external influences are absent.
- 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

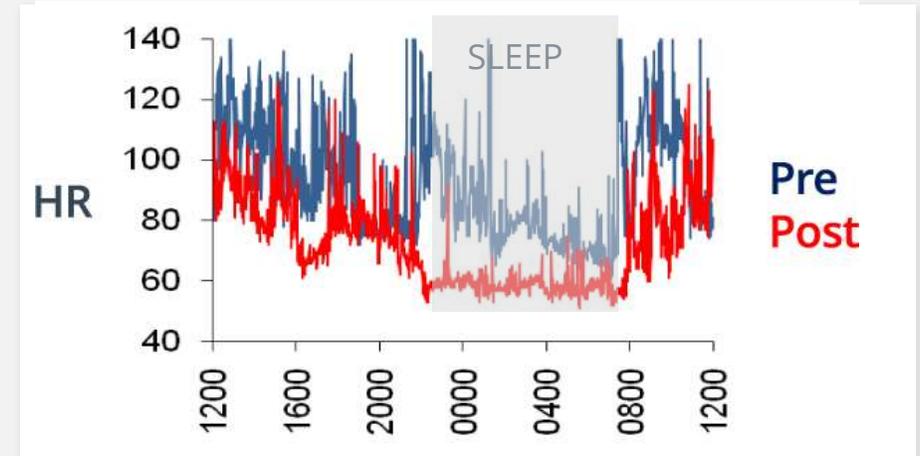
Case Study 1

- Depressed individual upon initial diagnosis
- Treated for 18 days with antidepressants



Case Study 2

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



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 independent University researchers
82%	200 patients (30 normals, 30 depression, 30 GAD, 110 other mixed psychopathologies)	Australian & New Zealand Journal of Psychiatry 1998; 32; 187-198



33-50% - Diagnostic accuracy in the Primary Care Setting ⁽¹⁾

(1) Depression in Primary Care Vol 1: US Dept. Health

Defensible Position Based on IP and Data Assets



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:

- 15,000+ 12 hour ECG files with a corresponding mental health diagnosis
- This data set would take 5 years and cost \$30 million plus to replicate
- Continuous source of new insights and clinical indications

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



- Corporate Wellness Providers
- Insurance Companies
- Government
- Digital health/Wearable Companies
- Elite Sports

B2B2C

US \$26Bn Industry



- Insurance Companies
- Wellness Providers
- Digital Health Companies

Targeting First FDA Submission 2017

510k Premarket Notification Flow Chart



Lodged

Pre-submission
meeting request



March 2016

Pre-submission
Meeting held late
March



Q4 2016

Initial Validation Trial
Completed with
Johns Hopkins
University



Q1 2017

Confirmatory study
to support 510k
Submission
commences (Johns
Hopkins and
commercial CRO's)



H2 2017

510k
Submission
De Novo
pathway

Positive FDA meeting confirming:

1. de novo classification and regulatory pathway
2. Indications for use
3. Proposed software level of concern

Clinical Study with Johns Hopkins University

Study Objective

- To validate the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals

Study Timeline

- Anticipated data collection completed Q4 2016
- Simple, quick, powered to only need 60 participants
- 30 subjects with MDD, 30 Normal Controls

Johns Hopkins University (JHU)

- Ranked #1 in the U.S. by US News & World Report for 22 years of the survey's 25 year history

Principal Investigators

Dr Naresh Punjabi

Professor of Medicine and Epidemiology at JHU. Published more than 100 research papers.

Dr Francis M. Mondimore, M.D.

Associate Professor in the Department of Psychiatry and Behavioural Sciences and Director of the Mood Disorders Clinic, where he leads a team of clinicians specializing in the care of persons with mood disorders.

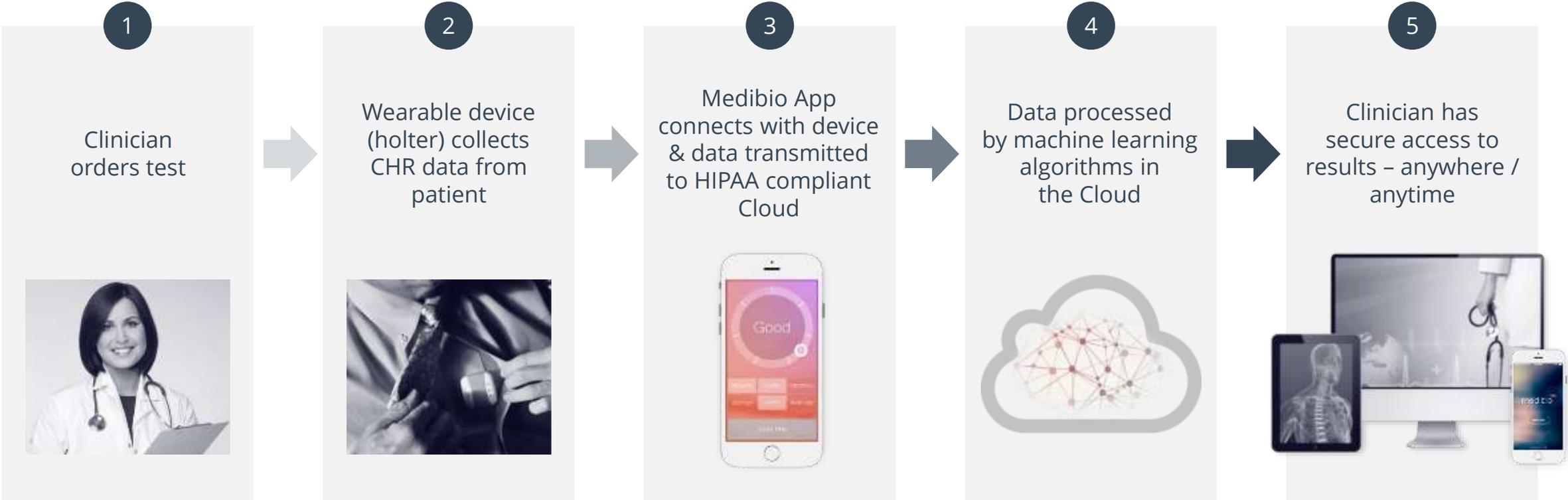


Dr Naresh Punjabi



Dr Frank Mondimore

Clinical Work Flow in Primary Care Setting



Initial Clinical Market Opportunity – 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**

Cost Savings Drives Payer Adoption

Typical MDD Patient Journey \longrightarrow Years to Proper Treatment

Developing Condition	Undiagnosed Condition	Diagnosis	Treatment Titration	Management
Variable	3-6 months	3-6 months over multiple doctor visits	3-6 months over multiple doctor visits Average of 4 antidepressants	Episodic doctor visit every 3-6 months



Digital Mental Health \longrightarrow Continuous & Real-time

Monitoring & Diagnosis	Treatment Titration	Management
Continuous feedback & diagnosis	Remote, daily feedback on drug effectiveness	Continuous feedback & management / data-based doctor visits

\$6,000/yr.

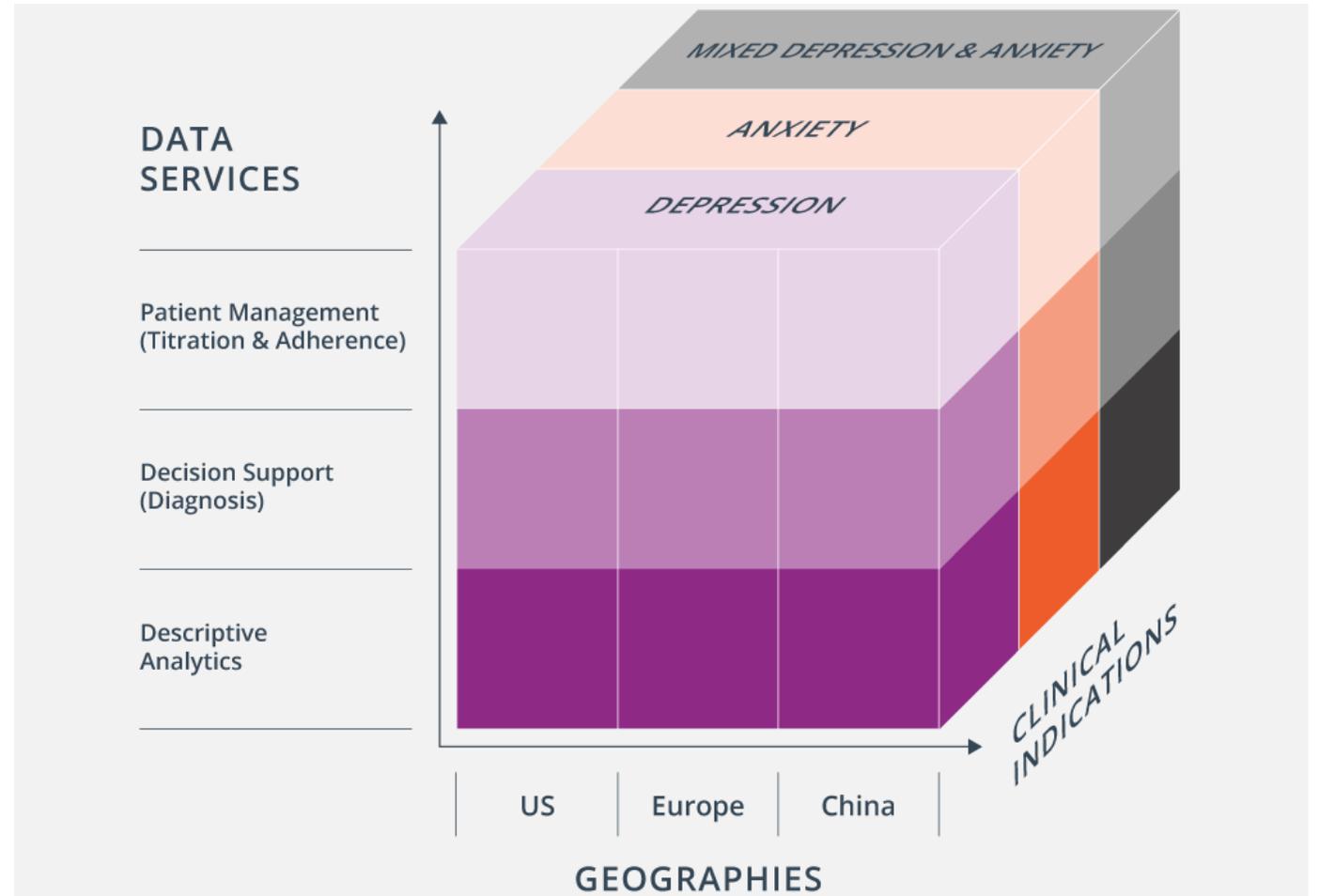


\$3,000/yr.

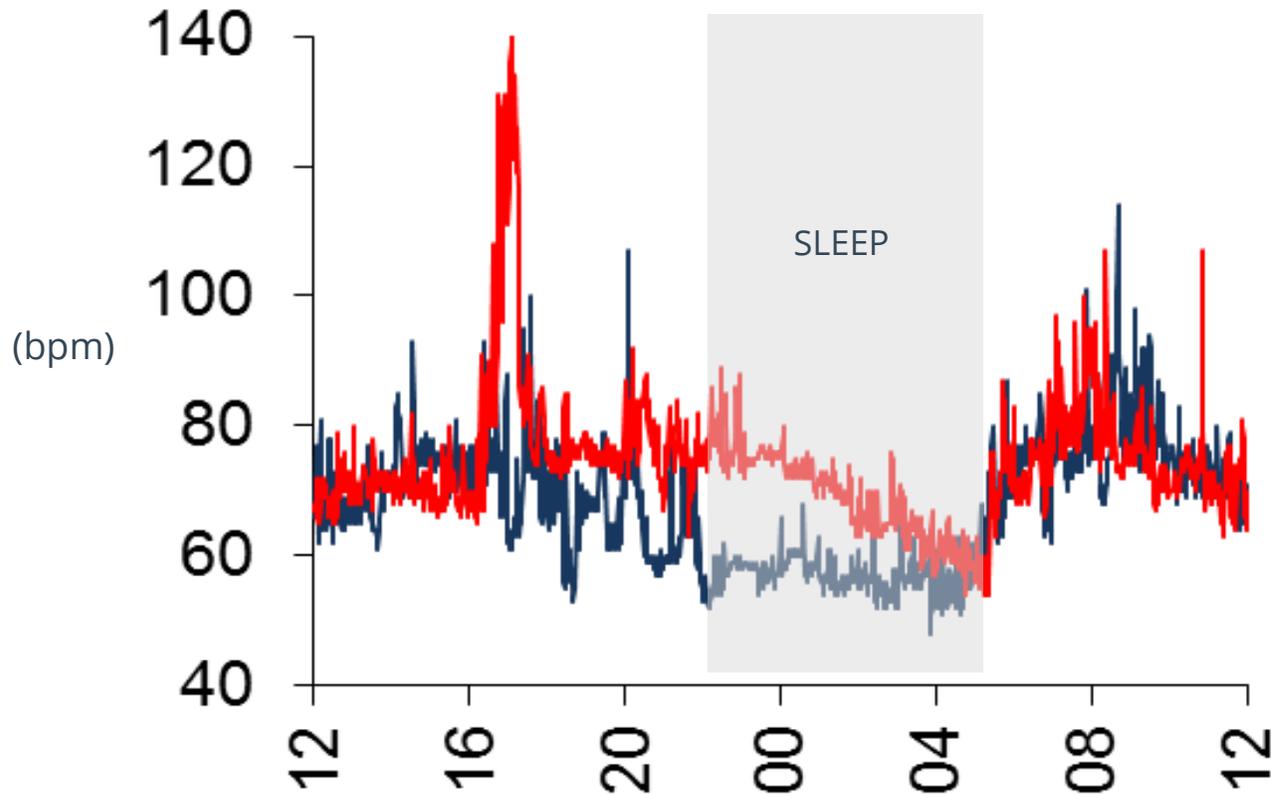
50% cost saving in annual direct costs between managed and unmanaged depression.

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



Chronic Stress - Serial Changes



Profile

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

	24 Hour Mean	Sleep Mean
Pre Senior Position	67	57
6 months after Senior management role	74	65

- Before promotion to senior executive role
- 6 months after promotion to senior executive role

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

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:

- **Normal** – No indication of stress, no action required
- **Slight** – Some signs of stress, no action required
- **Mild** – Some signs of stress, action required to prevent escalation
- **Moderate** – Multiple signs of significant stress, action recommended
- **Severe** – Signs of significant stress, action required
- **Very Severe** – Signs of extreme stress, immediate action required

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 Stress Product



Individual Assessment Report

- Stress rating and trends
- Sleep analysis
- Longitudinal comparisons

Group Dashboard

- Aggregate View – Client
- Participation Profile
- Organization risk summary

- Australian National Wellness Partner (Health Services Provider): (~6,000 Australian employees). Existing Corporate Wellness clients have in excess of 500,000 Australian staff.
- Vital Conversations (WA based wellness partner): Pilot Program completed, potential of 5,000 Australian staff (200,000 staff internationally). Number of additional clients
- WellNovation: Discussions with a client with 360,000 participants in the Middle East.



Revenue Model

Clinical 'Moderate' Model

Diagnosis: \$45/test

Monitoring: \$22.50/patient

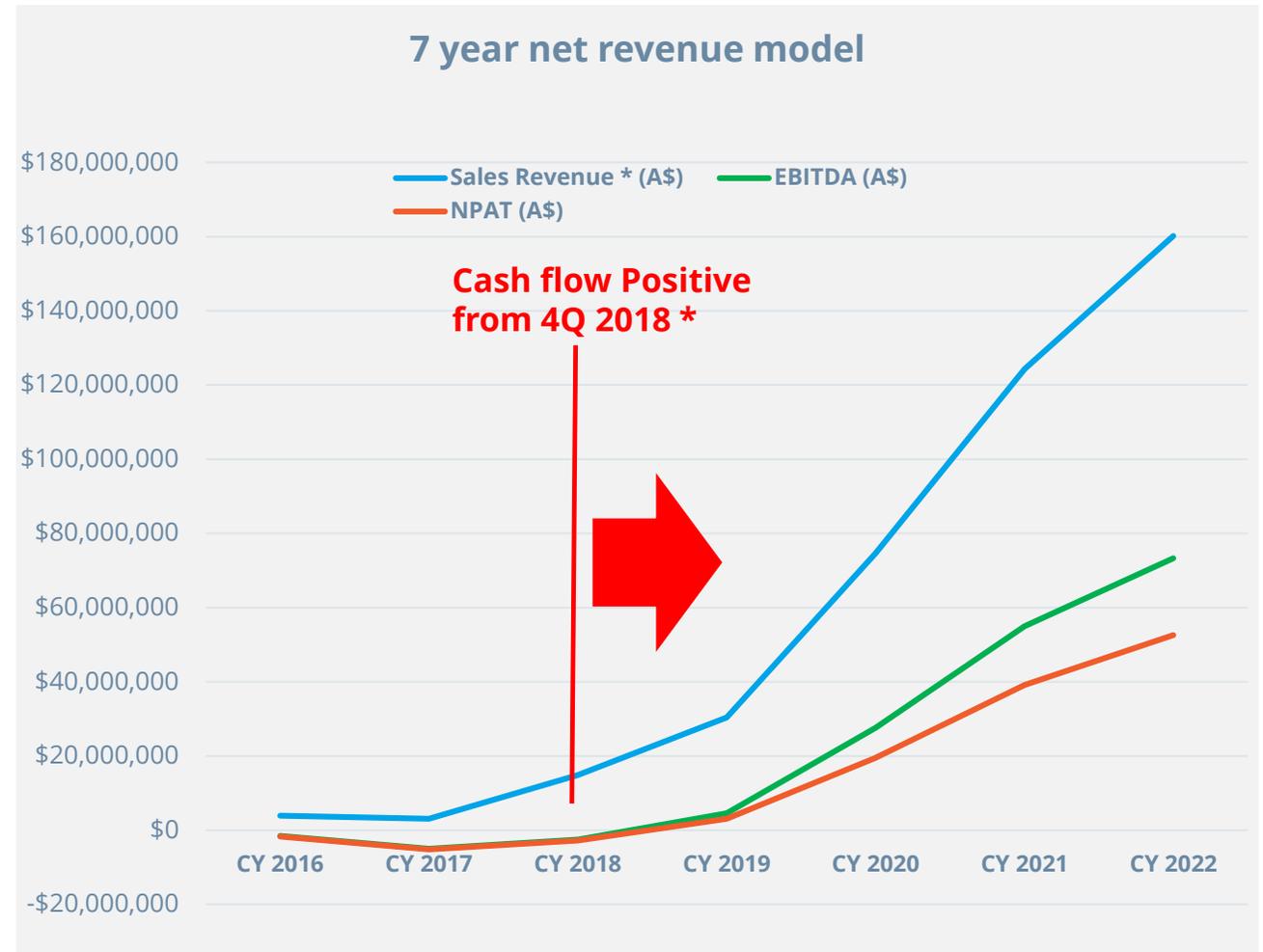
of tests in 2020: 800K (~1.1% of TAM)

B2B 'Moderate' Assumptions

Initial Assessment: \$60/test

Retest program: \$10/test

of tests in 2020: 500K (~1% of TAM)



* Assumes a \$10m capital raise H1 2017

Competitor Overview

TECHNOLOGY	DESCRIPTION	FDA	DIAGNOSTIC ACCURACY	EQUIPMENT COST	TEST COST
Medibio	CHR Wavermform 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

Corporate Snapshot

ASX TICKER	MEB
Shares on Issue	105M
Warrants (\$0.10 – Expire April 2018)	15M
Warrants (\$0.30-\$0.80 - Expire Apr 2017)	12.7M
Last Trading Price	A\$0.31
Valuation (Existing Capital)	US\$24.1M
Milestone Shares*	20M
Debenture (convertible 2020 @ \$0.31)	US\$2.5M
VALUATION (FULLY DILUTED)	US\$33.6M

Available Cash – \$1.0M (plus ~ \$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 or CE Mark

Medibio's analytics platform will transform the assessment and management of mental health

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

Appendices

Voice of customer Survey - USA

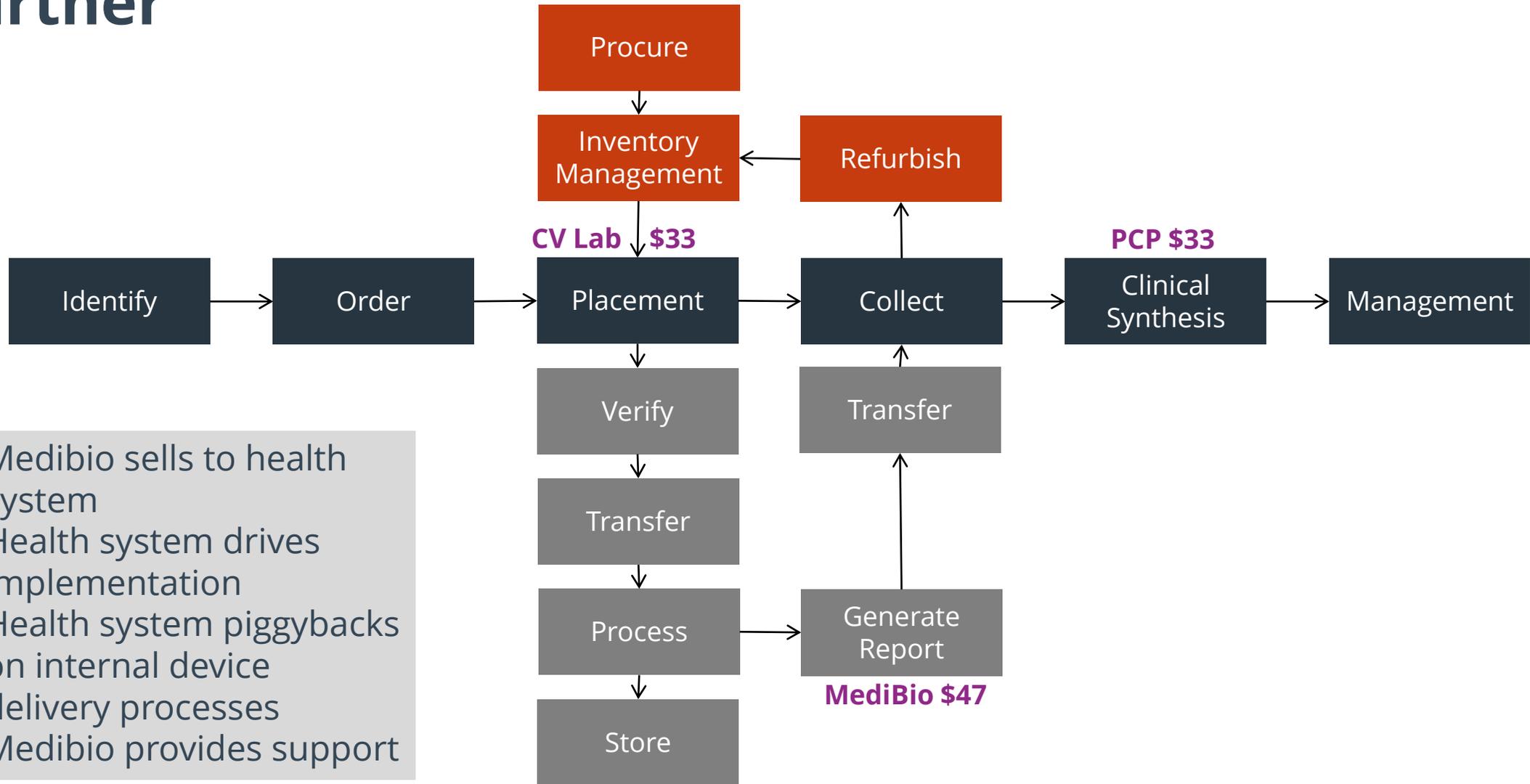
Key Findings

- Majority (91%) of clinicians are likely to consider using the device as a supportive diagnostic tool.
- Primary care physicians (PCP) and psychiatrists are likely first users as they are more likely to see patients first before referring them to therapists.
- Primary care physicians are also more likely to be largest users for this device as a diagnostic tool followed closely by psychiatrists/CNS as most patients with mental health issues are likely to meet a PCP/psychiatrist or CNS before referral to a therapist
- Majority (82%) of clinicians would use the device to monitor effectiveness of therapy
 - 63% of the clinicians surveyed would use the device for monitoring patients every 1 – 3 months
 - 18% would use it at least once every 4 – 6 months

Factors influencing decision to use

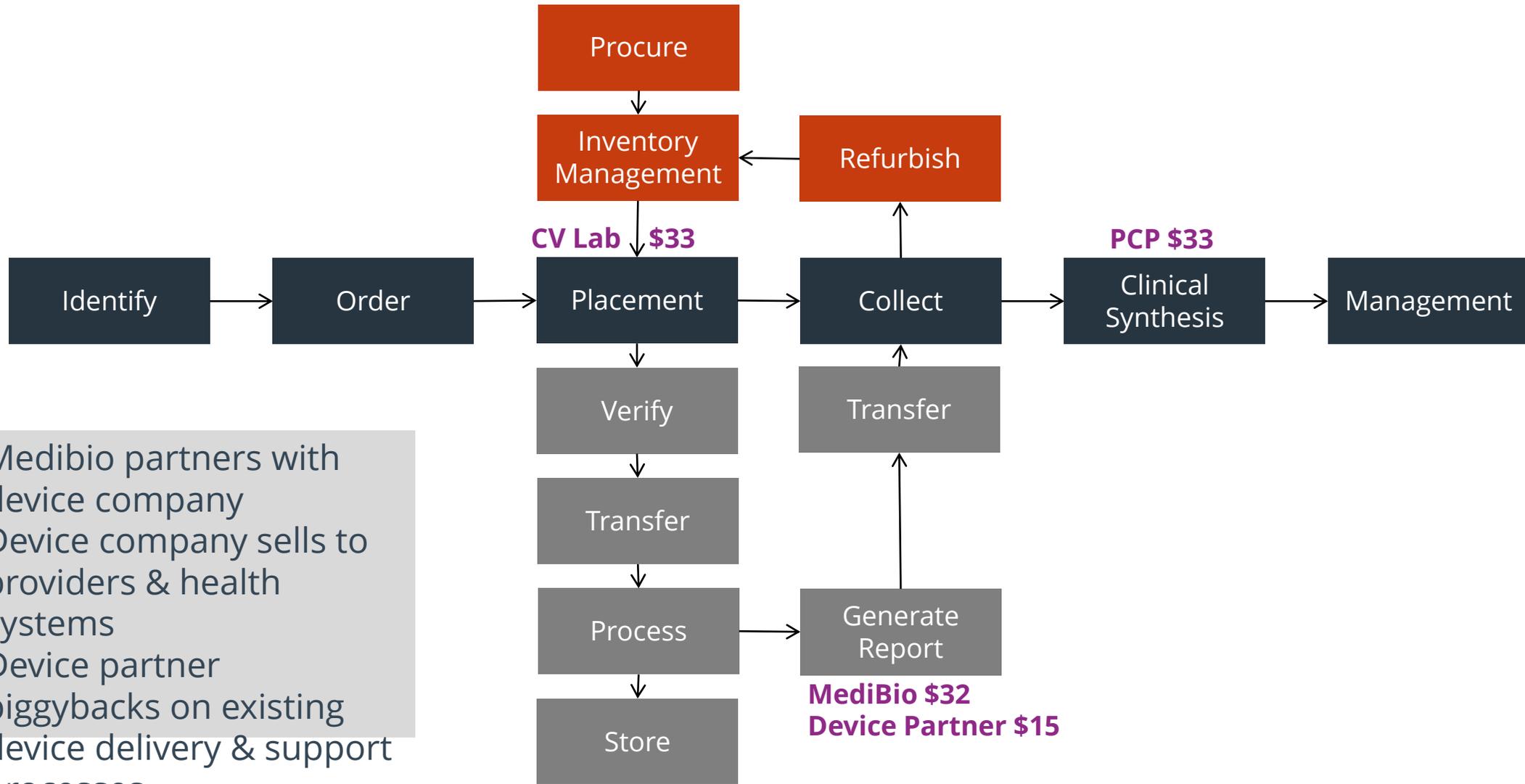
- Insurance coverage (reimbursement) was the most significant factor influencing clinicians' decision to use the device
- Ease of use, price and clinical evidence were the next most important factors influencing use
- Diagnostic accuracy, reliability and validity of the device also ranked high in the clinical use decision
- Other factors included availability / accessibility of diagnostic procedure, client consent, comfort and compliance and ease of ordering diagnostic test

Clinical Workflow Integration: Health System Partner



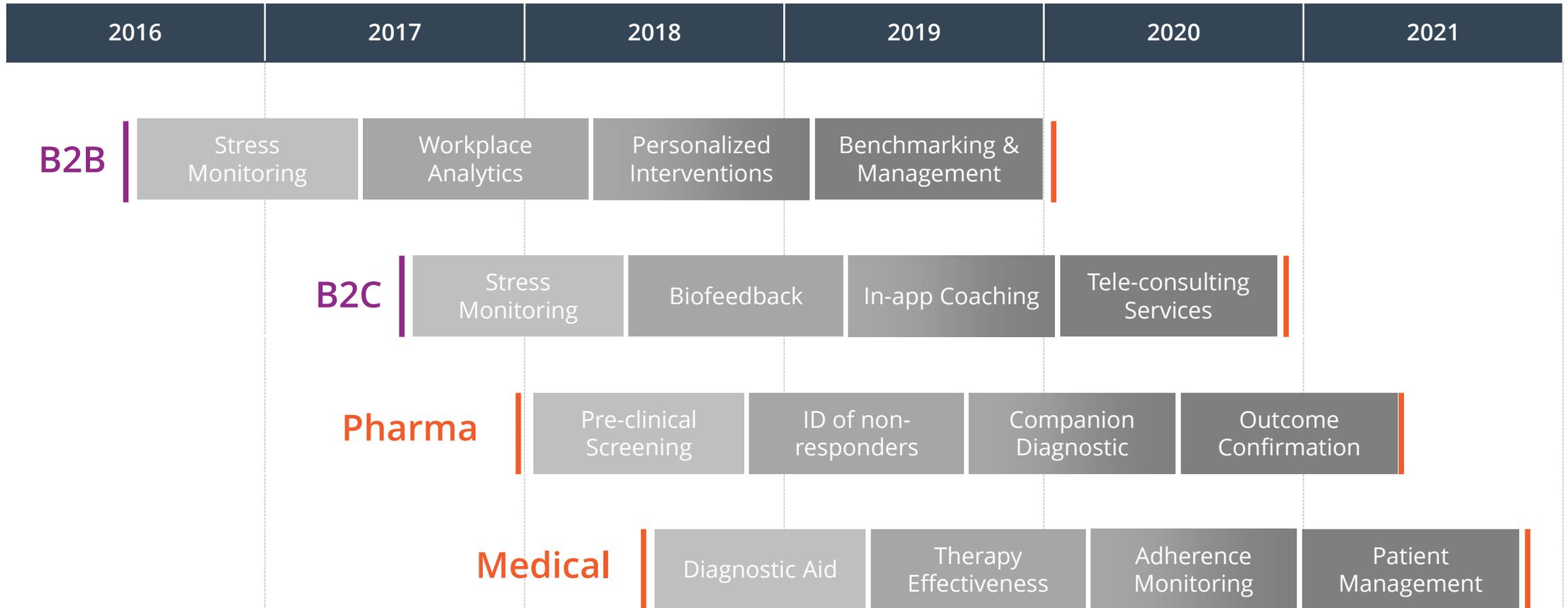
- Medibio sells to health system
- Health system drives implementation
- Health system piggybacks on internal device delivery processes
- Medibio provides support

Clinical Workflow Integration: Device Partner



- Medibio partners with device company
- Device company sells to providers & health systems
- Device partner piggybacks on existing device delivery & support processes

Robust Roadmap into Multi-billion \$ Verticals



Depression Study Series (Exemplar)

	H2 2016	2017	2018	2019	2020	
Measurement	<p>Dx (mod-sev) Exploratory n=60, 2 sites \$0.35M</p>	<p>Dx (mod-sev) Confirmatory n=200, 4-5 sites \$1.2M</p> <p>● 510k filing</p> <p>Status/Tx effic. Exploratory n=40, 2 sites \$0.25M</p> <p>Dx Chronotropic n=40, 2 sites \$0.25M</p>	<p>◆ Launch</p> <p>Status/Tx effic. Confirmatory n=150-200, 4-5 sites \$0.9 - 1.2M</p> <p>● 510k filing</p> <p>◆ Expanded claims</p>	<p>◆ Expanded claims</p>	<p>◆ Expanded claims</p>	<p>Assumptions</p> <ul style="list-style-type: none"> • Study execution times: Exploratory: 4-6 mo Confirmatory: 9-12 mo • Study budgets: \$5k/subject + materials +/- CRO • De Novo 510(k) review time average: 8 months • Parallel execution of studies is resource-dependent
Outcomes				<p>Time-to-goal Exploratory n=40, 2 sites \$0.45M</p>	<p>Time-to-goal Confirmatory N=300-400, 7-10 sites \$1.5 - 2.5M</p> <p>● 510k filing</p> <p>◆ Expanded claims</p>	

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)*



medibio

INNOVATION IN MIND

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