Medibio Limited
Stage 1 Market Assessment, Validation and Strategic Planning

February 4, 2015

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Executive Summary

Situation Analysis

- Medibio Limited has a unique proprietary diagnostic tool for detecting mental disorders and is looking to introduce its product into global markets, primarily targeting depression in the US, and then following with Europe and ROW
- Medibio Limited has partnered with The Ametus Group to evaluate the US market and initiate the strategic planning process, focusing on the following in Stage 1:
  - Market Analysis and Validation of Most Profitable Markets- US, EU (limited)
  - Reimbursement Evaluation
  - Strategic Business Planning and Exit Scenarios
- Given the nature of today's healthcare environment, with the Affordable Care Act (ACA) and Accountable Care Organization's (ACOs), where physicians are expected to be as efficient as possible and do more with less, Medibio Limited's diagnostic tool would be an excellent fit, providing an objective tool to diagnose and monitor treatment of depression, that would not take as much physician time to administer compared to the current methods of diagnosing depression, such as spending hours interviewing patients. It may help with early detection and prevention of escalation, thus improving patient outcomes.

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Overall Insights and Conclusions from VOC

Voice of Customer (VOC) Interview Summary

- There is good US mental health clinician interest and recognition of need for a biomarker-based diagnostic to show treatment progression and make diagnoses more efficient
- Need well-designed clinical studies that clearly define value and role of Medibio Limited technology
  - NEBA device provides an initial clinical, regulatory and market framework
- Strategic focus on publications and US clinician education regarding Medibio Limited diagnostic is key
- Professional societies outreach is critical, using a prioritized, multi-specialty approach to educate and build support amongst clinicians
- Reimbursement and cost of diagnostic are both considerations for clinicians
- Targeted research deployment of Medibio Limited device may be valuable in gaining clinician recognition of value and in growing interest in use

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Best Fit for Technology per VOC

- Clinician consensus from interviews is that primary care physicians in the US are likely the first adopters as they are more likely to see patients first before referring to specialty clinics
- Psychiatrists and therapists (LP, LPCC, LICSW, LMFT) will be the next group to adopt as they provide the bulk of mental health care in the US in specialty or stand alone clinics and practices
- Largest users will be psychiatrists given their familiarity with use of biomarkers such as heart rate unless extensive training is provided to other MH clinicians
- PCP's will have the largest patient base of use but will use it primarily for differential diagnosis
- Most acceptable use to mental health clinicians is as a supportive measure for their subjective and behavioral-based primary diagnoses
- Most clinicians see the diagnostic being used at their respective sites of care and do not want to outsource to specialty diagnostic clinics so referral for diagnostic procedure to cardiology or sleep clinics is unlikely

Adoption & Reimbursement Strategy

Timelines for widespread adoption are gated by:

- Availability of pivotal data demonstrating clinical value of Medibio Limited technology
- Coverage and reimbursement for Medibio Limited as a supporting diagnostic tool
- Coverage and reimbursement for Medibio Limited as a therapy progression monitoring means
  - Using the NEBA Health clinical study as a baseline (approx. 300 patients) and an assumed patient monitoring period of 6 months after baseline diagnosis, an estimated timeline for availability of a reimbursement code and widespread adoption would be approximately 3 - 5 years from start of a pivotal study of the Medibio Limited device
- If a viable cash pay model exists, initial clinical adoption could begin sooner

Reimbursement Strategy:

- It appears that the existing CPT & ICD9 codes for cardiac rhythm monitoring devices may be leveraged. However, the recommendation is to expand indications for payment from existing payors/insurers within the existing CPT & ICD9 codes
- Strategy is to start at the regional level and expand in multi-phase regional approach
- Simultaneously pursue VA system, governed under independent reimbursement system
- After establishing regional reimbursement & refining program, approach major national insurers such as Cigna, United Health Group, & Aetna

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Global Population & Depression

Global Population in 2013:	7,162.1	Percent of Globe
US Population	322.6	4.50%
EU Population	507.4	10.40%
ROW	6,097.1	85.10%

- 340 million people or 5% of the global population has depression, with less than 25% being treated
- Approximately 29 million people or 9% of the US population has depression, with 50% being treated
- Approximately 60 million people or 8% of the population in Europe suffers from depression, 50% going untreated
- It is estimated that population growth is 1.2% / year per http://en.wikipedia.org/wiki/Population_growth, 1.2%/year growth rate

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http://www.worldometers.info/world-population/
http://news.yahoo.com/migration-helps-boost-eu-population-507-4-million-154620250.html

Global Market Universe

Initial Differential Diagnosis

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)	Already Diagnosed	Treated (millions)	# People Untreated (millions)	Price per monitoring (initial)	Untreated (millions)	Total
US Population	322.6	9%	29.0	14.5	Already Diagnosed	$0.00	14.5	$45.00	$653.3	$653.3
EU Population	507.4	8%	40.6	20.3	Already Diagnosed	$0.00	20.3	$30.00	$608.9	$608.9
ROW	6,332.1	5%	316.6	76.0	Already Diagnosed	$0.00	240.6	$14.85	$3,573.2	$3,573.2
Global Market	7,162.1				Already Diagnosed	$0.00			$4,835.3	$4,835.3

On-going Monitoring

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)	Price per monitoring (initial)	Treated (millions) (1/year)	# People Untreated (millions)	Price per monitoring (initial)	Untreated (millions) (4/year)	Total
US Population	322.6	9%	29.0	14.5	$22.50	$326.63	14.5	$22.50	$1,306.5	$1,633.2
EU Population	507.4	8%	40.6	20.3	$15.00	$304.44	20.3	$15.00	$1,217.8	$1,522.2
ROW	6,332.1	5%	316.6	76.0	$7.43	$564.57	240.6	$7.43	$7,151.2	$7,715.8
Global Market	7,162.1					$1,195.6			$9,675.5	$10,871.2

Total Market Opportunity

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)		Treated (millions)	# People Untreated (millions)		Untreated (millions)	Total
US Population	322.6	9%	29.0	14.5		$326.6	14.5		$1,959.8	$2,286.4
EU Population	507.4	8%	40.6	20.3		$304.4	20.3		$1,826.6	$2,131.1
ROW	6,332.1	5%	316.6	76.0		$564.6	240.6		$10,724.4	$11,289.0
Global Market	7,162.1					$1,195.6			$14,510.9	$15,706.5

http://www.worldometers.info/world-population/
http://news.yahoo.com/migration-helps-boost-eu-population-507-4-million-154620250.html

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Global Market Universe

- The Global Market for Initial Differential Diagnosis of Depression in the Untreated Population is $4.8 Billion, with the US market at approximately $653 Million, $609 Million in Europe, and $3.6 Billion in ROW

- For the On-going Monitoring of patients that are already treated, the Global opportunity is $1.2 Billion, with $327 Million in the US, $304 Million in Europe, and $565 Million in ROW. The On-going Monitoring opportunity for the Untreated population is about $9.7 Billion for the global market, with $1.3 Billion in the US, $1.2 Billion in Europe, and $7.2 Billion in ROW.

- Thus, the Total Global Market Opportunity is $15.7 Billion, with $2.3 Billion in the US, $2.1 Billion in Europe, and $ 11.3 Billion ROW

With a capture rate of 5% in the US, Medibio Limited would realize $115 Million in Gross Revenues.

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Moderate Revenue Projection

	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE " REVENUE PROJECTION
	TOTAL YR 1	TOTAL YR 2	TOTAL YR 3	TOTAL YR 4	TOTAL YR 5
Medibio Limited Revenue					
United States					
Diagnosis	857,365	3,470,614	4,448,865	9,004,502	13,668,834
Monitoring	857,365	6,145,593	13,417,018	19,142,435	30,914,137
Hardware Rental	3,443	27,160	67,831	99,725	157,249
Hardware Purch.	5,739	31,494	41,380	53,156	95,873
Europe					
Diagnosis	-	1,639,056	1,451,384	3,147,431	5,521,013
Monitoring	-	1,639,056	3,582,157	5,952,102	11,067,958
Hardware Rental	-	9,874	24,541	44,008	81,129
Hardware Purch.	-	16,456	24,446	32,445	61,868
ROW					
Diagnosis	-	1,830,099	1,782,896	3,757,644	6,456,386
Monitoring	-	949,861	2,196,078	3,889,280	7,424,481
Hardware Rental	-	11,552	30,174	57,277	109,059
Hardware Purch.	-	19,253	31,036	45,171	86,305
Worldwide Revenue					
Diagnosis	857,365	6,939,770	7,683,145	15,909,576	25,646,233
Monitoring	857,365	8,734,510	19,195,254	28,983,816	49,406,576
Hardware Rental	3,443	48,586	122,546	201,010	347,438
Hardware Purch.	5,739	67,204	96,862	130,772	244,046
TOTAL MEDIBIO LIMITED REVENUE	**1,723,912**	**15,790,070**	**27,097,808**	**45,225,174**	**75,644,292**
TOTAL GROSS REVENUE	**2,462,732**	**22,557,243**	**38,711,154**	**64,607,392**	**108,063,275**

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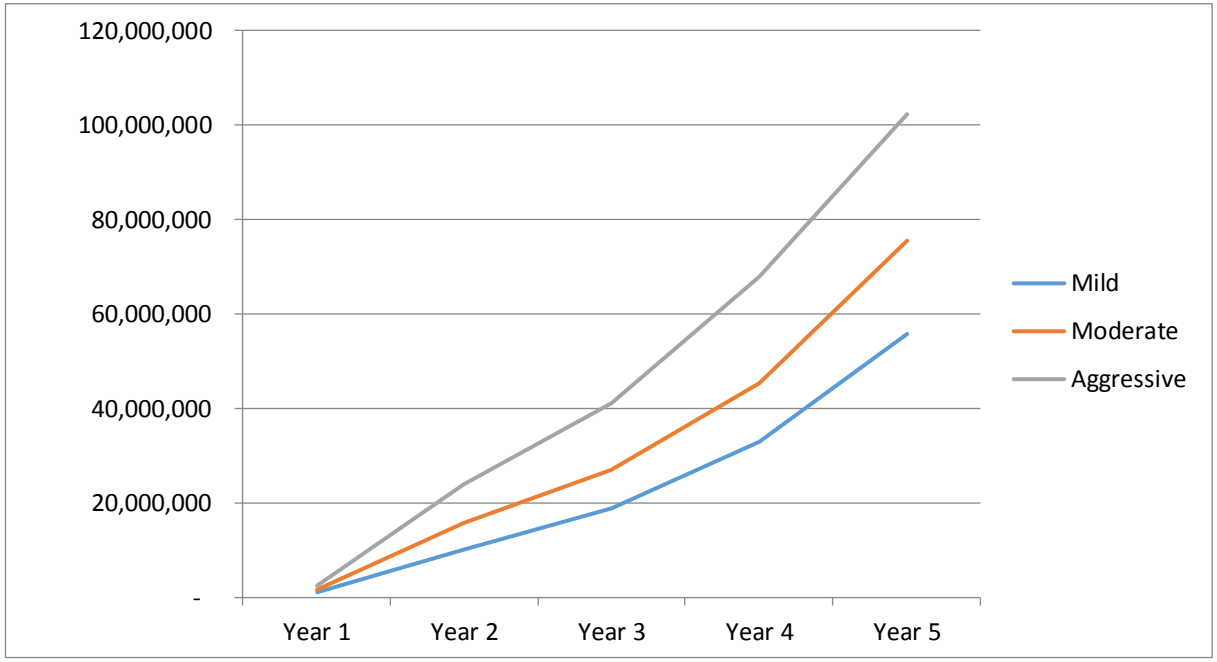
Note: Gross revenue is prior to distributor commissions and reflects end customer gross sales.

Comparison: Medibio Limited Net Revenue

Mild, Moderate, Aggressive

COMPARISON PROJECTION - MEDIBIO LIMITED NET REVENUE (Software and Hardware)



COMPARISON NET REVENUE PROJECTION (Software and Hardware)

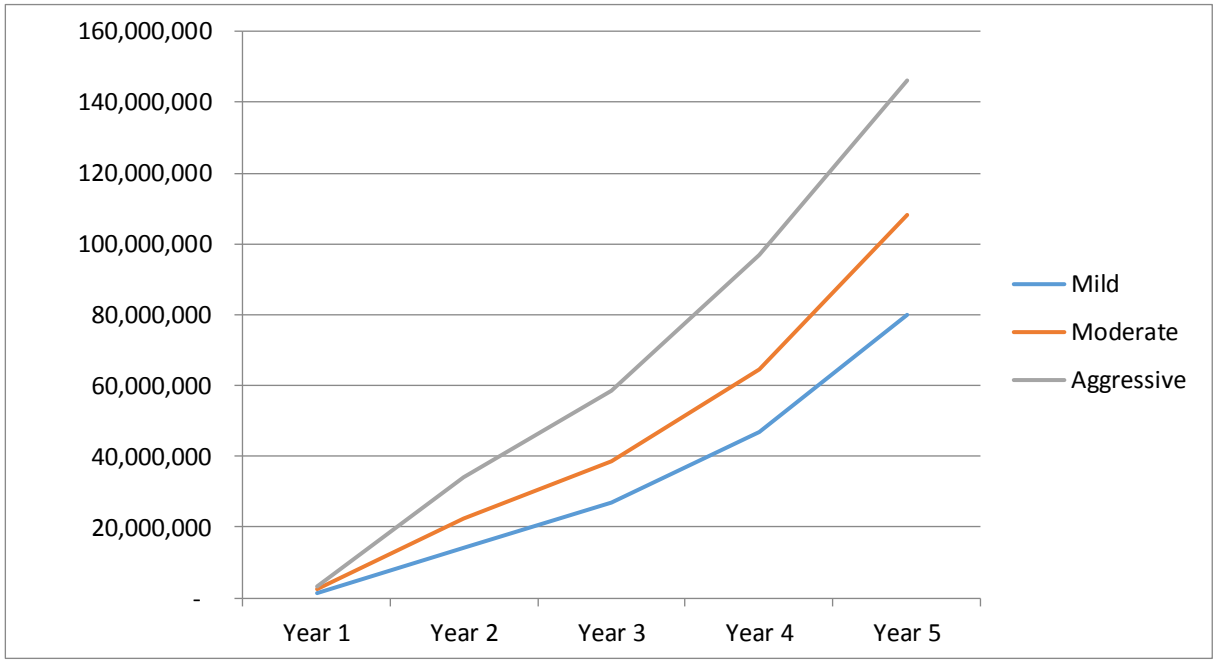
	Year 1	Year 2	Year 3	Year 4	Year 5
Mild	919,420	10,005,430	18,775,268	32,902,150	55,866,230
Moderate	1,723,912	15,790,070	27,097,808	45,225,174	75,644,292
Aggressive	2,298,550	23,933,534	41,062,041	67,932,852	102,388,937

Note: Numbers are Global

Comparison: Gross Revenue

Mild, Moderate, Aggressive

COMPARISON PROJECTION - GROSS REVENUE (Software and Hardware)



COMPARISON REVENUE PROJECTION - GROSS REVENUE (Software and Hardware)

	Year 1	Year 2	Year 3	Year 4	Year 5
Mild	1,313,457	14,293,471	26,821,811	47,003,071	79,808,899
Moderate	2,462,732	22,557,243	38,711,154	64,607,392	108,063,275
Aggressive	3,283,642	34,190,762	58,660,058	97,046,931	146,269,910

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Note: Numbers are Global

Pricing Recommendations

Software Recommendation: Per Patient Charge

Based upon market feedback, the existing reimbursement system in the US and the business model that presents the most revenue upside, the recommended approach is to charge a per patient fee for service.

The amount charged for initial diagnosis can be significantly higher given an existing precedence of higher reimbursement for the differential diagnosis of psychological disorders versus the monitoring of treatment effectiveness. The amount charged per patient for treatment monitoring is targeted at 50% of the diagnosis fee.

Hardware Recommendation: **Customers Acquire Devices From Medibio Limited or Another Manufacturer. Price Hardware to Drive Placements and Access to Technology and Testing.**

The fact that monitoring devices are imperative to enabling patient testing, it is recommended the devices are priced at a level to drive technology adoption and revenue resulting from the per patient interpretive testing fees that present a much larger business opportunity (rather than the hardware acquisition revenue). In many instances health care organizations will have access to Holter monitors presently residing within their system. However, certain organizations will not have access to these devices. In those instances, devices can be purchased from any of the many existing Holter monitor manufacturers or they can be purchased from Medibio Limited directly. It is recommended that the capital equipment pricing is not price prohibitive which would present a barrier to product adoption. OEM devices that are marketed by Medibio Limited on a monthly leasing or outright acquisition basis will provide a turn-key solution at a reasonable price for new customers and will drive utilization.

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Distribution Channel Recommendation

Recommendation to Build Hybrid Sales Channel Utilizing Both Strategic Partners and Distributor Organizations

- Supported and Managed by Medibio Limited Marketing and Sales Management Team
  - In-Field Sales Training, Support and Customer Relations
- Less Significant Up-Front Investment in Sales Channel Structure
- Hybrid Approach Diversifies Risk by Utilizing Multiple Parties and Does Not Create Reliance on a Single Party
- Moderately Paced 4-Phase Controlled Regional Roll-out in US
- Hybrid Sales Organization
  - Strategic Partners and Independent Rep Groups/ Distributor Organizations
  - Distribution Rights Granted Based Upon Specific Market Segments and Customer Call Points
  - Add Direct Clinical Sales Specialists in Key Geographies (CA, TX, MI, MA, FL) Over Time to Support Largest Territories
- Strategic Partners and Distributors Carry Majority of Receivables
- Commission Rates Fit Within Medibio Limited Business Model's Gross Margins
- Moderate Level of Company Personnel Resources Required
- Relationship with Strategic Partners May Naturally Lead to Acquisition
- Augment With Web Strategy to Gain Additional Exposure and Revenue

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Strategic Partner Recommendation

- Work with Pharmaceutical manufacturers to co-promote Medibio Limited to Primary Care Physicians (PCPs). Pharmaceutical companies continue to look for ways to tap into the large undiagnosed and untreated population with depression in the PCP pool.
- There are opportunities to work with Medical Device companies manufacturing holter monitors as they want to increase sales and develop a broader need for their products. Options include commission programs, joint ventures, licensing agreements, and so on.
- Develop low cost holter monitor with medical device partner or technology company
  - System that is potentially compatible with Google Android and Apple iOS software
    - Many mobile phones have already added or are adding health technology and heart monitors to their devices
    - Create and sell an application for Android and iOS with a fee based structure
- Create a scalable low cost web strategy that can work with clinicians and independent of clinicians
  - Develop Global Medibio Limited website that is open to the public to input their data and to get a diagnosis for a fee

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Exit Strategy Considerations

- Timing of when to exit
  1) Development phase
     - If greater resources are needed sooner than later to extract value and or speed commercialize to be first to market
  2) Growth phase
     - With revenue generally comes a higher acquisition price
  3) Mature phase

- Development of a broader portfolio of products and additional algorithms to increase market capitalization

- Contingent on the structure of the exit methodology, reporting requirements, tax, and regulatory laws. The various options can be materially different and timelines for each often vary.

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Exit Scenario Recommendations

- Near-term
  - Develop program to work with Pharmaceutical Strategic Partners
  - Network with Medical Device and OEM manufactures

- Mid-term
  - After further product and clinical development it would be the appropriate time to elevate the conversations with the key Strategic Pharmaceutical partners (9-12 months prior to commercialization)

- Longer-term
  - Generate clinical significance and revenue to increase market capitalization and acquisition price for exit strategy. Most likely acquisition via pharmaceutical or medical device company.

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Medibio Limited Project
Stage 1
Market Analysis and Validation

Clinical Need and Driving Adoption

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Worldwide Facts & Statistics on Mental Health

- Globally, 1 in 4 (25%), suffer from mental disorders in both developed and developing countries
- Four of the six leading causes of years lived with disability are depression, alcohol use disorders, schizophrenia, and bipolar disorder. (World Health Organization (WHO), 2013)
- Mental illness accounts for more than 15% of the overall burden of disease from all causes in established market economies, such as the U.S. – slightly more than that of cancer. (Global Burden of Disease Study, WHO, World Bank, and Harvard University, 2008)
- Mental illness in the U.S., Canada, and Western Europe ranks first among illnesses that result in disability
- In 2010, depression ranked 2nd for global disease burden. By 2020, depression is projected to be the leading cause of years lived with disability worldwide (National Institute of Mental Health (NIMH), WHO, 2013)
- The global cost of mental illness is estimated at nearly $2.5 trillion (T) (2/3 in indirect costs) in 2010, with a projected increase to over $6T by 2030 (NIMH, 2013)
- Mental health problems are more common than cancer and heart disease combined. (Substance Abuse and Mental Health Services Administration (SAMSHA))

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US National Facts and Statistics on Mental Health

- 81.6 million Americans (26.2% or 1 in 4) experience some form of mental disorder each year. 46.4% will experience a mental illness in their lifetime. (U.S. population of 311.5 million in 2011, National Household Survey of Drug Abuse, 2006)
- 9% of the U.S. adult population is estimated to have depression
- 8.76% of the U.S. population has a severe mental illness. (SAMSHA)
- More than 50% of adults and 70% of children and adolescents are not receiving any treatment for their mental illness. (SAMHSA 2012, University of Maryland, 2012)
- Nationally, direct treatment costs (public and private) in 2002 were estimated at $100.1 billion and indirect costs were $217.5 billion. (American Journal of Psychiatry (Am. J. Psych.), Jun 2008)
- In 2006, health care costs reached 16% of the nation's GDP, on a path to reach 20% by 2016. Mental disorders were an estimated 6.2%. The economic costs of mental disorders are not captured by an analysis of health care costs because, unlike other medical disorders, the costs of mental disorders are more "indirect" than "direct." (Am. J. Psych., 2008)
- Every $1 spent on mental health services saves $5 in overall healthcare costs. (American Psychological Association)

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Clinical Need Definition: Why Screen For Mental Disorders?

Approximately 20% of medical patients suffer from mental disorders. A recent study showed that 5 – 9% of patients in primary care settings suffer from depression alone, and up to 50% of these cases go undetected and untreated

Patients with mental disorders:

- Suffer needlessly
- Have poorer medical outcomes
- Contribute to rising healthcare costs
- Cost employers $17 billion in lost workdays each year

Because psychiatric symptoms resemble those of many organic illnesses, physicians often spend valuable time trying to rule out medical causes that do not exist

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Business Environment

- Increased focus on mental health diagnosis and treatment due to ACA and Mental Health Parity Act (2008)
  - Mental and behavioral health treatment one of 10 essential benefits required in new insurance policies sold on the federal health exchange as well as to patients on Medicaid
  - Reduction in 50% mental health Medicare co-pay to 20% by 2015
  - Medicare payment increases for psychotherapy services
  - Antidepressants and antipsychotic drugs added to Medicare Part D formulary
- Coverage of mental health conditions variable by state in US
- Growth of patient-centric care models (ACO, CCO etc.) and 'basket of care' reimbursement are driving broader-based mental health approaches
- Growing focus on prevention and early intervention, especially ACO and CCO-based care
- ACO's, Medical Homes incorporating mental health clinicians into care teams
  - 14% of Americans getting care through ACO's, the number is growing
- PCP's poised to become key gatekeepers in mental health diagnosis and will need to triage with mental health professionals for effective treatment (beyond prescribing pharmaceuticals)
- Cost pressures and payor coverage gaps in mental health is big issue
- Shortage of mental health providers especially in rural areas
- Enhanced primary care reimbursement under ACA – Medicare and private payors

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Market Trends and Conditions

- Medicaid expansion under ACA enabling access to care for approx. 2.65 million Americans with mental health conditions
- NIMH Research Domain Criteria (RDoC) initiative is causing some clinicians to view bio-measurements for mental health as “research”, not for widespread clinical use
  - RDoC represents an opposite approach to diagnosis and treatment from current DSM
- Current clinician belief that no adequate biomarker-based tests exists today, informs flawed perception of limited utility of biomarker-based diagnostics and requires extensive re-education
  - “…..the disappointing fact is that not even one biological test is ready for inclusion in the criteria sets for DSM-V“ (Allen Frances, Chair, DSM-IV Task Force)
- De novo clearance of first brain wave testing diagnostic device for ADHD (NEBA) in 2013 is a positive regulatory development
- Reimbursement for mental health diagnostics is uncertain and a cash pay model for mental health diagnostics may need to be considered for market entry in the near term

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Medibio Limited
Voice of Customer Survey
Methodology, Results & Conclusions

Proprietary and Confidential

Medibio Limited VOC Survey: Sample

Total number of clinicians: 11

Gender	Clinician count
Male	4
Female	7

Years of practice	Clinician count
0 - 5 years	0
6 - 10 years	3
11 - 15 years	2
16 - 20 years	4
20 - 30 years	0
30+ years	2

Clinician Specialty	Clinician count
MD	1
MD psychiatry	3
Nurse practitioner, psychiatry	1
PhD Psychology	1
MA level therapist (LP, LPCC, LICSW,LMFT)	5

Practice Setting	Clinician count
Private practice	6
Hospital/group practice	2
Private practice and academic position	1
Private practice and hospital	1
K-12 school and private practice	1

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Medibio Limited VOC Survey: Methodology

- Non-random clinician sample was chosen to participate in a preliminary survey to gauge clinician perceptions and insights on Medibio Limited technology
- Clinicians interviewed covered the spectrum of mental health providers (primary care physicians, MD psychiatrists, licensed psychologists and psychotherapists with diverse licensure) who can conduct MH diagnostic assessments and/or prescribe medications to clients
- Survey participants were provided with a brief overview of the Medibio Limited product, product development and research findings, and were shown charts indicating various signature heart rate patterns corresponding with a variety of mental illnesses
- Once clinicians had information on the Medibio Limited product and the purpose of the survey, they were asked questions from the Clinical Need and Technology Adoption Questionnaire developed for this purpose
- Questionnaire responses were tabulated and analyzed for key patterns and insights regarding the clinical acceptability and potential use of the Medibio Limited technology by this group of US mental health clinicians

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Clinical Need and Technology Adoption Questionnaire

Gender:

Training degree and licenses:

Years of clinical practice:

Clinical Practice setting:

1. How much time do you typically have to make a diagnosis for a client?

2. What tools do you use to make a mental health diagnoses?

3. Do you currently use any objective, evidence based, diagnostic devices/procedures in your clinical practice?

4. If you had access to an objective, non-invasive diagnostic device such as the Medibio Limited product what factors would influence your decision to use it?

5. Would you use this device as a supportive diagnostic tool or a primary diagnostic?

6. Would you use such a device to monitor your client's progress over time? If yes, how often would you use it?

7. If reimbursement was available and administering this test was simple, and you were given the choice, would you recommend administering this test in-house (by yourself or a trained person in your clinic) or would you outsource this diagnostic testing to another facility?

8. Under what circumstances do you see yourself **not** using this Medibio Limited device?

9. What do you think would be needed for broad adoption of such technology by mental health clinicians, insurance/payors and patients in the US?

10: Mental health services and medications are offered by a variety of clinical providers ranging from primary care physicians, MD psychiatrists, PhD psychologists to PhD or Masters level licensed clinical counselors, marriage and family therapists and social workers. Of these various specialties who do you think would be the first adopters of a new diagnostic device? Do you see one or more of these specialties being the largest adopters?

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Medibio Limited VOC Survey Results: Diagnostic Assessment Process

Time taken for diagnosis	Clinician response count
0-59 min	3
60 -119 min	4
120-179 min	3
180 min +	1

Currently use diagnostic medical device	Clinician response count
Yes	0
No	11

Diagnostic tools currently used by clinicians
• Verbal history- client and significant others
• Structured interview schedule based on DSM categories
• PHQ-9, GAD-7, BDI, Mood Questionnaires
• MMPI and other personality questionnaires
• Clinical MHS exam
• Full psychological battery
• Functional assessment
• Focused neuro-physical exam
• Frontal release exam
• EKG, BP machine, heart rate monitor to rule out cardiac issues

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Medibio Limited VOC Survey Results: Clinician responses on use of device

Use of device as a diagnostic tool

- 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
- None of the clinicians reported wanting to use the device as a primary diagnostic tool
- 9% clinicians did not see a need for this device (owing to existence of standard heart rate monitoring devices and other standard diagnostic tools like BP monitors) and would not use it

Monitoring to gauge therapeutic intervention effectiveness:

- Majority (82%) of clinicians would use the device to monitor effectiveness of therapy
- 18% would not use for monitoring or were unsure if they would use it (research/no therapy appointments)

Intervals of Use for Monitoring

- 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
- 18% would not it at all for monitoring (because they only do diagnostic assessments or they believed the tool is better suited for research)

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Medibio Limited VOC Survey Results: Factors Influencing Decision to Use Device

- 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

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Medibio Limited VOC Survey Results: Clinician Insights on Likely Site of Use

- Most clinicians (82%) would use the Medibio Limited device at their own site of care which varied from hospital/group practice to private community care practices
- No clinicians would outsource the testing, assuming ease of use and availability of reimbursement
- Would only send to specialized diagnostic centers like laboratories, cardiology clinics or sleep clinics if they found the procedure very complicated to implement in their own site

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Medibio Limited VOC Survey Results: When Would Clinicians NOT Use the Device?

Clinicians said that they would **not** use the Medibio Limited diagnostic device under the following circumstances:

- Reimbursement was complicated and time-consuming
- For clients presenting with panic disorder, severe anxiety or psychoses
- For clients who refused the diagnostic device and were potentially non-compliant with the requirements of the diagnostic procedure
- If the value of the device / diagnostic compared to standard heart rate monitoring devices was unclear
- If reliability was low
- If the device was too expensive, even if covered by insurance
- If only limited client populations could be served

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Medibio Limited VOC Survey Results: What is Needed for Broad Adoption of Device?

Respondents identified the following factors as being important in driving broad adoption of this device in the US:

- Education of providers, payors and patients
- Intensive marketing and advertising efforts to increase awareness and visibility of device in TV and other media (direct to consumer)
- Sufficient clinical data to demonstrate good reliability and validity for the device
- Large scale adoption by hospitals and clinics
- Coverage by Medicare, Medicaid and insurance companies
- Written materials and training workshops
- Accessibility, ease of use and durability of device
- Word of mouth recommendations and publications

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Medibio Limited VOC Survey Results: Key Insights from VOC Research Responses

- Broad variations in interest across range of mental health clinicians in Medibio Limited therapy
- Supportive diagnostic use and therapeutic intervention monitoring have been identified as preferred uses for this technology
- Education will be key - some medical specialties were not sure if this device would be of use especially if other heart rate monitoring devices were available and others saw it as a research tool rather than for clinical use
- Pivotal data demonstrating benefits of diagnostic and enhancement of therapy delivery are critical for use by majority, especially non-MD therapists
- Desire to have diagnostic available in-house/in-clinic versus outsourcing
- Concerns about length of time to run diagnostic; most would prefer shorter diagnostic period
- Medibio Limited diagnostic device and procedure should fit within current patient care model and reimbursement considerations
- Majority of mental health clinicians would use a biomarker-based diagnostic once clinically proven and reimbursable

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Medibio Limited Device SWOT Analysis: STRENGTHS

1. MH Clinician interest in use of a validated diagnostic tool
2. Non-invasive, based on extensive research and data
3. Uses biological markers, not dependent upon self reported parameters
4. Objective versus subjective tool; can be used by all clinicians regardless of their diagnostic style
5. Helps provide a biological explanation for certain disease states - removes stigma
6. Provides an evidence-based means to validate existence of disease state
7. Utility in supportive diagnostic role and monitoring effectiveness of therapies
8. Potential to offer significant cost and time savings to practitioners and providers
9. First to market with limited or no direct technological competition

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Medibio Limited SWOT Analysis: WEAKNESSES

1. Seen as research tool rather than clinical support option by some clinicians
2. Time consuming diagnostic - 24 hours versus 1-3 hour diagnostic interview
3. High clinical acceptance and satisfaction with the current subjective and behaviorally-based diagnostic techniques for all 4 diagnoses currently addressed by Medibio Limited
4. Symptom cluster and behavior based diagnoses typically obviate need for additional diagnostic confirmation (except in case of rare diagnostic uncertainty)
5. Lack of reimbursement
6. Initial limited test menu that only addresses depression

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Medibio Limited SWOT Analysis: OPPORTUNITIES

1. Significantly reduce form factor to allow greater integration with patient ADL
2. Broaden device application for diagnosing other mental health illnesses
3. Definitive demonstration of clinical utility and incorporation into treatment guidelines
4. Reimbursement specific to EKG-based diagnostic device
5. Obtain indications for use specific to key populations: children and seniors
6. Significant unmet need to increase patient diagnosis rates to address the 50% that are presently not screened or diagnosed
7. Drive higher patient compliance to maintain drug treatment to address the 40-67% of patients discontinue use within three months

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Medibio Limited SWOT Analysis : THREATS

1. Existence of comorbidities (mental health and medical or mental health and substance use) in large number patients - fewer patients with a single pathology

   "Comorbidity is the rule rather than the exception. More than 68 percent of adults with a mental disorder had at least one medical condition. Comorbidity is associated with elevated symptom burden, functional impairment, decreased length and quality of life and increased costs." Goodell, Druss and Walker, 2011

2. Some MD clinicians feel that using standard heart rate and blood pressure measurements and clinical assessment of such parameters are adequate substitute for Medibio Limited product
3. In light of the ongoing NIMH RDoC initiative, some US clinicians may perceive the Medibio Limited device as a research tool than a viable clinical adjunct.
4. Clinicians who feel threatened by 'biologicalization of psychology' will not use the device
5. Clinicians who prescribe medication may not be willing to wait 24 hours to a week to get the results to confirm the diagnosis and then prescribe medication
6. Current reimbursement practices may not support a long drawn out diagnostic procedure

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Medibio Limited Enablers and Limiters

ENABLERS

- Majority of clinicians interviewed interested in using Medibio Limited diagnostic
- De novo 510K clearance of first neuropsychiatric EEG-based ADHD diagnostic device has established confirmatory diagnostic device paradigm at FDA
- Evolving cost effectiveness may drive the need for diagnostics to increase accuracy rate of subjective diagnoses by clinicians
- Bundle of care payment model supports efficiency in mental health diagnosis and treatment outcomes tracking

LIMITERS

- Mental health practice-based clinical data
- Current lack of mental health diagnostic-specific reimbursement
- DSM and ICD-based clinical paradigm dominates diagnosis and treatment
- Some clinicians are uncertain of routine need for confirmatory mental health diagnostic device and procedure
- Biomarker-based diagnoses are not currently a core aspect of mental health clinical paradigm
- Prolonged time frame for diagnostic procedure and interpretation

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Overall Insights and Conclusions from VOC

- There is good US mental health clinician interest and recognition of need for a biomarker-based diagnostic to show treatment progression and make diagnoses more efficient
- Need well-designed clinical studies that clearly define value and role of Medibio Limited technology
  - NEBA device provides an initial clinical, regulatory and market framework
- Strategic focus on publications and US clinician education regarding Medibio Limited diagnostic is key
- Professional societies outreach is critical, using a prioritized, multi-specialty approach to educate and build support amongst clinicians
- Reimbursement and cost of diagnostic are both considerations for clinicians
- Targeted research deployment of Medibio Limited device may be valuable in gaining clinician recognition of value and in growing interest in use

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Targeted Physician Groups

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Categories of Mental Health (MH) Providers in US

With Prescription Privileges:

- **Psychiatrists:** MD or DO physicians specializing in psychiatry and trained in MH diagnosis. Some may provide psychotherapy and counseling services.
- **Primary Care Physicians:** Family practice MD physicians who may or may not be trained adequately in MH diagnosis. They do not provide psychotherapy or counseling services.
- **Psychiatric mental health nurse practitioners/nurses:** Master's or doctoral level nurse practitioners or nurses specializing in psychiatry. Trained in MH diagnosis; some may provide psychotherapy.

Without Prescription Privileges:

- **Licensed clinical psychologists:** Doctorate in psychology (PsyD/PhD). Trained in MH diagnosis, psychotherapy, and psychological testing. Some states license psychologists at a master's level.
- **Licensed professional clinical counselors:** Master's or doctorate in counseling. Trained in MH diagnosis, counseling and psychotherapy services.
- **Licensed marriage and family therapists:** Master's or doctorate in family and marriage therapy. Trained in MH diagnosis, counseling and family and marriage therapy.
- **Licensed clinical social workers:** Master's or doctorate in social work and additional training in psychotherapy and counseling services and MH diagnosis

Not Licensed for Broad Mental Health Diagnosis and Care:

- **Addictions counselors:** specialize in addictions treatment
- **Pastoral/Religious counselors:** combine spirituality & theology in providing supportive services
- **Art/Music Therapists**: combine artistic mediums in providing supportive services

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Role of Different Providers in Adoption of Technology

- Non-medical mental health specialties (psychotherapists) identified medical specialties (medical professionals (PCP/psychiatrist/CNS) as the initial and also the most frequent users of the Medibio Limited device
- Some medical specialties were not sure if this device would be of use especially if other heart rate monitoring devices were available and others saw it as a research tool rather than for supportive clinical use
- Due to their role as the likely point of first contact with patients with mental and behavioral disorders, Primary Care Physicians will have key triage and feeder roles to the other clinicians, including psychiatrists
- Based on their training, MD psychiatrists will be most comfortable with adopting a biomarker-based diagnostic like Medibio Limited and will likely be the heaviest users
- Use of a diagnostic device such as Medibio Limited would facilitate the diagnostic process in PCP offices and potentially drive greater ability to identify mental health issues in patients, a key shortfall that is described by the two sources below:

  "Primary care providers now furnish over half of mental health treatment in this country and about 25 percent of all primary care recipients have diagnosable mental disorders (most commonly, anxiety and depression). Yet many mental health problems are not identified in primary care, perhaps as many as 50 percent. " Bazelon Center for Mental Health Law.

  "Over 70 percent of primary care visits stem from psychosocial issues. Most primary care physicians are not equipped or lack the time to fully address the wide range of psychosocial issues that are presented by patients. " National Association of State Mental Health Program Directors, June 2012

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Best Fit for Technology per VOC

- Clinician consensus from interviews is that primary care physicians in the US are likely the first adopters as they are more likely to see patients first before referring to specialty clinics
- Psychiatrists and therapists (LP, LPCC, LICSW, LMFT) will be the next group to adopt as they provide the bulk of mental health care in the US in specialty or stand alone clinics and practices
- Largest users will be psychiatrists given their familiarity with use of biomarkers such as heart rate unless extensive training is provided to other MH clinicians
- PCP's will have the largest patient base of use but will use it primarily for differential diagnosis
- Most acceptable use to mental health clinicians is as a supportive measure for their subjective and behavioral-based primary diagnoses
- Most clinicians see the diagnostic being used at their respective sites of care and do not want to outsource to specialty diagnostic clinics so referral for diagnostic procedure to cardiology or sleep clinics is unlikely

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Expected Timeline for Adoption

Timelines for widespread adoption are gated by:

- Availability of pivotal data demonstrating clinical value of Medibio Limited technology
- Coverage and reimbursement for Medibio Limited as a supporting diagnostic tool
- Coverage and reimbursement for Medibio Limited as a therapy progression monitoring means
  - –Using the NEBA Health clinical study as a baseline (approx. 300 patients) and an assumed patient monitoring period of 6 months after baseline diagnosis, an estimated timeline for availability of a reimbursement code and widespread adoption would be approximately 3 - 5 years from start of a pivotal study of the Medibio Limited device
- If a viable cash pay model exists, initial clinical adoption could begin sooner

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Recommended Next Steps

- Assess existing clinical data for ability to provide insights into diagnostic use in day-to-day clinical practice
- Conduct pilot clinical study to demonstrate technology integration with US care pathways and gain insight into metrics for pivotal demonstration of clinical utility
- Engage professional societies and AMA to develop reimbursement code(s)
- Engage CMS and private payors to gain insights into clinical evidence requirements
- Conduct provider and patient survey to determine if cash pay model is viable for a subset of patients
- Develop insights and rationale for validity of diagnostic device in patients with significant co-morbidities

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Strategic Commercial Partners

Psychiatry & Psychology Organizations

- Psychiatry and psychology are key critical specialties to endorse the Medibio Limited technology for both initial diagnosis and for ongoing patient monitoring. Working with Key Opinion Leaders (KOL) in the psychiatry and psychology specialties on the clinical studies and validation will be a great asset in accelerating adoption of the Medibio Limited system.
- Per the feedback from the questionnaires, we advise not to change what Psychiatrists and Psychologists have been doing, but rather to add the Medibio Limited diagnostic as part of their standard of care. Once Medibio Limited's technology becomes adopted over a few years, it can start to replace current practices where applicable to drive down costs and improve outcomes with evidence based medicine.

Academic Centers to consider working with:

- Mayo Clinic Department of Psychiatry and Psychology
  - Innovative and ranked among the Best for psychiatry by U.S. News & World Report.
- John Hopkins Department of Psychiatry and Behavioral Sciences
  - Dr. Mesnik is working with Dr. Punjabi and could possibly connect the two departments
- Department of Psychiatry at Harvard Medical School
  - Searching for more evidence-based medicine

Private Centers in the Twin Cities to consider working with:

- Allina Health Mental Health, St. Paul, MN
- Associated Clinic of Psychology, Minneapolis, MN

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Primary Care Physicians

- Primary Care Physicians, General Practitioners, and Internal Medicine Physicians (PCPs) have a larger undiagnosed and untreated patient population with depression
- PCPs have one of the greatest opportunities to utilize Medibio Limited technology with patients that exhibit characterizes of depression as a frontline diagnostic
- However with no objective diagnostic readily available to PCPs it remains an unmet need leaving the door open for Medibio Limited to capitalize on the opportunity
- Especially if the PCPs don't want to send the patient off to someone else for a formal assessment or the patient is reluctant to see other professionals

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Data on Depression Screening in Primary Care

- Only 25 percent of patients receive follow-up visits meeting Healthcare Effectiveness Data and Information Set (HEDIS) criteria of three visits within the first 12 weeks and among those patients who initiate antidepressant use, however, up to 40 to 67 percent discontinue use within 3 months in real-world settings. This is considerably higher than discontinuation rates reported in the context of clinical trials, where early treatment discontinuation rates range from 16 to 29 percent.

- Mass screening in primary care may help clinicians identify missed depression cases and initiate appropriate treatment. Additionally, screening may help clinicians identify patients earlier in their course of depression. In both of these cases, it is presumed that usual care delivers effective treatment and that treating these patients would improve their depression and alleviate their suffering sooner or more thoroughly than if they had not been screened.

- Unlike other screening tests, screening all patients for depression, including those previously identified as depressed, may be useful since it might help identify ineffectively treated patients whose treatment needs modification.

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Data on Depression Screening in Primary Care

- The United States Preventive Services Task Force (USPSTF) has suggested there is not enough screening for depression. Their data shows that if patients are screened for depression in primary care that between 12 and 50 percent of those screening positive would meet criteria for Major Depressive Disorder (MDD), with most estimates falling between 24 and 44 percent. Thus, the majority of patients screening positive will not meet criteria for MDD, though some of these may still benefit from counseling or treatment. Clearly, screening instruments are not sufficient for diagnosing depression, but do indicate the need for more detailed follow-up by a clinician to determine whether the person meets diagnostic criteria for a depressive disorder, to explore other possible causes for depression (such as hypothyroidism or medication or substance use), and assess for co-existing psychiatric disorders.
- This data suggests that if there was an objective diagnostic tool for depression that was broadly used, it would identity those in need and help them.
  - In addition, a material number would also be tested that would not have depression.
    - Thus, the population of patients that could be tested is larger than the 9 percent of the population generally used as the population with depression because some of those screened would test negative

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Accredited Sleep Centers

- Accredited sleep centers by the American Academy of Sleep Medicine could be good commercial partners to help with the monitoring process and could improve compliance and technique. They may also offer additional data points to further support and validate Medibio Limited's algorithm.

- Potential reimbursement advantages for some insurance programs

- Reduces the risk of holter monitors not being returned, lost, or damaged

- Select sleep centers have been accredited by the AASM to provide home sleep testing for the appropriate patients

- While accredited sleep centers may be good partners in the near to mid-term, there appears to be a trend toward acquisition and consolidation of sleep centers in the US

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Academic and Private Sleep Centers

Academic sleep centers to partner with and or run a pilot program include:

- Mayo Clinic Center for Sleep Medicine in Minnesota
  - –The Center for Sleep Medicine is one of the largest sleep medicine facilities in the United States. Treating 6,500 new people each year
- Johns Hopkins Sleep Center
- Harvard Medical School Sleep Disorders Clinic at Beth Israel Deaconess Medical Center
  - –One of the busiest sleep clinics in New England with an excess of 5,000 patient visits per year
- Stanford Center for Sleep Sciences and Medicine
  - –The birth place of sleep medicine and has a robust and comprehensive research program

Private sleep centers to partner with and or run a pilot program include:

- Allina Health – Minneapolis, MN
- Park Nicollet Methodist Hospital Sleep Center – St. Louis Park, MN
- Medical City Hospital Sleep Center – Dallas, TX

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Pharmaceutical Commercial Partners

- Pharmaceutical companies are some of the best partners for Medibio Limited and the relationship would be materially accretive to both parties.

- Data shows that approximately half the population of depressed people go undiagnosed and untreated and other studies show high dropout rates for patients that start taking antidepressants.

- With PCPs and other clinicians utilizing Medibio Limited system as a frontline diagnostic for depression it would address a significant portion of the population that continues to go untreated as an initial diagnostic and furthermore to keep patients on the appropriate pharmaceuticals where applicable to stay healthy with ongoing monitoring of their progress with Medibio Limited software. Additionally having a diagnostic that is widely used would increase the candidate pool for prescription antidepressants. This could be highly motivating to the pharmaceutical industry.

- We see the definitive depression diagnosis from Medibio Limited as a strong driver compared to a subjective discussion between the PCP and patient about taking action on treatment solutions and potentially taking antidepressants

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Pharmaceutical Commercial Partners

Top commercial Pharmaceutical partners in the Antidepressant market

- Pfizer
  - –Zoloft
- Forest Pharmaceuticals Actavis
  - –Lexapro
  - –Celexa
- Eli Lilly
  - –Prozac
  - –Cymbalta
- GlaxoSmithKline
  - –Wellbutrin
- Merck
  - – Remeron

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Medical Device Commercial Partners

Target Device Manufactures in the Holter Monitor and ECG Market

- Forest Medical
- Preventice
- Lifewatch
- Cardionet
- QRS Diagnostics
- Phillips

Distribution Sites

<u>These rank lower on our list of commercial partners:</u>

McKesson Corporation

- The oldest and largest health care services company in the nation, McKesson plays an integral role in health care. They serve more than 50% of American hospitals, 20% of physicians, and 100% of health plans, and is the largest pharmaceutical distributor in North America. Having said this, their primary focus is toward hospital-based customers rather than psychiatrists and general practitioners.

Cardiology Clinics

- With Cardiology Clinics regularly using holter monitors they are a natural adjunct whereby they could use the data they collect and have collected to also diagnose depression where applicable in their patient population

Hospital ECGs and Rhythm Monitoring centers

- Many hospitals in the US have ECG departments with holter monitors and other equipment that could support Medibio Limited data monitoring

Nursing Home Organizations

- As a location to facilitate testing. Not likely a driver to promote diagnosis.

Strategic Partner Recommendation

- Work with Pharmaceutical manufacturers to co-promote Medibio Limited to Primary Care Physicians (PCPs). Pharmaceutical companies continue to look for ways to tap into the large undiagnosed and untreated population with depression in the PCP pool.
- There are opportunities to work with Medical Device companies manufacturing holter monitors as they want to increase sales and develop a broader need for their products. Options include commission programs, joint ventures, licensing agreements, and so on.
- Develop low cost holter monitor with medical device partner or technology company
  - System that is potentially compatible with Google Android and Apple iOS software
    - Many mobile phones have already added or are adding health technology and heart monitors to their devices
    - Create and sell an application for Android and iOS with a fee based structure
- Create a scalable low cost web strategy that can work with clinicians and independent of clinicians
  - Develop Global Medibio Limited website that is open to the public to input their data and to get a diagnose for a fee

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Market Overview & Opportunity

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Global Population & Depression

Global Population in 2013:	7,162.1	Percent of Globe
US Population	322.6	4.50%
EU Population	507.4	10.40%
ROW	6,097.1	85.10%

- 340 million people or 5% of the global population has depression, with less than 25% being treated
- Approximately 29 million people or 9% of the US population has depression, with 50% being treated
- Approximately 60 million people or 8% of the population in Europe suffers from depression, 50% going untreated

- It is estimated that population growth is 1.2% / year per http://en.wikipedia.org/wiki/Population_growth, 1.2%/year growth rate

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http://www.worldometers.info/world-population/
http://news.yahoo.com/migration-helps-boost-eu-population-507-4-million-154620250.html

WHO – Global Issue - Depression

Depression is a common mental disorder. Globally, more than 350 million people (~5% of population) of all ages suffer from depression.

At its worst, depression can lead to suicide. Suicide results in an estimated 1 million deaths every year.

Despite the known effectiveness of treatment for depression, the majority of people in need do not receive it. Where data is available, this is globally fewer than 50%, but fewer than 30% for most regions and even less than 10% in some countries.

Barriers to effective care include the lack of resources, lack of trained providers, and the social stigma associated with mental disorders.

There are many possible treatments for depression; and equally, if not more, barriers to getting treatment. Fewer than 25 percent of people across the world have access to treatments for depression. (10) The World Health Organization recently studied what it calls the “treatment gaps” in mental health care and found that worldwide, the median rate for untreated depression is approximately 50 percent. (11) In some countries, fewer than 10 percent of people with depression receive any treatment. (12)

When people do get treatment, it is often inadequate.

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http://www.who.int/mental_health/management/depression/wfmh_paper_depression_wmhd_2012.pdf?ua=1 May 2012

Market Need

- ACA: Affordable Care Act
  - 3 Part Aim:
    1. Improving the experience of care for individuals
    2. Improving the health of populations
    3. Lowering per capita costs
- Accountable Care Organizations:
  - Evolving concept - set of health care providers—including primary care physicians, specialists, and hospitals—that work together collaboratively and accept collective accountability for the cost and quality of care delivered to a population of patients.
  - Rewarded for shared savings / improved patient outcomes
- Physicians need to do more with less and drive efficiencies in care delivery model

http://www.accountablecarefacts.org/

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Healthcare Market/ Need to Increase Efficiencies

The 2010 Physicians and Health Reform Survey

"Partners in Health: How Physicians and Hospitals Can be Accountable Together. Kaiser Institute for Health Policy"

- 2,379 respondents
- Completed in August 2010
- In response to healthcare reform act

Key findings:

- 74% of physicians will take steps to change their current practice style in the next 1-3 years
- 40% of physicians said they will drop out of patient care in the next 1-3 years, either by retiring, seeking a non-clinical job within healthcare, or by seeking a non-healthcare related job
- While over half said the health reform will cause patient volumes in their practice to increase, 69% said they no longer have the time or resources to see additional patients
- 59% said the reform will cause them to spend less time with their patients
- 56% said the reform will diminish the quality of care

- This will likely further accelerate the paradigm shift toward more efficient patient care and the need for technology to compensate for diminishing physician resources

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Healthcare Market/ Need to Increase Efficiencies

Medscape- The Year in Medicine 2012: News That Made a Difference - December 4, 2012

- **26% of Small Practices May Close**
- One third of physicians in small group practices who responded to a survey this spring expect their 2012 income to fall below what they earned last year, and in practices of 10 or fewer participants, 26% surveyed said they might have to close their practice within the next 12 months. Although the survey did not ask physicians to name reasons for the financial squeeze, 56% reported that Medicare and Medicare payments provided 75% of their income. "The coming retraction this survey hints at would mean longer drives to less-personal, higher-cost medical care for millions of Americans," said one commentator.

US Physicians Suffer More Burnout Than Other Workers

- Physicians in the United States suffer from more burnout than other workers in the United States, according to a national survey of more than 7000 US physicians. Of the surveyed physicians, 37.9% exhibited high levels of emotional exhaustion, 29.4% showed evidence of a high level of depersonalization, and 12.4% had a low sense of personal accomplishment. Taken together, investigators found that 45.8% of physicians were experiencing at least 1 symptom of burnout, based on a high emotional exhaustion score or a high depersonalization score. "Policy makers and health care organizations must address the problem of physician burnout for the sake of physicians and their patients," the authors, led by Tait D. Shanafelt, MD, Mayo Clinic, Rochester, Minnesota, write.

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Market Overview: Depression

Number of Patients Diagnosed

- Nearly **1 in 3 Americans** are suffering from a mental disorder in any given year, or *over 75 million people (32.4%)* [1]
- According to depression statistics from the Centers for Disease Control and Prevention (CDC), about 9 percent of adult Americans have feelings of hopelessness, despondency, and/or guilt that generate a diagnosis of depression [2]
- Twice as common in women as men, but it may be that women are more likely to talk about it and seek help [3]
- About 1 woman in 5 has depression in the US[4]
- In seniors, depression can be the root cause of memory problems, confusion, and in some cases, delusions. Caregivers and doctors may mistake these problems for signs of dementia, or an age-related decline in memory. Getting treatment lifts the cloud for the majority of older people with depression. Psychotherapy is particularly useful for people who can't or don't want to take medication. [3]
- Depression affects 2% of grade school kids and one out of ten teenagers [3]
  - Challenging to diagnose – often children "act out" or engage in risky behavior

http://psychcentral.com/blog/archives/2010/05/03/mental-health-statistics/ (2010) [1]
http://www.everydayhealth.com/health-report/major-depression/depression-statistics.aspx [2]
www.webmd.com/depression [3]
http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118473.htm [4]

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Depression in Europe

- Depression is treatable, but about 50% of major depressions still go untreated
- In Europe alone, an estimated 60 million people suffer from depression. More than 40 per cent of those fail to receive any treatment and only 25-35 percent of patients treated for depression in clinical studies experience remission or relief from all of their disease symptoms [1]
- One in seven people suffer from a severe mood disorder during their lives. Each year, about 7% of the population suffer from a major depression. This figure rises to over 25% if anxiety and lighter forms of depression are included.
- Depression can also lead to high blood pressure, myocardial infarction, stroke and probably, some research suggests, cancer. In turn, cardiovascular diseases, cancer and diabetes lead to an increase in depression. The combination of noncommunicable diseases and risk factors is associated with higher suffering and mortality.
- Depression is present in about 25% of people visiting family doctors, but health care staff often miss it
- About 50% of people with depression do not receive any form of treatment, owing to a combination of treatment avoidance due to shame and denial, a lack of services and/or the inability of staff to identify the problem
- Antidepressant medications are widely prescribed: annually, about 10% of the adult population take them. Psychotherapies have been shown to be equally effective, and cognitive behavioral therapy (CBT) is popular. Well-evaluated interventions are increasingly available on the Internet, enabling self-help.
- The challenge to mental health services is to make effective interventions, provided by competent staff, widely available. People need to feel secure when visiting mental health services, trusting they will receive effective and respectful treatment.

http://www.euro.who.int/en/countries/tajikistan/news/news/2012/10/depression-in-europe (Oct 10, 2012) [1]
https://investor.lilly.com/releasedetail.cfm?releaseid=151920 (1/5/2005) [1]

Treatment options

Mild to Moderate Depression:

- Cognitive Behavioral Therapy
- Interpersonal Therapy
- Psychodynamic Psychotherapy
- Anti-depressants (sometimes combined with talk therapy appears to be particularly effective)
- Light therapy (phototherapy) for SAD
- St. John's Wort supplement (for mild Depression)
- Pets – provide unconditional love, relieve loneliness, and give the owner/patient a sense of purpose
- Social Support network – book club, gym, group activities
- Vagus nerve stimulation (VNS) for patients with treatment-resistant depression that does not improve with medication, like a pacemaker for the brain, sends electrical pulses to the brain through the vagus nerve in the neck to ease depression by affecting mood areas of the brain.
- Another option for patients with treatment-resistant or severe melancholic depression is electroconvulsive therapy (ECT). This treatment uses electric charges to create a controlled seizure.
- A newer option for people with stubborn depression is repetitive transcranial magnetic stimulation (rTMS). This treatment aims electromagnetic pulses at the skull.
- More than 80% of people get better with medication, talk therapy, or a combination of the two.
- Very good studies now show that regular, moderately intense exercise can improve symptoms of depression and work as well as some medicines for people with mild to moderate depression. Exercising with a group or a good friend adds social support, another mood booster.

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Effectiveness of Antidepressants

- Approximately 60 to 70 percent of patients respond to the first antidepressant that is prescribed or to an increased dosage of that drug, according to Mathis.
- But patients must take regular doses of a prescribed antidepressant for at least 3 to 4 weeks before they are likely to experience the full therapeutic effect. And if patients start to feel better, they should not stop taking the antidepressant.
- “Even if you start to feel better, you may be in between episodes,” says Mathis. “Depression tends to be chronic and requires everyday treatment just like high blood pressure.”
- If you get used to an antidepressant and just quit it, you may experience some withdrawal symptoms such as anxiety and irritability. Worst of all, depression may recur.
- Patients should continue taking an antidepressant for 6 to 12 months, or in some cases longer, according to the National Institute of Mental Health (NIMH). This gives medication time
- should carefully follow their doctor’s instructions.
- Mathis estimates that about 10 percent of depressions are treatment resistant and won’t respond to prescribed antidepressants.
- That means that 20 to 30 percent of patients may not respond to the first antidepressant that is prescribed for them. NIMH-funded research has shown that patients who did not get well after taking a first medication increased their chances of becoming symptom-free after they switched to a different medication or added another medication to their existing one.
- With appropriate treatment, many people with depression experience improvement of their symptoms and return to living normal and productive lives.

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http://www.fda.gov/downloads/forconsumers/consumerupdates/ucm095990.pdf (January 9, 2009)

Top 5 Drugs Prescribed for Depression

2012

Top Two Prescribed Depression Drugs – Zoloft and Lexapro

- Zoloft and Lexapro are the most powerful of the newer generation of depression medications. Zoloft proves to be an SSRI, or selective serotonin reuptake inhibitor, antidepressant. It has a proactive impact on the body through boosting your serotonin levels. This medicine is commonly given to adults who possess from minor to medium levels of symptoms related to depression. Lexapro and Zoloft were both tested in a study that found that patients had the fewest severe side effects versus the other depression drugs. This same study decided that they were both best choices for serious depression as well. Both have the most infrequent levels of side effects like weight gain, insomnia, and agitation.

Top Third Prescribed Depression Drug – Prozac

- Another commonly prescribed anti-depression drug is Prozac. Like with Zoloft, it is an SSRI. Prozac has another benefit that the other depression drugs can not boast. It is the one and only SSRI that the FDA has given approval for children as little as seven years old to take. Prozac is therefore deemed to be a very safe prescribed depression medication.

Top Fourth Prescribed Depression Drug – Wellbutrin

- Wellbutrin battles depression in a different manner altogether. It fights it by impacting the levels of dopamine, serotonin, and norepinephrine in the body. Wellbutrin also finds use in occasionally treating those victims of either ADHD, also known as Attention Deficit Hyperactivity Disorder, or SAD, similarly called Seasonal Affective Disorder. Wellbutrin is therefore perhaps the most useful of the major five prescribed depression drugs for treating related and different conditions to depression.

Top Fifth Prescribed Depression Drug – Cymbalta

- Cymbalta also works differently than the other top four prescribed depression drugs. It is an SSNRI, standing for a selective serotonin norepinephrine reuptake inhibitor. It works on the body's levels of norepinephrine and serotonin. Cymbalta is never used to treat children. It is most commonly utilized to help out adults who are the victims of major depression.

http://www.honestdiscounts.com/blog/top-5-prescribed-drugs-for-depression/2012

Pharmacological Treatment

Top 25 Psychiatric Drugs Prescribed in US 2011

2011	2009	2005	Brand name	Used for…	U.S. Prescriptions (% change from 2009)
1	1	1	Xanax (alprazolam)	Anxiety	47,792,000 -9%
2	17	11	Celexa (citalopram)	Depression, Anxiety	37,728,000 -36%
3	4	2	Zoloft (sertraline)	Depression, Anxiety, OCD, PTSD, PMDD	37,208,000 -8%
4	3	5	Ativan (lorazepam)	Anxiety, panic disorder	27,172,000 -4%
5	5	4	Prozac (fluoxetine HCL)	Depression, Anxiety	24,507,000 -6%
6	2	3	Lexapro (escitalopram)	Depression, Anxiety	23,707,000 (- 16%)
7	6	NA	Desyrel (trazodone HCL)	Depression, Anxiety	22,591,000 -15%
8	7	16	Cymbalta (duloxetine)	Depression, Anxiety, fibromyalgia, diabetic neuropathy	17,770,000 -6%
9	10	9	Valium (diazepam)	Anxiety, Panic disorder	14,694,000 -6%
10	8	13	Seroquel (quetiapine)	Bipolar disorder, Depression	14,213,000 (- 11%)
11	11	10	Paxil (paroxetine HCL)	Depression, Anxiety, Panic disorder	13,990,000 (- 6%)
12	9	6	Effexor XR (venlafaxine HCL ER)	Depression, Anxiety, Panic disorder	12,469,000 (NA for HCL ER)
13	22	10	Wellbutrin XL (bupropion HCL XL)	Depression	12,151,000 -77%
14	12	14	Risperdal (risperidone)	Bipolar disorder, Schizophrenia, irritability in autism	12,092,000 -14%
15	11	NA	Amphetamine salts (Generic)	Attention deficit disorder	9,682,000 -36%
16	15	NA	Abilify (aripiprazole)	Bipolar disorder, Schizophrenia, Depression	8,881,000 -8%
17	19	NA	Vyvanse (lisdexamfetamine)	Attention deficit disorder	8,467,000 -50%
18	NA	NA	Wellbutrin SR (bupropion HCL SR)	Depression	8,456,000 -75%
19	13	NA	Vistaril* (hydroxyzine)	Anxiety, tension	7,268,000 -9%
20	NA	NA	Amphetamine salts ER (Generic)	Attention deficit disorder	6,499,000 -67%
21	18	19	Buspar (buspirone)	Sleep, Anxiety	6,334,000 -15%
22	20	17	Zyprexa (olanzapine)	Bipolar disorder, Schizophrenia	4,576,000 (- 15%)
23	16	NA	Concerta (methylphenidate)	Attention deficit disorder	4,328,000 (- 45%)
24	NA	NA	Methylphenidate (generic)	Attention deficit disorder	4,248,000 (NA)
25	25	NA	Pristiq (desvenlafaxine)	Depression	4,039,000 -61%

Top Drugs in 2011 listed to treat Depression:

1) Celexa
2) Zoloft
3) Prozac
4) Lexapro
5) Desyrel
6) Cymbalta
7) Seroquel
8) Paxil
9) Effexor XR
10) Wellbutrin XL

http://psychcentral.com/lib/top-25-psychiatric-medication-prescriptions-for-2011/00012586

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Opportunity

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Monitoring Opportunity

Initial Monitoring at Diagnosis

On-going Monitoring may vary by treatment option

- Drug therapy
- Talk therapy
- Other

Diagnosis vs Monitoring Opportunity

Based upon primary research discussions, it appears that there is a need and desire to utilize the monitoring device for initial differentiated diagnosis and also for ongoing monitoring of therapy effectiveness. Recommended cadence of testing is as follows:

- Monitor at initial diagnosis & patient starts Therapy
- Monitor at 4 weeks
- Monitor at 12 weeks
- Monitor at 26 weeks (6 month mark)
- Monitor at 52 weeks (one year mark)
- Monitor at Annual check-ups

Considerations:

- Meds take 4-6 weeks to take affect, may take up to 6 months
- 20-30-% of patients may need a different medication prescribed since they will not respond to first med
- Re-start monitoring with introduction of new med

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Best Approach for using Holter Monitors

Multiple Scenarios were evaluated that include:

A. Psychiatrist / psychiatry group leases / owns Holter monitors and their personnel perform CRM testing on patients and feeds results directly into Medibio Limited software product to get results (this may allow the psychiatry group to get more reimbursement for CRM testing)

B. Fee for Service Scenario - Psychiatrist / psychiatry group writes the orders for patient to go get CRM test with Holter monitor by an outside party (such as a cardiology center) within a HC system, another department within their HC organization)

C. OEM or strategic partners that would offer competitive pricing
   - Medibio Limited bundling/packaging via OEM private label scenario
   - Alliances with manufacturers that supply preferred pricing

Based upon initial findings, it appears that Scenario A is the most likely scenario to better ensure patient compliance and capture a higher level of reimbursement. Scenario B may play out the minority of the time.

Global Market Universe

Initial Differential Diagnosis

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)	Already Diagnosed	Treated (millions)	# People Untreated (millions)	Price per monitoring (initial)	Untreated (millions)	Total
US Population	322.6	9%	29.0	14.5	Already Diagnosed	$0.00	14.5	$45.00	$653.3	$653.3
EU Population	507.4	8%	40.6	20.3	Already Diagnosed	$0.00	20.3	$30.00	$608.9	$608.9
ROW	6,332.1	5%	316.6	76.0	Already Diagnosed	$0.00	240.6	$14.85	$3,573.2	$3,573.2
Global Market	7,162.1				Already Diagnosed	$0.00			$4,835.3	$4,835.3

On-going Monitoring

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)	Price per monitoring (initial)	Treated (millions) (1/year)	# People Untreated (millions)	Price per monitoring (initial)	Untreated (millions) (4/year)	Total
US Population	322.6	9%	29.0	14.5	$22.50	$326.63	14.5	$22.50	$1,306.5	$1,633.2
EU Population	507.4	8%	40.6	20.3	$15.00	$304.44	20.3	$15.00	$1,217.8	$1,522.2
ROW	6,332.1	5%	316.6	76.0	$7.43	$564.57	240.6	$7.43	$7,151.2	$7,715.8
Global Market	7,162.1					$1,195.6			$9,675.5	$10,871.2

Total Market Opportunity

Market Universe	Population	Prevalence of Depression	# Total People (millions)	# Treated (millions)		Treated (millions)	# People Untreated (millions)		Untreated (millions)	Total
US Population	322.6	9%	29.0	14.5		$326.6	14.5		$1,959.8	$2,286.4
EU Population	507.4	8%	40.6	20.3		$304.4	20.3		$1,826.6	$2,131.1
ROW	6,332.1	5%	316.6	76.0		$564.6	240.6		$10,724.4	$11,289.0
Global Market	7,162.1					$1,195.6			$14,510.9	$15,706.5

http://www.worldometers.info/world-population/
http://news.yahoo.com/migration-helps-boost-eu-population-507-4-million-154620250.html

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Global Market Universe

- The Global Market for Initial Differential Diagnosis of Depression in the Untreated Population is $4.8 Billion, with the US market at approximately $653 Million, $609 Million in Europe, and $3.6 Billion in ROW

- For the On-going Monitoring of patients that are already treated, the Global opportunity is $1.2 Billion, with $327 Million in the US, $304 Million in Europe, and $565 Million in ROW. The On-going Monitoring opportunity for the Untreated population is about $9.7 Billion for the global market, with $1.3 Billion in the US, $1.2 Billion in Europe, and $7.2 Billion in ROW.

- Thus, the Total Global Market Opportunity is $15.7 Billion, with $2.3 Billion in the US, $2.1 Billion in Europe, and $ 11.3 Billion ROW

With a capture rate of 5% in the US, Medibio Limited would realize $115 Million in Gross Revenues.

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Best Approach for using Holter Monitors

Multiple Scenarios were evaluated that include:

A. Psychiatrist / psychiatry group leases / owns Holter monitors and their personnel perform CRM testing on patients and feeds results directly into Medibio Limited software product to get results (this may allow the psychiatry group to get more reimbursement for CRM testing)

B. Fee for Service Scenario - Psychiatrist / psychiatry group writes the orders for patient to go get CRM test with Holter monitor by an outside party (such as a cardiology center) within a HC system, another department within their HC organization)

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   - Alliances with manufacturers that supply preferred pricing

Based upon initial findings, it appears that Scenario A is the most likely scenario to better ensure patient compliance and capture a higher level of reimbursement. Scenario B may play out the minority of the time.

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Reimbursement Assessment for Use of Cardiac Rhythm Testing for Mental Health Diagnoses

Overview & Summary

The use of cardiac rhythm measurement for the diagnosis of mental health conditions should only confront one of the three common barriers that challenge emerging new technologies. Existing coding and payment structures are supportive of Medibio Limited's business plan. The barrier will be getting private insurers to accept current and new clinical evidence to support covering a technology which today is only approved for cardiac conditions.

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Reimbursement Fundamentals

- Reimbursement Assessments focus on three fundamental, independent variables:
  - Coding – Is there a CPT code that clinicians can use to bill professional services to government and private insurers?
  - Payment – Are the current payment amounts sufficient for clinicians to adopt, and not too expensive that payers will balk at covering?
  - Coverage – Do government and private insurers provider coverage for the services for the specific clinical indication(s)?

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Coding

Is there a CPT code that clinicians can use to bill professional services to government and private insurers?

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Types of Heart Rate Measurements

- The Medibio Limited heart rate measurement system is presumed to be comparable to holter monitoring which is generally described as *"portable devices that record heart rhythms continuously for up to 48 hours. These devices are used to record events that occur at least once a day."*
- Types of heart rate monitoring that would not apply are:
  - Outpatient mobile telemetry
  - Non-continuous devices with memory
  - Continuous memory loop devices
  - Implantable continuous memory loop devices
  - The above monitoring all use different CPT codes

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Coding for Heart Rate Rhythm

- Physicians and other licensed health care professionals, including psychologists use five digit CPT™ codes issued by the American Medical Association (AMA) to describe the professional services they provide. There is one series of existing CPT™ codes for heart rate monitoring that appears appropriate for the Medibio Limited technology

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CPT™ Codes for Heart Rate Monitoring

- **93224 -** *Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage, with visual superimposition scanning; includes recording, scanning analysis with report, physician review and interpretation*
- Services for this type of monitoring can also be separately identified and billed as follows:
  - **93225** *recording (includes hook-up, recording, and disconnection)*
  - **93226** *microprocessor-based analysis with report*
  - **93227** physician review and interpretation

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Coding Summary

- Clinicians who would perform heart rate measurement for mental health diagnoses should be able to use existing CPT codes
- These codes are appropriate for use by psychiatrists, psychologists, family practice physicians and other similarly qualified MDs who could be expected to diagnosis mental health conditions
- The same ICD-9 diagnosis codes for mental health would apply, as well

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Payment

Are the current payment amounts sufficient for clinicians to adopt, and not too expensive that payers will balk at covering?

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Payment for Heart Rate Measurement

- Medicare sets payment rates for each service described by a CPT™ code. Those payment amounts are publically available. Private insurer amounts vary widely and are not publically available. The private payer amounts below are estimates:

	Medicare	Private Insurance*
93224	$91.71	$138
93225	$26.87	$ 40
93226	$37.97	$ 57
93227	$26.87	$ 40

(The latter three allowances equal the “global fee” of #93224)

- These allowances vary across the country for both Medicare and private insurers
- *Private insurance amounts vary widely, but are typically 35 – 75% higher than Medicare’s, depending on the payer and geographic location

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Supervision Requirements

- The federal Medicare program identifies three levels of supervision that apply to diagnostic testing. Private payers often, but not always, concur. In order of magnitude, they are:
  - ***Personal supervision*** means a physician must be in attendance in the room during the performance of the test
  - ***Direct supervision*** means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the test. It does not mean that the physician must be present in the room when the procedure is performed.
  - ***General supervision*** means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the test. The training of the no physician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

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Supervision and Payment

- The CPT™ code range #93224-93227 requires only “General” supervision so that minimally trained clinic staff can administer the test
- A physician would be responsible for interpreting the results based on the report generated by Medibio Limited
- Based on current usage, it can be presumed that the supervision and payment conditions today for the diagnosis of cardiac disease will be sufficient for physician adoption for mental heath diagnosis

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Payment Summary

- If the capital expense of the Medibio Limited equipment, proprietary software algorithms and the work associated with the testing are comparable to existing holter monitoring, the current payment levels should be sufficient for clinician adoption – it has already been established
- The supervision requirements for holter monitoring for cardiac conditions are well understood and should expect to be applied for use in diagnosing mental health status
- Payers will understand they are comparable expenses and will not seek to create different payment levels
- Clinicians understand that Medicare always pays less than private insurance and Medicaid (coverage for the poor) pays even less than Medicare

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Coverage

Do government and private insurers provider coverage for the services for the specific clinical indication(s)?

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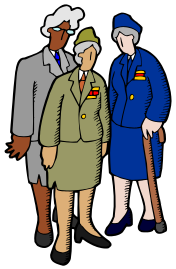
Government Payers

- CMS (Center for Medicare and Medicaid Services)
  - Medicare: patients 65 years of age and over
  - Medicaid: low income individuals and families (administered in conjunction with state governments)



- Military Health Systems
  - US Department of Defense: TRICARE – active duty and retired military personnel and families. Represents about 253 military hospitals and clinics
  - Department of Veterans Affairs: VA Medical System – those injured during combat . 53 VA hospitals and staffed clinics

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Coverage Determinations

- The focus on “government” payers for this analysis is on Medicare which has two levels of coverage decision making
  - National Coverage Determinations (NCDs) affect all Medicare beneficiaries
  - Local Coverage Determinations (LCDs) affect beneficiaries in specific jurisdictions
- The vast majority of coverage decisions are “Local” and are made by the Medicare Administrative Contractors (MACs) in the jurisdictions they serve. Consequently coverage policies can vary widely across the US. Fortunately, this is not the case with EKG (holter) monitoring.
- Please see the following map of Medicare jurisdictions

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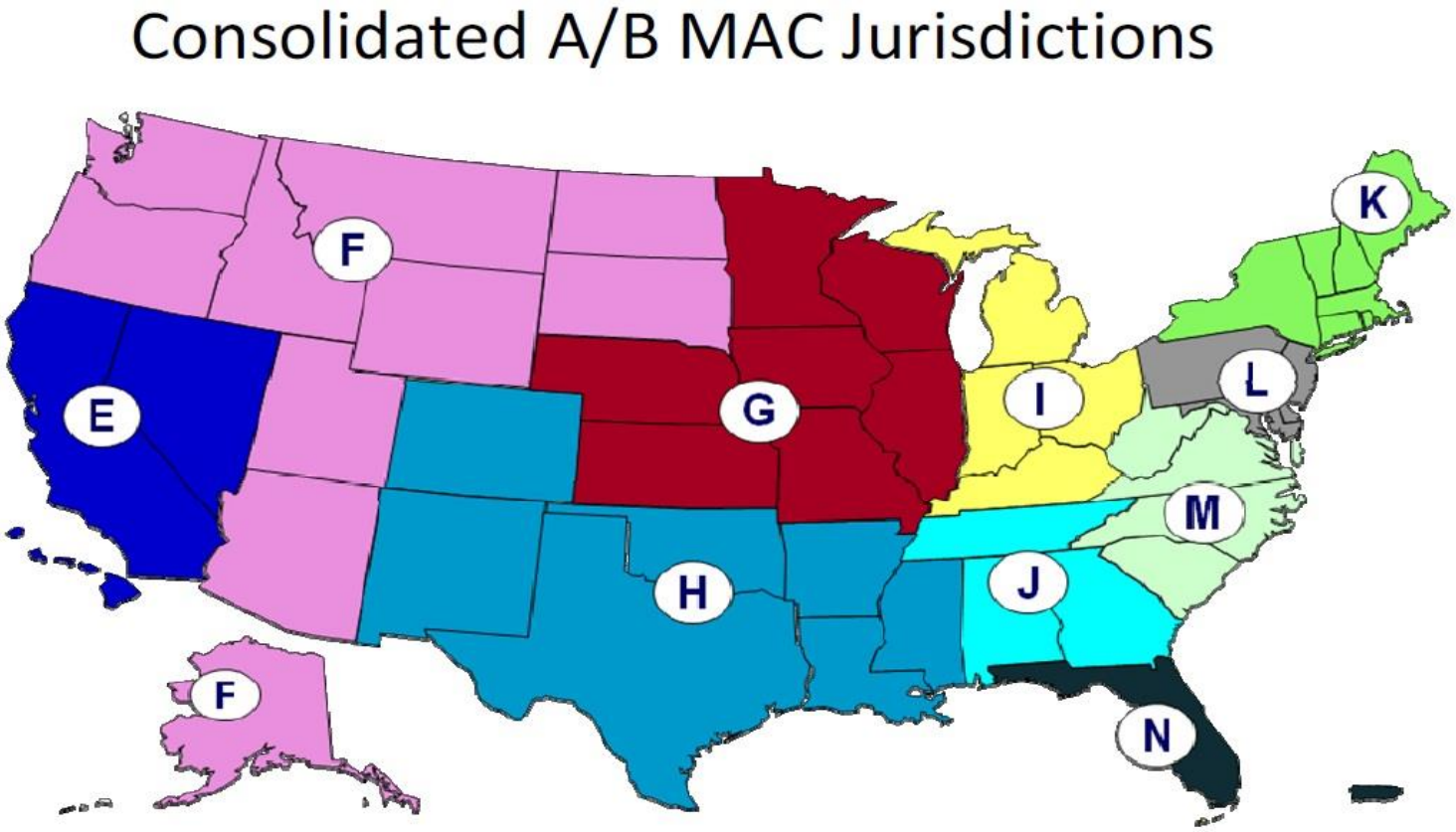
Medicare Jurisdictions



There are 10 jurisdictions administered by 7 contractors thereby yielding different Local Coverage Determinations

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Medicare Coverage

- Medicare NCD for Electrocardiographic Services (20.15) – does not specifically cite holter monitoring
- There are several LCDs including Wisconsin Physician Services LCD L29584 for Electrocardiographic (EKG or ECG) Monitoring (Holter or Real Time Monitoring). This LCD is virtually the same among all MACs and accompanies this report in the Appendix

Typical Medicare Coverage –
(L26854) Holter Monitoring

1. Symptoms: arrhythmias, chest pain, syncope (lightheadedness) or near syncope, vertigo (dizziness), palpitations, transient ischemic episodes, and dyspnea (shortness of breath)
2. Evaluation of the response to antiarrhythmic drug therapy
3. Evaluation of myocardial infarction (MI) survivors with an ejection fraction of 40% or less
4. Assessment of patients with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes
5. Other acute and sub acute forms of ischemic heart disease
6. To detect arrhythmias post ablation procedures

Any other use of holter monitoring would be considered “not reasonable and necessary” until such time as Medicare was convinced of the clinical utility of holter monitoring for mental health diagnosing

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Private Insurers

- Medicare is the largest single payer of healthcare in the US
  - Private insurers often, but not always, follow Medicare coverage decisions
  - Medicare, Medicaid, TRICARE and VA (government payers) all pay less than private insurers for the same services
- There are about 1,100 private health plans
  - Most private payers make their own coverage decisions
  - They also have varying payment levels, but they pay more than government payers

Summary of Private Payer Coverage

- Medical policies for all of the payers below were researched – none would cover holter monitoring for the diagnosis of mental health; they are all specific to physiologic conditions
  - Aetna Medical Policy #0019 – Holter Monitors: Coverage Criteria
  - Blue Cross Blue Shield of Michigan - Mobile Ambulatory Event Monitors Cardiac Outpatient Telemetry
  - Health Net - #NMP495 Implantable Cardiac Event Monitors
  - Cigna Cardiac Event Monitors; #0085
- Aetna and BCBS Michigan policies are appended to this is report as examples

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Aetna-Holter Monitor Coverage Criteria

1. As a method to assess treatment effectiveness in individuals with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes, supraventricular arrhythmias or ventricular tachycardia; *or*
2. Autonomic cardiac neuropathy associated with diabetes mellitus; *or*
3. Idiopathic hypertrophic or dilated cardiomyopathy; *or*
4. In individuals with pacemakers to assess paroxysmal symptoms, myopotential inhibition, pacemaker medicated tachycardia, anti-tachycardia pacing device functioning, rate-responsive physiologic pacing function; *or*
5. Individuals with pain suggestive of Prinzmetal's angina; *or*
6. Post myocardial infarction with left ventricular dysfunction; *or*
7. Symptoms related to rhythm disturbances (e.g., frequent palpitation, syncope, unexplained dizziness, frequent arrhythmias).

Aetna considers Holter monitoring experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established

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Blue Cross Blue Shield of Michigan

Indications for external 48-hour ECG recording (CPT/HCPCS codes 93224-93227) include one or more of the following

1. Symptoms such as:
   - Arrhythmias(ICD-9 codes 426.0-426.9, 427.0-427.42, 427.60-427.9)
   - Chest pain (ICD-9 codes 411.1, 786.50, 786.51, 786.59)
   - Syncope (lightheadedness) or near syncope (ICD-9 code 780.2)
   - Vertigo (dizziness) (ICD-9 code 780.4)
   - Palpitations (ICD-9 code 785.1)
   - Transient ischemic episodes (ICD-9 codes 780.02, 781.0, 781.4)
   - Dyspnea (shortness of breath) (ICD-9 codes 786.00-786.09)
2. Evaluation of the response to antiarrhythmic drug therapy (ICD-9 codes V58.69)
3. Evaluation of myocardial infarction (MI) survivors with an ejection fraction of 40% or less. (ICD-9 codes 410.00-410.92, 411.0, and 412)
4. Assessment of patients with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes (ICD-9 codes 413.0-413.9)
5. Other acute and sub acute forms of ischemic heart disease. (411.0-411.89)
6. To detect arrhythmias post ablation procedures.

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Health Net Coverage

- Health Net medical policy cites The American College of Cardiology (ACC), the American Heart Association (AHA), and the European Society of Cardiology (ESC) guidelines when using holter monitoring
  - According to these organizations, *"Ambulatory 24-hour Holter recording can be used in patients with frequent (i.e., several episodes per week) but transient tachycardias. An event or wearable loop recorder is often more useful than a 24-hour recording in patients with less frequent arrhythmias. Implantable loop recorders may be helpful in selected cases with rare symptoms (i.e., fewer than two episodes per month) associated with severe symptoms of hemodynamic instability."*

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Cigna Coverage-Holter Monitoring

- As a diagnostic tool to evaluate symptoms suggestive of cardiac arrhythmias (e.g., frequent palpitations, unexplained dizziness, or syncope)
- Assessment of pacemaker or implantable cardioverter defibrillator (ICD) function for ANY of the following:
  - frequent symptoms of palpitation, syncope, or near syncope
  - suspected component failure or malfunction
  - assessment of response to drug therapy in an individual with an ICD
- Assessment of potential myocardial ischemia in suspected variant angina or known coronary artery disease when such information will impact management
- Assessment of antiarrhythmic drug therapy in an individual with a treated arrhythmia
- Child with ANY of the following:
  - hypertrophic or dilated cardiomyopathy
  - possible long QT syndrome

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Steps to Secure Coverage

- Payers remain skeptical about new technology applications until such time as clinical evidence can make a compelling case
- It will also require support from Key Opinion Leaders within the industry and current clinical users
- There are no defined standards regarding how much evidence is required, but more is always better
- The new technology evaluation criteria which follow provide a basis for understanding payer expectations

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Blue Cross Blue Shield Association – Technology Evaluation Criteria

1. The technology must have final approval from the appropriate regulatory body
2. The scientific evidence must permit conclusion concerning the effect of the technology on health outcomes
3. The technology must improve the net health outcome
4. The technology must be as beneficial as any established alternatives
5. The improvement must be attainable outside the investigative setting

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Coverage Process

- About 1/4th of the private insurers create their own medical coverage policies (the large companies) – the others follow Medicare. Coverage decisions will be based on
  - Peer-reviewed, published clinical literature
  - Evaluation of evidence for safety and efficacy
  - Support from physician community medical societies and KOLs
  - Documented cost-effectiveness

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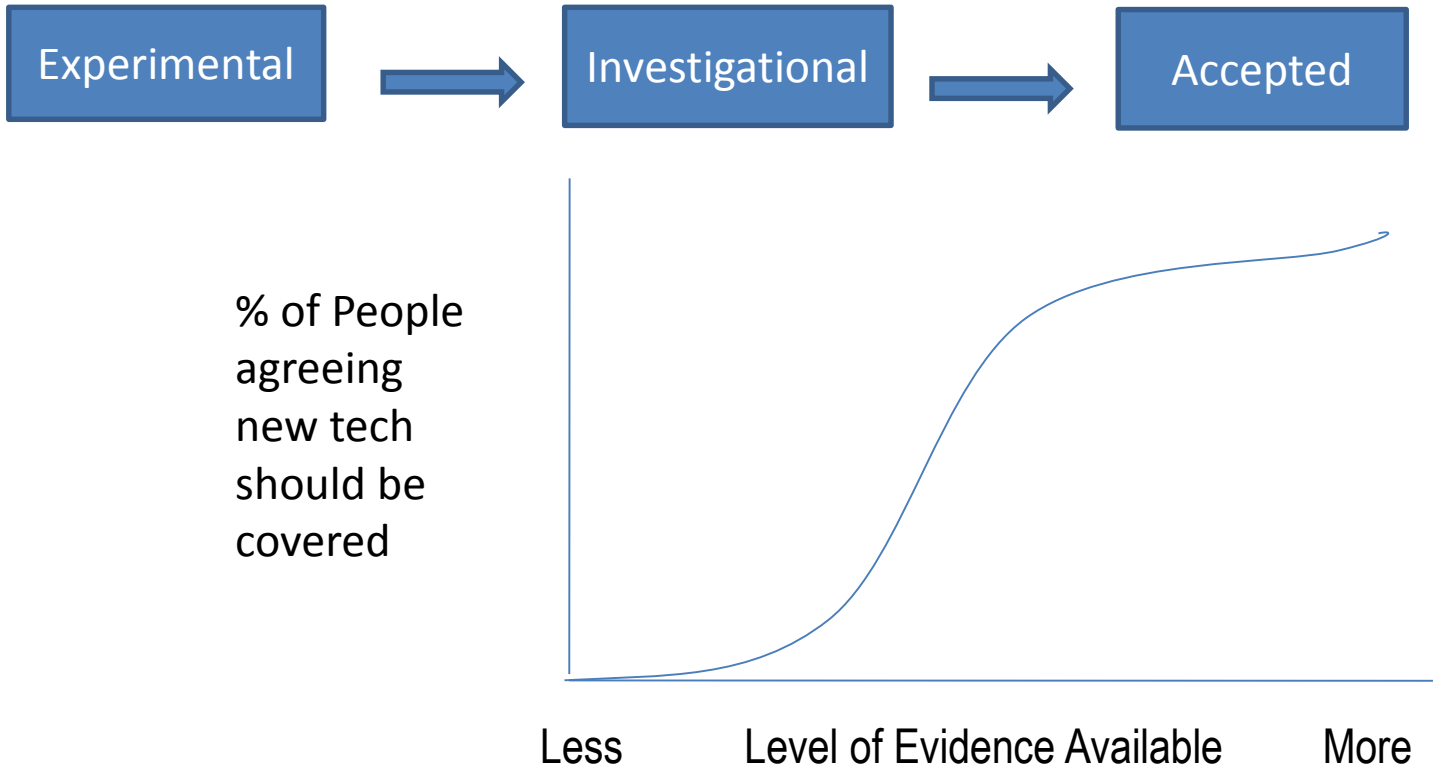
Coverage Adoption



Securing Coverage takes time and effort – it's not automatic

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Coverage Summary

- Medibio Limited will need to compile a significant amount of evidence to convince payers that holter monitoring can reliably diagnose mental health disorders
- Medical societies (i.e. The American College of Cardiology) can also be expected to provide resistance to the expansion of holter monitoring beyond cardiac conditions - it's a physician "turf" issue
- There are no standards for the type of evidence or the size of representative clinical studies – certainly the more the better
- It is likely that when such testing is accepted for coverage, it must complement (not replace) other testing tools

That being said – payers are always looking for more objective data upon which medical decision-making can be made. Assuming heart rate measurement can objectively diagnose mental health conditions and it is supported by broad clinical science, it will likely get covered, though, it will take time.

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Recommended Next Steps

- Based upon this situation analysis and summary, the recommendation is to expand indications for payment from existing payors/insurers within the existing CPT & ICD9 codes
- Strategy is to start at the regional level and expand in multi-phase regional approach
- Simultaneously pursue VA system that governed under independent reimbursement system
- After establishing regional reimbursement & refining program, approach major national insurers such as Cigna, United Health Group, & Aetna

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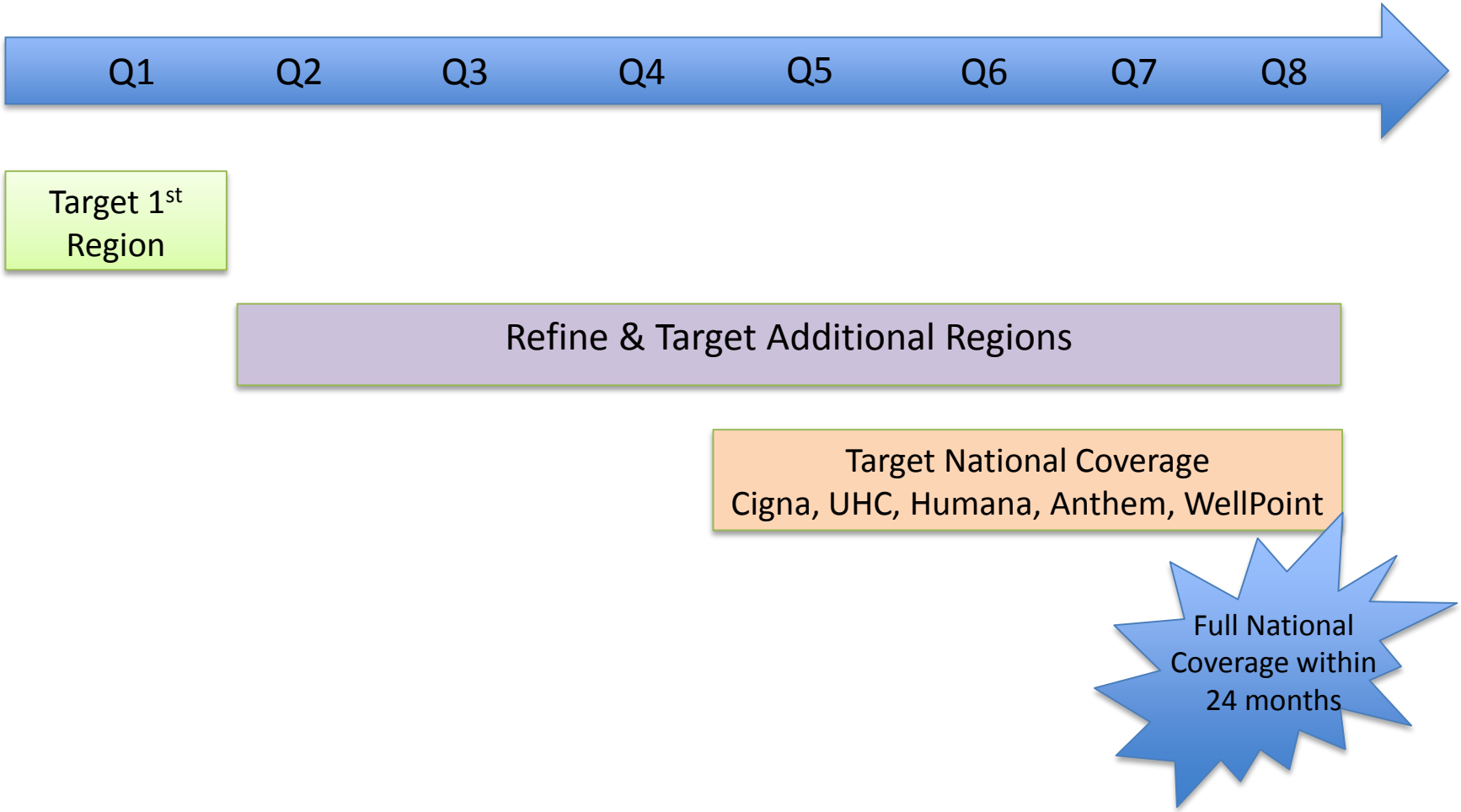
Estimated Reimbursement Timeline



While the development of a more comprehensive reimbursement plan is warranted, this depicts a high level overview of anticipated timeline

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Strategic Business Planning & Exit Scenarios

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Medibio Limited

Medibio Limited
Business Model

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Product Definition And Global Pricing

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Medibio Limited Product Configurations

Product Definition Scenarios

1. Medibio Limited Software Package
   A. Differential Diagnosis and Monitoring Capabilities

2. Medibio Limited CRM Diagnostic Hardware
   A. Medibio Limited Branded Holter Monitor via OEM Arrangement

3. Full Solution Set Includes Medibio Limited Software and Medibio Limited Holter Monitor Hardware

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Product Pricing Plan

Software

There are several potential product pricing scenarios to consider that include:

1. Variable Seat (User) Based License Subscription to Service and Interpretation
2. Fixed Monthly Licensing or Leasing Fee for Service and Interpretation
3. Per Patient Charge for Service and Interpretation

Recommendation: Per Patient Charge

Based upon market feedback, the existing reimbursement system in the US and the business model that presents the most revenue upside, the recommended approach is to charge a per patient fee for service.

The amount charged for initial diagnosis can be significantly higher given an existing precedence of higher reimbursement for the differential diagnosis of psychological disorders versus the monitoring of treatment effectiveness. The amount charged per patient for treatment monitoring is targeted at 50% of the diagnosis fee.

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Product Pricing Plan

Hardware

Many options exist for the hardware (monitoring devices) product acquisition and pricing:

1. Acquisition from Medibio Limited
2. Hardware Purchase From Other Holter Monitor Manufacturers
3. Fixed Monthly Leasing Fee for Monitoring Hardware
4. Per Click Fee Per Patient

Recommendation: Customers Acquire Devices From Medibio Limited or Another Manufacturer. Price Hardware to Drive Placements and Access to Technology and Testing.

The fact that monitoring devices are imperative to enabling patient testing, it is recommended the devices are priced at a level to drive technology adoption and revenue resulting from the per patient interpretive testing fees that present a much larger business opportunity (rather than the hardware acquisition revenue). In many instances health care organizations will have access to Holter monitors presently residing within their system. However, certain organizations will not have access to these devices. In those instances devices can be purchased from any of the many existing Holter monitor manufacturers or they can be purchased from Medibio Limited directly. It is recommended that the capital equipment pricing is not price prohibitive which would present a barrier to product adoption. OEM devices that are marketed by Medibio Limited on a monthly leasing or outright acquisition basis will provide a turn-key solution at a reasonable price for new customers and will drive utilization.

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US Pricing Schedule

Product Description	End User List Price	Distributor Commission 30%	Medibio Limited Realized Revenue
Medibio Limited Software Differential Diagnosis	$45 Per Patient Treatment	($13.50)	$31.50
Medibio Limited Software Patient Monitoring	$22.50 Per Patient Treatment	($6.75)	$15.75
Medibio Limited HM	$500 (One-time acquisition price)	($150)	$350

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Intl Developed Markets Pricing Schedule

Product Description	End User List Price	Distributor Commission 30%	Medibio Limited Realized Revenue
Medibio Limited Software Differential Diagnosis	$30 Per Patient Treatment	($9)	$21
Medibio Limited Software Patient Monitoring	$15 Per Patient Treatment	($4.50)	$10.50
Medibio Limited HM	$375 One-time acquisition price	($112.50)	$262.50

*Assumes SW ASP Equivalent to 67% & Hardware Equivalent to 75% of US Price Schedule

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Intl Emerging Markets Pricing Schedule

Product Description	End User List Price	Distributor Commission 30%	Medibio Limited Realized Revenue
Medibio Limited Software Differential Diagnosis	$14.85 Per Patient Treatment	($4.45)	$10.40
Medibio Limited Software Patient Monitoring	$7.43 Per Patient Treatment	($2.23)	$5.20
Medibio Limited HM	$250 One-time acquisition price	($75)	$175

*Assumes SW ASP Equivalent to 33% & Hardware Equivalent 50% of US Price Schedule

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Pre-Reimbursement Payment

- Prior to the establishment of reimbursement and/or in instances where certain insurers will not reimburse for diagnostic and monitoring testing of patients with the Medibio Limited product, there is a reasonable likelihood that a given percentage of patients will be willing to pay “out of pocket” for the diagnostic and monitoring at a reduced fee schedule of ½ the reimbursed amount.

- The number of patients that may be willing and able to pay out of pocket will vary depending upon the total amount charged, socioeconomic status and physician office practices.

- Patients with depression are generally from a lower socioeconomic class

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US Pricing Schedule (Unreimbursed)

Product Description	End User List Price	Distributor Commission 30%	Medibio Limited Realized Revenue
Medibio Limited Software Differential Diagnosis	$22.50 Per Patient Treatment	($6.75)	$15.75
Medibio Limited Software Patient Monitoring	$11.25 Per Patient Treatment	($3.38)	$7.88
Medibio Limited HM Rental	$500 to acquire or $25 per month to rent	$150 when acquired or $7.50 per month when rented	$350 when acquired or $17.50 per month when rented

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Role of Medibio Limited Technology

- The initial role of the Medibio Limited technology will be in clinical studies that seek to clearly establish the place and utility of this technology in clinical practice
- Once definitive clinical utility data exist, it will likely enter use as a supportive diagnostic tool and for monitoring therapy progression
- With use is validated for one mental health condition, adoption for additional diagnoses will likely follow a shorter adoption curve
- Reduction of time required for definitive diagnosis may be a key element of success for this technology in a ‘basket of care’ reimbursement environment

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Keys to Successful US Commercialization

- Clinical data from well designed clinical studies that address FDA as well as payors
- Data from 300+ patients per indication will be required for FDA clearance as diagnostic support (similar to NEBA device, cleared in 2013)
- Clinician thought leaders need to be supportive or ‘positively neutral’
- Multiple clinical studies (in addition to US pivotal data) will be needed for broad Medicare and private payor reimbursement
- Validation of patient care pathway under ACA and emerging ‘mental health team’ environment is critical to ensure clinical data focused on the “right” diagnostic and triage clinicians is generated
- Enhance market capture by quick follow-on introduction of reduced time diagnostic algorithm and/or device
- Standard of care acceptance would be enhanced by a lower form factor, less burdensome diagnostic modality as compared to need for patients to spend extended time at a specialty diagnostic site for a Holter monitor

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Potential Areas of Future Growth

- Use of heart rate patterns to diagnose other mental health illnesses
- Finding a way to simplify the patient device interface and make it more durable and less noticeable
- Using it to diagnose or monitor mental illness in other populations- children and seniors
- Cross cultural applications- different cultures deal with mental illness differently – See if device has applicability across cultures
- Use in longitudinal research to track mental health trajectories over time
- Use in combination with other biomarkers to develop a 'bio-signature' for major mental illnesses
- Add to initiatives on developing new and objective methods in classifying and diagnosing mental illnesses

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Sales Channel Structure

Proprietary and Confidential

Distribution Channel

Several Options Exist for the Structure of a National Distribution Channel in the US

1. Direct Sales Force
2. Strategic Commercial Partners
   - Manufacturers of Complimentary Devices and Pharmaceuticals
3. Independent Sales Representatives and Distributors
   - National and/or Regional Level
4. Direct to Customer via Internal Marketing, In-House Sales Organization, and via a website.

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Distribution Channel

Consideration 1- Direct Sales Force

- Direct Presence and Strong Focus Toward Product
- Strong Technical and Clinical Knowledge
- Full Immediate One-Phase Commercial Release
- Significant Investment in Sales Structure
  - Direct Sales Organization
    - Minimum 25 Direct Sales Representatives
    - Typically Model out $1M Actual Revenue Per Rep Within 1 Year
    - Sales Force Personnel Allocated Based Upon Geographic Opportunities and Demands
  - Carry 100% of Receivables
  - Compensation Structure:
    - Sales Representatives- $80K Base and $40K-$60K Commission; Total Compensation- $120K-$140K
    - Sales Management- $120K Base and $60K Commission; Total Compensation- $180K
    - Add 20 percent for benefits
  - Company Personnel Resources
    - National Sales Director/ VP
    - Regional Sales Managers
    - Marketing Team to Support Sales Force
    - Customer Service Department to Process Orders and Directly Support Customer Base

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Distribution Channel

Consideration 2- Strategic Commercial Partners

- Strong Existing Customer Base and Business
- Industry Credibility Already Established
- Medibio Limited Product Should be Key to Their Strategic Initiatives
- Much Lower Investment in Medibio Limited Sales Structure vs. Direct
- Could Utilize Multiple Strategic Partners Based Upon:
  - Geography
  - Type of Product They Presently Manufacture (Pharma versus Device)
  - Customer Call Points (Physician Type, Site of Care, etc.)
- Strategic Partner Could Carry 100% of Receivables
- Medibio Limited Likely Secondary to Products They Manufacture (Lower Gross Margins, Dependence on Outside Party)
- Commission Structure:
  - Typically in the 25-40% Range Depending Upon Partner Responsibilities
- Company Personnel Resources
  - Sales Management, Marketing and Customer Service Personnel Requirements are Lower

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Distribution Channel

Consideration 3- Independent Reps and Distributor Organizations

- Strong Industry Working Knowledge and Relationships
- Some Industry Credibility Already Established
- Complimentary Products and/or Services Currently Exist in Their Portfolio which is Good Strategic Fit With Their Core Business
- Strong Desire to Grow Revenue via New Product Introductions
- Much Lower Investment in Medibio Limited Sales Structure
- Could Utilize Both Independent Rep Groups and Distributor Organizations Based Upon Each Parties Strengths in Certain Geographies or Market Segment
- Distributors Could Carry Inventory of Hardware and Some Receivables
- Indirect Sales Groups Present an Increased Challenge to Establish and Maintain Focus Toward Medibio Limited Product Line Versus Other Products They Represent
- Commission Structure:
  - Independent Representatives- 20-25% Range
  - Distribution Organizations- 25-35% Range (due to carrying inventory, receivables, etc.)
- Company Personnel Resources
  - Sales Management, Marketing and Customer Service Personnel Requirements are Lower

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Distribution Channel

Consideration 4- Internal Marketing and In-House Sales Organization

- Significantly Lower Investment in Medibio Limited Sales Structure
- Direct Control Over Sales Initiatives and Focus
- Limited Industry Working Knowledge, Credibility and/or Relationships
- Limited to No In-The-Field Sales and/or In-servicing Capabilities
- Much Lower Exposure to Customer Targets and Slower Approach to Building Market
- Could Be Utilized to Support Efforts and Activities of Strategic Partners and/or Distributors
- Commission Structure:
  - In-House Sales Representatives- Base Salary of $30K Plus Commission of 5-15%
- Company Personnel Resources
  - Less Field Sales Management
  - Higher Level of Marketing, In-House Sales and Customer Service Personnel Requirements

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Distribution Channel Recommendation

Recommendation to Build Hybrid Sales Channel Utilizing Both Strategic Partners and Distributor Organizations

- Supported and Managed by Medibio Limited Marketing and Sales Management Team
  - In-Field Sales Training, Support and Customer Relations
- Less Significant Up-Front Investment in Sales Channel Structure
- Hybrid Approach Diversifies Risk by Utilizing Multiple Parties and Does Not Create Reliance on a Single Party
- Moderately Paced 4-Phase Controlled Regional Roll-out in US
- Hybrid Sales Organization
  - Strategic Partners and Independent Rep Groups/ Distributor Organizations
  - Distribution Rights Granted Based Upon Specific Market Segments and Customer Call Points
  - Add Direct Clinical Sales Specialists in Key Geographies (CA, TX, MI, MA, FL) Over Time to Support Largest Territories
- Strategic Partners and Distributors Carry Majority of Receivables
- Commission Rates Fit Within Medibio Limited Business Model's Gross Margins
- Moderate Level of Company Personnel Resources Required
- Relationship with Strategic Partners May Naturally Lead to Acquisition
- Augment With Web Strategy to Gain Additional Exposure and Revenue

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Key Assumptions for Business Model Financials

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Key Assumptions

- The Revenue Model only captures the market for Depression
- Factoring in additional diagnosis would significantly increase topline revenue
- 350 million people suffer from depression globally = approx. 5%
- Fewer than 25 percent of people across the world have access to treatments for depression. Used 24% for model.
- According to depression statistics from the Centers for Disease Control and Prevention (CDC), about 9 percent of adult Americans have depression
- About 3 percent of adults have major depression, also known as major depressive disorder, a long-lasting and severe form of depression
- In Europe alone, an estimated 60 million people suffer from depression. More than 40 per cent of those fail to receive any treatment and only 25-35 per cent of patients treated for depression in clinical studies experience remission or relief from all of their disease symptoms

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Reimbursement Assumptions

- Reimbursement is expected to increase over time at the below rates, coinciding with availability of clinical data and obtaining coverage on a regional and then national basis

Year 1				Year 2			
Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Quarter 5**	**Quarter 6**	**Quarter 7**	**Quarter 8**
Pre reimbursement	*Pre reimbursement*	*10% Reimbursement*	*25% Reimbursement*	*40% Reimbursement*	*60% Reimbursement*	*80% Reimbursement*	*100% Reimbursement*

Software Assumptions

Monitoring Frequency:

Software Reporting and CRM Monitoring:

- Testing 5 times the first year
- Initial diagnosis
- 4 weeks
- 12 weeks
- 26 weeks
- 52 weeks

Annual on-going monitoring

- One time per year unless they switch meds/therapy

Notes Considerations:

- If meds change, restart schedule above on new medication
- 20-30% of patients need to switch to a second medication
- 10% of patients on drug therapies are drug resistant and other methods of treatment need to be taken

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Hardware Assumptions

Holter Monitors - Hardware:

- Assume 50% Purchased and 50% Leased by Clinicians from Medibio Limited
- Of the 50% that Purchase Holter monitors, Assume 10% are coming from Medibio Limited, remaining Holter monitors are being obtained elsewhere / already exist in clinician facility
- Assume each monitor is out for 3 days per patient
- 250 practicing days {(52 * 5) - 10 holidays}/3 days = 83 patients/year/monitor

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Revenue Plan

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Moderate Revenue Projection

	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE" REVENUE PROJECTION	"MODERATE " REVENUE PROJECTION
	TOTAL YR 1	TOTAL YR 2	TOTAL YR 3	TOTAL YR 4	TOTAL YR 5
Medibio Limited Revenue					
United States					
Diagnosis	857,365	3,470,614	4,448,865	9,004,502	13,668,834
Monitoring	857,365	6,145,593	13,417,018	19,142,435	30,914,137
Hardware Rental	3,443	27,160	67,831	99,725	157,249
Hardware Purch.	5,739	31,494	41,380	53,156	95,873
Europe					
Diagnosis	-	1,639,056	1,451,384	3,147,431	5,521,013
Monitoring	-	1,639,056	3,582,157	5,952,102	11,067,958
Hardware Rental	-	9,874	24,541	44,008	81,129
Hardware Purch.	-	16,456	24,446	32,445	61,868
ROW					
Diagnosis	-	1,830,099	1,782,896	3,757,644	6,456,386
Monitoring	-	949,861	2,196,078	3,889,280	7,424,481
Hardware Rental	-	11,552	30,174	57,277	109,059
Hardware Purch.	-	19,253	31,036	45,171	86,305
Worldwide Revenue					
Diagnosis	857,365	6,939,770	7,683,145	15,909,576	25,646,233
Monitoring	857,365	8,734,510	19,195,254	28,983,816	49,406,576
Hardware Rental	3,443	48,586	122,546	201,010	347,438
Hardware Purch.	5,739	67,204	96,862	130,772	244,046
TOTAL MEDIBIO LIMITED REVENUE	**1,723,912**	**15,790,070**	**27,097,808**	**45,225,174**	**75,644,292**
TOTAL GROSS REVENUE	**2,462,732**	**22,557,243**	**38,711,154**	**64,607,392**	**108,063,275**

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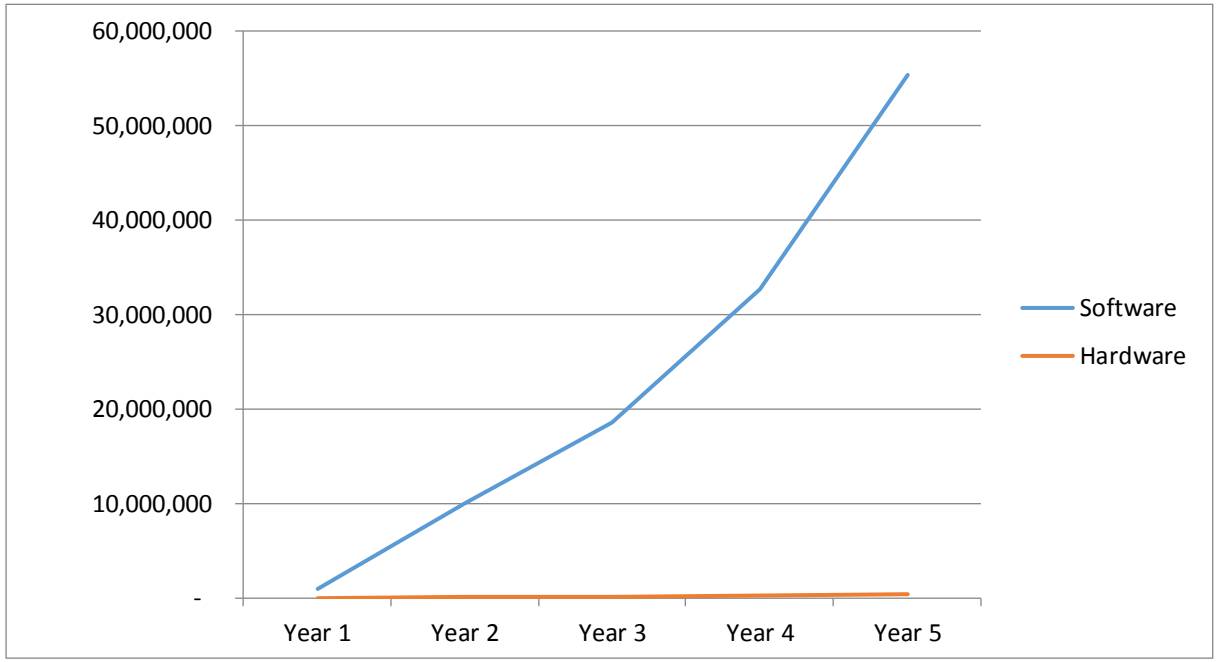
Note: Gross revenue is prior to distributor commissions and reflects end customer gross sales.

Net Revenue - Mild

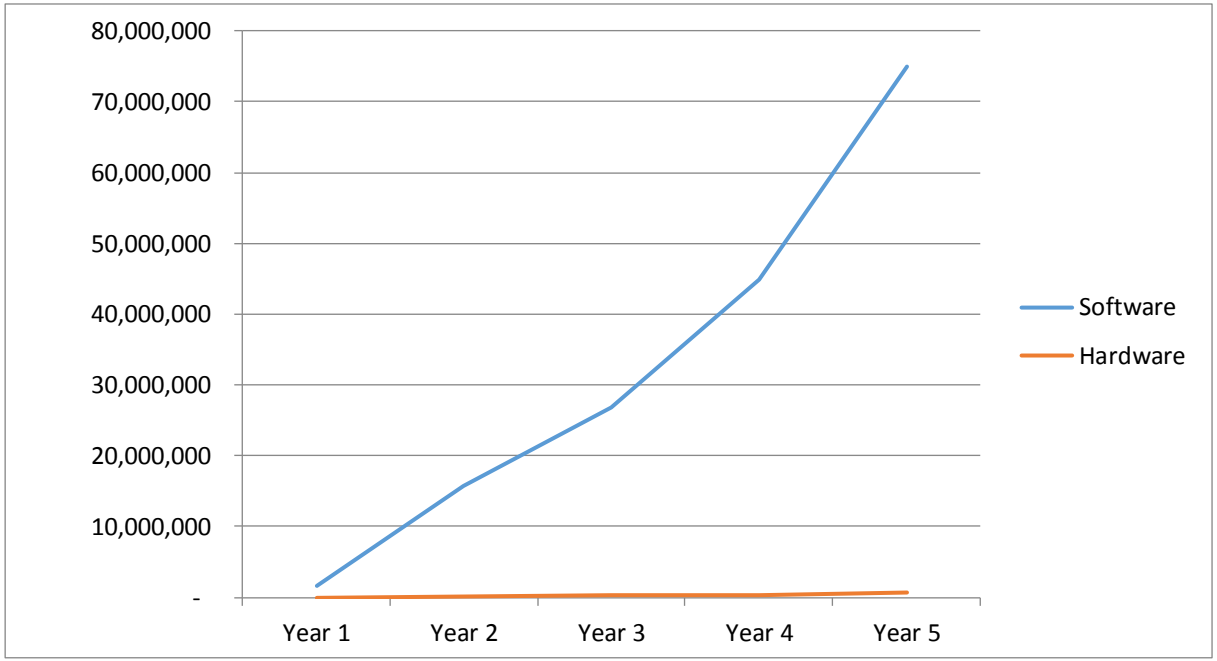


MILD NET REVENUE PROJECTION

	Year 1	Year 2	Year 3	Year 4	Year 5
Software	914,523	9,932,986	18,624,730	32,659,535	55,428,549
Hardware	4,897	72,443	150,537	242,614	437,680

Note: Numbers are Global

Net Revenue - Moderate

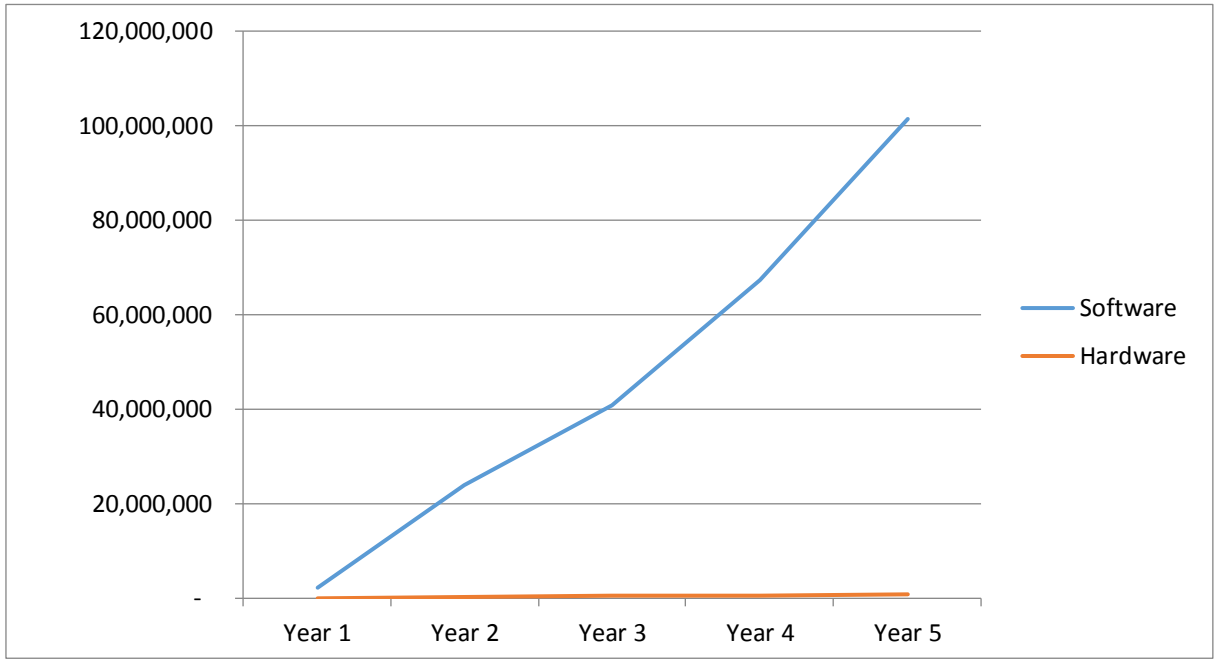


MODERATE NET REVENUE PROJECTION

	Year 1	Year 2	Year 3	Year 4	Year 5
Software	1,714,730	15,674,280	26,878,399	44,893,393	75,052,809
Hardware	9,182	115,790	219,408	331,782	591,484

Note: Numbers are Global

Net Revenue - Aggressive



AGRESSIVE NET REVENUE PROJECTION

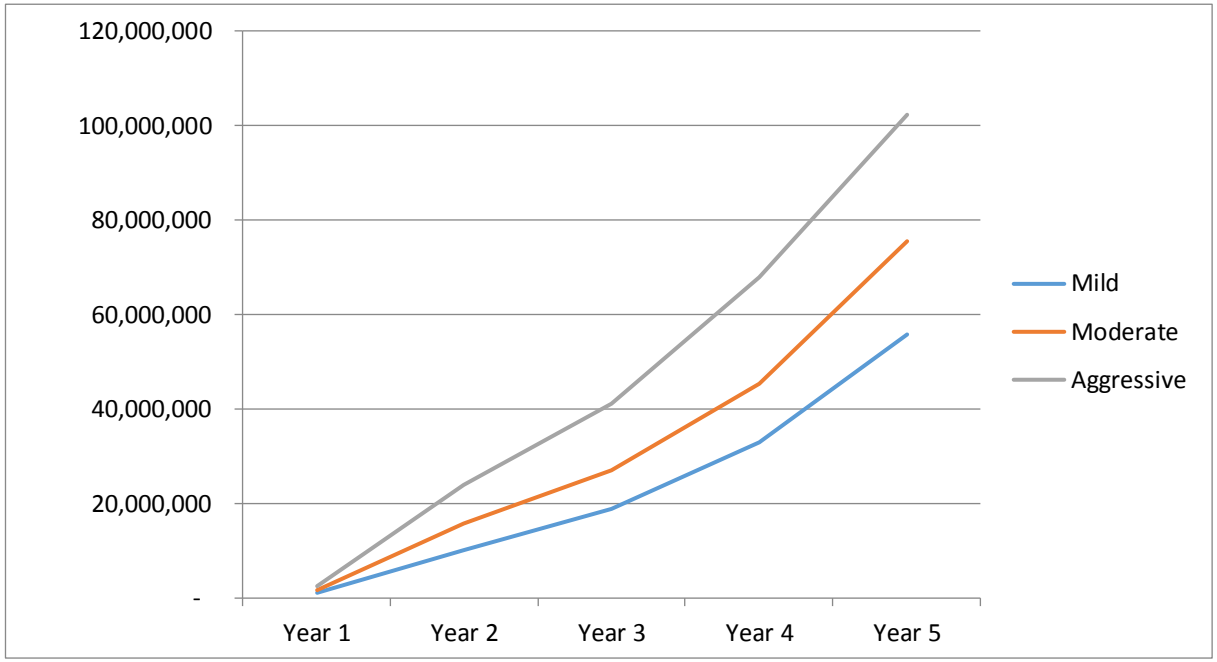
	Year 1	Year 2	Year 3	Year 4	Year 5
Software	2,286,307	23,759,713	40,727,888	67,434,961	101,580,010
Hardware	12,243	173,820	334,152	497,891	808,927

Note: Numbers are Global

Comparison: Medibio Limited Net Revenue

Mild, Moderate, Aggressive

COMPARISON PROJECTION - MEDIBIO LIMITED NET REVENUE (Software and Hardware)



COMPARISON NET REVENUE PROJECTION (Software and Hardware)

	Year 1	Year 2	Year 3	Year 4	Year 5
Mild	919,420	10,005,430	18,775,268	32,902,150	55,866,230
Moderate	1,723,912	15,790,070	27,097,808	45,225,174	75,644,292
Aggressive	2,298,550	23,933,534	41,062,041	67,932,852	102,388,937

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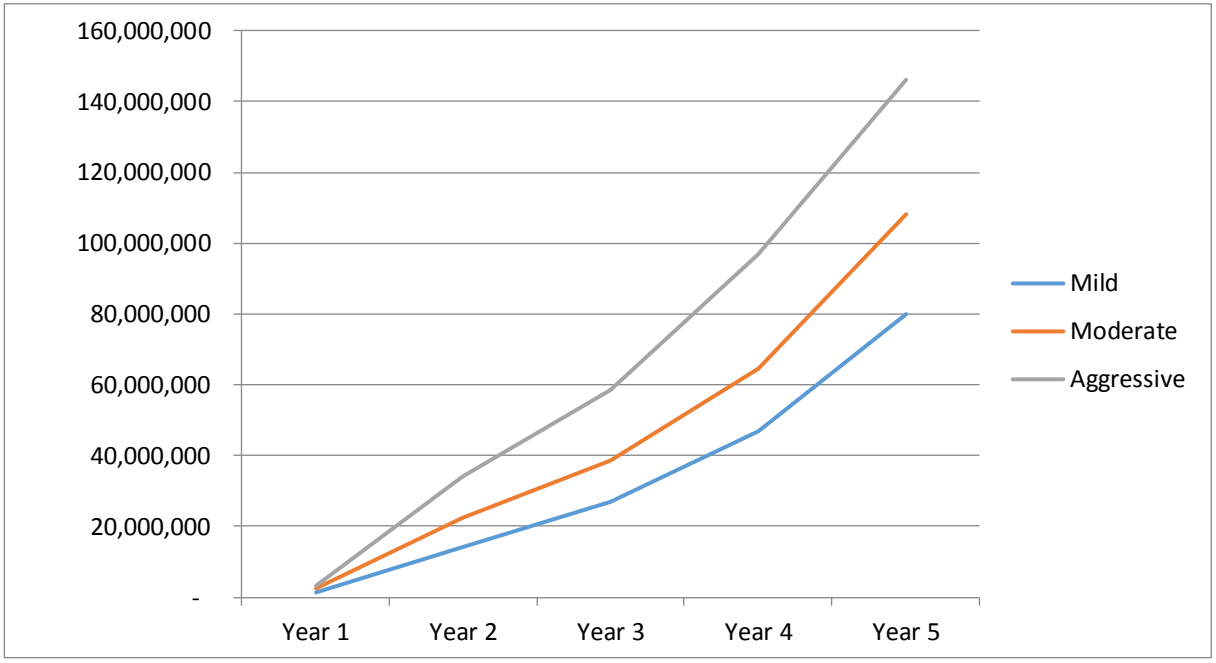
Note: Numbers are Global

Comparison: Gross Revenue

Mild, Moderate, Aggressive

COMPARISON PROJECTION - GROSS REVENUE (Software and Hardware)



COMPARISON REVENUE PROJECTION - GROSS REVENUE (Software and Hardware)

	Year 1	Year 2	Year 3	Year 4	Year 5
Mild	1,313,457	14,293,471	26,821,811	47,003,071	79,808,899
Moderate	2,462,732	22,557,243	38,711,154	64,607,392	108,063,275
Aggressive	3,283,642	34,190,762	58,660,058	97,046,931	146,269,910

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Note: Numbers are Global

Exit Scenarios

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Pharmaceutical Strategic Buyer

- High strategic fit with Pharmaceutical companies that produce antidepressant medication. Many are vertically integrating their channels to gain market share. Some US companies are looking for OUS assets to mitigate US taxes.
- New technology to monitor effectiveness and show positive impact of drugs could increase patient compliance to maintain drug therapy thereby increasing sales
- Pharmaceutical manufactures can leverage their global enterprise network, clinical and regulatory teams, and distribution channels to accelerate growth and create greater profitability, facilitating a higher multiple and acquisition price for Medibio Limited
- Most Pharmaceutical companies have large Primary Care sales forces that could quickly impact the market with Medibio Limited
- Top five potential Strategic Buyers and highest prescribed antidepressant drugs
  1) Pfizer
     - Zoloft
  2) Forest Pharmaceuticals
     - Lexapro
  3) Eli Lilly
     - Prozac
  4) GlaxoSmithKline
     - Wellbutrin
  5) Merck
     - Remeron

Pfizer

Actavis + Forest Laboratories, Inc.

Lilly

gsk

MERCK

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Medical Device Strategic Buyer

- Strong strategic fit with Medical Device manufactures in the diagnostic and treatment therapy space. Specifically, medical device companies that manufacture ECGs, Holter Monitors, and Anti-depression therapies.
- Medical device companies can often move faster than Pharmaceutical manufacturers and be more focused on the critical areas that are accretive to the near term development needs of Medibio Limited's portfolio. However, most device companies lack the Primary Care sales force and other call points that Pharmaceuticals have in abundance.

1) GE Healthcare
    - Diagnostic division - ECG, holter monitors, and software analysis systems
2) Phillips Healthcare
    - Diagnostic division – ECG, holter monitors, and software analysis systems
3) Cyberonics Inc
    - Vagus nerve stimulation (VNS Therapy®) for treating depression
4) NeuroSigma
    - The Monarch external Trigeminal Nerve Stimulation (eTNS) for treating depression
5) Neuronetics, Inc.
    - NeuroStar TMS Therapy System for treating depression

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Financial Strategic Buyers

- Strong precedence exists with growing trend toward acquisition of medical diagnostic companies by private equity firms
- Private Equity Firms with Focus on Medical Device
  - Warburg Pincus
  - Galen Partners
  - Bancorp Piper Jaffray Ventures
  - KKR
  - The Carlyle Group
  - Water Street Healthcare Partners
  - Summit Partners
  - Bain
  - Split Rock Partners

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Other Strategies

- Spinoff
  - Medibio Limited as a separate public company to unlock value
- Subsequent Public Offerings
- Licensing Agreements
- No Exit
  - Continue to build the enterprise, make acquisitions, joint ventures, and expand offerings

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Unlikely fit

We evaluated the following enterprises and believe they are not as strong of a fit to acquire Medibio Limited

1) Insurance companies
   - United Health Care
   - Humana
   - BCBS
2) Healthcare Provider
   - Kaiser Permanente
3) Software Companies
   - IBM Healthcare
   - Oracle Healthcare

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Exit Strategy Considerations

- Timing of when to exit
  1) Development phase
     - If greater resources are needed sooner than later to extract value and or speed commercialize to be first to market
  2) Growth phase
     - With revenue generally comes a higher acquisition price
  3) Mature phase

- Development of a broader portfolio of products and additional algorithms to increase market capitalization

- Contingent on the structure of the exit methodology, reporting requirements, tax, and regulatory laws. The various options can be materially different and timelines for each often vary.

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Exit Strategy Recommendations

- Near-term
  - Develop program to work with Pharmaceutical Strategic Partners
  - Network with Medical Device and OEM manufactures

- Mid-term
  - After further product and clinical development it would be the appropriate time to elevate the conversations with the key Strategic Pharmaceutical partners (9-12 months prior to commercialization)

- Longer-term
  - Generate clinical significance and revenue to increase market capitalization and acquisition price for exit strategy. Most likely acquisition via pharmaceutical or medical device company.

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The End

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Appendix

NEBA & Other Technology Overviews

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NEBA Device Overview

- NEBA Health - ADHD diagnostic device cleared by FDA via de novo 510K in July 2013
- FDA created an entirely new category of medical device to regulate NEBA. These devices are called Neuropsychiatric Interpretive EEG-based Assessment Aids (NIEA's)
- EEG technology, 15 min test to measure theta/beta wave ratios
- Clinical study: 275 children and adolescents
- Independent data review expert panel concluded that the NEBA System aided clinicians in making a more accurate diagnosis of ADHD when used in conjunction with a clinical assessment for ADHD, compared with doing the clinical assessment alone
- Labeled as allowing individual clinician to improve diagnostic accuracy closer to that of a multidisciplinary team
    - Overall accuracy: clinician plus NEBA, 88%; clinician alone, 61%)
- Labeled as reducing over diagnosis to as low as 3% when used in series with a clinician's work up (highlighting augmentation by device, instead of driving clinician redundancy for diagnosis)
- Business model: Capital equipment placement and per use model
    - Rental of NEBA system starting at $79/month per website
- However, skepticism as to utility is voiced by clinicians and is potentially limiting large scale deployment and use of NEBA, even though NEBA is clearly an aid to diagnosis and not the definitive element
- Do single output diagnostics all face this potential issue of acceptance, given mental health diagnosis complexities?

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NEBA Overview – Current payment structure

INSURANCE

For Parents

Some third party payers cover NEBA. Your out-of-pocket costs may vary depending on your insurance provider, your policy and your clinician's office policies. See the FAQ for more details.

Using NEBA Benefit Services, you can verify your benefits prior to your office visit:

- Call (888)539.4267
- Fill out our NEBA Benefit Services Enrollment form.
- Fax it to (706)650.2160 or scan to benefits@nebahealth.net

For Clinicians

NEBA Health has a variety of programs and formats to meet your office needs.

- NEBA Benefit Services provides pre-authorization services and benefit queries at no cost to your office or patient.
- We have payment management models that make integrating NEBA into your office a snap.
- Contact your team member for more information.

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NEBA Overview – Cost Details

How much does NEBA Cost?

It depends. The total out-of-pocket for NEBA will never be more than **$425** and your out-of-pocket cost will likely be significantly less. Why?

- Your out-of-pocket depends on your particular insurance provider and policy.
- NEBA's cost varies by region.
- If you have a financial need, talk to your provider about NEBA-Cares™.
- For participating providers, NEBA-Cares may cover up to 100% of NEBA's cost.

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NEBA – News coverage and insights for Medibio Limited

Brainwave Test for ADHD: For Patients or Profit?
July 17, 2013

By KATIE MOISSE

KATIE MOISSEMore From Katie »

Health Editor

via **GOOD MORNING AMERICA**

The device, dubbed NEBA for "Neuropsychiatric EEG-Based Assessment Aid," was approved by the U.S. Food and Drug Administration Monday to help confirm an ADHD diagnosis, a complex label borne by some 6.4 million U.S. kids. But critics say the gadget puts profits before patients.

"I don't know that this is going to help the situation at all," said Rachel Klein, a professor of child and adolescent psychiatry at NYU Langone Medical Center. "I think it's going to make people spend money needlessly."

During a 15-minute test, the NEBA system measures and compares two kinds of brainwaves through electrodes on the scalp. Studies have found that kids with ADHD tend to have different brainwave ratios than those without the disorder, but Klein said there's "nothing to suggest" the comparison works to diagnose individual children.

"When a child walks into the office, we already know there's a problem. The issue is whether it's ADHD or something else," she said, noting that learning disabilities and certain mood disorders can share symptoms with ADHD. "We have no idea whether [the makers of NEBA] have been able to discriminate ADHD from something else."

NEBA Health, the Augusta, Ga., company that makes the device, has yet to publicly release data from a trial of 275 children on which the FDA based its approval.

"The study results showed that the use of the NEBA System aided clinicians in making a more accurate diagnosis of ADHD when used in conjunction with a clinical assessment for ADHD, compared with doing the clinical assessment alone," the FDA said in a statement, providing no further details about the comparison or the significance of the results.

Multiple calls to NEBA Health were not immediately returned.

An ADHD diagnosis is typically based on interviews with parents and teachers, though Klein admits not all general practitioners have time to take such a thorough history.

"There's no way someone can do the child justice in a 10- or 20-minute visit," she said, stressing that the diagnosis should be reserved for child psychiatrists and psychologists with the proper training. "You need a lot of background information, and you just don't have the time to get it in a regular medical practice."

Klein fears that busy GPs might buy into the NEBA system, which generates a readout of brainwave activity similar to the squiggly lines of a lie detector test, as a way to simplify a complex diagnosis.

"They can charge for it and it gives you a pseudo-scientific basis for the diagnosis – a piece of paper with little wiggles and you can say they're not the wiggles you expect," she said, adding that she hopes parents "understand the limitations of the test" and "realize they don't have to rely on commercial promotions."

Insights

- Uncertainty and skepticism in press and from certain mental health KOLs is key hurdle to overcome in current environment
- Common issue: Ability of diagnostic to discern single disease from complex symptomatology and overlays
- Diagnostic clearly needs to connect marker to actual clinical symptoms and variations

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Other mental health diagnostics

- Monash University technology - electrovestibulography for schizophrenia, depression and other mental health diagnosis
- Development and commercialization of technology ('EVestG') underway by Neural Diagnostics Pty Ltd

Market Overview & Opportunity

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Cost to Treat Depression WW

- The WHO has already reported that mental illnesses are the leading causes of disability adjusted life years (DALYs) worldwide, accounting for 37% of healthy years lost from NCDs.[4] Depression alone accounts for one third of this disability.[5] The new report estimates the global cost of mental illness at nearly $2.5T (two-thirds in indirect costs) in 2010, with a projected increase to over $6T by 2030. What does $2.5T or $6T mean? The entire global health spending in 2009 was $5.1T. The annual GDP for low-income countries is less than $1T. The entire overseas development aid over the past 20 years is less than $2T.[3]

http://www.nimh.nih.gov/about/director/2011/the-global-cost-of-mental-illness.shtml (September 28, 2011)

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US Mental Disorders & Depression

- Nearly **1 in 3 Americans** are suffering from a mental disorder in any given year, or *over 75 million people (32.4%)*.[1]

- According to depression statistics from the Centers for Disease Control and Prevention (CDC), about 9 percent of adult Americans have feelings of hopelessness, despondency, and/or guilt that generate a diagnosis of depression.[2]

[1] http://psychcentral.com/blog/archives/2010/05/03/mental-health-statistics/ (2010) [1]

[2] http://www.everydayhealth.com/health-report/major-depression/depression-statistics.aspx (data updated 01/23/2013)

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Reward Shared Savings

- The Affordable Care Act's most significant contribution to creating ACOs is in the traditional Medicare fee-for-service system. The law includes a provision that allows Medicare to ***reward healthcare organizations with a share of the savings that would result from improving care quality and reducing the cost for their eligible Medicare populations..*** To participate in this **"shared savings program,"** healthcare organizations need to become Accountable Care Organizations (ACOs).
- The Centers for Medicare and Medicaid Services (CMS) are currently testing several models of care delivery re-design that aim to improve the efficiency of American healthcare systems, improve quality, and contain costs—in other words, to provide accountable care. These include such initiatives as the Advanced Payment Incentive, Pioneer ACO demonstrations, in addition to the Medicare Shared Savings ACO program.
- The **Congressional Budget Office** projects that the Shared Savings Program will save the Federal government $5 billion between 2010–and 2019.
- However, the real cost savings of ACOs have yet to be determined. Much will depend on the extent to which ACOs are formed; how effective they are in improving quality and containing costs; whether the Medicare-sponsored program works on a fee-for-service foundation or if the payment model needs to be modified; the capabilities of ACOs of handling different expectations of different payers; etc.
- In the end, however, the true *value* of ACOs will be determined not only by cost savings but by assessing improvements in quality while being cost effective

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http://www.accountablecarefacts.org/

ACA Facts

- The belief is that, if well conceived and implemented, ACOs can achieve both cost and quality improvements because the coordinated and collaborative nature of the delivery system itself is paid for and **rewarded for its outcomes, not for its volume of services.**
- A recent study conducted by **Oliver Wyman**, a management consulting firm, estimates that **25 to 31 million Americans are currently receiving health care services from an Accountable Care Organization (ACO) and more than 40% of Americans live in areas with at least one ACO.**
  - An ACO is defined in this study as providers participating in a Medicare Pioneer ACO project, Medicare Shared Savings Program, a Medicaid coordinated care initiative, the Medicare Physician Group Practice (PGP) Transition, or in a shared savings/risk arrangement with a commercial payer.

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http://www.accountablecarefacts.org/

High Start-up Investment for ACOs

- The start-up investment required to establish and sustain an Accountable Care Organization (ACO) is considerably higher — $11.6 to $26.1 million — than the $1.8 million estimated by CMS in its proposed rule for launch and one year of ongoing operations, according to a **study** by the American Hospital Association.
- May hinder / slow adoption

Estimate of ACO Investment	Average*
CMS (based on a range of an estimate of 75-150 ACOs)	$ 1,800,000
AHA** (200-bed, single hospital system)	$11,600,000
AHA ** (1200-beds, 5-hospital system)	$26,100,000

*Average amounts represent estimated costs for the start-up and ongoing costs for year 1.

**Draft estimates based on pending case studies. Includes start-up and ongoing costs for a typical year. Some costs may have already been incurred or be allocable to other budgets.

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http://healthsystemcio.com/2011/05/17/aha-says-aco-costs-far-exceed-cms-estimates/

http://www.aha.org/content/11/aco-white-paper-cost-dev-aco.pdf

WHO Global Fact Sheet Info

Key facts

- Depression is a common mental disorder. Globally, more than 350 million people of all ages suffer from depression.
- Depression is the leading cause of disability worldwide, and is a major contributor to the global burden of disease.
- More women are affected by depression than men.
- At its worst, depression can lead to suicide.
- There are effective treatments for depression.
- Depression can be reliably diagnosed and treated by trained health workers delivering primary health care. Recommended treatment options for moderate-severe depression consist of basic psychosocial support combined with antidepressant medication or psychotherapy, such as cognitive behavior therapy, interpersonal psychotherapy or problem-solving treatment. Psychosocial treatments are effective and should be the first line treatment for mild depression. Medicines and psychological treatments are effective in cases of moderate and severe depression.
- Antidepressants can be an effective form of treatment for moderate-severe depression but are not the first line of treatment for cases of mild depression. They should not be used for treating depression in children and are not the first line of treatment in adolescents, among whom they should be used with caution.

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http://www.who.int/mediacentre/factsheets/fs369/en/ (October 2012)

Snapshots From Around The World

• A 2007 international household survey of 84,850 respondents in 17 countries found that unmet needs for mental health treatment are pervasive and especially deserving of concern in less-developed countries. (13)

• An international study looking at six locations (Spain, Israel, Australia, Brazil, Russia and the United States) found it unlikely that a person would receive treatment for depression even after seeing a primary care health practitioner and being diagnosed with depression. This study found the probability of receiving treatment for depression was more influenced by the existing health care systems and financial barriers than by the clinical characteristics of individual

patients. (14)

• In a recent literature review, researchers reported that only 14 percent of people in Belgium seek treatment within a year of onset of depression. (15)

• A recent study of several Latin American countries found a significant treatment gap for depression in the elderly. This study, in Peru, Mexico and Venezuela, found that most participants with symptoms had never received treatment. (16)

• There are only 26 psychiatrists for approximately 80 million inhabitants of Ethiopia, according to a recent survey. (17) Some countries have only a single psychiatrist. In many countries around the world there are a limited number of health professionals available or trained to provide effective treatments.

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http://www.who.int/mental_health/management/depression/wfmh_paper_depression_wmhd_2012.pdf?ua=1 May 2012

Diagnosing Depression

- Diagnosing Depression
  - No Lab tests. Physicians rely on patients' description of the symptoms
  - Patients are asked about medical history and medication use since these may contribute to symptoms of depression.
  - Discussing moods, behaviors, and daily activities can help reveal the severity and type of depression.
    - This is a critical step in determining the most effective treatment.

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Diagnosing Depression

Diagnosing the Disease

Medical professionals generally base a diagnosis of major depressive disorder on the presence of certain symptoms listed in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.* Diagnosis depends on the number, severity, and duration of these symptoms:

- depressed mood
- loss of interest or pleasure in almost all activities
- changes in appetite or weight
- disturbed sleep
- slowed or restless movements
- fatigue, loss of energy
- feelings of worthlessness or excessive guilt
- trouble in thinking, concentrating, or making decisions
- recurring thoughts of death or suicide

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http://www.fda.gov/downloads/forconsumers/consumerupdates/ucm095990.pdf (January 9, 2009)

US Mental Disorders & Depression

- HealthDay News -- U.S. spending on mental illness is soaring at a faster pace than spending on any other health care category, new government data released Wednesday shows.
- The cost of treating mental disorders rose sharply between 1996 and 2006, from $35 billion (in 2006 dollars) to almost $58 billion, according to the report from the Agency for Healthcare Research and Quality, part of the U.S. Department of Health and Human Services.
- At the same time, the report showed, the number of Americans who sought treatment for depression, bipolar disorder and other mental health woes almost doubled, from 19 million to 36 million.
- Antidepressant use among U.S. residents almost doubled between a similar time frame, 1996 and 2005.
- Spending on mental illness showed a faster rate of growth over the 10-year period (1996-2006) analyzed than costs for heart disease, cancer, trauma-linked disorders, and asthma.

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http://health.usnews.com/health-news/family-health/brain-and-behavior/articles/2009/08/05/us-spending-on-mental-health-care-soaring August 2005

Depression Statistics

- According to depression statistics from the Centers for Disease Control and Prevention (CDC), about 9 percent of adult Americans have feelings of hopelessness, despondency, and/or guilt that generate a diagnosis of depression.[1]
- About 3 percent of adults have major depression, also known as major depressive disorder, a long-lasting and severe form of depression. In fact, major depression is the leading cause of disability for Americans between the ages of 15 and 44, according to the CDC. [1]
- According to the National Institute of Mental Health (NIMH), the largest scientific organization dedicated to mental health issues, women are 70 percent more likely than men to experience depression during the course of their lifetimes. Research has shown that this is in part due to hormones.
- Depression is also considered a worldwide epidemic, with 5 percent of the global population suffering from the condition, according to the World Health Organization.[1]
- According to the NIMH, depression affects:
  - More than 40 percent of those with post-traumatic stress disorder
  - 25 percent of those who have cancer
  - 27 percent of those with substance abuse problems
  - 50 percent of those with Parkinson's disease
  - 50 to 75 percent of those who have an eating disorder
  - 33 percent of those who've had a heart attack

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[1] http://www.everydayhealth.com/health-report/major-depression/depression-statistics.aspx (data updated 01/23/2013)

Prevalence of Depression: Race/Age

- According to a 2010 study by the CDC, African-Americans have the highest rate of current depression (12.8 percent), followed by Hispanics (11.4 percent), and whites (7.9 percent).
- The average age for a person to be diagnosed with depression is 32. Those diagnosed between the ages of 18 and 24, when there's a 10.9 percent rate of depression, are at the greatest risk for self-harm. The depression rate drops to 6.8 percent among those age 65 and older, however, suicide rates in elderly men are higher than other age groups, perhaps due to untreated depression and other illnesses.
- Depression is involved in more than two-thirds of the 30,000 suicides that occur in the United States every year.

[1] http://www.everydayhealth.com/health-report/major-depression/depression-statistics.aspx (data updated 01/23/2013)

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Undiagnosed Depression

- Major depressive disorder is a leading cause of disability in the United States, affecting nearly 15 million adults each year. Studies have linked it to serious health problems such as obesity, type 2 diabetes, cardiovascular disease, and cancer. A recent study suggests depression can speed up the aging process by making our cells age faster.
- Major depression often goes undiagnosed or untreated because people won't address it or those around them don't recognize its signs.
- Still a lot of stigma about mental illness
- Some symptoms are not visible to others

http://www.everydayhealth.com/health-report/major-depression-resource-center/sanjay-gupta-why-major-depression-can-go-undiagnosed.aspx (1/09/14)

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Europe – Mental Health Disorders

- Mental health problems account for nearly 20% of the total burden of ill health in Europe, coming second only to cardiovascular disease.
- The economic costs for the 15 countries that were members of the European Union (EU) before 1 May 2004 are conservatively estimated to be at least
- 3–4% of gross national product (Gabriel & Liimatainen, 2000). In fact, most of the quantifiable costs occur outside the health sector, being due to lost employment, absenteeism, poor performance within the workplace and premature retirement.
- Typically, they account for between 60% and 80% of the total economic impact/consequences of major mental health problems
- Other important consequences, such as stigmatization, social exclusion and fundamental abuses of human rights, are rarely included in economic analyses – because they are not measurable in cost terms – but should not be ignored.

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http://www.euro.who.int/__data/assets/pdf_file/0010/108955/E85489.pdf (WHO 2005 report)

Treatment Options

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Treatment options

- In a large study by the National Institute of Mental Health, 70% of people became symptom-free through medications -- though not always with the first medicine. Studies show the best treatment is combining medication and talk therapy.
- healthy diet can be part of an overall treatment plan. Build your diet around plenty of fruits, vegetables, and whole grains to help boost your physical and emotional health.
- Some studies suggest omega-3 fatty acids and vitamin B12 -- especially for people for may not get enough of these nutrients -- may ease the mood changes that are part of depression. Fatty fish such as salmon, tuna, and mackerel contain omega-3 fatty acids. So do flaxseed, nuts, soybeans, and dark green vegetables. Seafood and low-fat dairy products are sources of B12. Vegetarians who eat no meat or fish can get B12 in fortified cereals, dairy products, and supplements.
- Serotonin is a brain chemical that enhances your sense of well-being. Carbohydrates raise the level of serotonin in your brain. Low-fat carbs such as popcorn, a baked potato, graham crackers, or pasta are options. Vegetables, fruit, and whole grain options also provide fiber.
- caffeine can make you nervous, jittery, or anxious. While possible links between caffeine and depression haven't been definitively established, cutting back on caffeinated drinks may help lower your risk of depression and improve sleep.
- Painting, photography, music, knitting, or writing in a journal: These are all ways people explore their feelings and express what's on their mind. Being creative can help you feel better
- Make Time for Mindful Relaxation

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Triggers of Depression

- Triggers:
- Stress and anxiety can increase your depression symptoms and make it harder to recover. Learning to mentally relax can help restore a sense of calm and control. You might consider a yoga or meditation class. Or you could simply listen to soothing music while you take a long, hot bath
- relearn good sleep habits. Start by going to bed and getting up the same time each day. Use relaxation techniques to help you fall asleep. Healthy sleep makes you feel better physically and mentally.
- Avoid alcohol and drugs
- Low vitamin B12 can trigger depression – adding supplements to diet may help
- Men – with aging, lower levels of testosterone may also cause depression
- Trigger – underactive or occasionally overactive thyroid
- Rheumatoid arthritis or osteoarthritis – chronic pain – increases depression
- Per menopause & menopause – hormone fluctuations
- Empty nest adjustments
- Type II Diabetes
- Drinking – 1 out of 4 older people who drink heavily will suffer from depression
- Sleep issues- insomnia, sleep apnea, restless leg syndrome
- Retirement (financial insecurity, lack of purpose) – stay social, hobbies, activities, travel
- Heart disease
- Some blood pressure medicines -- as well as certain antibiotics, antiarrhythmic, acne products, and steroids, among other drugs -- may be associated with depression or other mood changes.
- Health hurdles – Parkinson's disease, stroke
- Mood Boosters: Pets, laughter, Volunteering

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Drug Therapies

- Antidepressant drugs can also help. These medications can improve mood, sleep, appetite, and concentration. There are several types of these drugs available. Drug therapies often take at least 4 to 12 weeks before there are real signs of progress and may need to be continued for 6 months or longer after symptoms disappear. (Source: excerpt from Depression: NWHIC)
- With treatment, most people feel relief within 4-6 weeks of treatment. (note for model – WebMD)
- It can take one to three months for medications to take their full effect, although they often begin to show signs of working more quickly.

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http://www.rightdiagnosis.com/d/depression/treatments.htm

Anti-Depression Meds

Selective Serotonin Reuptake Inhibitors (SSRIs)

Brand Name	Generic Name
Celexa	Citalopram
Lexapro	Escitalopram
Paxil	Paroxetine
Pexeva	Paroxetine
Prozac	Fluoxetine
Zoloft	Sertraline

Monoamine Oxidase Inhibitors (MAOIs)

Brand Name	Generic Name
Emsam (Skin Patch)	Selegiline
Marplan	Isocarboxzaid
Nardil	Phenelzine
Parnate	Tranylcypromine

http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118473.htm

Tricyclic Anti-Depression Meds

Brand Name	Generic Name
	Amitriptyline
	Amoxapine
Norpramin	Desipramine
	Doxepin
Tofranil	Imipramine
Pamelor	Nortriptyline
Vivactil	Protriptyline
Surmontil	Trimipramine

http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118473.htm

Atypical Anti-Depression Meds

Brand Name	Generic Name
	Amitriptyline
	Amoxapine
Norpramin	Desipramine
	Doxepin
Tofranil	Imipramine
Pamelor	Nortriptyline
Vivactil	Protriptyline
Surmontil	Trimipramine
	Maprotiline
	Trazodone
	Nefazodone
Remeron	Mirtazapine
Wellbutrin	Bupropion
Effexor	Venlafaxine
Cymbalta	Venlafaxine
Pristiq	Desvenlafaxine

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http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118473.htm

Reimbursement

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References

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B. Aetna Medical Policy #0019 – Holter Monitors: Coverage Criteria

C. Blue Cross Blue Shield of Michigan - Mobile Ambulatory Event Monitors Cardiac Outpatient Telemetry

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