

ersonal use only



Medlab Clinical Ltd (ASX.MDC)

NanaBis™ IND/Trial Acceptance

WEBINAR – 19 January 2021

© Medlab Clinical Limited 2021. All rights reserved.



DISCLAIMER

This presentation has been prepared by Medlab Clinical Limited ABN 51 169 149 071 ("Company"). It does not purport to contain all the information that a prospective investor may require in connection with any potential investment in the Company. You should not treat the contents of this presentation, or any information provided in connection with it, as financial advice, financial product advice or advice relating to legal, taxation or investment matters.

No representation or warranty (whether express or implied) is made by the Company or any of its officers, advisers, agents or employees as to the accuracy, completeness or reasonableness of the information, statements, opinions or matters (express or implied) arising out of, contained in or derived from this presentation or provided in connection with it, or any omission from this presentation, nor as to the attainability of any estimates, forecasts or projections set out in this presentation.

This presentation is provided expressly on the basis that you will carry out your own independent inquiries into the matters contained in the presentation and make your own independent decisions about the affairs, financial position or prospects of the Company. The Company reserves the right to update, amend or supplement the information at any time in its absolute discretion (without incurring any obligation to do so).

Neither the Company, nor their respective related bodies corporate, officers, their advisers, agents and employees accept any responsibility or liability to you or to any other person or entity arising out of this presentation including pursuant to the general law (whether for negligence, under statute or otherwise), or under the Australian Securities and Investments Commission Act 2001, Corporations Act 2001, Competition and Consumer Act

2010 or any corresponding provision of any Australian state or territory legislation (or the law of any similar legislation in any other jurisdiction), or similar provision under any applicable law. Any such responsibility or liability is, to the maximum extent permitted by law, expressly disclaimed and excluded.

Nothing in this material should be construed as either an offer to sell or a solicitation of an offer to buy or sell securities. It does not include all available information and should not be used in isolation as a basis to invest in the Company.

This presentation contains reference to certain intentions, expectations, future plans, strategy and prospects of the Company. Those intentions, expectations, future plans, strategy and prospects may or may not be achieved. They are based on certain assumptions, which may not be met or on which views may differ and may be affected by known and unknown risks.

The performance and operations of the Company may be influenced by a number of factors, many of which are outside the control of the Company. No representation or warranty, express or implied, is made by the Company, or any of their respective directors, officers, employees, advisers or agents that any intentions, expectations or plans will be achieved either totally or partially or that any particular rate of return will be achieved. Given the risks and uncertainties that may cause the Company actual future results, performance or achievements to be materially different from those expected, planned or intended, recipients should not place undue reliance on these intentions, expectations, future plans, strategy and prospects.

The Company does not warrant or represent that the actual results, performance or achievements will be as expected, planned or intended.

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

US FDA
IND
Approved

40%
IMPROVEMENT
IN PAIN
SCORES*

REDUCTION
IN OPIOID
DOSAGE

PATENTED



SAFE,
TOLERABLE &
EFFICACIOUS

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

ersonal use only

FDA GRANTS IND FOR NANABIS™

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 database

GLOBAL PHASE III SCHEMATIC (N=360)

2:1 RANDOMISATION

- Cease all analgesia
- Start PRN Oxycodone IR

TITRATION (2 weeks)

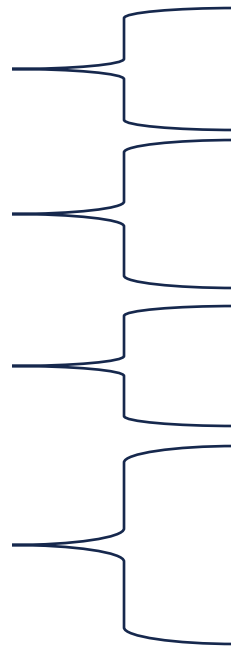
- Opioid withdrawal (SOWS)
- Dose optimization and stabilisation

1:1 RANDOMISATION

MAINTENANCE (3 weeks)

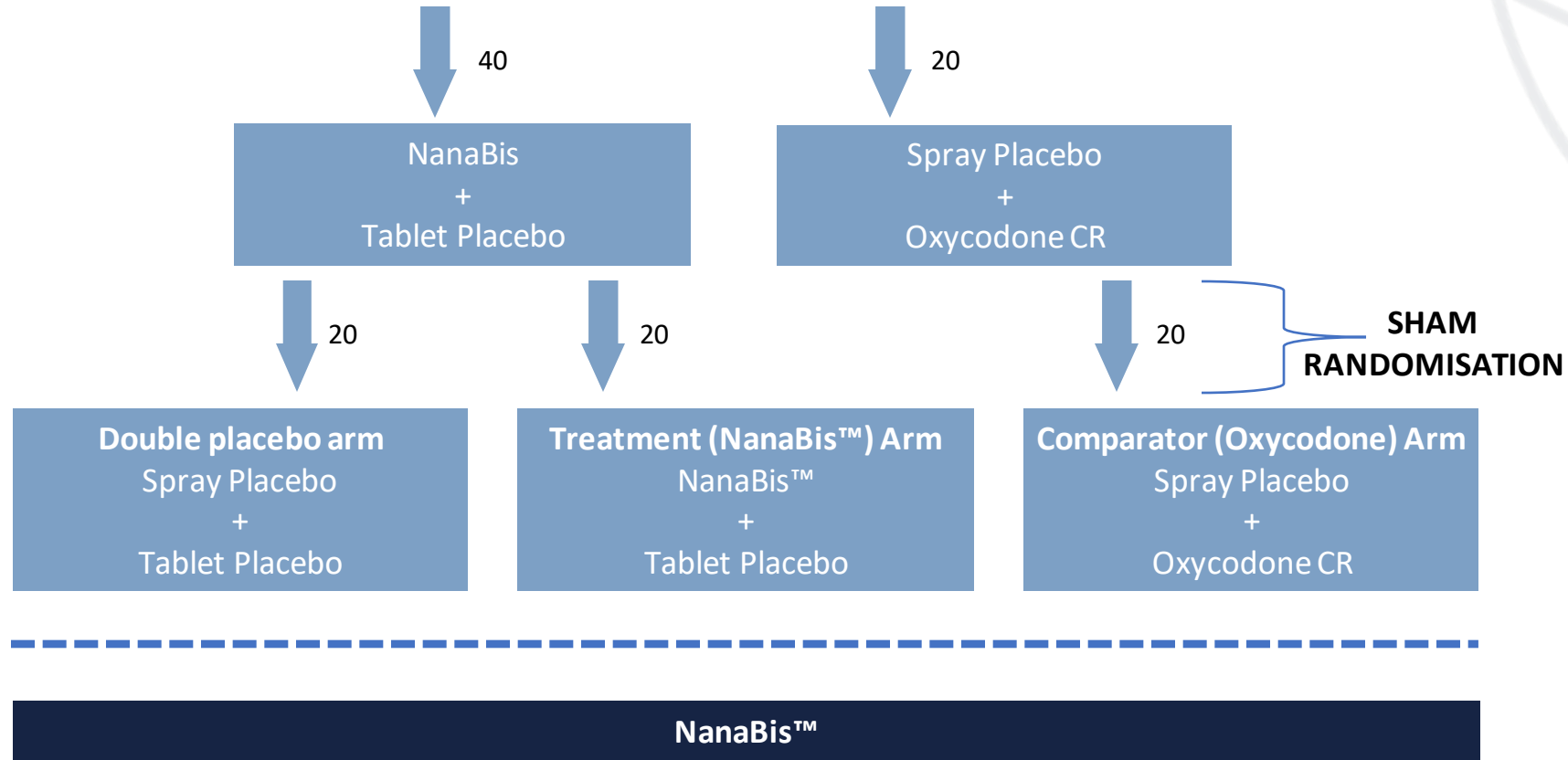
INTENTION CLOSE

COMPASSIONATE EXTENSION (12 weeks)



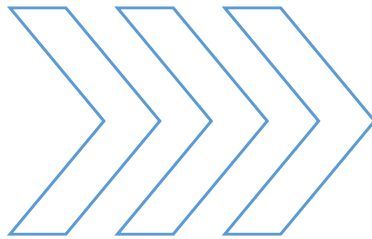
Screening (1 week)

- Metastatic bone pain is the only main cause of pain
- Pain detect score (PDQ₇) > 18
- Pain severity (NPRS) ≤ 8 and stable
- Maintenance analgesia includes opioid/s and is stable



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

ersonal use only

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

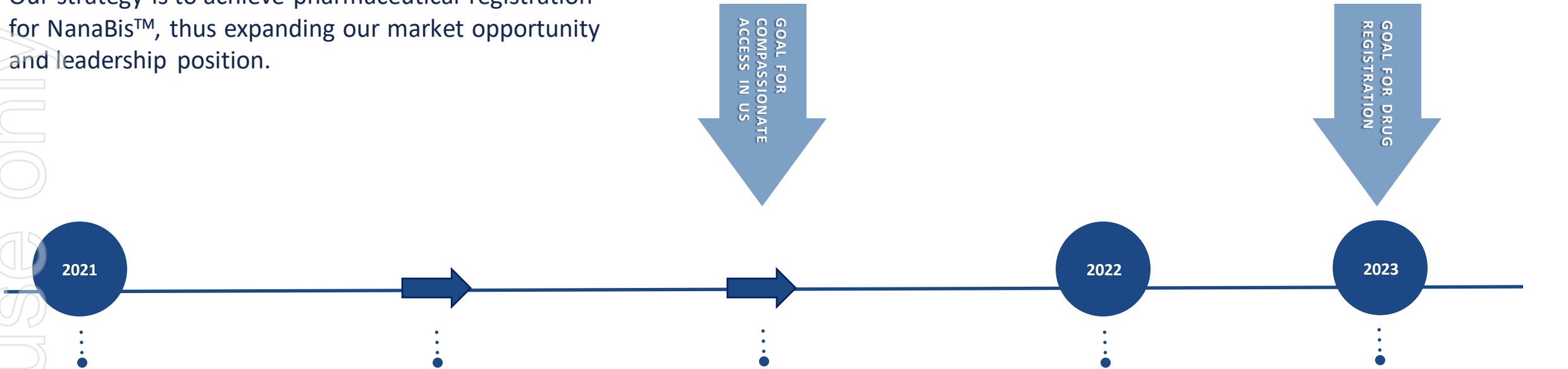
US \$69.3B Global market opportunity (2017)

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.



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.

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



ersonal use only



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
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

ersonal use only