

# Commercialising Neuroscience – market specific IP strategies

**AusBiotech2010**  
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# Company overview & key highlights

ASX:CGS

- Profitable technology company
- Providing medical expertise as well as a patented software solution
- Founded in 1999 in Melbourne and now employs 42 people in Aust, USA & UK
- A strong focus on neuro-science
- Core business providing services to clinical drug trials generating approx \$10m revenue p.a.
- Management team combines backgrounds in neuro-science, software development, and large pharma operational expertise

# Measuring change in cognition

- Many existing instruments in medicine are used for change decisions.
  - Rapid & repeatable & highly reliable
  - Not dependent on expert
  - Surrogate makers of physiological status
  - Generate interval level data (eg, temp).
  - Uncontaminated by repeating the test
  - Broad range of possible values
  - Bi-directional sensitivity
  - Not culturally, socially, educationally biased



“Cognitive thermometer”

# Philosophy: Measuring cognitive change is different to measuring cognitive impairment

## Practical

Brief  
Easy to give  
Easy to understand  
Non-expert administration  
Standardized  
Everyday equipment

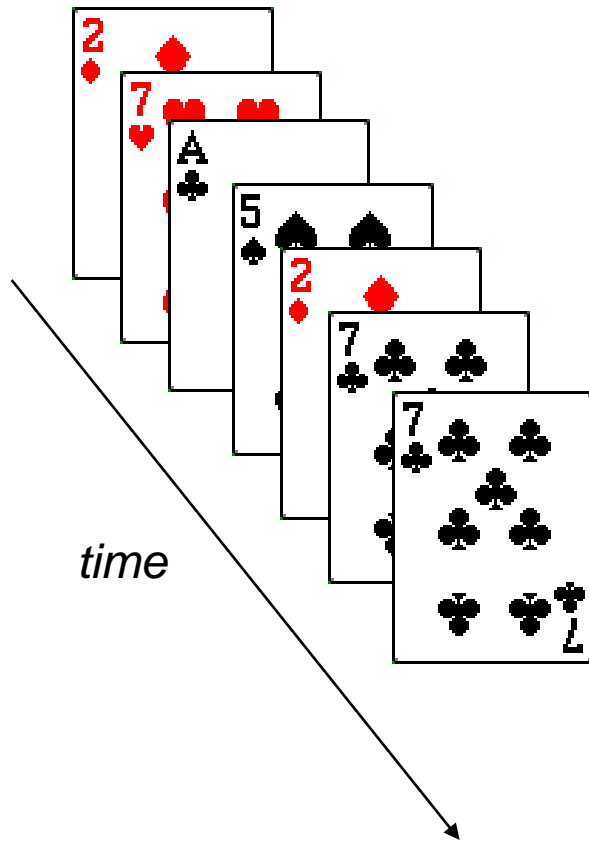
## Methodological

Practice effects  
Fatigue/Motivation  
Length of test-retest intervals  
Number of re-tests possible

## Statistical

Data normally distributed  
No floor or ceiling  
No range restriction  
No correlation b/w variance and mean  
Stable  
Small coefficient of variation

# CogState Card Test design principles



Stimulus material is constant (one card at a time)

Stimulus-Response mapping requirements constant.  
On each trial respond “YES” or “NO”

Simple rule used for each task

Is it there?

Is the card red?

Have you seen this card before?

Is it the same as the previous card?

Measure speed and accuracy of each response

# Generic problem with multiple specific applications

- **Clinical drug trials**

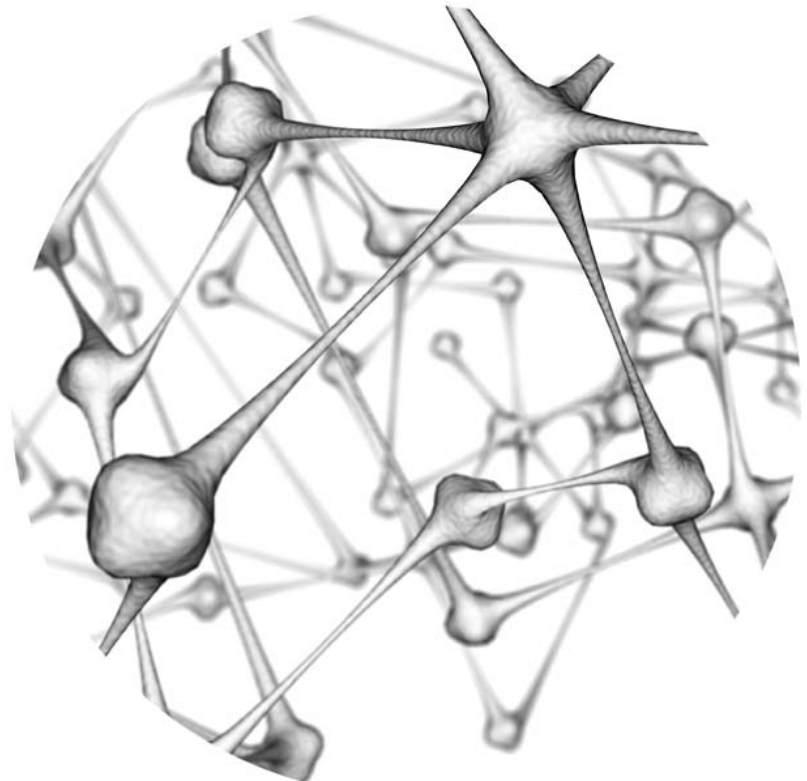
- Customers are pharma / biotech companies
- Quantify the effects of drugs on human subjects in clinical trials

- **Sport**

- Customers are athletes, parents, schools, doctors, sports teams or sporting associations
- Quick and efficient web based tool that can assist doctors in facilitating the safe return of athletes to the playing field and/or classroom following a concussion

- **Dementia screening**

- An efficient and non-invasive tool to identify cognitive decline associated with dementia
- R&D activity currently in Alzheimer's disease, Mild Cognitive Dementia and HIV Dementia



- Some traditional IP
  - but in clinical drug trials, the business model is not based around utilising our patented IP
- Selling a solution to the question, “does this drug change the thinking of an individual?”
- Business model based on:
  - Expertise of staff
  - Scientific credibility
  - Brand awareness
  - Scientific and commercial validation

# CogState IP strategy

- Patent position
  - Patents issued in Aust, USA & Japan
    - Difficulties with patenting software
    - Difficulties in finding something novel in psychological testing
- Validation critical for use by pharma
  - Track record / reputation
  - Scientific validation
    - Research studies
    - Published data in reputable journals
  - Commercial validation
    - Use by other pharma
- Copyright and trademark protection subsequently

# Barriers to entry

- With little IP protection in place, how do you keep out competitors
  - Scientific background and theoretical knowledge
  - Software development process
    - Not just that it works
    - Ease of use
    - Feature rich
  - Scientific validation
  - KOL support
  - Commercial validation
  - Operational expertise to deliver
- Time commitment is a major barrier to entry

# Case Study #1

[www.axonsports.com](http://www.axonsports.com)



Axon Sports, a joint venture between CogState and Quixote Investment LLC, was launched in the US in August 2010

Partners providing sports product marketing and distribution expertise

Total US market estimated at US\$150 – US\$275 million p.a.

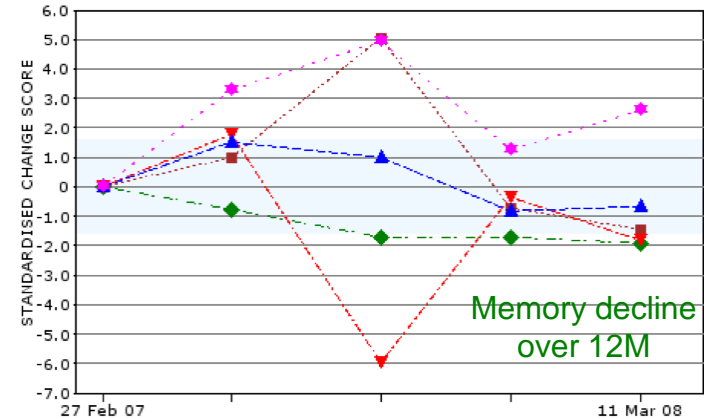
Intellectual Asset Management (IAM) issues:

- competitor failed to attract opportunity
- scientific and staff track record
- niche brand, but extremely well respected
- patent protection was important
- distributed model fitted business plan

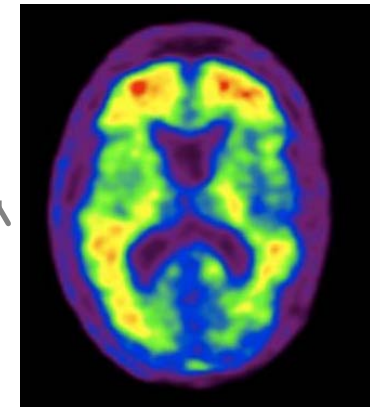
# Case Study #2

## Early detection of Alzheimer's disease

- Cognitive decline on the CogState memory test predicts a 3 fold increased risk of early AD
- Our studies in 50+ year olds have shown 53% with memory decline have excess amyloid on PET scans vs 18% without memory decline
- Excess amyloid predicts very high risk of progression to AD in the next 10-20 years
- Provides a model for non-invasive and cost effective early detection of AD in the community
- Additional clinical validation studies are being performed in collaboration with major academic studies:
  - The CSIRO Australian Imaging Biomarker & Lifestyle (AIBL) study
  - Alzheimer's Aust (Vic) Community screening study
  - Pharma funded AIBL/Rate of Change Study



PET-amyloid scan +ve



## Issues related to the market

- Mass market vs niche market
- Brand awareness and brand positioning more important
- Science is important, but not everything
- Business model likely to be different
  - Distribution partners may be more concerned about IP protection before investing heavily in brand and alliance
- Very public profile raises different concerns about IP
  - Is the same strategy appropriate?

# Conclusion

- Traditional IP protection is not the only option
- Business plan and asset base important considerations
- The market for the product may be determinant of IP strategy
- Consider if strategy will change in the future



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