



Yesterday's traditional wisdom  
Tomorrow's innovative health solutions

**QUALIFYING FOOD AS MEDICINE-WHERE DO WE START?**  
**FOOD FOR MEDICINE AND MEDICINE FOR FOOD SEMINAR**  
**17 NOVEMBER 2013**

Confidential

**CONTENTS**

- ❖ Introduction Of Biotropics Malaysia Berhad
- ❖ Qualifying Tradition With Science : The Process
- ❖ Food To Medicine : Biotropics Products

**BIOTROPICS MALAYSIA BERHAD**

- ❖ Incorporated in February 2007 as GLC.
- ❖ Main aim to develop and commercialize Malaysia's bio-resources into superior natural health products.
- ❖ Products includes proprietary standardised extracts, all-natural dietary supplements, ingredients for nutraceutical, functional food and cosmeceutical applications.

**BIOTROPICS ... INNOVATION FOR INTERNATIONAL & LOCAL**

In the market Since July 2009

Global Brand

Local Product - Nu Prep

Finished Goods

- Products in GNC, Vitamin Shoppes, on-line stores
- Top 5 best selling male's health product

Pharma grade Research

- Access to world-class technology & world's largest natural products database for rapid screening of potential herbs
- 11 patents filed

R&D Lab setup

- Develop new extraction process and proprietary extracts

CHEST Lab

- Collaboration with USM to set up a herbal standardization & monograph work to service industry

Herbal Extraction Technology

- Highest grade T. Ali extract in the int'l market
- Largest commercial scale extraction in Malaysia

Licensing & Commercialization

- MARDI, UPM

Acquire & Upgraded Phytex Biotech

Bio-partnership & Jakun community development

- Bio-prospecting & commercializing based on Boron Guidelines and CBO
- Set up of TA processing facility operated by Jakun community

Plantation Research

- Domestication, Agronomy, pest & disease research and propagation of seedling

**OUR PARTNERS & SERVICE PROVIDER**



**TRADITION...**

**QUALIFYING TRADITION WITH SCIENCE**



**BIODIVERSITY + TRADITION + SCIENCE = BIOTROPICS**

"We bring together Malaysia's biodiversity and health traditions, applying state-of-the-art science to develop superior natural products."

❖ Malaysia's rich biodiversity is abundance of bio-resources with more than 2,000 plants are believed to have therapeutic properties.

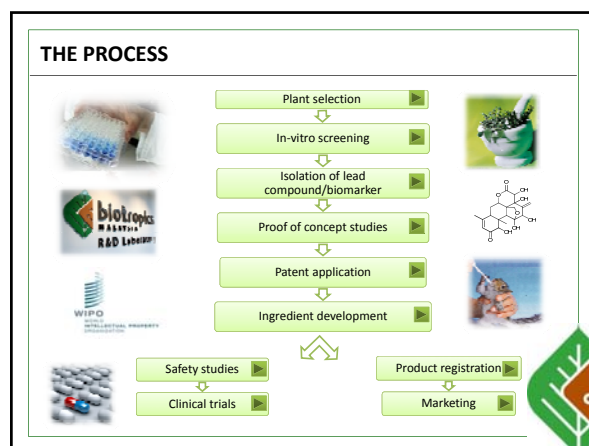
❖ A melting pot of knowledge and traditional practices derived from Malay, Chinese, Indian and indigenous people cultures. Over generations, have acquired intimate knowledge of plants and practiced different forms of traditional medicine for healing and health maintenance.

❖ At Biotropics, we are driven by our philosophy to turn yesterday's traditional approach to health and well-being, into tomorrow's innovative health solutions by verifying the time-honoured traditions through modern science activities.

❖ Advancing traditional preparation with modern science to achieve our goals of quality, safety, consistency and efficacy.

IT'S TIME TO UNLOCK

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**FOOD TO MEDICINE: BIOTROPICS PRODUCTS**

**PRODUCT 1: NU PREP LELAKI**

❖ The journal of the India archipelago and eastern which published in 1850 has mentioned about the use of Tongkat Ali

❖ Nu Prep Lelaki contains water-soluble, standardized, freeze-dried extracts from roots of Tongkat Ali (Physta®) using patented extraction technology.

❖ The patent developed through collaborative works of Malaysian Government and the renowned Massachusetts Institute of Technology, MIT for increasing testosterone synthesis, increasing testosterone release from cells, increasing sperm count, and increasing sperm motility (US Patent: 7132117, EU Patent: 1313491).

❖ 9 clinical studies were completed and the funding suggest that Physta® has potential benefit in increasing testosterone, bone strength, sexual health, anti-aging, Fertility, vitality and Ergogenic effect.

**NU PREP LELAKI : SUMMARY OF CLINICAL STUDIES CONDUCTED ON PHYSTA®**

No	Investigator/CRO	Design	Subjects	Remarks
1	Tambi MI Wellmen Clinic, Damai Service Hospital, Kuala Lumpur, Malaysia	placebo controlled, multiple dose (200,300 & 600 mg), 2 months	20 men aged 38 to 58, supplemented	• Testosterone: high normal levels compared to baseline • Safe (up to 600mg) - Liver function and renal function tests were normal.
2	Tambi MI Reproductive Research Center, Kuala Lumpur	Open label, 200 mg, 3 weeks	30 men, ages 31-52	• Extract increased free testosterone Index, DHEA
3	Talbott S., Talbott J., Negrete J., et. al. Supplement Watch Inc, Draper, UT, United States	Randomized, double-blind, placebo controlled, 100 mg	30 endurance mountain biking participants	• Testosterone levels significantly higher in active group (Physta®) vs placebo • Cortisol levels were significantly lower in active group (Physta®) vs placebo group
4	Tambi MI, Imran K Wellmen Clinic, Damai Service Hospital, Kuala Lumpur, Malaysia	Open label, 200 mg, 9 months	75 men with idiopathic male infertility	Improved sperm quality, increase in spontaneous pregnancy

**NU PREP LELAKI : SUMMARY OF 9 CLINICAL STUDIES CONDUCTED ON PHYSTA®...CONT.**

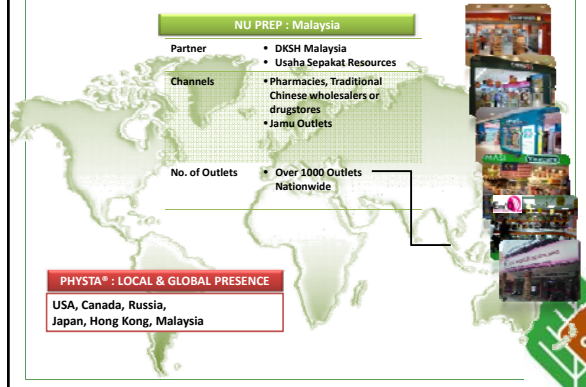
No	Investigator/CRO	Design	Subjects	Remarks
5	Udani J., Gruenwald J., Miller M., George A., et. al Medicus Research LLC	Randomized, double-blind, placebo controlled, 200 mg, 3 months	26 men with mild ED	Significant improvement in: • Erection Hardness Scale • Aging Males Symptom Score • Sexual Health Inventory for Men
6	Shaiful Bahari Ismail, Wan Mohammad WMZ, George A, et. al. Hospital Universiti Sains Malaysia	Randomized, double-blind, placebo controlled, 200 mg, 3 months	109 healthy men	Significant increase in physical function of SF-36, Improvement in overall IIEF domain in Physta® group, sperm profiles, semen volumes and fat mass loss (BMI >25kg/m²)
7	Talbott SM, Talbott JA, George A, et. al Supplement Watch Inc, Draper, UT, United States	Randomized, double-blind, placebo controlled, 200 mg, 4 weeks	63 men and women with moderate stress	• Hormone profiles was significantly improved (↑ testosterone, ↓ cortisol) • Significant improvements in POMS Physta group

## NU PREP LELAKI : SAFETY AND TOXICOLOGY

Safety Features	Benefits
Water-extraction method	<ul style="list-style-type: none"> <li>Isolates and maintains the active components to ensure the full benefits of Tongkat Ali.</li> <li>Water extraction keeps the technique close to the traditional method (of boiling Tongkat Ali)</li> <li>Solvent free Water based extract: reduce safety concern on residual solvent level.</li> <li>Freeze-drying ensures the biologically active components are preserved</li> </ul>
The extract is freeze-dried and then powdered	<ul style="list-style-type: none"> <li>Only pure extracts are completely water soluble. Ground sawdust cannot dissolve in water – genuineness</li> <li>Easy for the body to absorb</li> </ul>
100% Water soluble	
Standardized	<ul style="list-style-type: none"> <li>Ensures the active components are present at a consistent level</li> </ul>



## NU PREP LELAKI & PHYSTA : LOCAL & GLOBAL PRESENCE

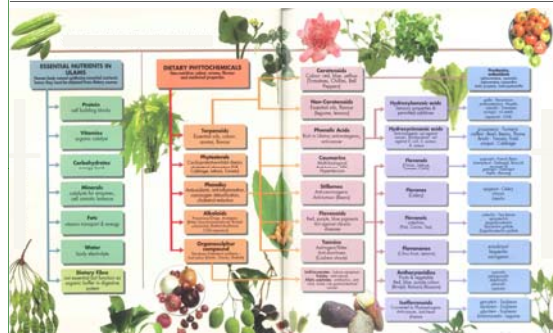


## PRODUCT 2: ULAM



A proprietary antioxidant formula containing natural extracts of herbs

## ULAM : NUTRIENTS



Source: Ulam salad herbs of Malaysia

## ULAM : BACKGROUND



- Conducted a screening program with FRIM and CENAR, UM for antioxidant content in at least 85 vegetables and ulams – few plant extract showed high anti-oxidant content.
- Ingredients in Ulam selection was based on high anti-oxidant content to mimic the healthy diet of Malaysians.

## ULAM : LINEMINUS™ (KESUM EXTRACT)

- Main Ingredient *Polygonum minus* (kesum)
- High in anti-oxidant activity : ORAC<sub>25</sub> about 20,000 TE/g
- IN-VITRO :
  - Acetyl Cholinesterase assay - strong inhibition in indicating potential activity in Pro-cognition/memory related area
- IN-VIVO:
  - Scopolamine induced deficits in learning and memory in mice in Barnes Maze model
  - Protective effects with 100mg/kg of LineMinus™ was seen.
  - Group received 100 mg/kg do not show scopolamine induced deficit in learning and memory (comparable to Donepezil).
- Patent Pending: PCT/MY2013/000033



**ULAM : CLINICAL TRIAL**

**Ramuan Health Ulam (BIOT1400) for the improvement of concentration and mood state in healthy volunteers**

*A Randomized, Double Blind, Placebo Controlled Crossover Study*



**SUPERULAM FOR THE IMPROVEMENT OF CONCENTRATION AND ATTENTION IN HEALTHY VOLUNTEERS**

PRODUCT	RAMUAN HEALTH ULAM BIOT1400
CRO	Medicus, US
Study Design	Randomized, Double- Blind, Placebo- controlled, crossover
Dosage	2 tablets before test
No. of Subjects	20 subjects; males n=10, females n=10
Age group	≥ 35 and ≤65 years old
Study duration	3 weeks
Objectives	CNS Vital signs: Composite Memory, Reaction Time, Complex Attention, Working Memory, Sustained Attention, Executive Functioning
1. Improve Attention	
2. Mood changes	1. POMS (POMS Profile Mood of State) Questionnaire- 2. Chalder Fatigue Scale
3. Safety	Adverse Event Analysis

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**STUDY SCHEDULE FOR TESTING AT DAY 0 AND DAY 7**

Between the two events 7 days of rest period

Randomisation at Day 0 and Day 7  
A single dose of herbal combination or placebo

BIOT1400 VISIT SCHEDULE	7:00 am	7:30 am	8:00 am	8:30 am	9:00 am	9:30 am	10:00 am	10:30 am	11:00 am	11:30 am	12:00 pm	12:30 pm	1:00 pm
Arrive at clinic	X												
Product Dosing			X										
CNSVTS TEST		X		X		X		X		X		X	
Scales/Questionnaires		X		X		X		X		X		X	
Dispense Snack									X				
Dispense Meal					X								X

Subjects who received herbal product during Day 0 received placebo during Day 7. Subjects who received placebo during Day 0 received the herbal product during Day 7.

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**CONCLUSION FROM CLINICAL STUDIES**

- ❖ Cognitive and working memory related scores showed significant improvement from baseline ( $p < 0.05$ ) in the product group
- ❖ Trends in certain domains of POMS questionnaires such as reduction in tension & confusion and increase in vigor in Active group
- ❖ Results suggest some possible neurostimulatory effect of the Product.
- ❖ No adverse events were reported
- ❖ **Conclusion:** Product is safe and has potential benefits towards cognitive function and mood



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**SUPERULAM : PUBLICATION**

**Research Article**  
**Effects of SuperUlam on the Improving Concentration and Mood: A Randomized, Double-Blind, Placebo-Controlled Crossover Study**  
Jon Vidari  
Received 18 July 2013; Accepted 4 October 2013  
Academic Editor: Marc Van der Linden

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**PRODUCT 3: WOMEN'S BLEND**

A proprietary blend of herbs that helps maintain healthy aging and vitality

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### WOMEN'S BLEND : KACIP FATIMAH

- ❖ Main Ingredient : Labisia Pumila (Kacip Fatimah)
- ❖ Traditionally used by the Malay women for many generations as a post partum medication to regain body strength, weight management and also manage menopausal symptoms
- ❖ **IN-VITRO :**
  - Inhibition of adipocyte differentiation activity : Help to minimize increment of adipocyte and content of triglyceride in body. Therefore inhibition in adipocyte differentiation help in weight management.
- ❖ **IN-VIVO:**
  - Proof of concept study showed reduction of weight gain for standard diet group and high fat fed rats compared to vehicle
- ❖ Patent Pending PCT/MY/2012/000008



### WOMEN'S BLEND : CLINICAL TRIAL TO EVALUATE THE EFFECT ON WEIGHT LOSS IN OVERWEIGHT SUBJECTS

PRODUCT	RAMUAN WOMEN'S BLEND – HERBAL COMBINATION
CRO	Palm Beach Research Centre, USA
Study Design	Randomized, Double- Blind, Placebo- controlled
Dosage	1 tablet in morning 1 tablet in evening
Study duration	12 weeks
No. of Subjects	45
Age group	18- 65 years old females with BMI 25- 35.9 kg/m <sup>2</sup>
Objectives	
1. Weight Loss	BMI, Waist & Hip circumferences
2. Quality of Life	1. Quality of Life Questionnaire 2. Sexual Health Questionnaire

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### CONCLUSION FROM CLINICAL STUDIES

- ❖ After twelve weeks of treatment
  - **RWB** - lost an average of 0.444 pounds
  - Placebo – gained average of 3.320 pounds
  - **RWB** - reduced hip 1.08cm and waist measurement 2.47 cm
  - Placebo – reduced hip 0.72cm and waist measurement 1.65 cm
- ❖ With regard to quality of life and sexual health, differences between the **RWB** group and placebo group were not found to be significant.
- ❖ Product is safe and has potential benefits towards weight management



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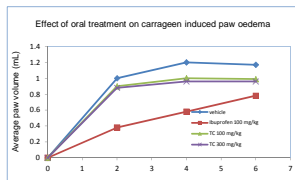
### PRODUCT 4: TINOCRISPA CAPSULE

- ❖ One of the ingredient in folk remedies for maintaining good health. A decoction of the stems, leaves and roots is used to treat fever, cholera, diabetes, rheumatism and snake bites decoction of the roots used for treatment of malaria fever and indigestion
- ❖ **IN VITRO :**
  - BLT2 binding activity : Antagonist activity
  - Function: prevent binding of LTb4 a potent chemoattractant on BLT2 receptors .
- ❖ **IN VIVO:**
  - Carrageen induced paw oedema in rat to study anti-inflammatory activities
  - Significant reduction in paw volume compared to vehicle at both evaluated 100 & 300 mg/Kg doses
- ❖ Patent Pending: US 61/467,096, PCT/MY2012/000033
- ❖ Product registration: MAL 12045088 T



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### TINOCRISPA CAPSULE : *IN VIVO* RESULTS



Sample	Dosage (mg/kg)	% inhibition		
Time		2h	4h	6h
Ibuprofen	100	56.6*	50.7*	36.6*
Extract	100	3.4	13.4*	9.7
	300	-6.1	11.6*	7.2

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THANK YOU



### Biotropics Malaysia Berhad (762243-P)

Lot 21, Jalan U1/19, Section U1,  
Hicom-Glenmarie Industrial Park  
40150 Shah Alam  
Selangor  
Malaysia

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

### PLANT SELECTION

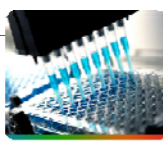
- ❖ Desktop research & Publication
  - Traditional information of candidate
  - Scientific information based on current research on the candidate
- ❖ Interview with indigenous community i.e Jakun from Tasik chini, Pahang
  - Forest dwellers
  - Relied heavily o the forest for their livelihoods
  - Depends on plants and herbs from the forest for general health and well being
- ❖ Herbal based Nursery
  - ❖ Final selection
  - ✓ Record of edibility
  - ✓ Opportunity for IP
  - ✓ Supply condition/Propagation feasibility



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### BIOASSAY INVITRO- SCREENING

- ❖ Similar to Pharma research approach, HTS in smaller scale and limited number of candidate
- ❖ Focus only on area of interest
- ❖ Selection of validated bioassay relevant to area of interest
- ❖ Evaluation various type of extract in selected bioassays

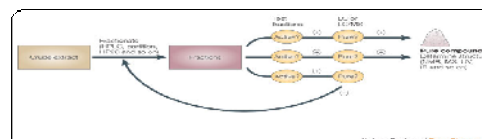


Antioxidant	Cardiovascular	Male health	Diabetes/Metabolic disorder	Inflammation
<ul style="list-style-type: none"> <li>• DPPH</li> <li>• ABTS</li> <li>• ORAC</li> </ul>	<ul style="list-style-type: none"> <li>• HMG COA reductase</li> <li>• CETP</li> </ul>	<ul style="list-style-type: none"> <li>• PDE 5</li> </ul>	<ul style="list-style-type: none"> <li>• DPPIV</li> <li>• Alpha Amylase</li> <li>• Alpha-glucosidase</li> </ul>	<ul style="list-style-type: none"> <li>• COX-1</li> <li>• COX-2</li> <li>• 5-LO</li> </ul>

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### IDENTIFICATION OF LEAD COMPOUND / BIOMARKER

- ❖ Costly and time consuming process
- ❖ Focus on active fraction by bioassay -guided isolation work
- ❖ Fractionation followed by in-vitro testing to identify highly active fraction
- ❖ Process to be repeated with high active fraction
- ❖ Identify major compounds/biomarker for standization work



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### PROOF OF CONCEPT STUDIES – IN VITRO TO IN VIVO

- ❖ To prove and confirm preliminary results from bioassay testing
- ❖ Important to select a validated and suitable model to reflect the activity seen bioassay screening
- ❖ Compare extract's activity with a known drug or herbal extract
- ❖ Able to give preliminary information on dose range , safety and cost feasibility
- ❖ One of the decision gate



#### EXAMPLE

Area	Bioassay	Animal models
Inflammation	5- LO	Mouse paw oedema model
Diabetes/Metabolic disorder	Alpha amylase	Acute starch tolerance test

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### PATENT APPLICATION

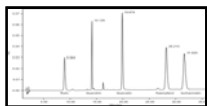
- ❖ A continuous detailed research on prior arts required throughout the process
- ❖ Based on existing prior arts strategy and focus of research can be decided
- ❖ Patent method / isolated compounds / enriched extract for a found activity
- ❖ Patent applications through Myipo/PCT/US/other countries
- ❖ Example patent application on well known plants:
  - Orthosiphon stamineus : EPO 2515923
  - Labisia Pumila : PCT PCT/MY2012/000008



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## INGREDIENT DEVELOPMENT

- A transition period from research to commercialization stage
- Raw material qualification from various source and finalize source
- Pilot and full scale trials to establish economical extraction process/establish a special process to produce enriched extract
- Establish method to conduct qualitative and quantitative standardization based previously identified biomarkers or other major compound



## SAFETY STUDIES – NON CLINICAL *IN VIVO* AND *IN VITRO*

- ❖ Level of safety studies depends
  - History of use of the herb
  - Data available on public domain on similar type of extract
- ❖ Non-clinical safety studies are needed to support Hun (ICHM3)
- ❖ Main Toxicology studies to consider
  - Acute study : Single Dose study
  - Sub acute : Repeat Dose study 14 to 28 days
  - Sub Chronic : Repeat Dose study usually 90 days
  - Chronic : Repeat Dose study duration depends on the intended period of exposure in humans
- ❖ Other product related toxicity studies
  - Ocular test
  - Dermal test
  - Patch test



## CLINICAL STUDIES

Main Purpose of clinical studies

- ❖ To confirm safety and efficacy in human
- ❖ To support product claims
- ❖ To support marketing activity on products efficacy
- ❖ To collect information on adverse effect

To consider when design a clinical studies

- ❖ Randomized, double blind placebo controlled studies to reduce spurious bias
- ❖ Tighter selection inclusion and exclusion criteria
- ❖ Reasonable samples size with Good power
- ❖ A CRO complies to ICH GCP compliance including IRB/ERB
- ❖ Target to publish in high impact international journals

**K&K synergize**  
"KUALA KUALA KUALA KUALA"



UNIVERSITI SAINS MALAYSIA



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## REGISTRATION

10/11/13

portal.tgk.gov.my/product\_search.cfm

Official Portal  
**National Pharmaceutical Control Bureau** Ministry of Health Malaysia  
Biro Pengawakan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia

Product Search (1) Selected Medicines Search (1) Selected Medicines Search (1) Selected Medicines Search (1) Selected Medicines Search (1)

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## MARKETING ACTIVITIES

### EVENTS



SUPPLY SIDE WEST 2013  
(NOV 24-25, 2013)



NATURAL PRODUCTS EXPO WEST  
(MARCH 6-10, 2013)



Vitafoods Asia  
(SEPT 4-5, 2013)

- ❖ Bring together the buyers and supplier that drive the dietary supplement, food, personal care and cosmetic market

### IN THE MEDIA



Dr. Shawn Talbott shares about Tongkat Ali in Natural Cures on Dr. Oz's Show.

### IN THE PUBLICATION



### IN THE PRESS

