

# Resonance Health Limited

CORPORATE PRESENTATION

April 2014 | ASX: RHT



ResonanceHealth



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# Resonance Health Ltd (RHT)

ASX Listed, HQ in Perth – staff of 13

Market Capitalisation ~ \$22m (360m shares on issue)

- Cash on hand \$750k (31 December 2013)
- Cash on hand ~\$850k (31 March 2014)
- Inventors, Board and Management own 27.6%

RHT develops and utilises patented magnetic resonance image analysis technology - primarily for the assessment of **liver disease** - providing non-invasive imaging alternatives for patients

RHT provides **radiology image analysis services** to the international pharmaceutical and clinical communities

**Experienced** management and team:

- **3 products** successfully through development and FDA approval
- 1 product FDA approved as '**companion diagnostic device**' (1 of only 19 in the world)
- Gained reimbursement for **FerriScan** in some markets
- Established long term relationships with **large pharmaceutical companies**
- **ISO Certification**



# Snap Shot



## RHT established to commercialise FerriScan®

- MRI based test to measure iron overload
- FDA approved
- FerriScan® is reimbursed in parts of the US, Canada and UK
- Used by 7 of the top 10 pediatric hospitals in the US
- Cash flow positive business unit, strong YOY growth



## Cardiac iron assessment

- Complements FerriScan® - proving a service for both liver and heart iron measurements



## HepaFat-Scan® gained FDA approval Dec 2013 for measurement of fatty liver

- Large addressable market due to obesity epidemic
- Poised for commercialisation

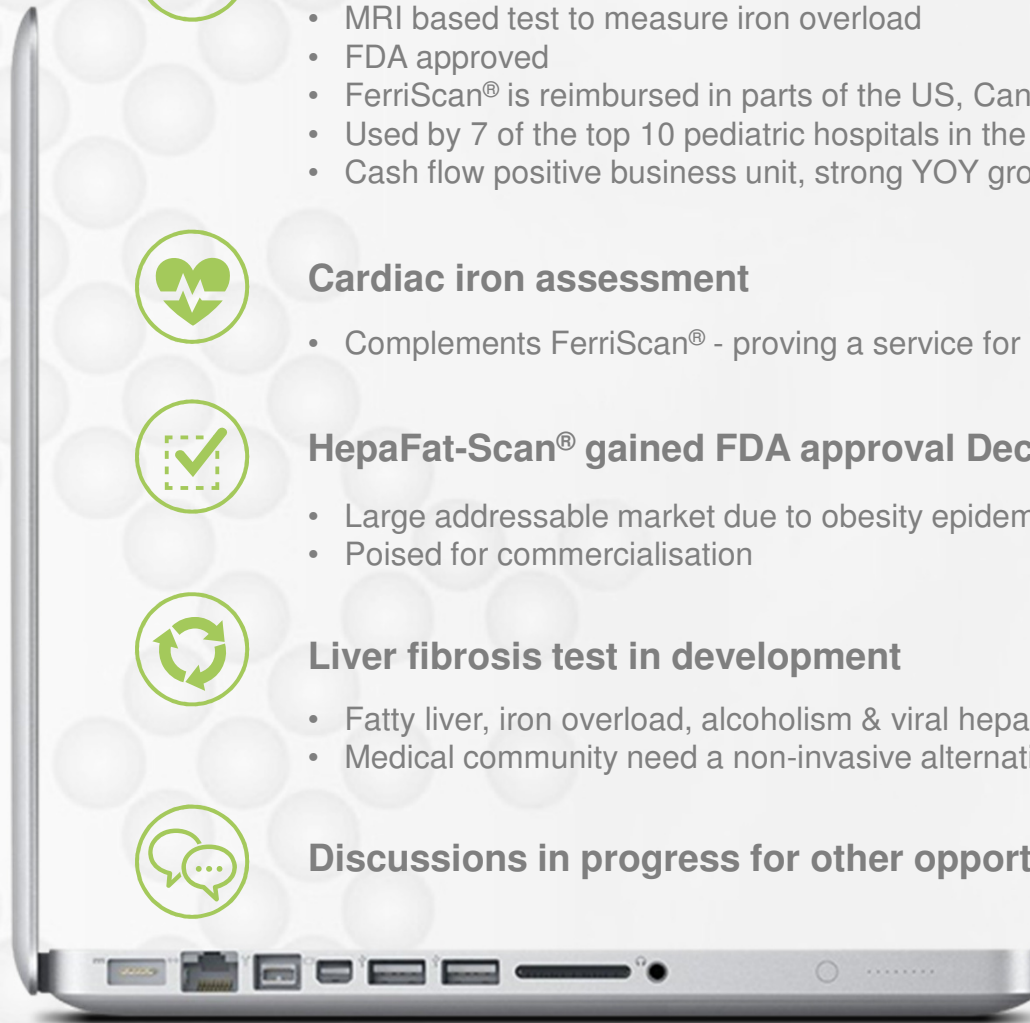


## Liver fibrosis test in development

- Fatty liver, iron overload, alcoholism & viral hepatitis are main causes of liver fibrosis and cirrhosis
- Medical community need a non-invasive alternative to the gold standard liver biopsy



## Discussions in progress for other opportunities



# Liver disease is a large target market

**Chronic liver disease** progressively destroys the liver tissue leading to liver fibrosis and cirrhosis

Liver disease is the only major cause of death **still increasing** year on year in the UK

Liver disease is one of the **top 10** causes of death in the US

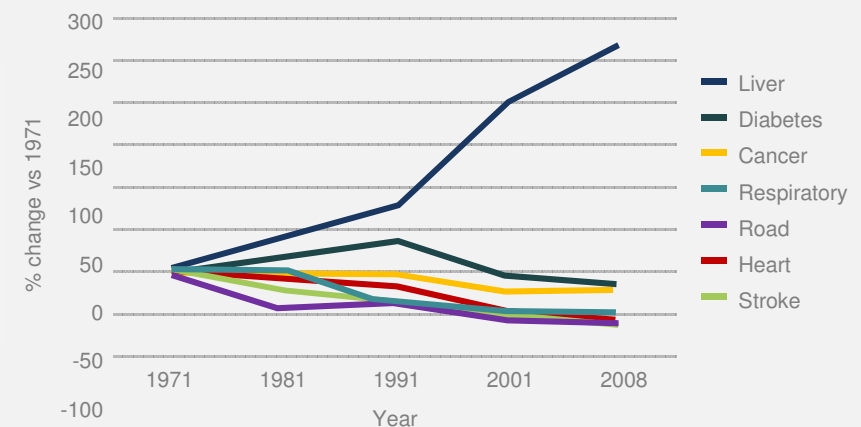
Liver disease is now a major health burden in **developing countries**

Liver cirrhosis is the **7th most common cause of death** in the world caused primarily by viral hepatitis, non-alcoholic fatty liver disease (NAFLD) and alcohol use

The progression of liver fibrosis can be **slowed, stopped or potentially reversed** if detected and treated early

## Movements in mortality 1971-2008

Deaths per million of population



Early diagnosis leads to better patient outcomes



# Liver Biopsy



## GOLD STANDARD

Invasive Diagnostic Method for Iron Assessment, Fatty Liver and Liver Fibrosis.

Biopsy sample is **1/50,000<sup>th</sup>** of the liver mass causing sampling errors that can leave the diagnosis in doubt.

Major complications:

-  Significant Pain 1:10
-  Bleeding 1:100
-  Bile leak: 1:1,000
-  Death: 1:12,000

# Growth through R&D and collaborations



FerriScan® (liver iron assessment)



Cardiac T2\* (cardiac iron assessment complements FerriScan®)



HepaFat Scan® (liver fat test)



Liver Fibrosis Test | R&D Phase



## RESONANCE HEALTH

is actively seeking opportunities to collaborate on projects which have synergies to the underlying strengths of the Company and provide a positive return to shareholders.

# FerriScan®

Measurement of liver  
iron concentration using  
**MR IMAGES**





# Iron Overload

The liver is the body's primary site for iron storage

Two primary causes of **Iron Overload**:

1. Excess dietary absorption of iron
  - Hereditary Hemochromatosis
  - Venesection (blood letting) is required to remove excess iron
2. Patients receiving multiple blood transfusion
  - Iron chelation drugs are necessary to remove the excess iron (Novartis iron chelator Exjade®, approved in 100 countries, 2013 revenue of US\$893m)

The human body has no natural mechanism for excreting excess iron

**FerriScan® replaces the liver biopsy test for the assessment of iron overload, providing an accurate and safe alternative to diagnose and monitor patients**

## Consequences of Iron Overload

- Impaired growth and deformities
- Liver fibrosis and cirrhosis
- Diabetes mellitus
- Infertility
- Cardiac failure and death



# Causes of Iron Overload

## Anaemias and blood disorders requiring repeat **blood transfusions**

### Thalassaemia

- Inherited blood disorder causing less hemoglobin resulting in several anemia and death if untreated
- **3rd most serious** public health problem in South East Asia following Malaria and HIV
- WHO estimates **100,000** new serious thalassaemia births in the world each year

### Sickle cell anaemia

- Red blood cells assume an abnormal (sickle) shape
- **75-100,000** cases in the USA (approx 1:500 African American births) – approx 15% have iron overload

### Myelodysplastic Syndrome (MDS)

- Bone marrow abnormalities resulting in lack of red blood cells
- **Over 100,000** cases in USA and Europe - approx 15% are transfused and become iron loaded

## Primary Iron Overload

### Hereditary Haemochromatosis

- Inherited iron overload disorder
- HH is the **most common genetic disorder** in western populations affecting **1 in 250** people from Northern European descent
- Over **2 million** cases in USA & Europe

## Non-Transfusion Dependent Thalassemia (NTDT)

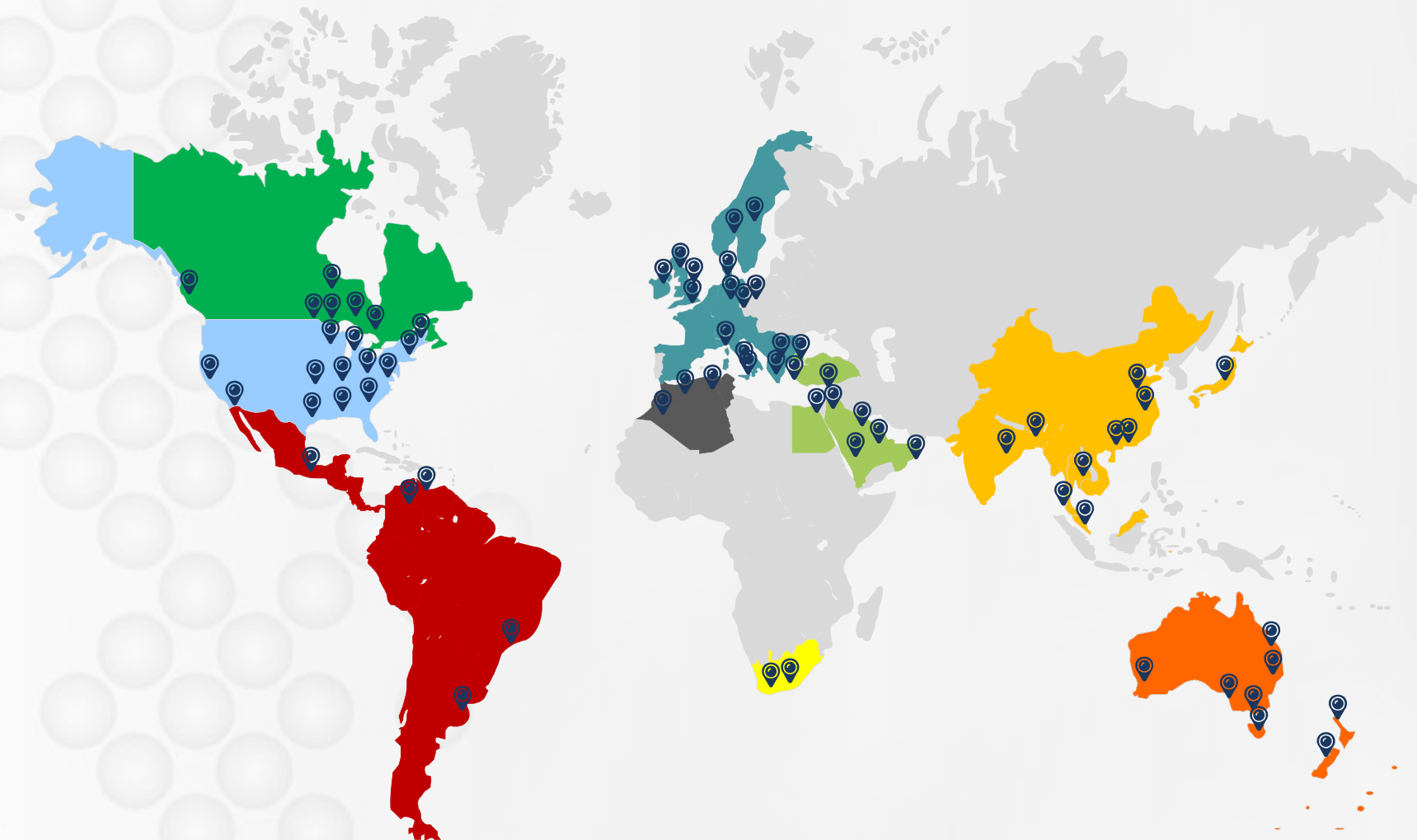
Iron overload due to both increased intestinal absorption of iron AND intermittent blood transfusions

Requires iron chelator to remove excess iron

### FDA mandates an approved 'companion diagnostic' to prescribe Exjade in NTDT

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm336478.htm>

# Global Access to FerriScan®

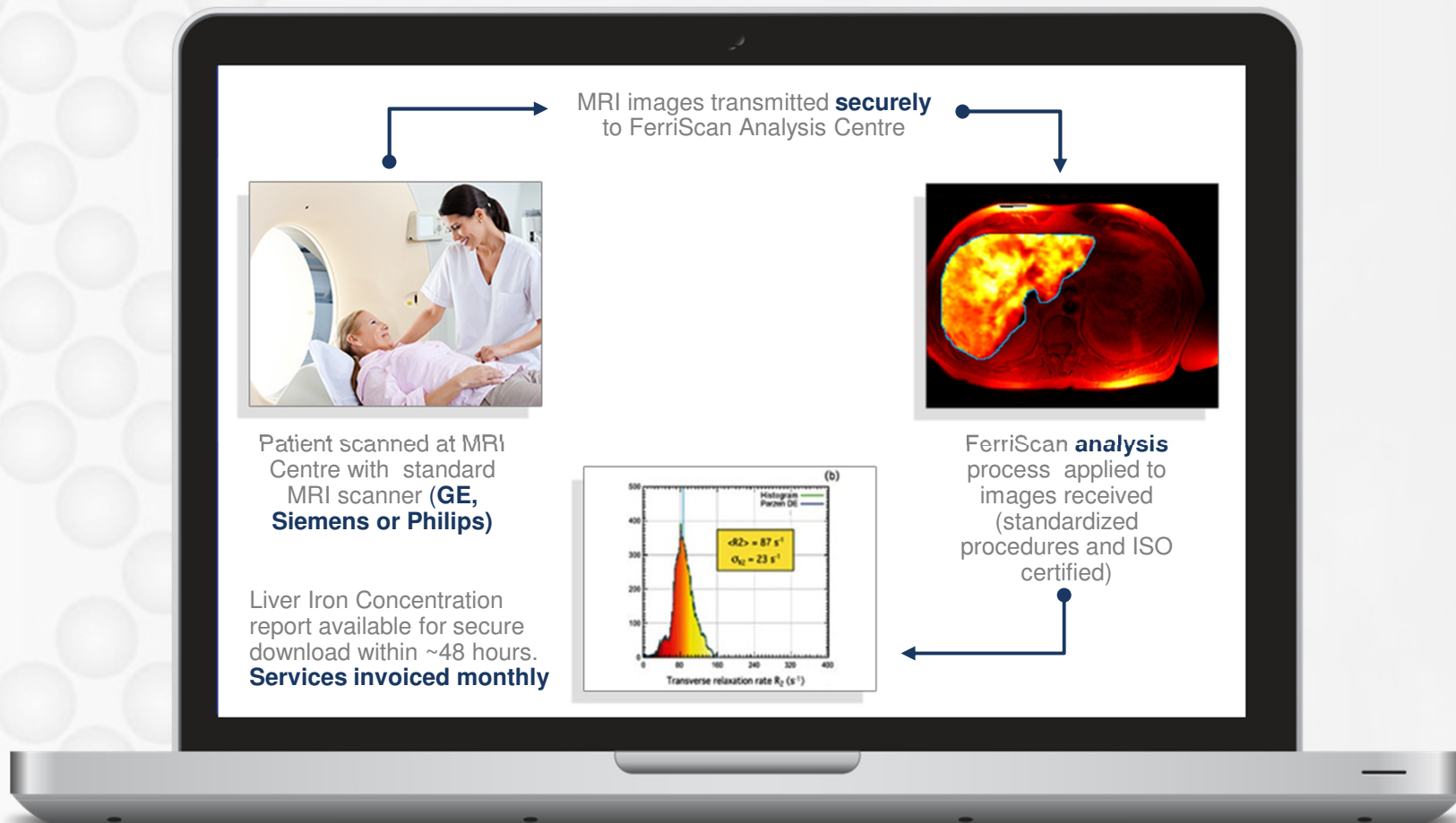


Some FerriScan® locations, 250+ have been activated



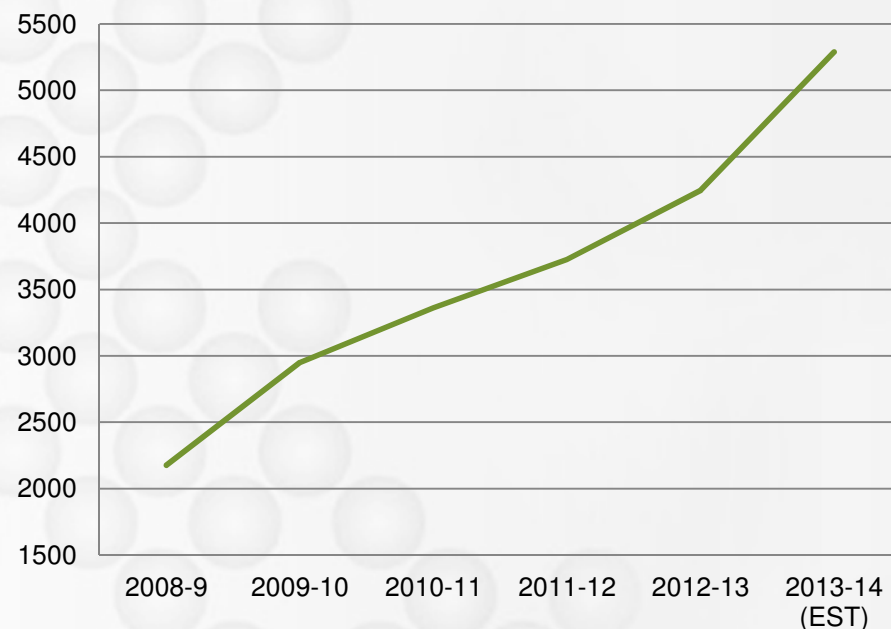
# Business Model

## HOW THE FERRISCAN SERVICE WORKS



# FerriScan<sup>®</sup> Growth

Annual Image Analysis Volumes

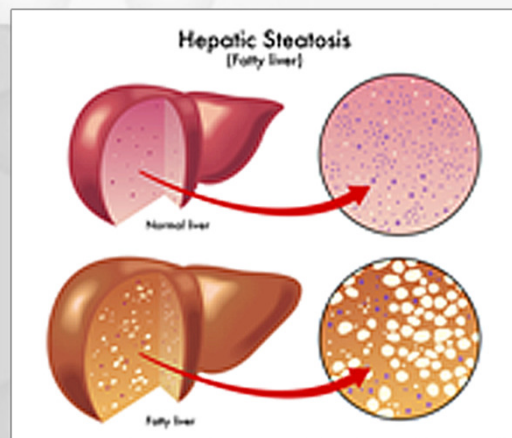


- **Revenue** earned from:
  - the use of FerriScan<sup>®</sup> in **clinical trials**
  - sale of FerriScan<sup>®</sup> **coupons** to Pharmaceutical companies to assist patient access to FerriScan<sup>®</sup>
  - FerriScan<sup>®</sup> **agreements** with hospitals
- FerriScan<sup>®</sup> is a **profitable business unit**



# HepaFat-Scan<sup>®</sup>

Measurement of fat in the liver  
using **MR IMAGES**





# Fatty liver market

**2/3** of American adults and **1/3** of American children are overweight.

Approximately **30%** of US population (~106 million) has **fatty liver disease**.

**NAFLD** (non-alcoholic fatty liver disease) is the most common cause of liver disease in the western world.

NAFLD is projected to be the leading cause of liver transplant in the US by **2020**.

The US Centre for Disease Control (CDC) predicts that by **2025** nearly **40%** of Americans will be obese including **20-30%** of American children.

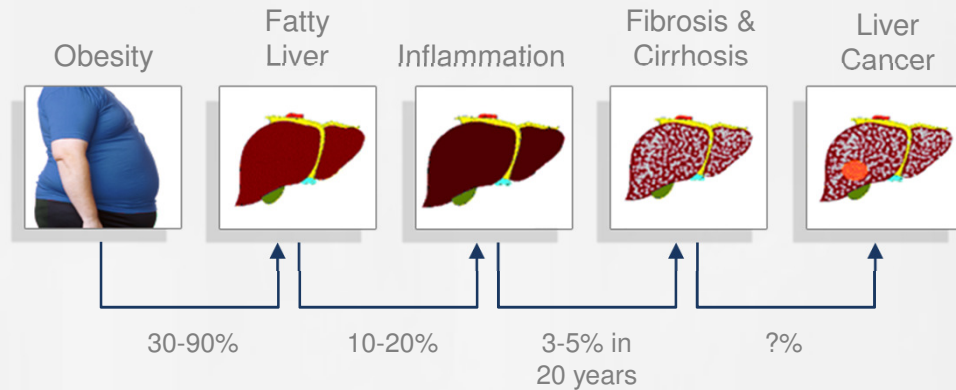
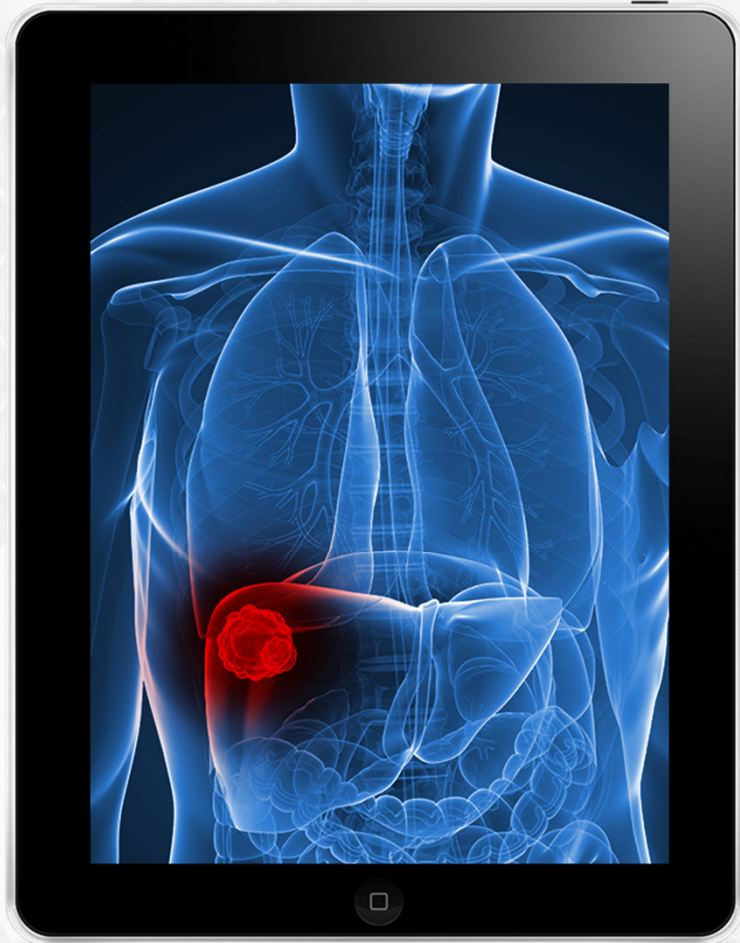
By **2025** it is estimated that **83%** of Australian men will be overweight or obese.

The prevalence of fatty liver disease in **China** has **doubled** in the **last 10 years**. Estimated to affect **5%** (60 million) of the population (2004 report) or **15%** in the more affluent regions of China.

The prevalence of NAFLD in urban **India** is **20-30%** and accounted for almost **50%** of the cases of liver cirrhosis.



# Non-alcoholic Fatty Liver Disease



If left untreated, fatty liver can lead to liver inflammation, fibrosis and cirrhosis.

Fatty liver disease can also lead to an increase in **liver cancer, cardiovascular death, reduces the effectiveness of antiviral therapy** and is closely associated with **Type 2 diabetes**.



# HepaFat-Scan® Advantages

- Measures the % of liver tissue containing fat which is directly **equivalent** to the biopsy measurement
- HepaFat-Scan® can be used as a **surrogate** for liver biopsy measurements of liver fat
- Ease to implemented, uses **standard MRI scanners**
- **Quick** 3 minute MRI scan
- **FDA approved**, progressing TGA and EU approvals
- Non-invasive, enabling earlier diagnosis and monitoring
- Only FDA approved method for measuring liver fat **validated** against liver biopsy measurements of liver fat
- HepaFat-Scan® has demonstrated **higher levels of sensitivity** and **specificity** than any other published method
- **Patent** lodged





# HepaFat-Scan<sup>®</sup> Competitive Positioning

## Ultrasound

Often used to diagnose fatty liver

**Qualitative** assessment of liver fat based on visual assessment

Can not detect small changes in liver fat

## CT

**Qualitative** assessment of fatty liver

Exposure to **radiation**

Diagnostic performance not considered clinically acceptable

## MRI

MRI can measure the ratio of fat: water protons in the liver tissue

Does not have a linear relationship with measurements made by liver biopsy

**May not reliably represent the liver fat content**

## Liver Biopsy

Measure the % of liver tissue cells containing fat

Study<sup>1</sup> comparing the consistency of pathologists measurements found:

- “**Poor agreement** between pathologist measurements of liver fat”
- “Measurements are strongly **observer dependent**”
- “Measurements are **not reproducible**”
- “Measurements **do not correlate** with computerised quantification of liver fat”
- “The **disagreement** among expert pathologists on the quantification of total liver fat is very disturbing”
- “This study highlights the **urgent need to develop novel tools for the assessment of liver fat...**”

1. Assessment of Hepatic Steatosis by Expert Pathologists: The End of a Gold Standard, Annals of Surgery, 2009

# HepaFat-Scan<sup>®</sup> Market



## Early diagnosis of fatty liver disease and monitoring of progress

US market assessment is in progress to identify initial clinical targets and go-to-market models

- **106m people** in the US have fatty liver disease
- Assume a fee of \$130 / test\*
- If 1% have an MRI HepaFat-Scan pa for diagnosis of fatty liver → **large potential**



## Liver surgery

- Patients with liver fat having major liver surgery have **increased risk** of death and more post-operative complications
- Liver fat decreases patient survival after liver transplant



\* based on US CPT codes for MRI post-processing. Ability to use these codes for HepaFat-Scan has not been explored with the AMA.

# HepaFat-Scan<sup>®</sup> Market

## Pharmaceutical Companies



Need an accurate non-invasive FDA approved tool to measure liver fat in their **clinical trials**



Resonance Health has **strong credentials** proving imaging core lab services to pharmaceutical companies for **10+ years**



**246 trials** currently registered on *clinicaltrials.gov* for non-alcoholic fatty liver disease

- 101 in the US
- 65 in Europe
- 36 in the Middle East
- 23 in China
- 11 in Canada



Resonance Health has an established **presence** and **relationships** in these regions



Resonance Health



# Liver Fibrosis

Measurement of liver  
fibrosis using

**MR IMAGES**



# Liver Fibrosis Measurement with MRI

Non-invasive measurement of liver fibrosis is a **large addressable market**

**Primary causes** of liver fibrosis:

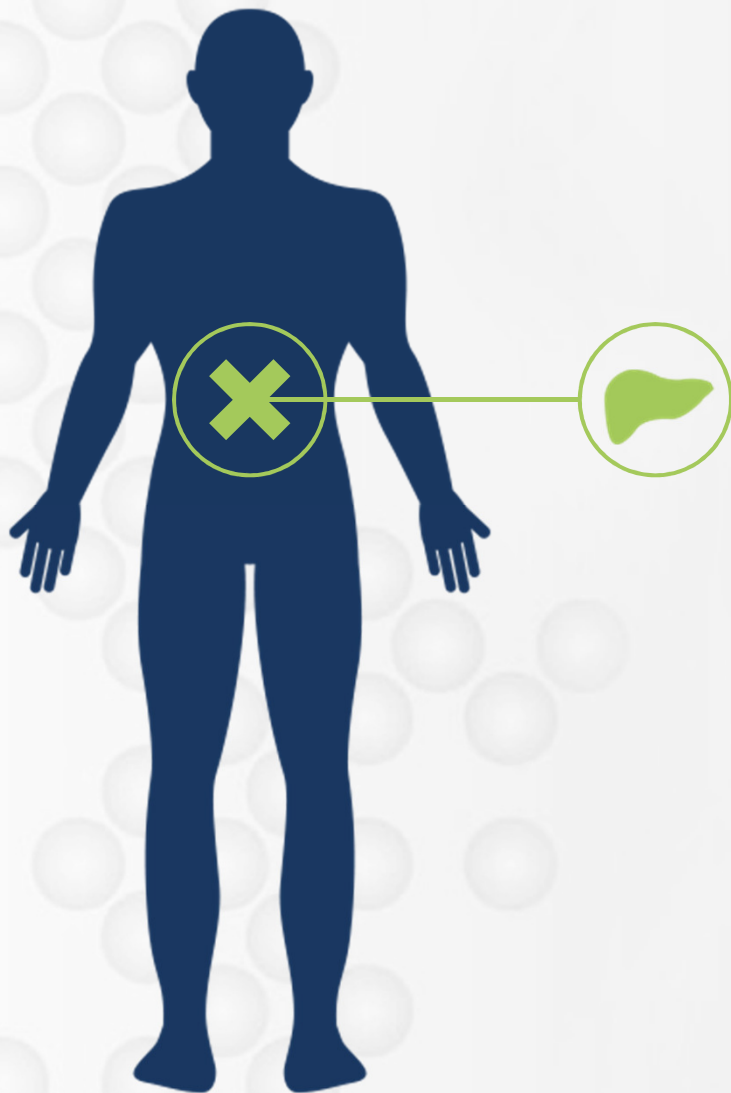
- Viral hepatitis – 170m people world wide have Hep C (2.7m in US)
- Fatty liver disease – 1/3 of American adults have fatty liver
- Iron overload
- Alcohol consumption

If left untreated, **liver fibrosis** can progress to **liver cirrhosis** – one of top 10 causes of death in the US and UK and a significant predictor of **liver cancer**

Early non-invasive diagnosis and effective management can significantly improve patient outcomes.



# Liver Fibrosis Diagnostic Tool - Status



Resonance Health completed a **clinical study** in 2012 to develop an MRI test to detect and score liver fibrosis in collaboration with **Pfizer** and the **Victorian Liver Transplant Unit**

Results were **equivocal**

Work has continued to **refine the methods** of image analysis which have produced results which are **very encouraging**

Work-in-progress to evaluate the benefits of using a **contrast agent** and to **independently validate the results**

Next results expected approximately **mid-year**

**845 studies currently registered** in *clinical trial.gov* for liver fibrosis



# Other Opportunities



**Another opportunity** is currently being investigated:

- MRI related technology
- Due Diligence in progress
- Non-Disclosure agreement prevents further disclosure at this time



Continue to **look for other opportunities** to expand the revenue base of the Company and increase shareholder value



# Summary

## **Profitable FerriScan® Business Unit**

- Strong growth in FerriScan® sales volumes
- Significant increase in number of FerriScan® sites activated
- Expansion into new geographies
- Strategic partnerships with large pharmaceutical companies

## **FDA approval for HepaFat-Scan® Q4 2013 – large addressable market**

## **Pipeline product - liver fibrosis test – very large addressable market**

## **Other collaborations are being explored to drive shareholder value**

## **Experienced management team**

- Excellent relationships with pharmaceutical companies



# Financial Results

**360m** shares on issue

Last capital raising in **2006**

Receipts from customers in FY 2012-13 of **AU\$1.9m**, up **34%** from previous year

Cash balance at 31 December 2013 **AU\$745k**

Cash balance at 31 March 2014 estimate **AU\$850k**

**No debt**



