

# **US INVESTOR PRESENTATION**

22-31 July 2015



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### **COMPANY SNAPSHOT**



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Mission: - Launch the first FDA approved objective, quantitative, diagnostic test for depression - Commercial launch of the first objective, quantitative test for stress for the corporate and consumer market

Vision: - Transform the assessment and management of Mental Health using our proprietary technology

**Ripe for** "It is critical to realise that we cannot succeed if we use DSM categories as the gold standard" - "We need a **Disruption:** quantitative method for diagnosing depression" (U.S. National Institute of Mental Health - May 2013)

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

- Capitalisation \$30m Valuation: - 90M shares @ \$0.33



US\$100 million revenue **Our 5 Year** - Workplace Stress market US\$60 million revenue - Depression Diagnostic Goal: - Consumer App Market tba

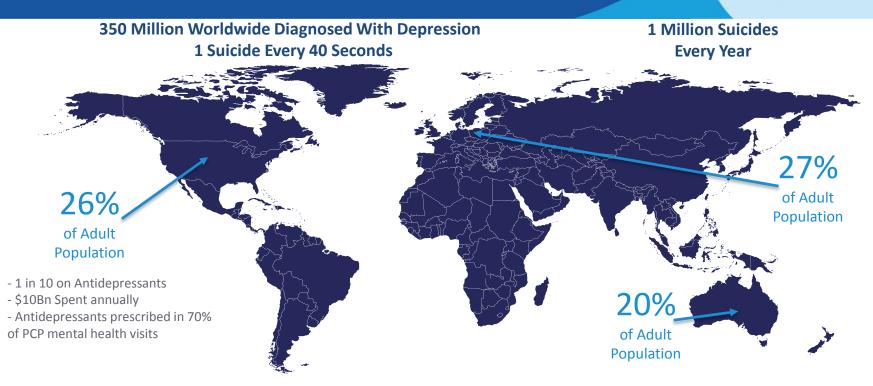
strong margins

Significant Earnings

### MENTAL HEALTH LANDSCAPE



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

http://www3.weforum.org/docs

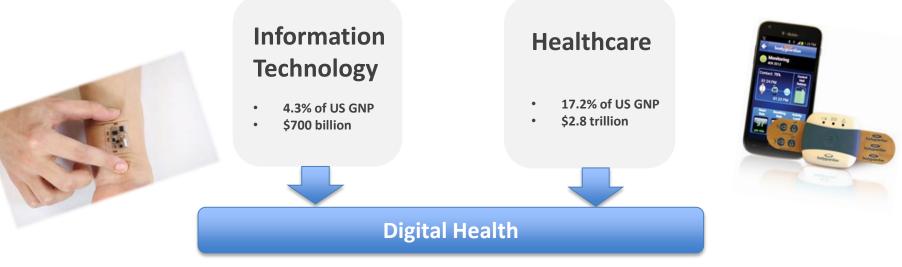
 ${\sf WEF\_Harvard\_HE\_Global Economic Burden Non Communicable Diseases\_2011.pdf}$ 

## WHAT IS DIGITAL HEALTH



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## **Convergence of 2 Huge Industries**

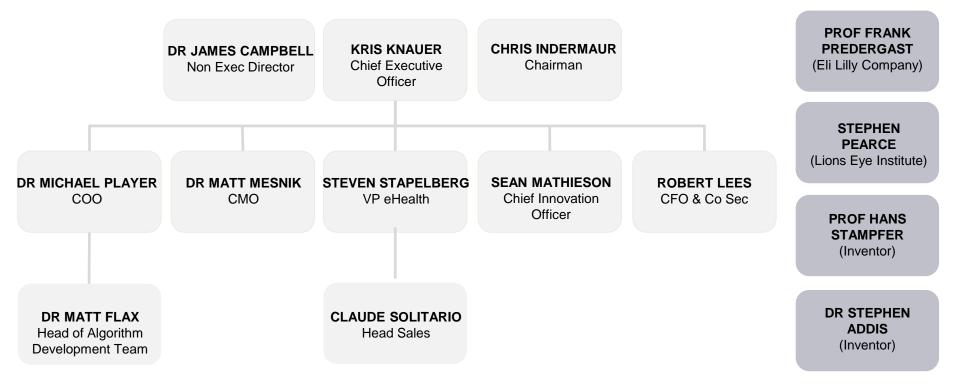


- Medibio is not revenue dependent upon regulatory approval
- The sole new and credible method for the assessment of stress levels, easily translated to the workplace, wearable, and the App market
- This stress market can be accessed without regulatory approval

#### **ORGANISATIONAL CHART**

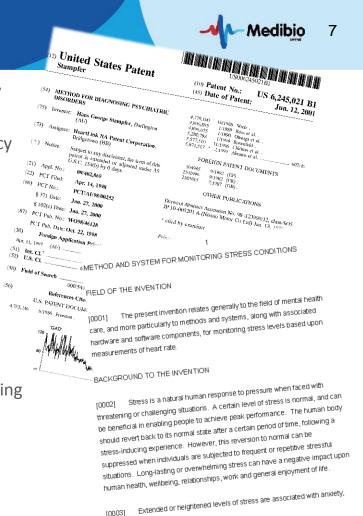






## INTELLECTUAL PROPERTY

- Comprehensive suite of patents covering the use of CHR technology for both:
  - medical diagnostics including assessment of treatment efficacy
  - stress assessment
- Patent suite for medical diagnostics includes:
  - "Method for Diagnosing Psychiatric Disorders"
  - USA(US624502), Canada, Australia, New Zealand, Israel
- Provisional Patents lodged in the US in June 2015: ٠
  - "Method and System for Monitoring Stress Conditions" covering the use of CHR for stress assessment
  - "Method and System for using CHR to Diagnose Psychiatric Disorders" covering new discoveries in past 18 months



[0003]

## THE PROBLEM WITH MENTAL HEALTH DIAGNOSIS

#### THE PROBLEM

- No objective test for mental illness
- The diagnostic "gold standard" is a clinical/expert opinion
- Diagnostic agreement between clinicians can vary considerably
- Misdiagnosis of depression (and other mental illness) places a huge cost burden on the healthcare system and the workplace

#### THE SOLUTION

- Quantitative, objective test
- Diagnosis based on patient's biological data (circadian heart rate)
- Simple, safe, quick, and unobtrusive
- Gives objective indication of treatment effectiveness
- Savings to the health system







## CONTEXT



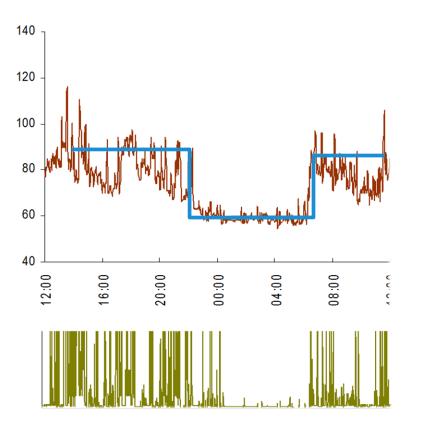
- The autonomic nervous system (ANS) plays a key role in circadian sleep-wake regulation of physiological activity including heart rate
- Conventionally mental illness is associated with disturbances in ANS/circadian regulation
- Mental state-linked ANS disturbance is observed via the cardiovascular system during sleep when external influences are absent
- Analysis of circadian heart rates (CHR) gives objective indications of 'core' physiological differences between different forms of mental illness such as anxiety, depression, and stress

#### **BREAKTHROUGH RESEARCH**



- MEB's technology based on over 15 years of research
- Different forms of mental illness such as anxiety and depression are associated with distinctly different patterns of CHR
- Distinct 'biomarkers' in heart rate data for depression and certain other mental illnesses
- CHR is 'state-dependent' a change in clinical status is associated with a change in CHR patterns
- Serial monitoring of patients under psychiatric treatment showed that:
  - effective intervention is associated with normalisation of CHR
  - ineffective intervention does not show normalisation
  - provides a tool for determining the treatment effectiveness

#### NORMAL INDIVIDUAL

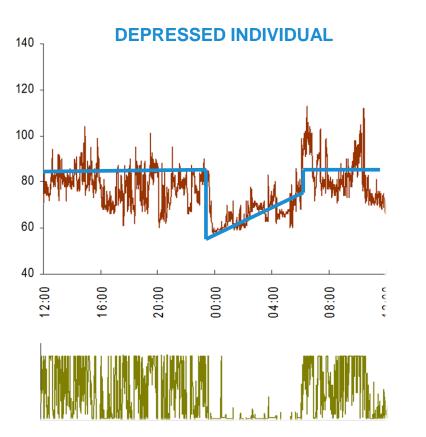


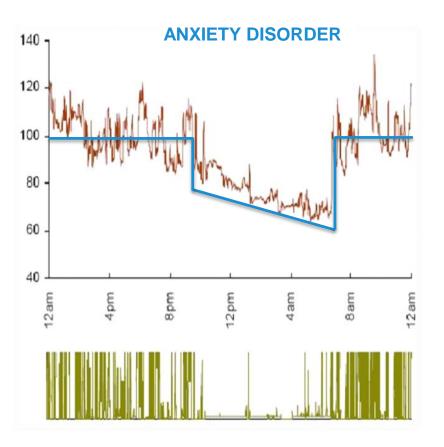
• Sleep rates are visibly lower and less variable than awake rates.

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- The onset of sleep and moment of waking show a clear change in the mean trend.
- Sleep and waking is usually brief and occurs quickly.
- Body movement data clearly correlates with heart rate, with a cessation of movement during the sleep period.

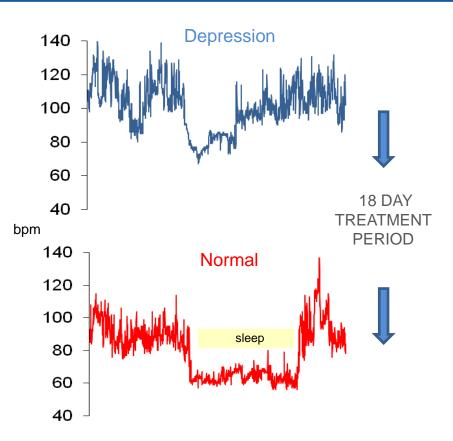
#### **DEPRESSION AND ANXIETY DISORDER**



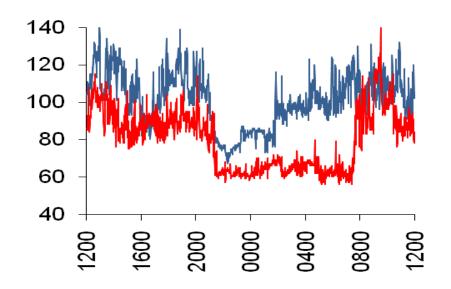


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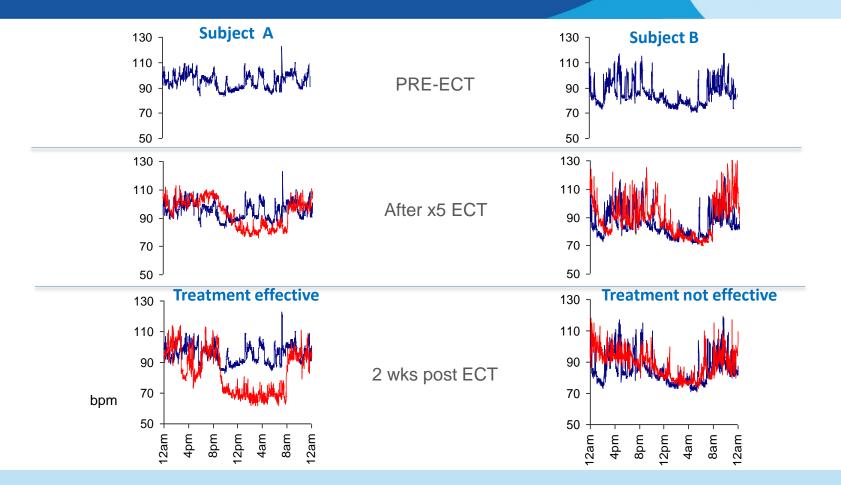
#### NORMALISATION OF DEPRESSION



- Depressed individual upon initial diagnosis
- Same individual after 18 days following effective intervention
  - Olanzapine 10mg (night)
  - Mirtazapine 60mg (night)
- Illustrates the 'state-dependent' nature a change in clinical status is associated with a change in CHR patterns



#### **MONITORING DEPRESSION TREATMENT**



## **ROAD TO VALIDATION**

#### JOHNS HOPKINS (JHU) STUDY OBJECTIVE

- To validate the use of Medibio's CHR technology to differentiate between depressed and non-depressed individuals
- Designed to provide clinical data to support FDA certification of Medibio's proprietary depression test
- Anticipated results available in Q4 2015
- Simple, quick, powered to only need 80-100 participants

#### UNSW/BDI STUDY OBJECTIVE

**STUDY TIMELINE** 

#### **STUDY TIMELINE**

- A comparative study of the Circadian Heart Rate patterns between patients with melancholic and non-melancholic depression.
- Anticipated results available in H1 2016
- Simple, quick, powered to only need 60-80 participants



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## THREE CLEARLY DEFINED MARKETS

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CLINICAL	NON-CLINICAL (Stress)		
MEDICAL (US\$30Bn)	CORPORATE (US\$19Bn)	CONSUMER (US\$26Bn)	
Primary Care Physicians Psychiatrists Psychologists Therapists Counsellors Cardiologists	High Risk Occupations • Defence • Police • Fire/Emergency Insurance Companies Corporate Wellness Professions Elite Sports	App Stores Insurance Companies Wellness Digital Health Companies	
	Elite Sports	"'bettermind	

## **MEDICAL DIAGNOSTIC MARKET**





Secure access to Diagnostic Reporting and Analysis – Anywhere/Anytime Clinician orders test





CHR collected from Patient and transmitted to HIPAA compliant Cloud Storage



CHR processed by machine learning algorithms Biometric data stored in HIPAA compliant cloud

## **MEDICAL DIAGNOSTIC MARKET – PATHOLOGY MODEL**

- 63 million annual ambulatory care visits in the US for mental health
  - 21 million to PCP's (30% of PCP's patients are treated for a psychiatric condition)
  - 31 million to Medical Specialists (psychiatrists/psychologists)
- PCP's are becoming the primary psychiatric care provider <sup>1</sup> (7% of all PCP visits involve prescribing of antidepressants)
  - 40% receive only psychiatric medication
  - 30% receive medication and are referred for therapy
  - 17% referred to a psychiatrist
  - 12% referred to a psychologist
- PCP Initial diagnostic market 21 million annual PCP visits @ \$45 ~ \$1 billion annually
- Ongoing monitoring 16 million with depression in US quarterly <sup>2</sup> @ \$22.50 ~ \$1.6 billion annually
- Identified a series of existing CPT<sup>™</sup> codes and payment structures which are supportive of, and can likely be leveraged for, MEB's business plan in the US

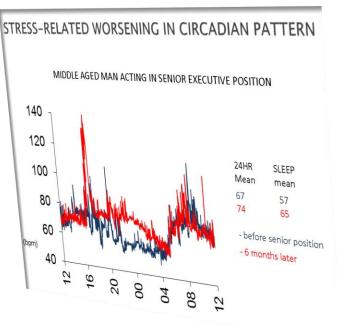
	Medicare	Private	Insurance	Assumption
93225	Recoding (Provider)	\$26.87	\$40	
93226	Analysis with Report (Medibio)	\$37.97	\$57	\$45
93227	Physician review & Interpretation (Provider)	\$26.87	\$40	

• Cloud based analysis and reporting = minimal costs per report

1. NIH – Mental health in family Medicine 2010 Mar7(1) 2. CDC 18

#### **CORPORATE STRESS PRODUCT**

- Stress leads to changes in autonomic regulation that are reflected in 'deviations' in CHR patterns
- MEB's technology provides an objective measure of the impact of stress on wellbeing via
  - the type and degree of deviation from normal CHR
  - the diagnostic significance of the deviation
- employees are classified into one of three distinct categories.
  - 'green' normal to mild (no immediate action needed)
  - 'amber' moderate (the impact of stress on wellbeing is approaching unhealthy levels)
  - 'red' severe (the impact of stress may have an unhealthy impact on wellbeing (recommend lifestyle changes)
- the intervention will be tailored to the individual employee based on the results of their stress assessment from the CHR technology.



## **CORPORATE STRESS AND MENTAL WELLNESS**





- 1. <u>www.stress.org/workplace-stress</u>
- 2. <u>www.evancarmichael.com/Work-Life/1877/Less-Stress-More-Profit--the-</u> Value-of-Corporate-Stress-Management-Training.html

#### DEMAND IN THE US DRIVEN BY MANY FACTORS

- 43% of the adults in the US suffer adverse health effects from stress
- stress is estimated to cost US employees \$300 billion annually
- over half of the 550 million working days lost annually in the U.S. from absenteeism are stress related<sup>1</sup>)
- Harvard estimate 60-90% of doctor's visits are caused by stress<sup>2</sup>
- need to reduce health care spend
- social responsibility/OHS Requirements

#### **US MARKET SIZE**

- 54 million employees in the US (+1,000 staff firms<sup>3</sup>)
- 90% of corporates have an existing wellness program
- Annual wellness spend \$100-\$500 per employee
- US\$2.5Bn revenue potential annually

#### **GO TO MARKET STRATEGY**

- partner with existing participants in the Corporate Wellness market
- Medibio will provide data analytics and reporting our core competency

3. US Census

## **CORPORATE STRESS PRODUCT IN PRACTICE**







Employee fitted with heart monitor and records ECG data over a 10-12 hour period





DATA INTEGRATION / VISUALISATION





Corporate Report "Stress Dashboard" de-identified statistical summary of the overall results

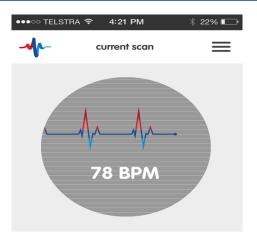


ECG Data is stored on HIPAA Compliant Cloudbased Platform and can be coded to protect the individuals identity

ECG Data is processed for diagnosis and results are stored on HIPAA Compliant Cloudbased Platform

## **CORPORATE DASHBOARD AND WIREFRAMES**

### Medibio 22



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#### Recording has begun.

Wearing the heart rate monitor while showering or during water sports may permanently damage the device.

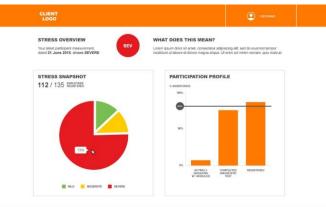


#### The management dashboard

The dashboard will enable management to track their employee progress in reducing stress through the program.

The dashboard can be configured to display aggregated information that is of importance such as:

- What is the stress profile of the workforce?
- How successful have the wellness initiatives been in reducing stress in the workplace?





#### **CORPORATE STRESS PRODUCT**

#### ASSESSMENT

Enable employees to check their stress levels

Personal early warning system for people at risk

Prevention is better than cure

#### **SUPPORT**

Provide educational material, support, and intervention based on their stress level

May recommend discussion with PCP

Provide the ability to conduct on-going monitoring to check progress

#### **EMPLOYER BENEFIT**

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Metrics on stress levels for job classes and types

Reduced absenteeism and increased productivity

Reduced claims and pressure on the health care systems

#### END TO END SOLUTION

## **STRESS CONSUMER APP**

- All Apps related to stress/mental health are:
  - based on reducing tension via breathing, yoga, and relaxing sounds
  - wellness products not stress identification and management
  - mental health Apps are based on a digitised version of the DSM
  - none offer objective stress assessment based on extended research
- Medibio's App:
  - Based on 15 years of medical research which is currently being validated by Johns Hopkins University and Black Dog Institute
  - An objective, health sector endorsed, objective stress assessment application and management tool
  - Ability to compare this test with previous scans run to check progress
  - Best in class intervention tailored to your stress level
    - 1. Source Technology News.com.au
    - 2. Accenture Digital Consumer Tech Survey 2014



4:21 PM

●●●○○ TELSTRA 🤶

You are approaching the danger zone. You have a vulnerability to stress, and the higher your score the more serious the problem is. You may well be suffering stress related symptoms, your relationships may be strained and you may not be operating in your most resourceful state.





\* 22% 💽

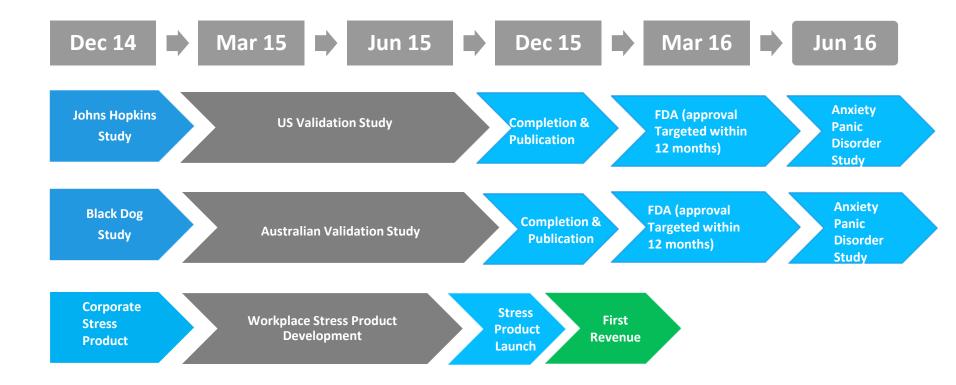
## **KEY COMPANY MILESTONES**



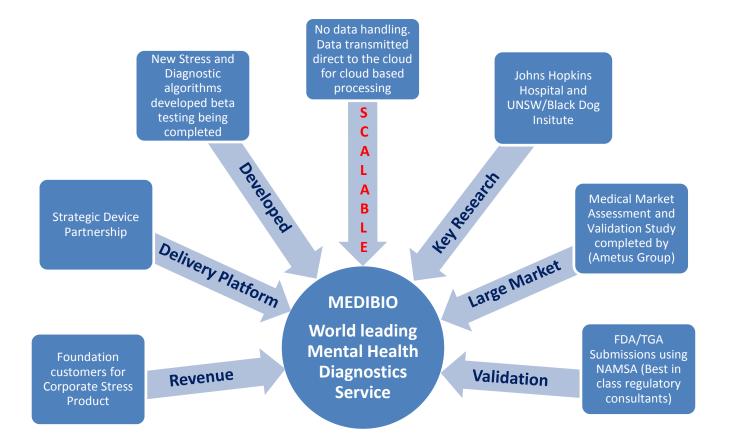
Timing	Milestone	Status
Q1 2015	Establish World-Class Advisory Board (Dr Prendergast)	$\checkmark$
Q2 2015	Acquire remaining patents covering the technology (USA/Canada)	$\checkmark$
	Complete beta testing of Stress Algorithms and lodge patent applications	$\checkmark$
	Strategic Device Partner	$\checkmark$
	Additional patent coverage on medical diagnostics	$\checkmark$
Q3 2015	Corporate Stress Commercial Pilot	
	Announcement of foundation customers	
	Pre-submission package delivered to the FDA and FDA feedback	
	Complete development of Corporate Stress product	
	Commercial launch of Corporate Stress product	
Q4 2015	Results from US/Australian validation studies published	
	Commercial launch of Consumer Stress App (subject to device)	

## TIMELINE TO COMMERCIALISATION





#### ALL THE BUILDING BLOCKS ARE NOW IN PLACE



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	Shares	Options	Description
Currently Issued	90.1 million	15,000,000 (Ex \$0.10 unlisted) 6,667,000 (Ex \$0.30 unlisted)	
Vendor Milestone 1	6,000,000	nil	(VALIDATION)
Vendor Milestone 2	6,000,000	nil	(ALGORITHIM)
Vendor Milestone 3	6,000,000	nil	FDA/CE MARK APPROVAL
ALL MILESTONES ACHIEVED	108.1 million	21.7 million	
Escrowed Shares	25,537,500		escrowed for 12 months
Board/Management Ownership	38,671,470		includes escrowed shares above
Top 20 Shareholders	63,330,745		(70.3%)

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