



NOVEMBER 4, 2013

COGNITIVE HEALTH

**FASTER LEARNING**

**ENHANCED MEMORY**

**IMPROVED MENTAL  
PERFORMANCE**



**A FOUNDATIONAL INGREDIENT FOR COGNITIVE HEALTH  
FORMULATIONS SUPPORTING MEMORY, LEARNING AND  
INTELLECTUAL PERFORMANCE**



GROWTH THROUGH INNOVATION

# TODAY'S MEETING

Welcome to the brave new world of Synapsa™!

## MARKET OPPORTUNITY

- Cognitive Health
- The information age demographic

## ABOUT SYNAPSA™

- A unique, proprietary ingredient

## DEEP DIVE ON THE RESEARCH

- 30 years of study
- Highlights of 4 clinical studies

## CLAIMS, IP & MORE

## DISCUSSION

**WE'RE PLEASED TO  
HAVE THE  
OPPORTUNITY TO  
MEET WITH YOU  
TODAY!**

# THE COGNITIVE HEALTH SEGMENT

Huge opportunity for growth

## CONSUMER CONCERN OVER MENTAL ABILITY GREW 47% OVER THE PAST DECADE – HEALTH FOCUS INTERNATIONAL

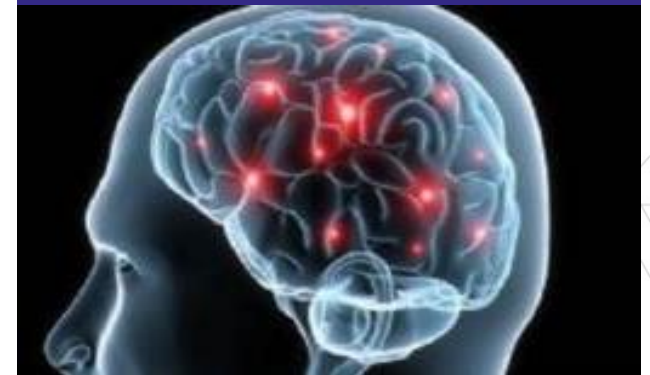
- Broad range of the population is concerned about mental functioning
  - 33% over 65
  - 26% 18-29

## “COGNITIVE HEALTH SUPPLEMENT SALES ARE POISED TO SKYROCKET” – NBJ

- 2011 U.S. cognitive health sales grew 6% to \$1.4B
- Ground floor opportunity: The category accounts for less than 5% of U.S supplement sales

**HUGE MARKET OPPORTUNITY WITH HIGH GROWTH PROSPECTS**

Attention  
Memory  
Language  
Learning  
Reasoning  
Problem solving  
Mood  
Sleep





# PEAK PERFORMANCE

An existing and growing opportunity

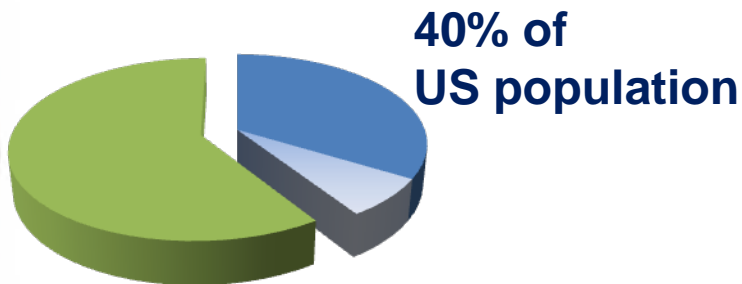
MOST COGNITIVE HEALTH SUPPORT STUDIES & SUPPLEMENTS FOCUS ON ISSUES OF **COGNITIVE DECLINE**

VAST NEED & MARKET OPPORTUNITY FOR SUPPORT IN AREAS OF **COGNITIVE PERFORMANCE RELATED TO STUDY & WORK**

## PEAK PERFORMERS IN THE USA

**Knowledge workers**  
Over 100 million in 2014  
(Infotrends, 2011)

**College & University Students**  
21.8 million in 2013  
(US Dept. of Education)



# ALREADY AN ACTIVE MARKET

## Caffeine & other “stimulants”



Nearly 63% of medical students report ‘academic performance’ as reason for consuming caffeine (Lee K-H, et al 2009)

### STUDENTS

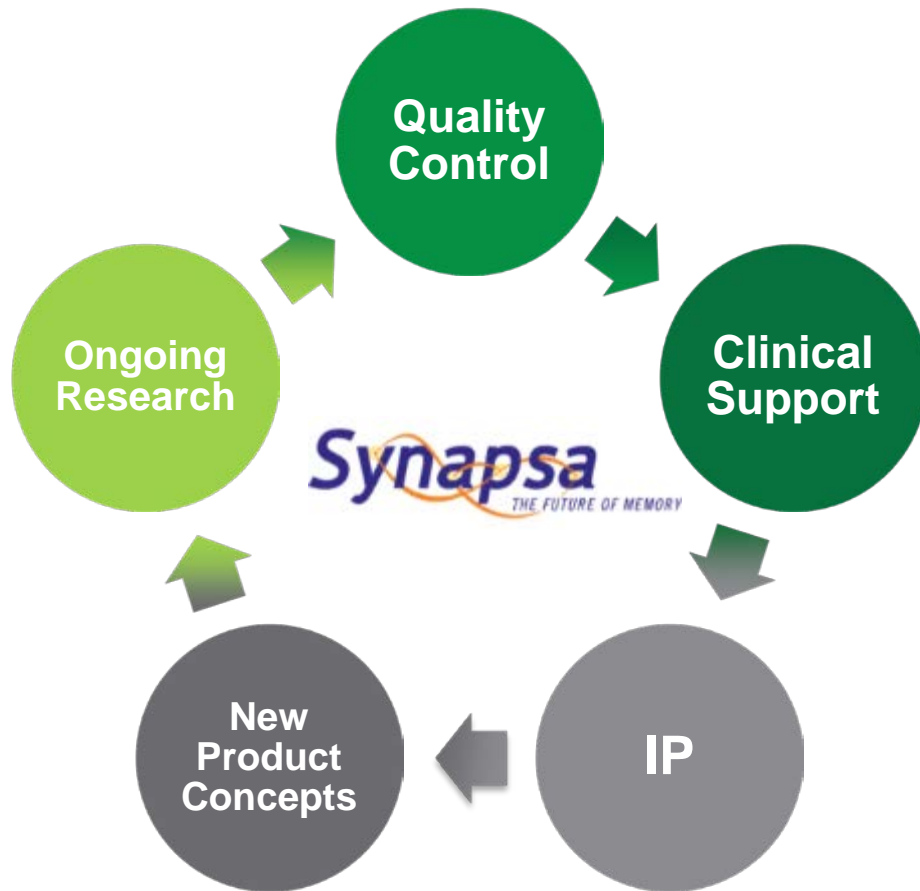
Undergraduate  
Post Graduate  
Medical  
Legal

### KNOWLEDGE WORKERS

Software  
Architects  
Engineers  
Scientists  
Financial services  
Legal  
Media/Social Media

# A PLATFORM FOR 'PEAK PERFORMANCE'

## Synapsa™ Natural Memory Support



Safe, *natural* support for healthy adults looking for 'peak performance'

- Learning
- Memory
- Academic performance
- Workplace performance

# THE FUTURE OF QUALITY

PATENTED EXTRACT  
SEED-TO-SHELF QUALITY





# A UNIQUE COMPOSITION

Clinically studied ingredient produced by patented process

## MULTI-PATENTED PROCESS

- India 185078 (2961/DEL/1996): extraction of a formulations mainly containing bacosides

The unique method of making Synapsa™ – the clinically-studied ingredient – is patented.







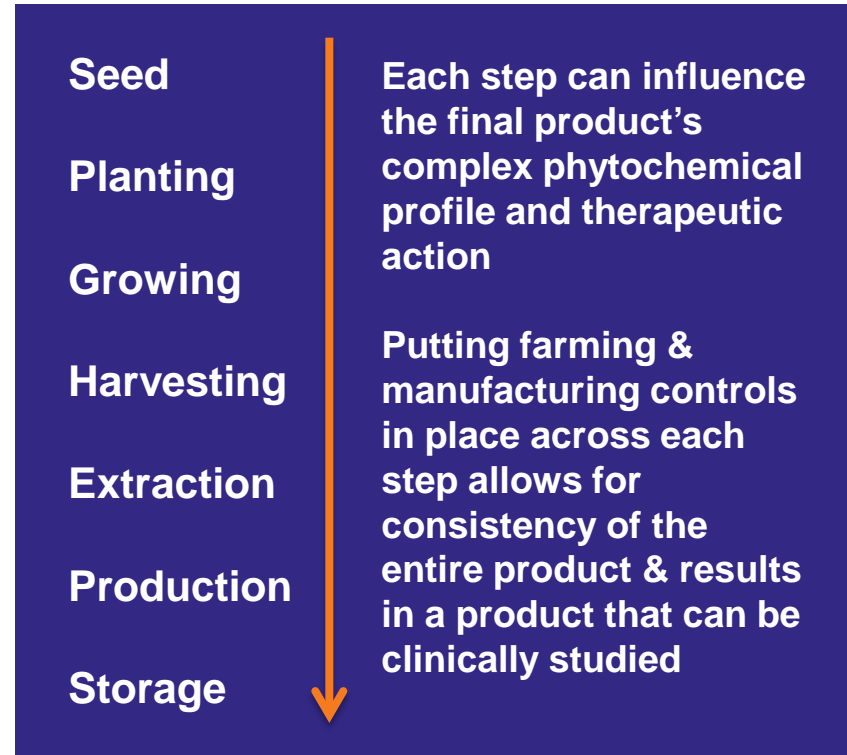
# SEED-TO-SHELF QUALITY

## Key to reproducible clinical trial results

Synapsa™ is a unique extract of *Bacopa monnieri*, with a wide range of active constituents that contribute to its therapeutic properties

Result of over 30 years extensive research & development at the Central Drug Research Institute (CDRI) in India

Consistent farming & manufacturing processes from to ensure a standardized level of quality



# THE FUTURE OF COGNITIVE RESEARCH

A FOCUS ON  
HEALTHY ADULTS





# COGNITIVE BENEFIT AREAS

Data from clinical trials show statistically significant results

**FASTER INFORMATION PROCESSING**

**IMPROVED LEARNING RATE**

**DECREASED FORGETTING RATE**

**IMPROVED MEMORY CONSOLIDATION**

**BETTER MULTI-TASKING ACCURACY**

**SYNAPSA™ STUDIES SHOW *BOTH* CHRONIC AND ACUTE EFFICACY**

These studies focus on healthy adults from 18 to 65



# COGNITIVE STUDY BACKGROUND

## Strong clinical support

- 7 'foundational' clinical trials
- 6 'targeted' randomized, double-blind, placebo-controlled clinical trials
- Additional clinical trials underway and planned
- Synapsa™ has been shown to be **safe, well tolerated** and **devoid of undesirable side effects** in clinical studies

The scientific evidence for the cognitive enhancing effect of Synapsa™ Natural Memory Support is based on 30 years of research



# SUMMARY OF CLINICAL PROGRAM

## Chronic and acute effects of Synapsa™

### Chronic Use of Synapsa™ – Key Studies

**Stough et al.** The chronic effects of an extract of Bacopa monnieri on cognitive function in healthy human subjects, *Psychopharmacology*, 2001; 156:481-484.

**Roodenrys et al.** Chronic effects of Brahmi on human memory, *Neuropsychopharmacology*, 2002; 27:279-281.

**Raghav et al.** Randomized controlled trial of standardized Bacopa monnieri extract in age-associated memory impairment, *Indian Journal of Psychiatry*, 2006; 48:238-242.

**Stough et al.** Examining the nootropic effects of a special extract of Bacopa monniera on human cognitive functioning, *Phytotherapy Research*, 2008; 22:1629-1634.

### Acute Use of Synapsa™ – Key Studies

**Nathan et al.** The acute effects of an extract of Bacopa monniera (Brahmi) on cognitive function in healthy normal subjects, *Human Psychopharmacology*, 2001; 16:345-351.

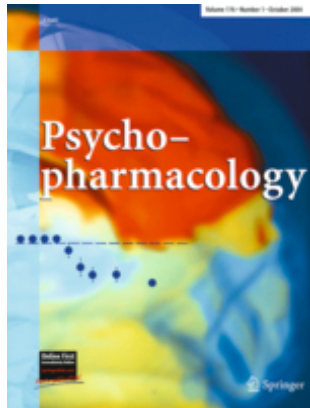
**Downey et al.** An Acute, Double-Blind, Placebo-Controlled Crossover Study of 320 mg and 640 mg Doses of a Special Extract of Bacopa monnieri (CDRI 08) on Sustained Cognitive Performance. *Phytotherapy Research* 2012; 27:1407-1413.

**Benson S, Downey LA, Stough C et al.** An Acute, Double-Blind, Placebo-Controlled Cross-over Study of 320 mg and 640 mg Doses of Bacopa monnieri (CDRI 08) on Multitasking Stress Reactivity and Mood. *Phytotherapy Research* 21 Jun 2013

# STOUGH, ET AL. 2001

## Visual processing, learning rate & memory consolidation

Details	Summary of Results
<ul style="list-style-type: none"> <li>• Double-blind placebo-controlled,</li> <li>• 46 healthy participants, 18-60 yrs</li> <li>• 3 months, 300 mg/d Synapsa™</li> <li>• Independent-group design</li> <li>• t = baseline, 5 &amp; 12 weeks</li> </ul>	<p>Significant improvement in:</p> <ul style="list-style-type: none"> <li>• Information processing</li> <li>• Memory consolidation</li> <li>• Reduction in state anxiety</li> </ul> <p>Maximal effects evident after 12 weeks</p>



Psychopharmacology (2001) 156:481–484  
DOI 10.1007/s002130100815

### RAPID COMMUNICATION

C. Stough · J. Lloyd · J. Clarke · L. A. Downey  
C. W. Hutchison · T. Rodgers · P. J. Nathan

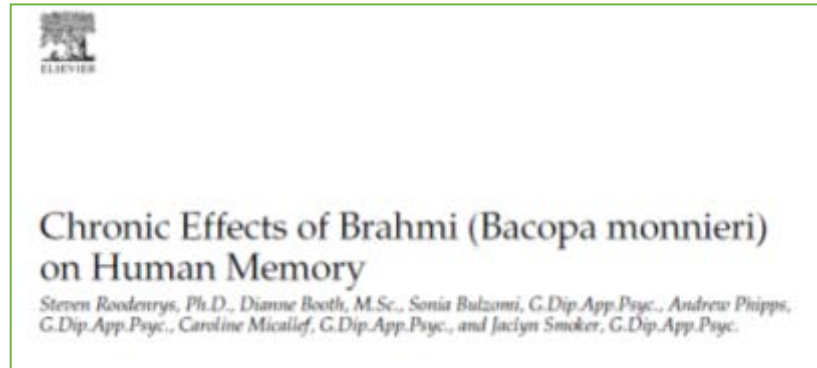
**The chronic effects of an extract of *Bacopa monniera* (Brahmi) on cognitive function in healthy human subjects**



# ROODENRYS, ET AL. 2002

## Information retention

Details	Summary of Results
<ul style="list-style-type: none"> <li>• Double-blind placebo-controlled,</li> <li>• 76 healthy participants, 40-65 yrs</li> <li>• 3 months, 300 mg/d Synapsa™, followed by 6 week post-trial assessment</li> <li>• t = baseline, 90 days &amp; 6 weeks post treatment</li> </ul>	<p>Significant effect on:</p> <ul style="list-style-type: none"> <li>• Retention of new information,</li> <li>• Verbal and visual short-term memory.</li> </ul>





# STOUGH, ET AL. 2008

## Working memory, visual information processing & accuracy

Details	Summary of Results
<ul style="list-style-type: none"><li>• Double-blind, placebo-controlled</li><li>• 107 healthy participants, 18-60</li><li>• 3 months, 300 mg/d Synapsa™</li><li>• t = baseline and 90 days</li></ul>	<p>Significant improvements in:</p> <ul style="list-style-type: none"><li>• Working Memory</li><li>• Visual Information Processing</li></ul>



# DOWNEY, ET AL. 2012

## Improved performance on cognitively demanding tests (acute)

Details	Summary of Results
<ul style="list-style-type: none"> <li>• Double-blind, placebo-controlled, cross-over</li> <li>• 24 healthy adults subjects</li> <li>• 320mg, 640mg acute doses Synapsa™</li> </ul>	<p>Improved performance on cognitively demanding tests from 320 mg dose (Cognitive Demand Battery)</p>

### THE CDR SYSTEM:

- Used in worldwide clinical trials since 1984. Over 900 trials.
  - Attention, Concentration, Vigilance
  - Working (Short-Term) Memory
  - Episodic (Long-Term) Memory

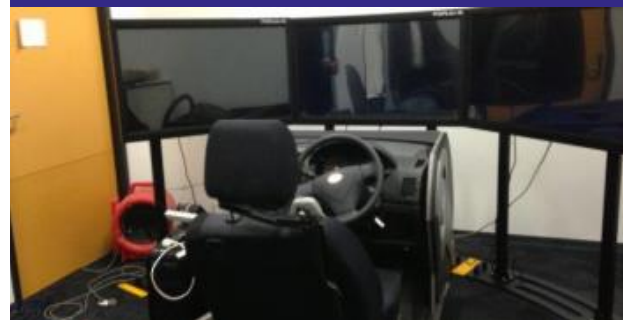


# ON-GOING STUDIES

## Additional indications/targets:

- Inattention
- Acute dosing
- Cognition enhancement
- fMRI
- Dementia/Alzheimer's
- Basic pharmacology

One of the most aggressive & comprehensive research programs of a cognitive health ingredient in the industry



# THE FUTURE OF EXCITING NEW PRODUCTS

NEW INDICATIONS  
NEW IP  
NEW CLAIMS



# ADDRESSING THE AGING POPULATION

Synapsa™: Australian Research Council's Choice of Bacopa

## ARCLI (AUSTRALIAN RESEARCH COUNCIL LONGEVITY INTERVENTION)

- 465 cognitively healthy older adults (60-75 years old) are being randomized to receive Synapsa™ (300 mg), Pycnogenol (150 mg), or placebo daily for 12 months
- Participants will be evaluated at baseline, 3, 6 and 12 months post-randomization for a variety of cognitive, cardiovascular, and biochemical parameters
- Design published in the Nutrition Journal, 2012

Aging population should want Synapsa™ now... and even more in the future





# PATENT PENDING FILING

A new patent on Synapsa™ for acute use

## APPLICATION PATENT

- Pending: Methods for **acutely** improving/enhancing cognitive performance in a human subject comprising administration of an extract of *Bacopa monnieri*.
- **Filing December 2013**

Patented support for test taking & other peak performance cognitive environments





# POTENTIAL PRODUCT CLAIMS

## Clinical support for different market offerings

- Clinically shown to improve the speed of information processing
- Supports the transition of short term memory to long term memory
- Aids in the retention of new information
- Helps improve learning rate & memory
- **A single ingredient that can support learning, memory, and mental performance**
- One ingredient. Better, faster learning.
- Better performance on cognitively demanding tests
- Improved mental performance when it counts

The scientific evidence for the cognitive enhancing effect of Synapsa™ is based on 30 years of research

\*The above claims are intended as suggestions only. Use of claims on product labeling and marketing materials should be vetted and approved by your regulatory and legal departments.





# TWO DISTINCT PRODUCT TYPES

Daily & Peak Performance at 320 mg/d

Daily  
Supplementation  
to Improve  
Learning &  
Memory



Same Day  
Supplementation for  
Improved Mental  
Performance in  
Cognitively  
Demanding  
Environments





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# PLT

HEALTH SOLUTIONS

GROWTH THROUGH INNOVATION

## APPENDIX



**PLT**  
HEALTH SOLUTIONS

GROWTH THROUGH INNOVATION

# COGNITIVE FUNCTIONING GLOSSARY

<b>Learning/Learning rate</b>	Acquisition new information or reinforcement of existing knowledge or skills. May involve synthesizing different types of information.
<b>Working Memory</b>	Process that provides temporary storage and manipulation of the information necessary for complex cognitive tasks such as learning, reasoning and language comprehension.
<b>Memory Consolidation</b>	Transition of information from short-term to long-term memory.
<b>Information Retention</b>	The second stage of memory after encoding and before retrieval.
<b>Visual Information Processing</b>	A measure of the ability to sustain attention.



# BACOPA MONNIERI ALTERNATIVES

Focus on aging & other. Lack of published and/or new studies.

<b>BACOPIN™</b>	<ul style="list-style-type: none"> <li>• Studies focusing on trauma &amp; children</li> <li>• Few published studies</li> <li>• No recent studies</li> <li>• Website not updated since 2005</li> </ul>
<b>BACOMIND™</b>	<ul style="list-style-type: none"> <li>• 3 Studies, 2 focusing on elderly &amp; 1 on children with low IQ</li> <li>• No ongoing support</li> </ul>
<b>BACOGNIZE™</b>	<ul style="list-style-type: none"> <li>• No clinical studies actually published</li> <li>• Borrowed science (from Synapsa™)</li> </ul>
<b>Generic</b>	<ul style="list-style-type: none"> <li>• No published clinical studies</li> <li>• Lack of transparency on sourcing/quality</li> </ul>