

# AGM - CEO Report 2016 Shareholder Update

Hall Chadwick, LvI 40, 2 Park Street, Sydney 4th November 10am

# KEY HIGHLIGHTS



#### **Progression in Cannabis Project - Nanabis**

SUPPLIER AGREEMENT	COMPLETED - APHRIA INC.
MANUFACTURER	COMPLETED - PHARMACEUTICAL PACKING
AGREEMENT	PROFESSIONALS
GMP AGREEMENTS	COMPLETED
AUTHORITY TO POSSESS	COMPLETED – HEALTH NSW
PERMIT AND LICENCE TO IMPORT	IN PROCESS, AWAITING APPROVAL - TGA
TRIAL DESIGN	<b>COMPLETED</b> – NEAF, RESEARCH TEAMS
ETHICS APPROVAL	NORTHERN SYDNEY LOCAL HEALTH DISTRICT (ROYAL NORTH SHORE HOSPITAL) – IN DRAFT, FINALISING SUBMISSION NOW
CLINICAL TRIAL APPROVAL	YET TO BE LODGED- TGA

## KEY HIGHLIGHTS (CONT)



- NANOCELLE™ ARTOVASTATIN (NANOSTAT™) Successful and repeatable outcomes have been achieved in our 5mg trial
- DEPRESSION Significant outcomes with completion of two phase 1 clinical trials using Medlab's NRGBiotic<sup>™</sup> (in market)
- DIABETES & OBESITY Significant outcomes with completion of initial human trials using new
  product developed from Medlab's MultiBiotic<sup>™</sup> (in market)

#### NUTRACEUTICAL SALES - SEPTEMBER 2016 QUARTER GROWTH:

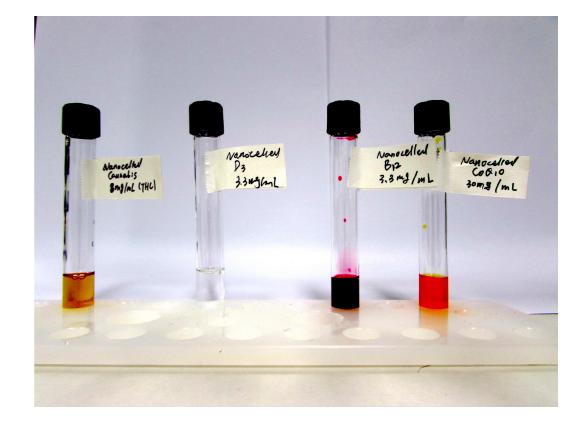
- + 20% over June 2016 quarter
- + 192% over September 2015 quarter
- R&D Tax grant of approximately \$910,000.00 expected.

# Medlab's NanoCelle<sup>™</sup> Platform



#### Medlab's patented delivery system

- Cannabis (Nanabis<sup>™</sup>)
- Atorvastatin (NanoStat<sup>™</sup>)
- Other NanoCelle<sup>™</sup> Active Pharmaceutical Ingredients (API's)









## NanoCelle<sup>™</sup> Cannabis (Nanabis<sup>™</sup>)



Ethics agreement drafted (NEAF) with Royal North Shore Hospital, headed by Professor Stephen Clarke, for one of the most significant studies in treating advanced cancer patients with intractable pain (cancer pain) - awaiting approval

#### PICTURES BELOW SHOW THE PROGRESSION OF NANABIS<sup>™</sup> FROM PLANT TO PROPOSED PRODUCT

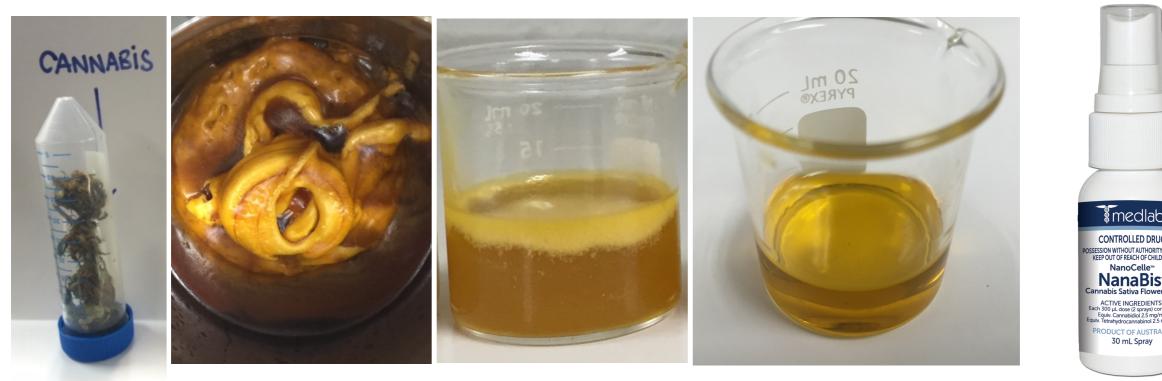
**Concentrated 80% Extracts** 

NanoCelled<sup>™</sup> CBD/THC

Plant

**Cleaned 80% Extract** 

**Proposed Product** 



### NanoCelle<sup>™</sup> Cannabis (Nanabis<sup>™</sup>)



Scheduling is a national classification system controlled by the TGA as to how medicines and poisons are made available to the public. The emphasis is on protecting public health and safety.



#### Medlab's proposed Nanabis<sup>™</sup> will be a Schedule 8 drug (Controlled drug)

A GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

#### Because we are making a Schedule 8 drug – GMP is a must





## NanoCelle<sup>™</sup> Cannabis (Nanabis<sup>™</sup>)



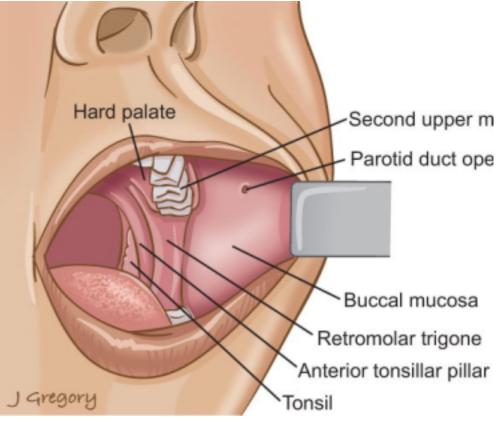
Medlab's pathway is to develop a new Schedule 8 pharmaceutical that can be used alongside or in place of both oxycodone and morphine sulfate (strong pain medication with multiple adverse side affects)

The uniqueness of Nanabis<sup>™</sup>, will be the tiny (sub-micron) particle size, available via spray to the buccal membrane (side of mouth), allowing rapid absorption and release of the medicine, superior to most other delivery platforms eg tablet, capsules and other sprays/liquids. **In other words, NanoCelle<sup>™</sup>.** 

2 sprays of Nanabis<sup>™</sup> will deliver the active cannabis (2.4mg CBD and 2.6mg THC) to the patient.



In collaboration with the University of Sydney, Sydney Medical School (Professor Stephen Clarke - Oncologist at Northern Cancer Institute/Royal North Shore Hospital)



### Why CBD & THC?



#### THC:

- Analgesic
- Anti-spasmodic
- Anti-inflammatory
- Psychotropic

#### **CBD**:

- Anti-convulsant
- Anti-psychotic
- Neuroprotective
- Immunomodulatory

### Other Cannabinoids: CBC,CBG,CBN,THC-V/CBC-V

Medlab's research determined both plant species 1:1 ratio for clinical efficacy

HEMP was not an acceptable plant due to its low yields of active compounds

### Cannabis Research – Cancer Pain



A recent (2007) global meta analysis of the pooled data from 52 studies that met pre defined quality standards showed that pain was prevalent in cancer patients:

- 64% in patients with metastatic or advanced stage disease.
- 59% in patients on anticancer treatment.
- 33% in patients after curative treatment.

"Nearly one of two patients with cancer pain is undertreated."

More than one-third of the patients with pain in the reviewed studies graded their pain as moderate or severe.

## NanoCelle<sup>™</sup> Atorvastatin (Nanostat<sup>™</sup>)

#### **Research outcomes**

- Fast absorption < 1 minute</li>
- Performs as expected to Atorvastatin
- This strongly indicates, superior absorption and utilisation by the body with speed and accuracy.
- Nanostat<sup>™</sup> work is now moving into bioequivalent studies to compare Nanostat<sup>™</sup> to regular Atorvastatin (Lipitor)



## Other NanoCelle™ Active Pharmaceutical Ingredient's



Some 23 API's in prototype

- Insulin
- Testosterone
- Antibiotic
- Progesterone
- Immunosuppressives
- PPI's
- ACEi's

COVERS MOST MAJOR DRUG CLASSES

DEMONSTRATES PORTABILITY OF NANOCELLE<sup>TM</sup> AS A DELIVERY PLATFORM

ALLOWS FOR MULTIPLE COMMERSIALISATION OPPORTUNITIES

PATENT STRENGTHENED & PUBLISHED USPTO SEPT 2016

## Outcome Of Depression Trials & NRGBiotic<sup>™</sup>



- Two Phase 1 human clinical trials successfully completed
- Trial period of 16 weeks
- Patients with depression for 2.5 years on SSRI (SSRI – Standard anti-depressant medication)
- NRGBiotic<sup>™</sup> used in conjunction with the SSRI significantly reduced both validated BDI and OQ45 scores, as opposed to SSRI's by themselves.

# Phase 2a study in the immediate future

Depression program running 8 months ahead of schedule



AUSTRALIA

In collaboration with the University of Queensland school of medicine

### NRGBiotic™



USED IN SUCCESSFUL DEPRESSION TRIALS – NRGBiotic<sup>™</sup> effectively improved medical markers and quality of life in patients diagnosed with Depression.

- Currently in AU and NZ markets
- Patent pending
- The World Health Organisation (WHO) has predicted that by 2030, depression will account for the highest level of disability recorded of any physical or mental disorder in the world.
- Over 1 million adults in Australia experience depression every year, with an estimated 45% of people experiencing a mental health condition in their lifetime.



# Outcomes of Diabetes/Obesity Trial

- Preliminary reports show a 12 week, randomised clinical trial confirms Medlab's probiotic formulation decreased HbA1c levels in study participants.
- HbA1c is the insulin marker used in diagnosing and managing Diabetes

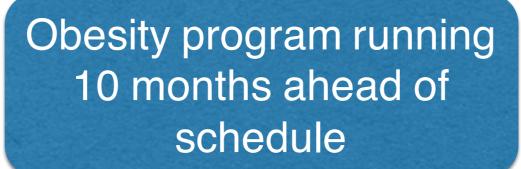
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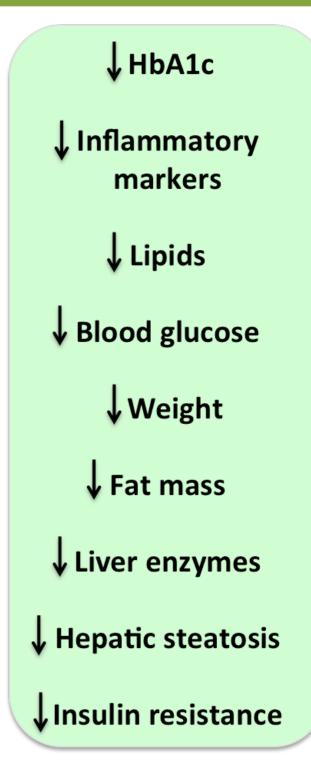
Clinical trial in collaboration with

The Boden Institute, University of

Sydney

 60 Participants split into 2 groups for randomised clinical trial – Controlled group and experimental group





## MultiBiotic™



SUCCESSFUL OBESITY TRIALS – Possible new therapy for pre-diabetic and type 2 diabetic patients.

- Trial product based on Medlab's MultiBiotic<sup>™</sup> which has been patented for Fatty Liver Disease, currently in AU, HK, CHINA and NZ markets
- New product currently in development
- Over 25-30 million people have diabetes in the US, whilst 86 million people have prediabetes (CDC)
- Australia estimates 1.7 Million diabetes patients
- A leading medical report in 2012 reports non-adherence rate of 35% to diabetic medication
   Phase



Phase 2a study in the immediate future

### **Nutraceutical Sales**



#### **Sales Highlights**

- Record sales month October 2016
- September 2016 quarter growth:
  - + 20% over June 2016 quarter
    - + 192% over September 2015 quarter

Over 1200 account holders across Australia & global territories





#### RESEARCH, COMMERCIALISATION AND GROWTH

Medlab's next 12 months centres around growth and escalation in all facets of the business. With principle activities focused on:

- Due to current success, progressing our research programmes faster than originally anticipated
- Growth in the nutraceutical business
- Development of trade agreements with interested third parties (Several already in discussion)
- Bringing Nanabis<sup>™</sup> (NanoCelle<sup>™</sup> Cannabis) to the AU market.

## In Summary



I am very proud of the accomplishments Medlab has achieved in such a short period of time. This could not have been done without our talented, dynamic and dedicated team.

Lastly, I would like to thank you our Shareholders for your ongoing support and without you this would not have been possible.

Social media links are provided for your reference.



Facebook: https://www.facebook.com/medlabAUS/

Instagram: https://www.instagram.com/medlab\_clinical/





Company: <u>https://twitter.com/medlabclinical</u> Sean Hall: <u>https://twitter.com/sean\_medlab</u>

### References



#### Cannabis Research slide:

van den Beuken-van Everdingen MHJ, de Rijke JM, Kessels AG, Schouten HC, van Kleef M, Patijn J, 2007. Prevalence of pain in patients with cancer: a systematic review of the past 40 years. Ann Oncol 18(9):1437-1449.

#### MultiBiotic, Potential Market slide:

Note: Prevalence estimate of 25 million includes 7 million undiagnosed patients. Reference: Diabetes Fact Sheet, 2011, Centers for Disease Control and Prevention. (data includes type 1 and type 2 diabetes).

#### NRGBitoic<sup>™</sup> slide:

Reddy, M. (2012). Depression-the global crisis. Indian journal of psychological medicine, 34(3), 201.