



Medlab Clinical Ltd (ASX.MDC)

# NanaBis™ IND/Trial Acceptance

WEBINAR – 19 January 2021

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# NANABIS™ - OUR LEAD CANDIDATE

## Scientifically optimised to perform better

- 1 to 1 ratio of CBD and THC delivering 2.5mg of each compound, in a nanoparticle (NanoCelle®) for improved bioavailability and absorption
- Commercial strategy is to achieve pharmaceutical registration for NanaBis™ for cancer bone pain, a US\$1.22B global market with 700,000 new patients annually in US, AU, Canada
- Trial programs showing improvement in pain scores:
  - Robust completion of Phase I/II study with primary and secondary endpoints met, demonstrating safety, tolerability and efficacy
  - Observational NanaBis™ study designed to gather real-world evidence continues; 668 of 2000 patients recruited, with 55% improvement in pain scores (as at last audit)
  - Demand via Special Access Scheme continues to grow, establishing proof of concept and generating early revenue
- \*40% improvement in pain scores recorded in Phase I/II study



# WHY IS NANABIS™ IMPORTANT?

EMA STEPWISE  
PAIN GUIDELINES

PAIN SCALE

**Mixed Opioids  
& Adjuvants**

10

**Low Dose Opioids  
& Adjuvants**

5

**NSAIDs & Other  
Non-Opioid Medications**

0



NanaBis™  
Therapeutic  
Entry Point

**64% of all bone cancer patients are currently not helped by existing pain therapy**

- NanaBis™ provides a viable alternative that can delay or alleviate the need to use opioids for pain management
- Effective and safe, preferably used before progression to opioids
- Efficacious in patients with “unmanageable pain” that is not being controlled by opioids and other pain medication

## Acceptance allows initiation of NanaBis™ pivotal Phase III trial in US

- The United States Food and Drug Authority (FDA) has granted Medlab an Investigational New Drug (IND) registration, allowing it to conduct its planned Phase III clinical trial in the US
- Medlab's lead pharmaceutical candidate NanaBis™ is a CBD:TBC therapeutic. It is under development as a non-opioid alternative for the treatment of cancer-induced bone pain
- Acceptance is an important validation of the robust safety and efficacy data supporting NanaBis™, in both clinical and real world settings
- Successful Phase III pharmaceutical trials could place NanaBis™ as the first medical cannabis pharmaceutical containing CBD and THC in the United States



## STRONG CLINICAL VALIDATION

# IND acceptance confirms merit. Strong safety, quality and clinical data collected to-date

- NanaBis™ has now secured support from UK and US government entities
- Positive FDA decision follows the UK National Institute of Health Research (NIHR) announcing support for set-up, recruitment and delivery of UK arm of the Phase III trial
- NanaBis™ will be the only THC:CBD pharmaceutical candidate in Phase 3 ethics-approved human trials for cancer pain management to be registered with the [clinicaltrials.gov](https://clinicaltrials.gov) database

# GLOBAL PHASE III SCHEMATIC (N=360)

## 2:1 RANDOMISATION

- Cease all analgesia
- Start PRN Oxycodone IR

## TITRATION (2 weeks)

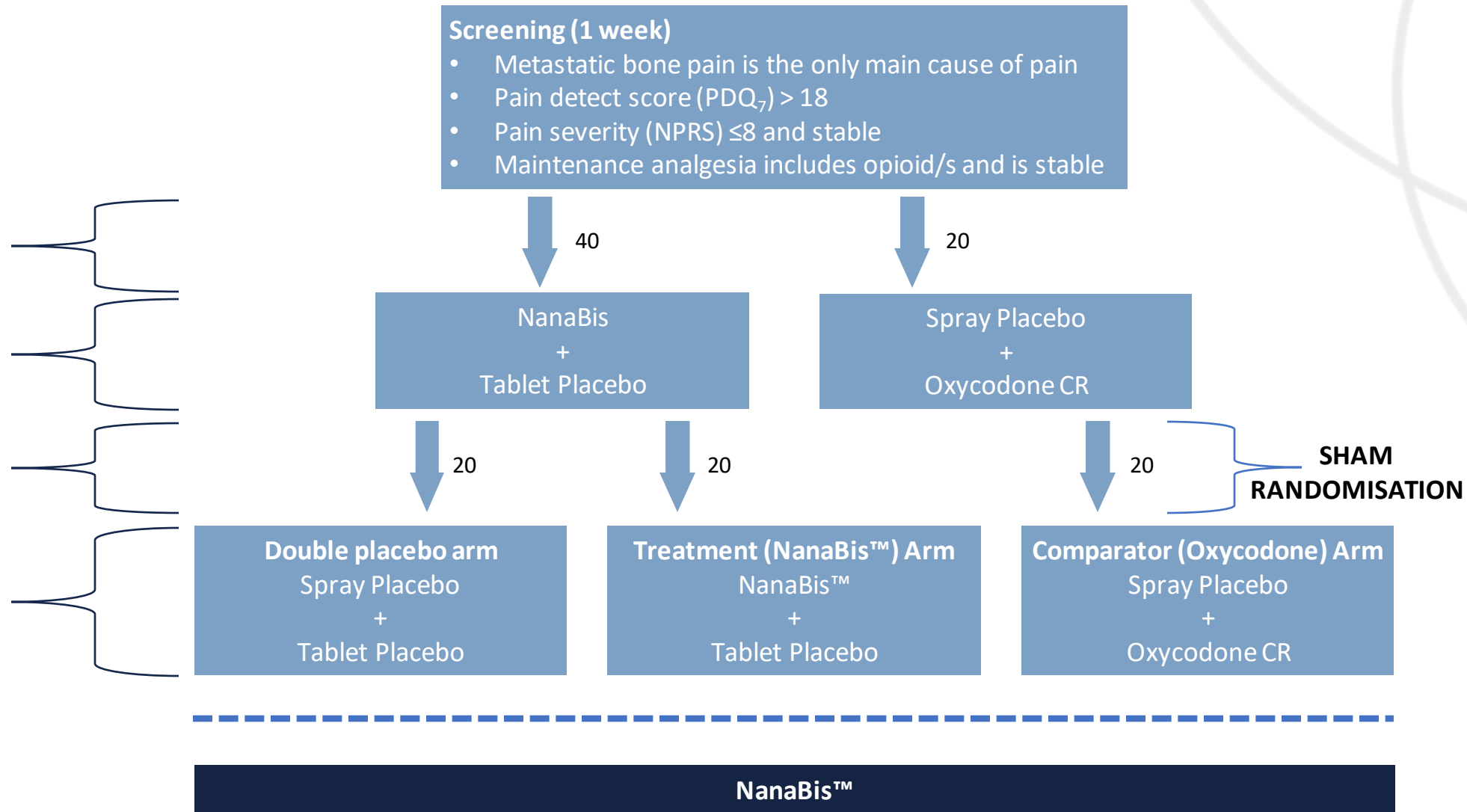
- Opioid withdrawal (SOWS)
- Dose optimization and stabilisation

## 1:1 RANDOMISATION

## MAINTENANCE (3 weeks)

## INTENTION CLOSE

## COMPASSIONATE EXTENSION (12 weeks)



# NANABIS™ ROUTE TO GLOBAL PATIENTS

Phase III trial initiation and filing for compassionate access well-established across three markets, paving way for an established patient base, clinical validation, early revenue and real-world data



## USA

Patient payable  
compassionate use –  
**APPLICATION PENDING**

Phase III trial  
progression –  
**IN PROGRESS**

**US FDA IND APPROVED**

## UK

Patient payable  
compassionate use –  
**UNDER INVESTIGATION**

Phase III trial  
progression –  
**IN PROGRESS**

**UK NIHR SUPPORTED**

## AUSTRALIA

Patient payable  
compassionate use –  
**IN PROGRESS**

Phase III trial  
progression –  
**IN PROGRESS**

# NANABIS™ REGULATORY TARGET

As cancer survival rates increase, so does the need for better approaches to address long-term pain often experienced by cancer patients.



## IMMEDIATE REGULATORY TARGET

### Cancer Bone Pain

**US \$1.22B** Global market (2019)  
with CAGR of 5.4%

Cancer Bone Pain (primarily in Breast, Prostate and Lung) impacts approx. 700,000 new patients (annually) in US, AU and Canada

## FUTURE TARGETS

### Cancer Pain

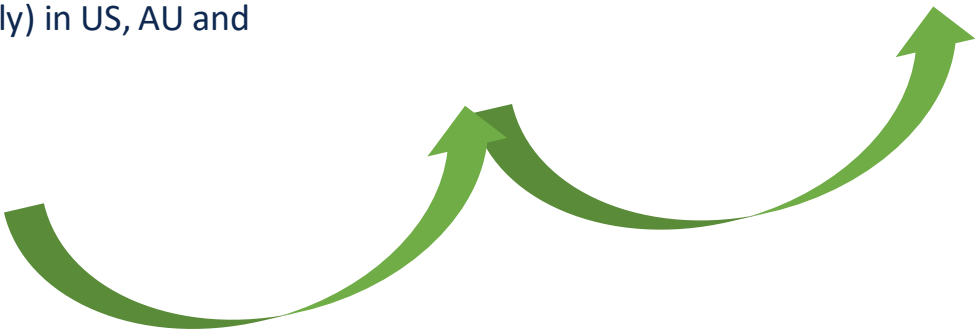
**US \$5.28B** Global market opportunity (2017)

CAGR 4.5%, estimated to be US \$7.54B (2025)

### Chronic Pain

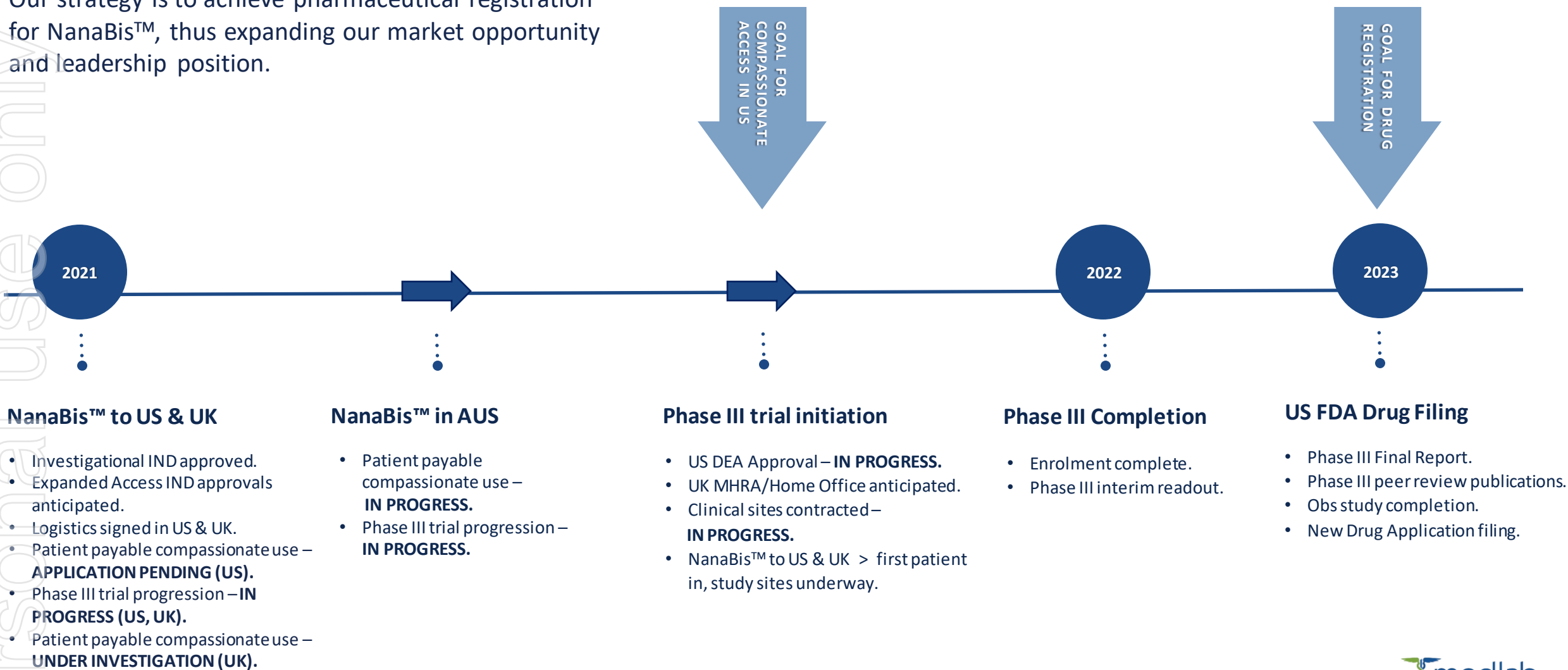
**US \$69.3B** Global market opportunity (2017)

CAGR 6.4%, estimated to be US \$151.7B (2030)



# NANABIS™ NEXT MAJOR STEPS

Our strategy is to achieve pharmaceutical registration for NanaBis™, thus expanding our market opportunity and leadership position.



## SUMMARY

# NanaBis™ 2021 opportunity – a potential company making event

- Safety and efficacy data shows NanaBis™ meets large unmet need in pain management dominated by opioids
- NanaBis™ is positioned to be the global leading medicinal cannabis pharmaceutical focused on pain management
- FDA IND grant now the second major validation of NanaBis™ as a pharmaceutical prospect, following UK NIHR support for Phase III trial
- Material trials success, reinforced by ongoing collection of real-world evidence
- Over 11,200 SAS approved units of NanaBis™ provided to-date
- Leading competitive position in “FDA pathway” strategy





**THANK YOU**

**HEAD OFFICE**

Medlab Clinical  
Units 5 & 6 11 Lord St, Botany  
NSW 2019, Australia

P +61 2 8188 0311  
E [sean\\_hall@medlab.co](mailto:sean_hall@medlab.co)  
M +61 411 603 378

**CALIFORNIA OFFICE (USA)**

Medlab Clinical US, Inc  
30021 Tomas  
Suite 150  
Rancho Santa Margarita,  
CA 92679, USA

P +1 949 636-4123