Medlab Clinical Ltd (ASX.MDC)

NanaBis™ IND/Trial Acceptance

WEBINAR – 19 January 2021

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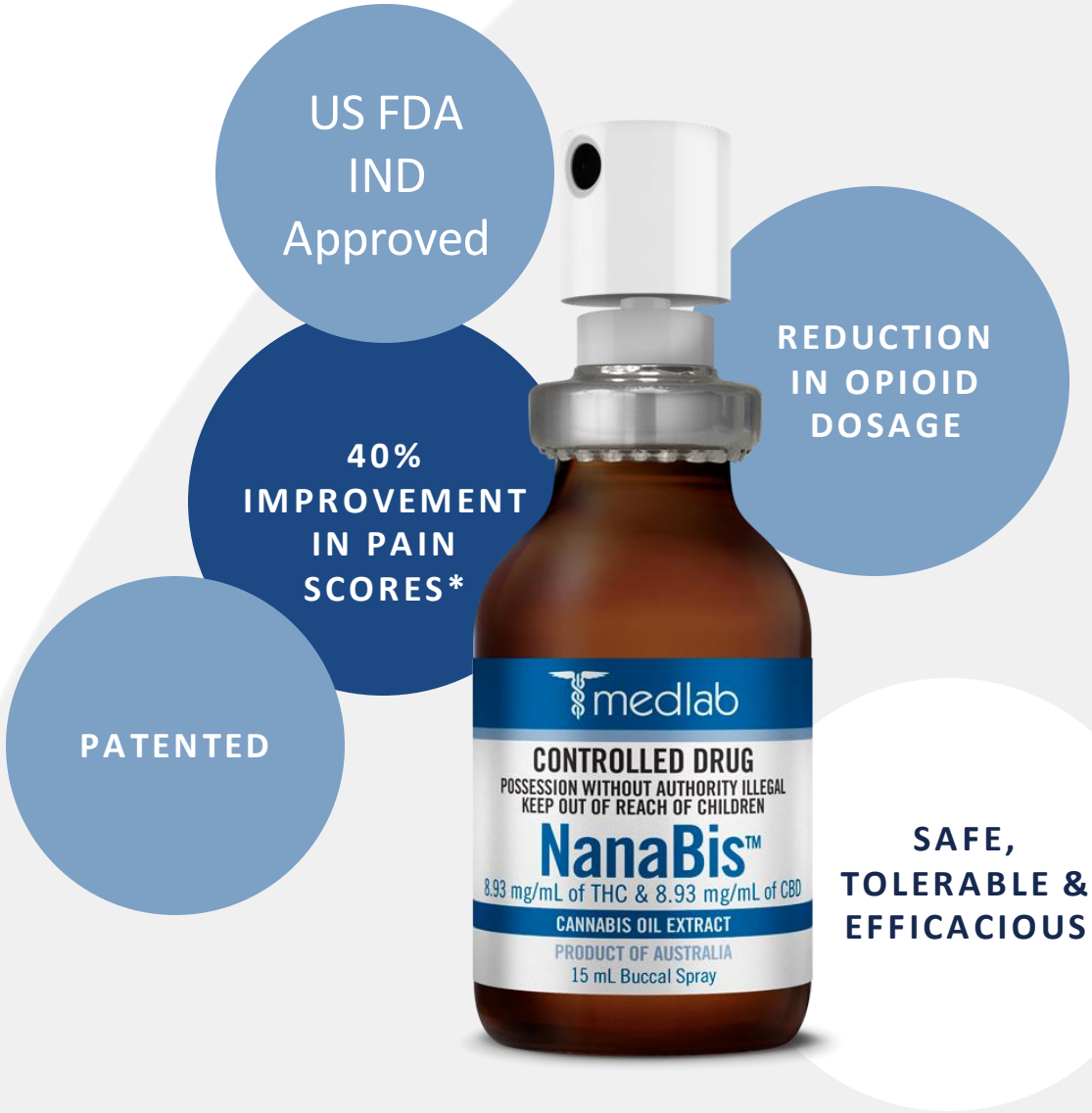
Scientifically optimised to perform better

- 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 clinicialtrials.gov database

GLOBAL PHASE III SCHEMATIC (N=360)

Screening (1 week)
- Metastatic bone pain is the only main cause of pain
- Pain detect score (PDQ_7) > 18
- Pain severity (NPRS) ≤8 and stable
- Maintenance analgesia includes opioid/s and is stable

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)

40 → NanaBis + Tablet Placebo

20 → Spray Placebo + Oxycodone CR

20 → **Double placebo arm** Spray Placebo + Tablet Placebo

20 → **Treatment (NanaBis™) Arm** NanaBis™ + Tablet Placebo

20 → **Comparator (Oxycodone) Arm** Spray Placebo + Oxycodone CR

SHAM RANDOMISATION

NanaBis™

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

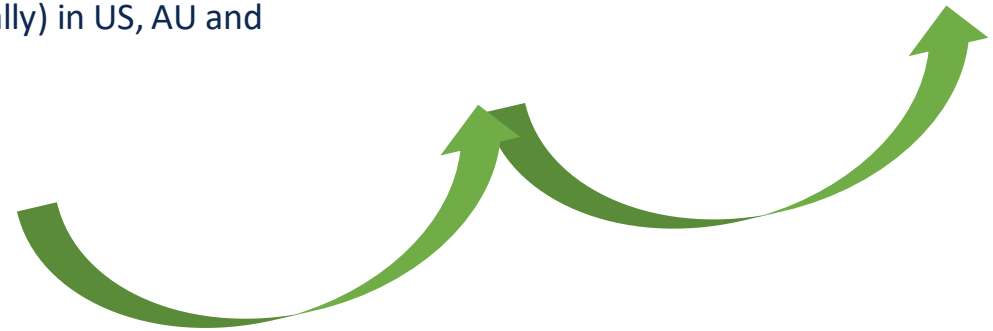
US $5.28B Global market opportunity (2017)

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)



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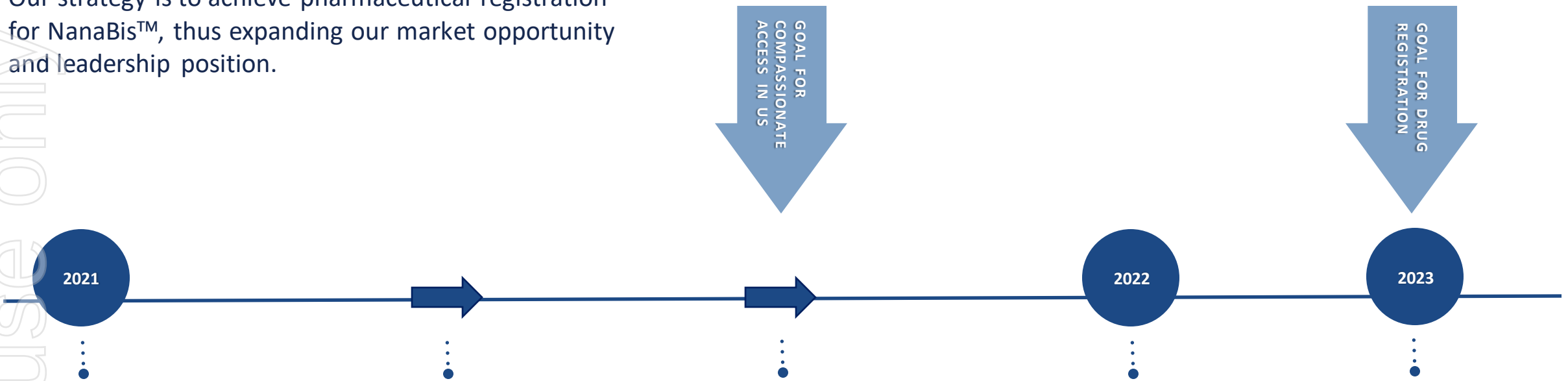
NANABIS™ NEXT MAJOR STEPS

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



NanaBis™ to US & UK

- Investigational IND approved.
- Expanded Access IND approvals anticipated.
- Logistics signed in US & UK.
- Patient payable compassionate use – **APPLICATION PENDING (US).**
- Phase III trial progression – **IN PROGRESS (US, UK).**
- Patient payable compassionate use – **UNDER INVESTIGATION (UK).**

NanaBis™ in AUS

- Patient payable compassionate use – **IN PROGRESS.**
- Phase III trial progression – **IN PROGRESS.**

Phase III trial initiation

- US DEA Approval – **IN PROGRESS.**
- UK MHRA/Home Office anticipated.
- Clinical sites contracted – **IN PROGRESS.**
- NanaBis™ to US & UK > first patient in, study sites underway.

Phase III Completion

- Enrolment complete.
- Phase III interim readout.

US FDA Drug Filing

- Phase III Final Report.
- Phase III peer review publications.
- Obs study completion.
- New Drug Application filing.

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

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