

22 April 2021

Company Announcements Office Australian Securities Exchange Exchange Centre 20 Bridge Street Sydney, NSW 2000

MEDLAB WEBINAR Reminder – NanaBis PIII Trial design

- As per ASX announcement, 8 April 2021 today's webinar presentation attached.
- Understanding NanaBis and PIII trials for AU, US, and UK.
- Registrations open until Presentation commences.

Medlab (ASX.MDC), an Australian Biotech using delivery platforms to enhance medicines particularly in the field of oncology and pain management is pleased to provide a PDF copy of the presentation being delivered by webinar today.

Registration details as per ASX announcement 8 April 2021 – NanaBis Phase III Trial Design, are as follows:

Topic: "NanaBis - an Oro-buccal Administered delta9-Tetrahydrocannabinol (d9-THC) & Cannabidiol (CBD) Medicine for the Management of Bone Pain From Metastatic Cancers" identifier NCT 04808531, Clinicaltrials.gov URL: <u>clinicaltrials.gov</u>

When: 22 April 2021, 10am Sydney Australia, via webinar

Register: http://www.medlab.co/asx

Q&A will be offered at the end of the presentation.

ENDS

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

About Medlab - www.medlab.co

Medlab Clinical LTD (ASX:MDC) is pioneering the development and commercialisation of a delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability.

Medlab's pipeline comprises of small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies.

Medlab's Patented lead drug candidate, NanaBis[™] has been developed for cancer bone pain as a viable alternative to opioid use. Data to date, strongly suggests NanaBis may be equally effective in non-cancer neuropathic pain.

NanaBis[™], as it moves in global P3 trials is public facing on <u>www.clinicaltrials.gov</u> NCT04808531. NanoCelle[©], the patented delivery platform is wholly owned by Medlab Clinical and developed in Medlab's owned OGTR Registered Laboratory. NanoCelle[©] is designed to address known medication problems, addressing global unmet medical needs.

Medlab operates in Australia (Head Office), USA, and the UK. Medlab – *better medicines, better patient care.*

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Medlab Clinical Ltd (ASX:MDC) Scientifically optimised for a better life

Understanding the NanaBis™ Phase III Trial

Investor Webinar Thursday 22nd April 2021

& medlab CONTROLLED DRUG SSESSION WITHOUT AUTHORITY ILLE ANNABIS OIL EXTRAC RODUCT OF AUSTRALI 15 mL Buccal Spray

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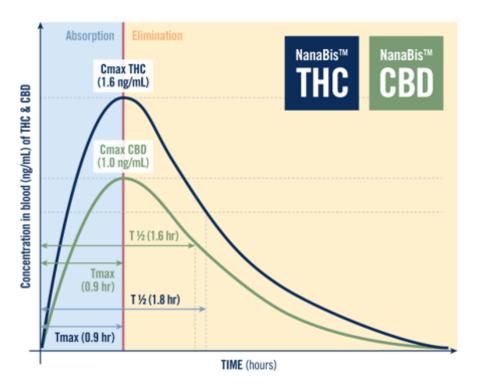




NANABIS[™] **OUR LEAD DRUG CANDIDATE**

A viable non-opioid analgesic...

1 to 1 (equimolar) THC and CBD ratio delivering 2.5mg of each compound, in a nanoparticle (NanoCelle®) for improved bioavailability and absorption.





Its all about delivery

Critical to NanaBis[™] and not seen in other similar offerings is the unique delivery platform, NanoCelle[®]

NanoCelle [®] Patent (as at 22/09/20)			
Jurisdiction	Application no.	Filing Date	Status
Australia	2016226280	02/03/16	Granted
Canada	2978179	02/03/16	Under Examination
Europe	1675948.3	02/03/16	Decision to Grant
New Zealand	735138	02/03/16	Under Examination
Singapore	11201707068X	02/03/16	Under Examination
United States	15/555038	02/03/16	Under Examination
Hong Kong	18103321.4	02/03/16	Under Examination

- NanoCelle[®] is a patented submicron delivery platform used to enhance medicines, via delivery, solubility, and/or efficacy **operating at a** scale of <90nm in particle size of API
- NanoCelle[®] is optimised for buccal absorption, **bypassing first pass metabolism**, a digestive mechanism known to significantly degrade compounds via gastrointestinal route
- NanoCelle[®] allows NanaBis[™] to rapidly cross the buccal membrane and utilises the facial lymphatics allowing for a **rapid systemic response**

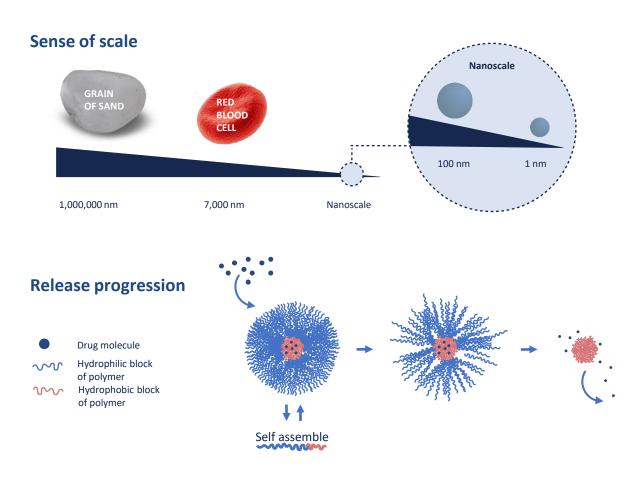
MEDLAB'S PROPRIETARY DELIVERY SYSTEM

NanoCelle[®] creates nano-sized water-soluble particles that enable optimised delivery of particles, overcoming issues with solubility and degradation

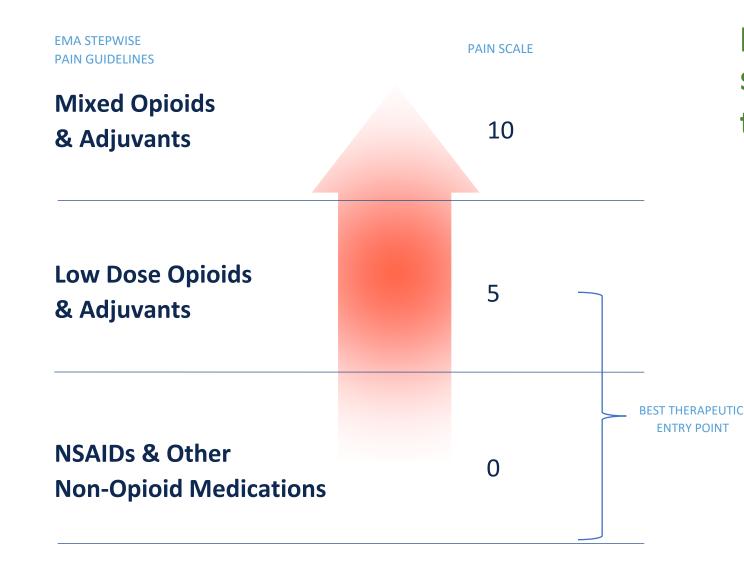
Meaning they can pass more easily into the bloodstream for faster absorption and metabolism whilst employing nontraditional routes of administration

HOW NANOCELLE® WORKS

- Creates an average particle size of 5 nm to approximately 90 nm (depending on payload)
- Consists of an inner hydrophobic core (active agents combined with lipid carrier or itself lipid-soluble) and outer hydrophilic shell (various surfactants)
- Utilises a variety of administration routes (oro-buccal, oral, topical, nasal) for a more optimised delivery of a medicine



WHY IS NANABIS[™] IMPORTANT?



64% of all bone cancer patients are currently not supported 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

A NON-OPIOID ANALGESIC TO TREAT BONE PAIN

Up to 75% of patients with bone metastasis endure crippling bone pain...

- Opioids or opioid derivatives remain the main method of treatment for cancer-related pain.
- Despite the known side-effects of opioids, there's been little advancement in the management of cancer pain.
- Extended patient life increases the burden of pain.
- Abuse and toxicity profiles underpin a need for opioid alternatives.
- Each year in the US, more than 2 million people abuse opioids. In 2016, an estimated 197,970 US hospital visits occurred for opioid-related poisonings.

Despite known problems, opioids are still the gold standard for pain treatment

NanaBis[™] provides a fast-acting and viable alternative to opioids, improving pain management and quality of life

OPIOID EPIDEMIC IN THE US

Opioid Related Deaths In the US*

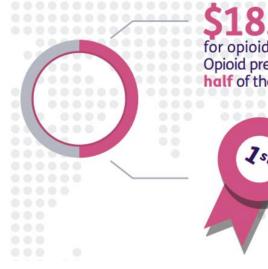


1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015

- Opioids
- Synthetic Opioids other than Methadone Opioid Pain Relievers other than synthetic opioids Illicit Opioids
- Opioid Pain Relievers
- Heroin Heroin

*Based on most up-to-date report from CDC²

There were 33,000 opioid related deaths in 2015



The anticipated D annual market size for opioid drugs in the US by 2020. Opioid prescriptions constitute more than half of the total prescription pain market¹



THE OPIOID EPIDEMIC BY THE NUMBERS



70,630 People died from drug overdose in 2019



1.6 million People had an opioid use disorder in the past year



745,000 People used heroin in the past year



1.6 million People misused prescription pain relievers for the first time



Deaths attributed to overdosing on synthetic opioids other than methadone (in 12 month period ending June 2020)

Sources

1. 2019 National Survey on Drug Use and Health, 2020. 2. NCHS Data Brief No. 394, December 2020. 3. NCHS, National Vital Statistics System, Provisional drug overdose death counts



10.1 million

People misused prescription opioids in the past year



2 million

People used methamphetamine in the past year

50,000

People used heroin for the first time



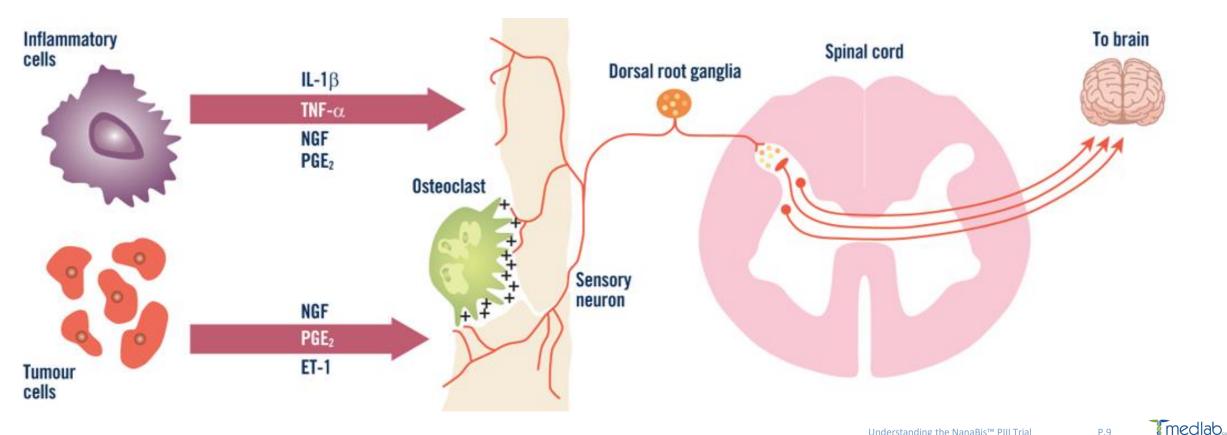
14,480 **Deaths attributed to** overdosing on heroin (in 12-month period ending June 2020)

Understanding the NanaBis[™] PIII Trial



THE SCIENCE BEHIND NANABIS[™] AND METASTATIC BONE PAIN

The pathophysiology of metastatic bone pain involves both inflammatory and neuropathic mechanisms whereby the tumour cells cause hyperactivity of surrounding nociceptors, osteoclasts and immune cells, sensitizes pain afferent fibres and spinal cord pain neurons as well as upregulating descending nociceptive stimulation in the CNS. NanaBis[™] acts at all these levels to reduce the sensitisation and injury of neurons, inhibit descending CNS nociceptive stimulation, and reduce the hyperactivity of the surrounding osteoclasts and immune cells.



NANABIS™ PHASE III TRIAL DESIGN

NANABIS[™] EVOLUTION

	2019	2020	2021	2023
Safety	N:12			
SAD/MAD open label		N:30		
RWE			N:805 / 2000	
Phase III				N:360

OUTCOMES

- Safe
- Tolerable
- Efficacious
- Pain reduction
- Improvement in QoL
- MMeQ reduction



Medlab is currently exploring ethical opportunities for compassionate use in the US and UK



SAD/MAD (RNSH) OUTCOMES

Primary and Secondary endpoints met - proving safety, tolerability and efficacy of NanaBis™

30 advanced cancer, unmanaged pain patients, single ascending dose / multiple ascending dose



Patient subset of breast or prostate cancers with bone metastasis had 40% improvement in pain scores from baseline



Improvements in Quality of Life measures (emotional functioning and insomnia)



MMEq (morphine in milligrams equivalent) significantly reduced - quantifiable measure of efficacy



Maximum concentration in serum to be 54 minutes

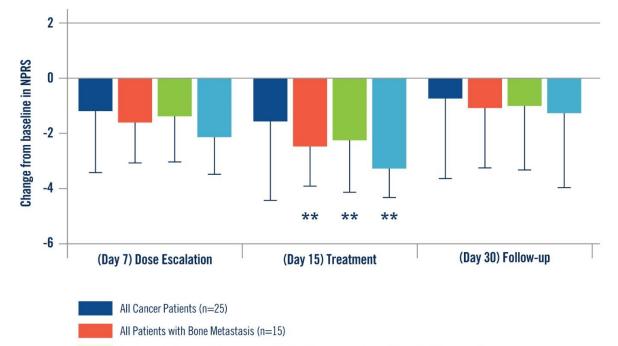
Results released in March 2020





NANABIS[™] DEMONSTRATED A SIGNIFICANT REDUCTION IN MMEQ

 Whilst dose tolerance was achieved at 60% of the maximum interventional requirement, it was demonstrated that cancer patients with bone metastases had significantly less morphine milliequivalents (MMEQ) than patients with cancer <u>but</u> no bone metastases.



Cancer of the Breast / Prostate / Lung / Spine / Melanoma with only Bone Metastasis (n=14)

Cancer of the Breast and Prostate with only Bone Metastasis (n=8)

SAMPLE 1 (all other cancers)					
Variable	Obs.	Mean	Std. Dev.	Min.	Max.
MMEq Day 1	17	214.0588	353.8235	15	1480
MMEq Day 7	14	174.4286	300.4153	15	1150
MMEq Day 13	14	225.2857	442.6972	15	1690
MMEq Day 16	14	212	391.7297	15	1510
MMEq Day 30	13	322.6923	714.5855	0	2650

SAMPLE 2 (Breast & Prostate)					
Variable	Obs.	Mean	Std. Dev.	Min.	Max.
MMEq Day 1	8	61	38.95785	0	126
MMEq Day 7	8	58	38.26225	0	126
MMEq Day 13	8	57.125	37.14619	0	119
MMEq Day 16	8	57.125	36.52568	0	119
MMEq Day 30	8	64.5	51.23057	8	171

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REAL WORLD DATA REPLICATES CLINICAL DATA

12-month observational (OBS) study underway, Data released every quarter

805 of 2000

Australian patients recruited (40.1%)

- Of which 16% in cancer-related pain, 84% in non-cancer-related pain
- Median averages = dosage 4 sprays per day corresponding to a 55% reported reduction in pain (unadjusted)
- Gender distribution = 65% female, 35% male across ages 20 – 80+

Real-world data

Observational Study

- Observational study shows positive results across all criteria to date
- Pain reduction on average remains consistent to prior NanaBis[™] discovery (55%) with reports indicating significant improvements in specific quality of life outcomes such as "general activities", "sleep" and "mood."
- Of 119 patients whom have completed 6-12 months, the company notes sustainability in pain reduction of a long term.

Patient JP "I have completely withdrawn from all opioids and recently walked the dog for a total distance of 1600m." Patient EC "Stopped all medications as NanaBis™ has been able to reduce the pain significantly. I have a backup script for oxycodone which hasn't been filled."

55% improvement in pain scores

Consistent with Phase I/II study



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Case study #2115-001Age66SexMIndicationCancer-related chronic pain (bone pain) in the clinical
context of stage 5 prostate cancer with bone metastases

NanaBis[™] PATIENT Case Study

Month	1 (baseline)	11*	Outcomes
NanaBis™ Dosage (sprays per day)	2-3 sprays (1 bd increasing to 1 tds)	24 sprays (8 tds)	
Average Pain	7	6	14% improvement
% relief from medication (last 24 hrs)	30%	80%	167% improvement
General activity (pain interference)	10	2	80% improvement
Mood (pain interference)	0	2	no improvement
Sleep (pain interference)	7	8	no improvement



Opioid-sparing effect:

33% reduction in Targin dosage by Month 7 after titration to 8 tds (total daily dose of 24 sprays/day)

 HREC:
 0052E_2019

 CTN:
 CT-2019-CTN-02371-1

 ACTRN:
 12619000513112

Results provided under consent. NanaBis™ under clinical investigation as a drug candidate and as such a non-ARTG medicine.





Case study #2025-005Age55SexFIndicationNon cancer-related chronic pain (muscular pain) in the
clinical context of rheumatoid arthritis and fibromyalgia

NanaBis[™] PATIENT Case Study

Month	1 (baseline)	12	Outcomes
NanaBis™ Dosage (sprays per day)	1 spray daily	4 sprays (1 mane, 1 midi, 2 nocte)	
Average Pain	6	6	no improvement
% relief from medication (last 24 hrs)	60%	30%	no improvement
General activity (pain interference)	10	8	20% improvement
Mood (pain interference)	6	2	67% improvement
Sleep (pain interference)	10	4	60% improvement



Opioid-sparing effect:

75% reduction in Oxycontin dosage by Month 12 (from 40mg bd to 10mg bd) with 3-4 sprays NanaBis™ per day

50% reduction in Oxycodone MR (Oxycontin MR) dosage after titration total daily dose of 3 sprays/day (1 tds) by Month 3 until Month 6.

Also reported less Endone usage "very occasional" use by Month 3 compared to baseline at 1 bd prn

Opioid reduction while maintaining pain control compared to baseline and improved quality of life measures in general activity, mood and sleep

 HREC:
 0052E_2019

 CTN:
 CT-2019-CTN-02371-1

 ACTRN:
 12619000513112

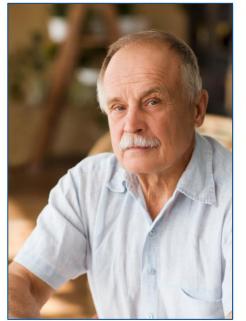
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Results provided under consent. NanaBis™ under clinical investigation as a drug candidate and as such a non-ARTG medicine

* Image of patient is for presentation purposes only

Understanding the NanaBis[™] PIII Trial

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Case study #3004-002Age64SexMIndicationCancer-related chronic pain (bone pain) in the clinical
context of myelofibrosis

NanaBis[™] PATIENT Case Study

Month	1 (baseline)	10*	Outcomes
NanaBis™ Dosage (sprays per day)	1 daily (nocte)	4 sprays (2-4 sprays a day)	
Average Pain	6	1	83% improvement
% relief from medication (last 24 hrs)	50%	90%	80% improvement
General activity (pain interference)	9	3	67% improvement
Mood (pain interference)	9	2	78% improvement
Sleep (pain interference)	10	1	90% improvement



Opioid-sparing effect:

Ceased Targin by Month 4 and reduced Endep to 50mg nocte (66% reduction) at 4 sprays of NanaBis[™] per day

Dosage of NanaBis™ remain stable at 4 sprays per day while maintaining reduced pain scores, improvement in mood, general activity and sleep for the remainder of the study compared to baseline

 HREC:
 0052E_2019

 CTN:
 CT-2019-CTN-02371-1

 ACTRN:
 12619000513112

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Results provided under consent. NanaBis™ under clinical investigation as a drug candidate and as such a non-ARTG medicine

* Image of patient is for presentation purposes only



ADVERSE EVENTS (AE)

- Total <u>real</u> AE circa 9% with total Serious AE circa 6%
- Cohort consists of patients with complex advanced disease – AE were expected
- Considering co-therapy for the patient cohort similar AE are noticed in standard therapy
- A number of patients reported 2 or more AE's
- A number of AE's were dose dependent, as an example high dose use was seen at 8 doses (16 sprays) per day.

Adverse Event Description	Mild	Moderate	Severe
Auditory hallucination	4%	-	-
Burning throat	4%		-
Constipation	8%	4%	-
Dizziness	40%	4%	-
Drowsiness	68%	44%	16%
Dry mouth	4%	12%	8%
Fatigue	4%	20%	12%
Fogginess	20%	8%	4%
Hallucinations	-	8%	-
Impaired Concentration	4%	-	-
Lethargy	-	4%	4%
Nausea	36%	20%	4%
Nightmare	4%	-	-
Numbness bottom lip	4%	-	-
Pain crisis post coming off IP	-	-	4%
Restless at night	Ξ.	4%	-
Vivid dreams	4%	-	-
Vomiting	20%	4%	12%

ab.

NANABIS™ PHASE III TRIAL

NanaBis™

An oro-buccal administered equimolar THC and CBD formulation as monotherapy for the management of opioidrequiring-bone-pain due to metastatic cancer: a phase 3 multi-centre, double-blind, randomized- withdrawal active and placebo controlled clinical study.



Primary

Demonstrate that at the end of the 6-week study period the proportion of responders in the NanaBis™ treated group is significantly greater than the proportion of responders in the placebo group.

Secondary

I) Demonstrate that at the end of the 6-week study period the proportion of responders in the Oxycodone CR treated group is significantly greater than the proportion of responders in the placebo group (study validation).

II) Demonstrate that at the end of the 6-week study period the proportion of responders in the NanaBis[™] treated group is non-inferior to the proportion of responders in the Oxycodone CR treated group.

III) Demonstrate that at the end of the 6-week study period the HR-QoL scores in the NanaBis™ treated group are significantly greater than in the Placebo group and non-inferior to the Oxycodone CR treated group.

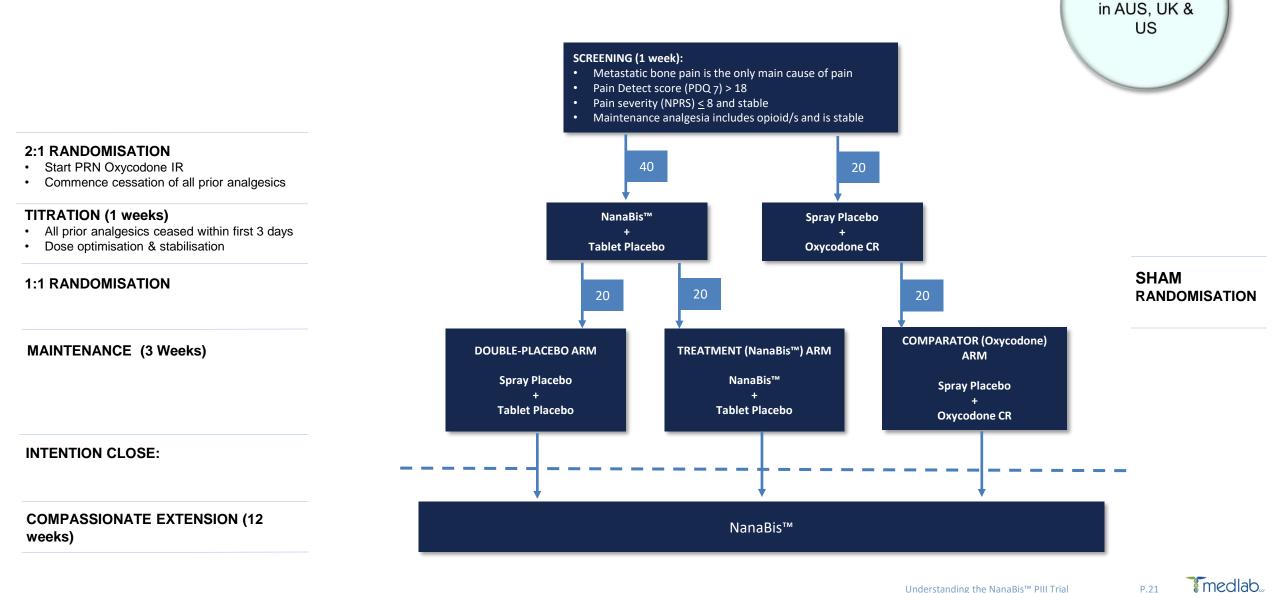
IV) Demonstrate that NanaBis[™] is safe and tolerable.

V) Demonstrate that half or more of the NanaBis[™] treated group preferred further treatment with NanaBis[™] in the open label extension study (note that all participants will be offered open label extension if appropriate).

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GLOBAL PHASE III SCHEMATIC (N=360)

NCT04808531 - Clinicaltrials.gov



Trial locations

NANABIS[™] NEXT MAJOR STEPS

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



2021

- Patient payable compassionate use APPLICATION PENDING (US).
- Phase III trial progression IN PROGRESS (US, UK).
- Patient payable compassionate use UNDER INVESTIGATION (UK).
- Site announcements.

NanaBis™ in AUS

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

- Phase III trial initiation:
 - US DEA Approval IN PROGRESS.
 - UK MHRA/Home Office anticipated.
 - Clinical sites contracted –
 IN PROGRESS.

GOAL FOR COMPASSIONATE ACCESS IN US

- First patient in, study sites underway.
- Ethics Approval.

Phase III Completion

2022

- Enrolment complete.
- Phase III interim readout.

US FDA Drug Filing

2023

GOAL FOR DRUG REGISTRATION

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

NANABIS[™] VALUE CREATION

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



Immediate Regulatory Target	Future Targets	Goal for Drug Registration
Cancer Bone Pain	Cancer Pain	Chronic Pain
US \$1.22B Global market (2019) with CAGR of 5.4%	US \$5.28B Global market opportunity (2017)	US \$69.3B Global market opportunity (2017)
Cancer Bone Pain (primarily in Breast, Prostate and Lung) impacts approx. 700,000 new patients (annually) in US, AU and Canada	CAGR 4.5%, estimated to be US \$7.54B (2025)	CAGR 6.4%, estimated to be US \$151.7B (2030)
We are disrupting t	he opioid market	

"medlab...

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Non-Executive Director

P.25 Understanding the NanaBis[™] PIII Trial



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THANK YOU

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