



1 October 2020

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

MEDLAB TO PRESENT AT KEY US INVESTOR CONFERENCES

Medlab Clinical Ltd (ASX: MDC) is one of very few companies globally with a clinical trial program underway for the use of medicinal cannabis for the treatment of cancer-related pain. The positive data generated in Phase I/II trials for our lead drug candidate NanaBis™ is focused on the potential to provide a viable alternative to opioids.

Medlab's progress with its clinical trials programs and drug registration path in Australian, US & UK are drawing increased international interest and in October Medlab has been invited to two leading industry investor conferences; The Jefferies US Cannabis Summit (Oct 7-8) – a virtual by invitation event with many global leading Cannabis companies involved and the BIO Investor Forum (Oct 13-15).

Dr Sean Hall, CEO of Medlab said "The drug development pathway that Medlab is pursuing, with respect to cannabis related offerings, is a differentiator and is somewhat unique. Investor interest in the US is now growing in biotech-led "FDA pathway" cannabis companies, which have the clinical data to validate quality, safety and medical claims in line with an expected global shift towards regulatory approved products."

The Key Points from our recent ASX Investor Deck posted September 21, 2020 will be presented at these conferences:

- The market opportunity for NanaBis™, targeting the treatment of cancer-induced bone pain.
- Detailed results of the previously reported Phase I/II trial outcomes which met primary and secondary endpoints, achieving a 40% reduction in pain (from baseline) and reduced dosage of opioids.
- Advantageous competitive positioning of Medlab
- Value of the NanoCelle® drug delivery platform which can be applied to a wide-range of known active ingredients and generic drugs. NanoCelle® has been applied to THC:CBD to create NanaBis™ a highly standardised medicinal cannabis product, delivered at sub-micron doses improving absorption and optimising performance.

Attached is a copy of the presentation prepared for the Jefferies Summit, which will then be replicated for the BIO Investor Forum.

INVITATION
OCTOBER 7-8, 2020

VIRTUAL



Jefferies Virtual Cannabis Summit

Please join us for the Jefferies Virtual Cannabis Summit on October 7-8, 2020. We would be delighted to have you join us. The Summit will consist of a variety of panels focused on key topics in the emerging cannabis industry and an opportunity for 1x1 / Group meetings.

Format: Panels and 1x1 / Group Meetings.

Time: 7 AM – 7 PM

Confirmed companies:

Aurora Cannabis Inc. (ACB)	IM Cannabis Corp. (IMCC CN)
Auxly Cannabis Group (XLY)	Jane Technologies (Private)
Avicanna (AVCN)	Kadenwood (Private)
Canopy Growth (CGC)	KushCo Holdings (KSHB)
cbdMD (YCBD)	Materia Ventures (Private)
Cellibre (Private)	Medipham (LABS CN)
Charlotte's Web (CWEB CN)	Medlab (Private)
Clever Leaves (Private)	Neptune Wellness (NEPT)
CV Sciences (CVSI)	Nextleaf Solutions (CSE: OILS – OTCQB)
Delta 9 Cannabis (DN)	Organigram (OGI)
EMMAC Life Sciences (Private)	Plena Global (Private)
Fire & Flower (FAF CN)	Rubicon Organics Inc. (ROMJ CN)
Flowr (FLWR)	Sundial Growers (SNDL)
Green Organic Dutchman (TGOD CN)	Supreme (FIRE)
Greenlane (GNLN)	Thought Leaders, Inc. (Private)
Green Tank (Private)	Valens (VLNS)
GrowGeneration (GRWG)	Vivo Cannabis (VIVO)
Helix Technologies (HLIX)	WeedMD (WMD)
Hexo (HEXO)	

If interested, please email izakoscielny@jefferies.com

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Jefferies

Any interested parties should contact either Jefferies (this is an invite only event) or BIO for registration details.

END

Authorisation & Additional information

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

About Medlab – www.medlab.co

Medlab Clinical Ltd is an Australian based biotechnology company, specialising in oncology related areas, such as pain management, quality of life and delivery platforms. Medlab holds multiple patents and is extensively published. Medlab's lead drug candidate is NanaBis targeting cancer bone pain.

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Medlab Clinical Ltd (ASX.MDC)

Jefferies Virtual Cannabis Summit

OCT 7 - 8, 2020

A differentiated, late-stage drug candidate
addressing unmanageable cancer pain

Sean Hall MD, MBA (clin pharm mtg)



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Corporate Video



<https://vimeo.com/399043450>

TOP VIEW OF MEDLAB



Medlab is an Australian Biotech Public Company (ASX:MDC) focused on advancement in cancer related therapeutics

Core to this focus is NanaBis™ with an advanced nanoparticle delivery platform, NanoCelle® focused on pain management of cancer patients with bone pain

EXECUTIVE SUMMARY:

- Progression thru FDA pathways for a Cannabis drug for cancer pain
- CMC is near completion and strong – Tasmanian Alkaloids (SK Cap) partnered in CMC
- Targeting opioid use – strong data to show opioid reduction
- Cancer pain is a huge market – possibilities for chronic pain (later) – bigger market
- Competitive positioning – www.clinicaltrials.gov shows 13 trials, of which 7 were withdrawn (Sativex®), others include Tetra Biopharma and Aurora
- Key differentiator = NanoCelle® – delivery platform – superior delivery/uptake
- NanaBis™ in market (AU) and gaining revenues
- Experienced team, strong pedigree, history of strong commercial deals

A NON-OPIOID ANALGESIC TO TREAT CANCER BONE PAIN

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

- Opioids or opioid derivatives remain the main method of treatment of 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



WHY NANABIS™?

Scientifically optimised to perform better

- 1 to 1 ratio THC and CBD
- Optimised by the NanoCelle® drug delivery platform for buccal in submicron doses (38nm) in an easy and convenient buccal spray
- High bioavailability, smaller doses and fast absorption into the bloodstream enhances performance and efficacy
- Highly purified, standardised blend ensuring pharmaceutical grade quality: GMP manufacturing and CMC (Chemistry, Manufacturing & Control) standards met

**Strong CMC
(Chemistry,
Manufacturing &
Control) + GMP
manufacturing by
TASALK**

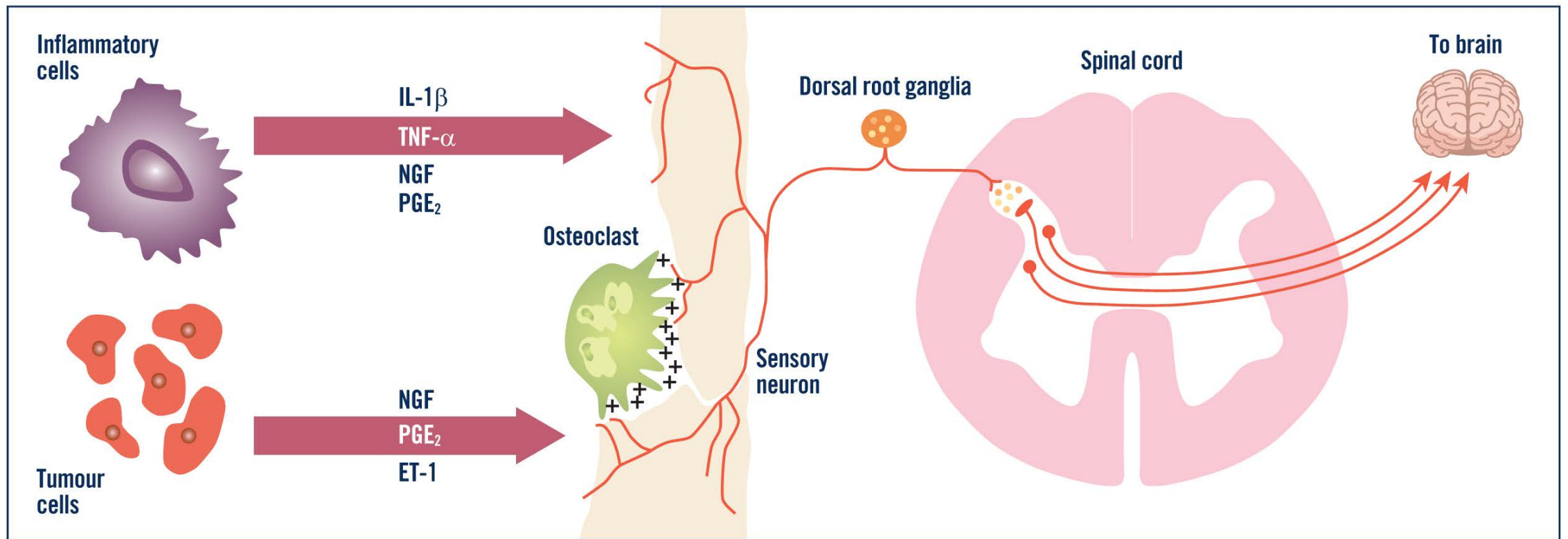
**Robust clinical
trials program
showing
improvement
in pain scores**

**NanoCelle®
delivery tech -
smaller doses
/ better
performance**

**Patent
Portfolio**

CLINICAL EXPERIENCE

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



IT'S ALL ABOUT DELIVERY

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

- NanoCelle® is patented and optimised for buccal absorption, unlike other similar offerings, bypassing first pass metabolism, a digestive mechanism known to significantly diminish compounds at absorption
- NanoCelle® allows NanaBis™ to rapidly cross the buccal membrane and utilises the facial lymphatics allowing for a rapid systemic response

NanoCelle® Patent (as at 22/09/20)			
Jurisdiction	Application no.	Filing Date	Status
Australia	2016226280	02/03/16	Granted
Canada	2978179	02/03/16	Filed
Europe	1675948.3	02/03/16	Under Examination
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	Filed

NanoCelle® Video



<https://vimeo.com/460460554/b2b541a8aa>



TRIALS PATHWAY

WHY IS NANABIS™ IMPORTANT?

EMA STEPWISE
PAIN GUIDELINES

PAIN SCALE

**Mixed Opioids
& Adjuvants**

10

**Low Dose Opioids
& Adjuvants**

5

**NSAID & Other
Non-Opioid Medications**

0



**NanaBis™
Therapeutic
Entry Point**

“64% of all bone cancer patients are currently not helped by existing pain therapy”
(Sep 2007 lit review)

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

NANABIS™ CLINICAL EXPERIENCE

Primary & Secondary endpoints met in Phase I/II study

- 30 advanced cancer 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)
- MME (morphine in milligrams equivalent) significantly reduced - quantifiable measure of efficacy
- Maximum concentration in serum to be 54 minutes
- Results released in March 2020

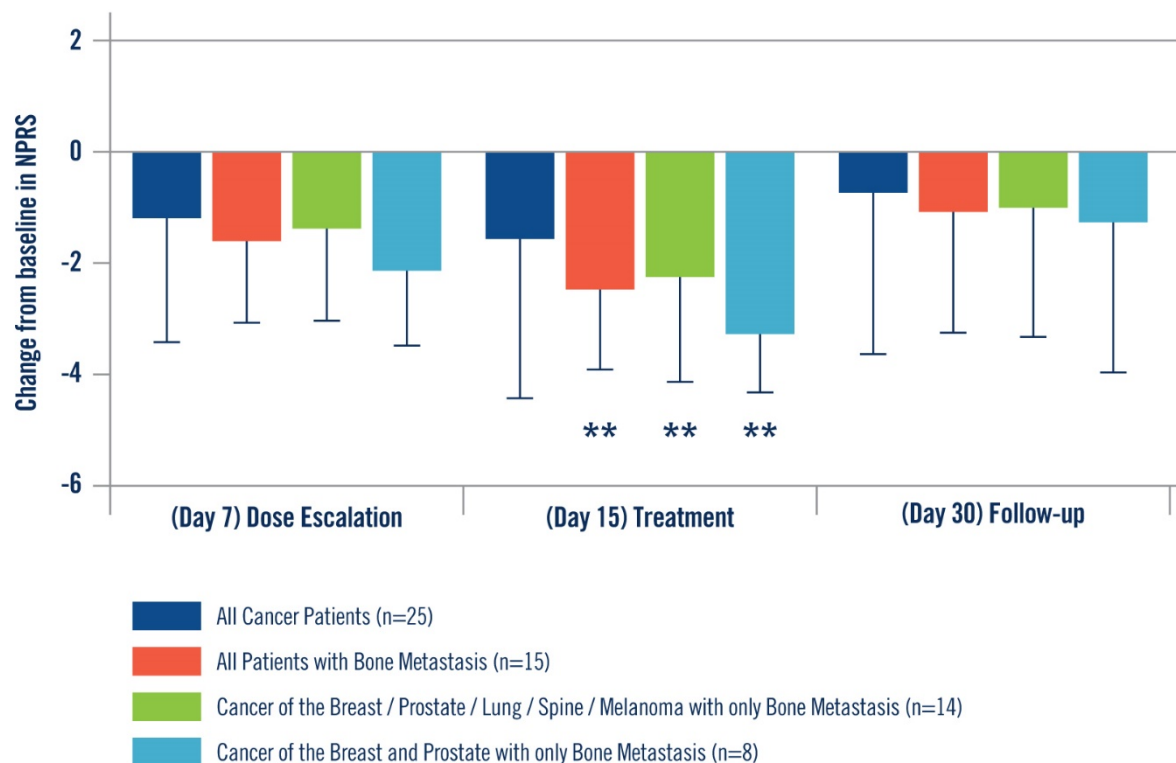


ROYAL NORTH SHORE
HOSPITAL



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 but no bone metastases



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 Cancers with Bone Mets)					
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

REAL WORLD DATA REPLICATES CLINICAL DATA

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

556 of 2000

Australian patients recruited (27.8%)

- Of which 15% in cancer-related pain, 85% in non-cancer-related pain
- Median averages = dosage 4 sprays per day corresponding to a 59.5% reported reduction in pain (unadjusted)
- Gender distribution = 58% female, 42% male across ages 20 – 80+

Real-world data

could expedite path to market

- Observational study is designed to provide real world evidence (RWE)
- Initiated following discussions with the US FDA regarding pathway to regulatory approval
- Strong body of RWE could reduce the total number of patients required to be observed in clinical trials

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.”

59% improvement in pain scores

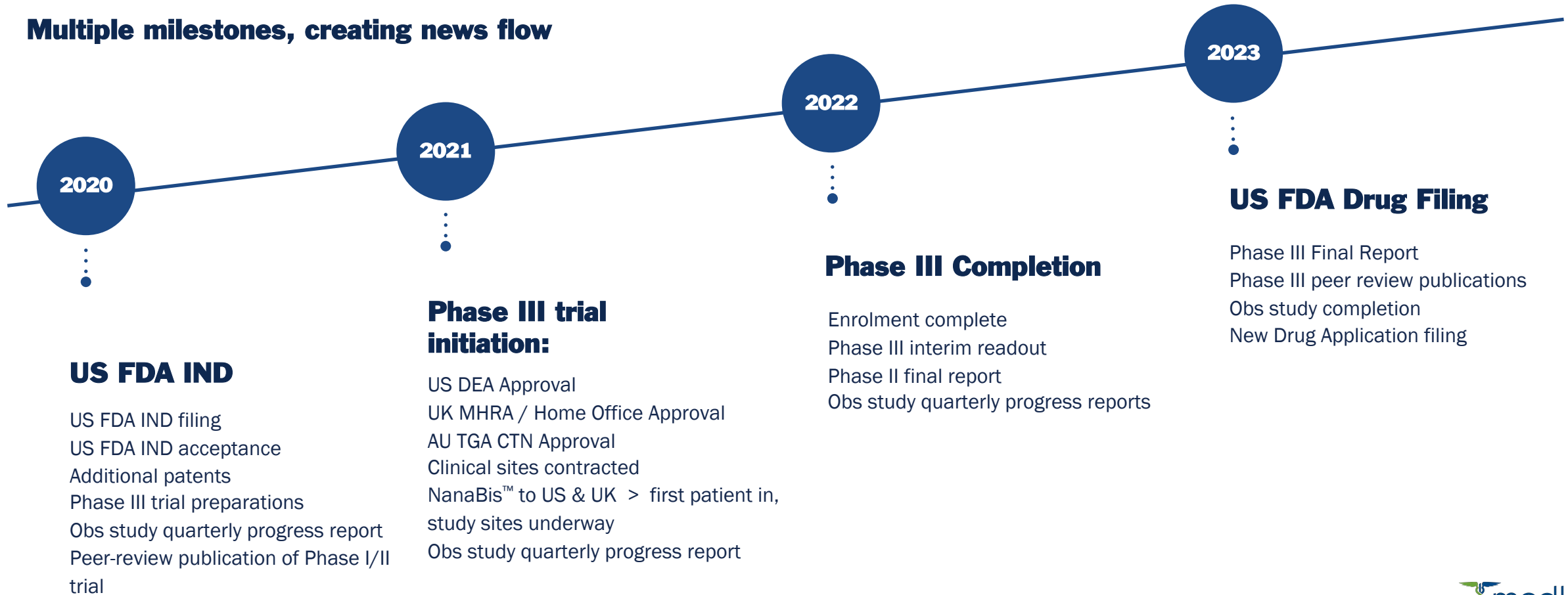
Consistent with Phase I/II study



NANABIS™ NEXT MAJOR STEPS

Our progress validates our product, reduces the risk, increases commercial opportunities, and sets us apart as a world class offering

Multiple milestones, creating news flow



ACCEPTANCE OF US FDA IND AN IMPORTANT VALIDATOR

- Investigational New Drug (IND) application to be filed with the US FDA in late 2020
- **IND acceptance is an important milestone – confirming merit of safety, quality and clinical data collected to date**
- Already seeing concessions from global regulators
- Pursuing a regulatory pathway extends the market opportunity and gives patients and prescribers confidence in quality, safety and efficacy

Unregulated medicinal cannabis

VS

Regulatory approved product

Unknown Ingredients

Unknown Sources

Adulterated Products

Does it impact current medications?

Trust?

Unknowns!



• • •
Evidence of safety

• • •
Evidence of efficacy and claims

• • •
GMP Manufacturing

• • •
Chemistry, manufacturing & control

• • •
Legality

• • •
Reimbursement or subsidies





MARKET OPPORTUNITY

NANABIS™ COMPETITIVE POSITIONING

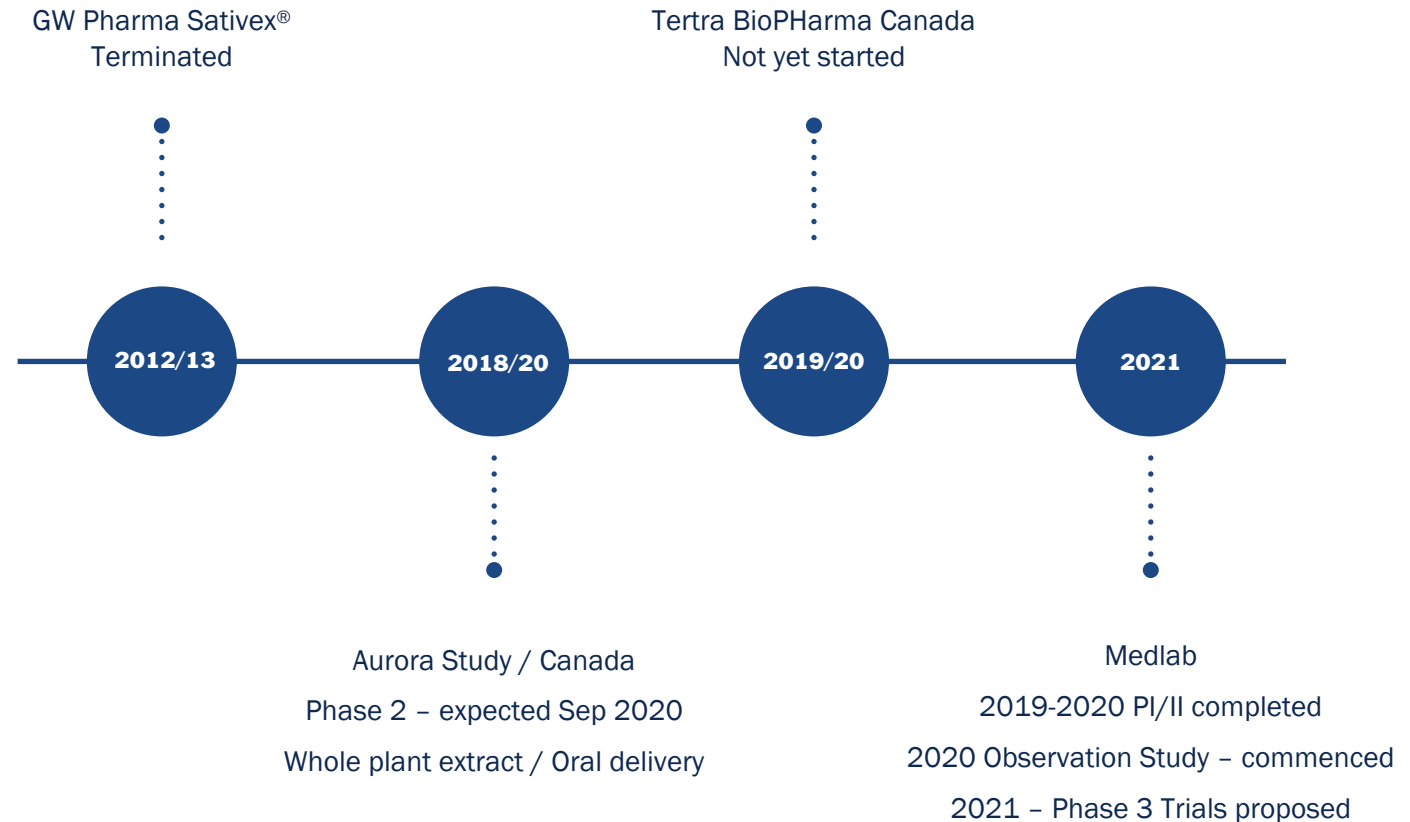
Currently 13 Trials on clinicaltrials.gov with “Cancer Pain” and “Cannabis”

- 7 are for Sativex® completed or terminated
- 4 of the balance “terminated or withdrawn”
- 1 is Aurora with a capsule – Interventional
- Tetra BioPharma – not yet recruiting & little information

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NIH U.S. National Library of Medicine

ClinicalTrials.gov

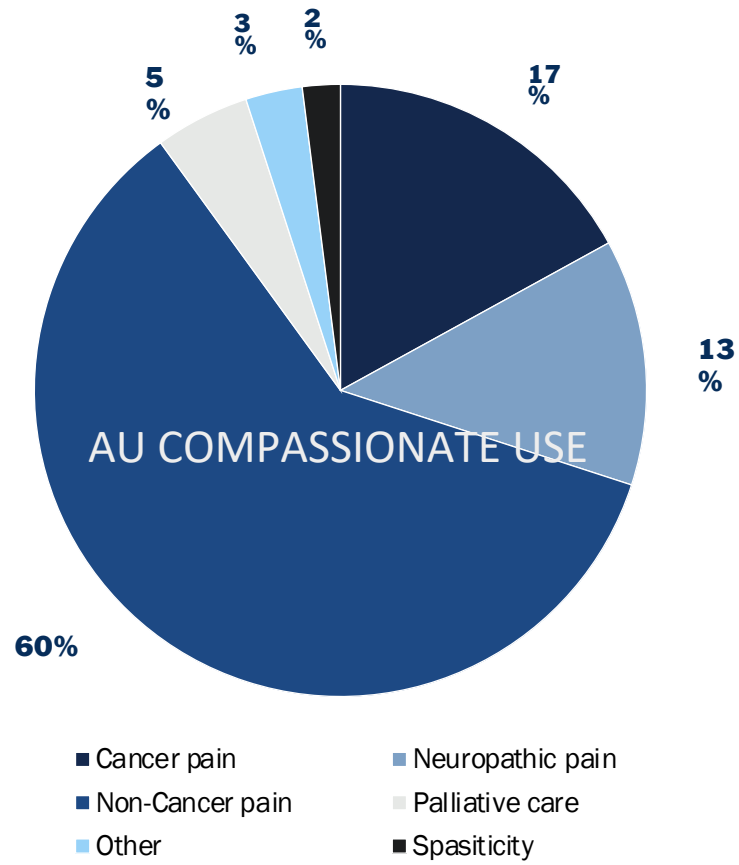


NANABIS™ HAS 1 COMPETITOR, SATIVEX® (FROM PUBLISHED LITERATURE)

- Early data emphasized Sativex® potential. NanaBis™ early data showing improved outcomes
- It is known Sativex® failed at FDA whilst chasing out advanced cancer pain but received approvals in AU and other territories for non-cancer/pain claims
- Sativex® trialed as an adjunctive medicine, whereas NanaBis™ is trialed as a monotherapy
- In comparison to Sativex®, NanaBis™ at 1/2 the dose provided a better PK response
- Due to the NanoCelle® delivery platform, NanaBis™ is NOT subject to 1st pass metabolism
- NanaBis™ unlike Sativex® contains NO ethanol, and NanaBis™ unlike Sativex®, is targeting a very homogeneous group of patients

	NanaBis™	Sativex®
Formulation	1:1 CBD and THC	1:1 CBD and THC
Dosage	Each 140 microlitre spray contains 1.25 mg THC and 1.25 mg CBD	Each 100 microlitre spray contains 2.7 mg THC and 2.5 mg CBD
Ethanol added to formulation		
Delivery route	Oro-buccal	Oral
Delivery platform (patent)		
Target Therapy	Monotherapy	Adjunctive
Bypasses 1 st pass metabolism		
PK Comparison	50% NanaBis™ = 100% Sativex®	50% NanaBis™ = 100% Sativex®
Early Trial published pain reduction	40% above baseline	30% above baseline
Patient target Group	Cancer/Bone metastasis	Cancer pain

NANABIS™ — MARKET OPPORTUNITY WITH SIGNIFICANT GLOBAL POTENTIAL



IMMEDIATE REGULATORY TARGET

Cancer Bone Pain

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

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

FUTURE TARGETS

Cancer Pain

\$5.28B Global market opportunity (2017)

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

Chronic Pain

\$69.3B Global market opportunity (2017)

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





SUMMARY

NEAR TERM CATALYSTS

**JUL –
DEC
2021**

- P3 progression statement
- Continual OBS Monitoring report

**JAN –
JUN
2021**

- US FDA IND approvals
- AU HREC approval
- UK HRA Approval
- US IRB Approval
- US DEA Approval
- NanaBis™ receipted in US and UK logistics
- Site(s) initiation
- 1st patient in
- Continual OBS Monitoring report

**NOW -
31 DEC
2020**

- ✓ US and UK logistics sites for NanaBis™
- ✓ Site(s) agreements
- ✓ Continual OBS Monitoring report
- US FDA Application - EA IND
- US FDA Application - IND
- AU HREC Application
- UK HRA Application

Dr PD: Looking forward to other Medicinal Cannabis variations using NanoCelle® due to the successes of NanaBis™

Dr CM: I prefer to prescribe your products than other oils because of its NanoCelle® technology

SUMMARY

NanaBis™ 2020 opportunity – a potential company making event

- Large unmet need in pain management dominated by opioids
- Material trials success, reinforced by ongoing collection of real-world evidence
- Leading competitive position in “FDA pathway” strategy
- Delivering strong in market results today
- Validates the NanoCelle® platform



A close-up, low-angle shot of a laboratory automation system. A robotic arm with a clear pipette tip is positioned over a 96-well plate filled with blue-capped microcentrifuge tubes. The scene is dimly lit with a cool blue color palette. Two thin, white, curved lines are overlaid on the image, framing the central text.

APPENDIX

COMPANY SNAPSHOT (ASX LISTED MDC)

NUMBERS SNAPSHOT

LISTED 2015	\$0.20
CURRENT PRICE	\$0.185
MARKET CAP CIRCA	\$51M
AV DAILY TURNOVER (2020)	428K

MAJOR SHAREHOLDERS:

SEAN HALL (DIRECTOR)	20.9%
FARJOY PTY LTD	11.0%
DREW TOWNSEND (DIRECTOR)	5.8%
MICHAEL HALL (DIRECTOR)	5.7%
UBS NOMINEES NOMINEES PTY LTD	2.7%
JP MORGAN NOMINEES AUSTRALIA PTY LTD	2.6%

Lead drug candidate is cannabis cancer bone pain

NanoCelle® Delivery has partnering potential

3 IN-MARKET SEGMENTS:

DRUG DEVELOPMENT:

a non-opioid analgesic for CIBP (cancer induced bone pain)



PLATFORM DEVELOPMENT:

a unique submicron delivery platform for improving drug solubility




NUTRACEUTICALS:

Via AU Pharmacies, with several under clinical investigation



NANABIS™ PART OF A BROADER MEDLAB R&D PORTFOLIO

Multiple options for partnering
or in-house development

NAME	INDICATION	PRE CLIN	SAFETY	P1	P2B	P3	COLLABORATORS		
Cannabis/platform									
NanaBis™	Cancer Pain (Bone Met)	Underway							
NanaBis™	Non-Cancer Pain								
NanoCBD™	Anxiety								
NanoCelle® Platform									
NanoStat™	Cholesterol Lowering								
Lidocaine	Pain								
Fexofenadine	Allergy								
Chloroquine	Anti-Malaria/Covid 19								
Metabolomic									
NRGBiotic™	Depression	Awaiting Results							
Mesothelioma	Large Bowel Cancer								

A close-up photograph of a woman in a laboratory setting. She is wearing safety goggles and a white lab coat. Her face is in profile, looking towards the right. A hand wearing a blue nitrile glove is holding a test tube, which is partially visible on the right side of the frame. The background is blurred, showing other laboratory equipment. Overlaid on the image are several thin, white, curved lines that create a sense of motion or design. The text "BOARD AND MANAGEMENT" is centered in the middle of the image in a bold, white, sans-serif font.

BOARD AND MANAGEMENT

BOARD OF DIRECTORS



Dr Sean Hall

MD, MBA (Clin Pharm Mgt)
CEO & Managing Director



Michael Hall

B.Com, CPA Non-Executive
Chairperson



Drew Townsend

B.Com, CA, MAICD,
Non-Executive Director



Laurence McAllister

Non-Executive Director

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Med
Director of Medical Research



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CA, ACSA, GAICD, Chief Financial
Officer, Chief Operations Officer,
Company Secretary



Ian Curtin Smith

Chief Information Officer



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Director of Pharmacovigilance
& Regulatory Affairs



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PhD



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Counsel - Founding Member/CEO
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ERA Consulting Group



Tasmanian Alkaloids

Manufacture and analytical



**Agilex Biolabs Pty
Ltd**

Human Assay, pathology



Nitto Avecia

Analytical



Aphria. Inc

Biomass supplier



THANK YOU

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