ASX : MDC

NanoCelle®

Jefferies Healthcare Conference

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Presented by Dr Sean Hall | CEO

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THE COMPANY

Industry:	Biotechnology
Rev Model:	Partnering
Customer:	Business-to-Business-to-Consumer
ASX:	MDC
Employees:	42

Aegris permittit, crevit vitam (**Translation**: *"Empowering patients, enhancing life")*

Medlab is an Australian headquartered, Biotechnology company currently listed on the ASX.

At the core of what Medlab does and whom it serves, Medlab focuses on clinical indications that we believe represent unmet or inadequately addressed medical needs and represent compelling commercial opportunities.

Our Values

At Medlab, our four core values reflect and shape the Company's personality and the relationships we develop with our people and our clients – they are at the heart of how we work.

- Patient-centric
- Innovative and disruptive
- Agile and dynamic
- Ethical

OVERVIEW

- Medlab listed on the ASX under "MDC" in 2015.
- Over 350,000 NanoCelle® doses supplied in via TGA-listed medicines or unapproved medicines in ethical patient payable, compassionate use programs or clinical trials.
- Australian grant recipients for R&D.
- Robust patent portfolio and published research

NanoCelle®	In-market and In-development	In-development
Core product offering Patented pharmaceutical-delivery platform allowing for a more effective method of administering pharmaceutical products compared to the traditional methods, which include intravenous, intramuscular, subcutaneous, oral (ingested and sublingual), rectal and inhalation. Uses include buccal, dermal and nasal delivery.	**NanaBis™** - Cannabinoids (THC+CBD) with FDA recognized active pharmaceutical ingredients ("APIs") Drug Master Files ("DMFs") for proposed indication of cancer bone pain (bone METs) and larger neuropathic pain populations. Completion expected late 2024. **NanoCBD™** - Cannabinoid (CBD) with an FDA-recognised API DMF with the goal of benefiting mild stress	**MDC2000** - Proposed FDA program using earlier, approved drug substance for depression, expectations of a 505(b)(2) pathway. **Nasal RNA** - Nucleic Acid collaboration with Woolcock Institute at Macquarie University and University of New South Wales in pre-clinical stages for a nasal vaccine delivery utilising nucleic acid leading to new vaccine and/or anti-viral technologies.

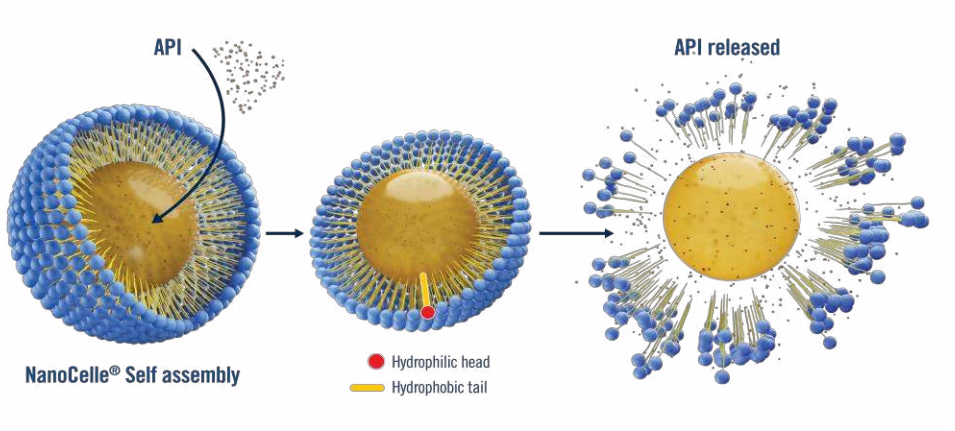
About NanoCelle®

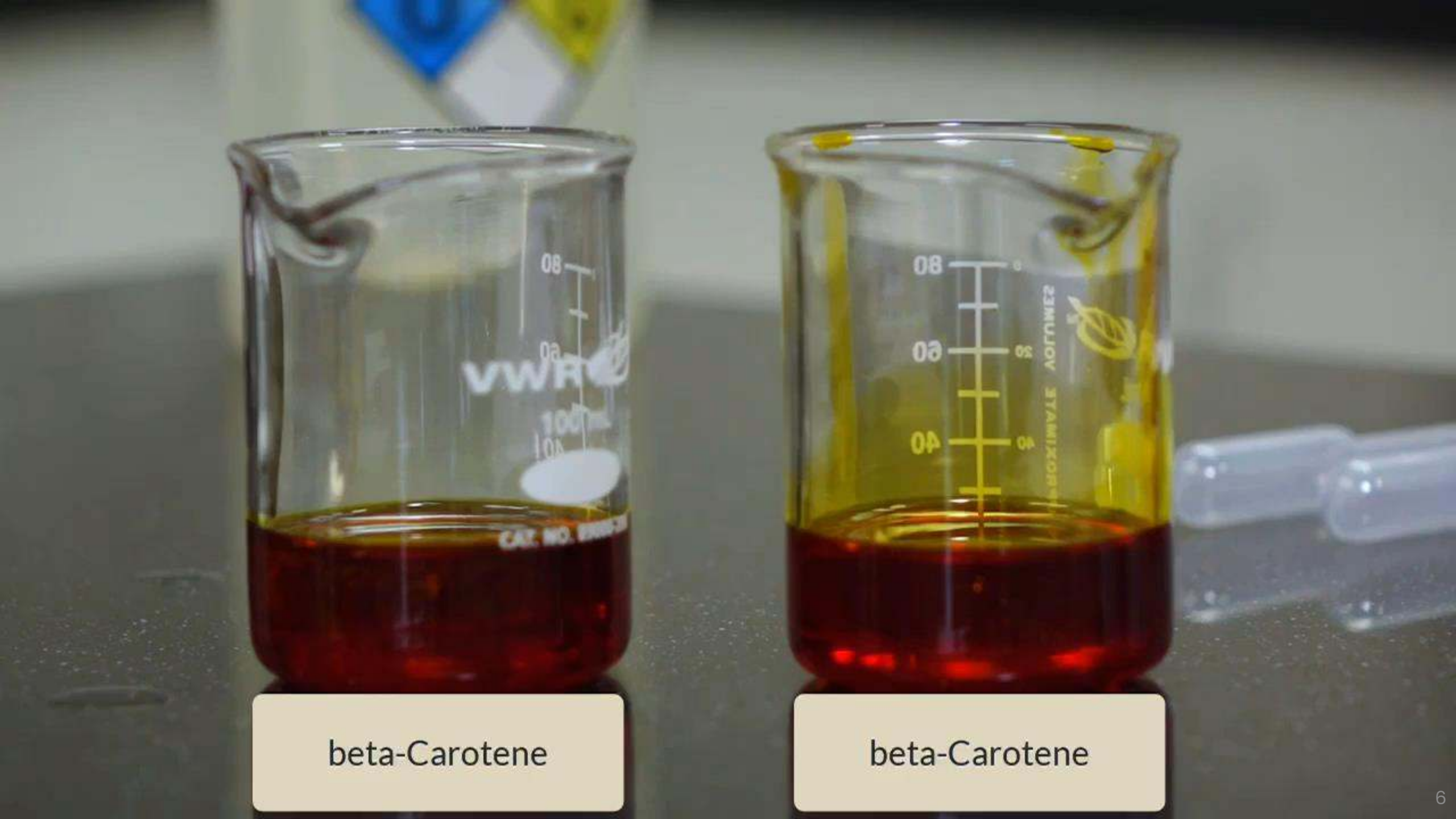
NanoCelle® has a diverse use - principally it is designed to improve a medicines bioavailability and improve patient compliance, this includes a reduced risk profile effectively making the medicine safer and more tolerable.

- NanoCelle® is the registered name of our clinically validated, patent protected delivery platform, that uses nanoparticles to significantly enhance medicines
- NanoCelle® bypasses the gastrointestinal tract, known as 1st pass metabolism, this means we can administer a lot less of a medicine, improve the patient's exposure to harmful side effects, whilst conferring the intended therapeutic benefits
- NanoCelle® is a key differentiator to our programmes, such as the cannabinoid cancer pain program - NanaBis™
- The NanoCelle® technology optimises the bioavailability of medicines, making compounds more easily and rapidly absorbed by the body
- The NanoCelle® process can additionally improve the stability of medicines [Patent Pending].

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)
- Utilizes a variety of administration routes (oro-buccal, oral, topical, nasal) for a more optimized delivery of a medicine




beta-Carotene
beta-Carotene

NANOCELLE® IN CANNABINOID-BASED MEDICINE

Medlab has two investigative offerings:

- **NanaBis™** as a 1.25mg CBD and 1.25mg THC nanoparticle actuation at 140uL
- **NanoCBD™** as a 2.5mg CBD nanoparticle actuation at 150uL

FIRST PASS METABOLISM – IMPORTANT

The first-pass metabolism (also known as first-pass effect or pre-systemic metabolism) is the phenomenon which occurs whenever the drug is administered orally, enters the liver, and suffers extensive biotransformation to such an extent that **the bioavailability is drastically reduced.**

TRANSLATION: Swallowing a medicine is slow and not very bioavailable – it's NOT efficient.

Tablets and Capsules →

NanoCelle® →

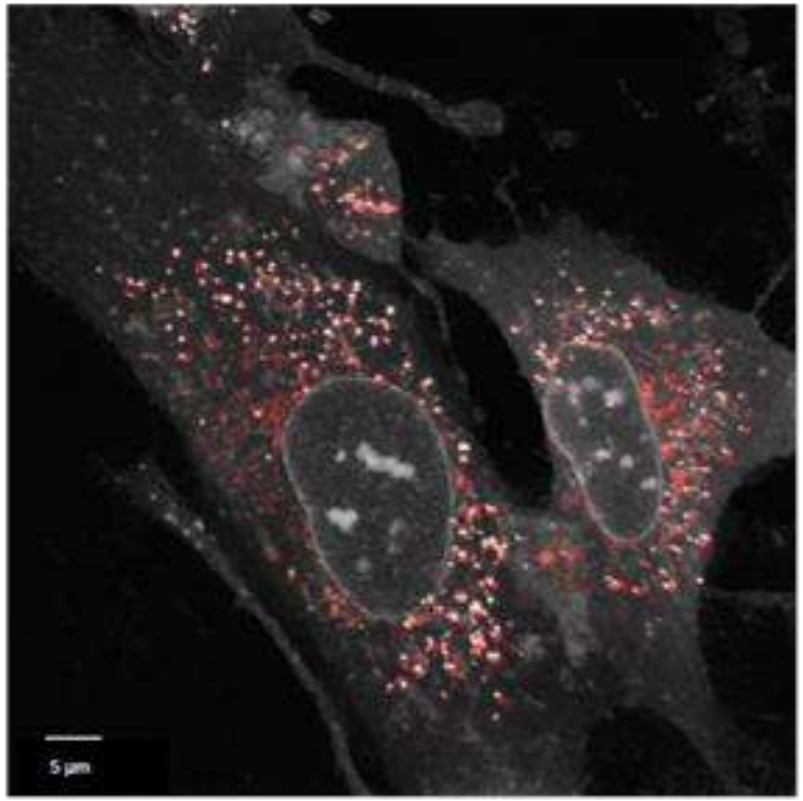
NanoCelle® superior delivery for speed and absorption

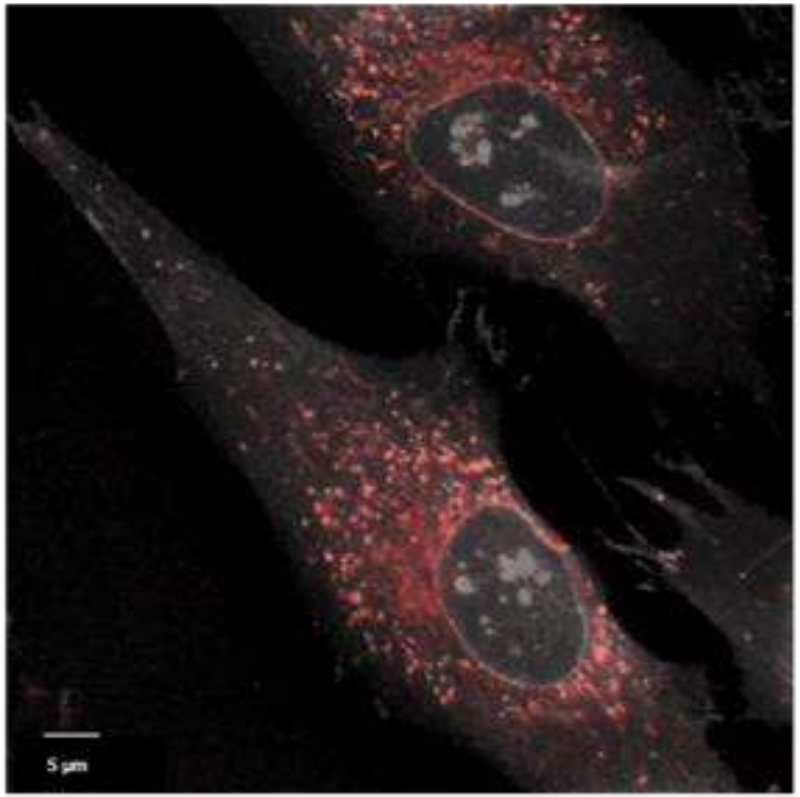
NanoCelle® BYPASSES First Pass Metabolism

ROUTE	SPEED Source: Pharmawiki.in, 2022	BIOAVAILABILITY*	CHARACTERISITICS
Intravenous	30-60 seconds	100%	Most rapid
Intramuscular	10-20 minutes	75≤100%	Large volume may be injected but painful method
Subcutaneous	15-30 minutes	75≤100%	Smaller volume than IM, may be painful
Oral – Ingested	30-90 minutes	5% or more	Convenient, first pass metabolism occurs
Oral - Sublingual	3-5 minutes	c.35% Source: National Library of Medicine, 2012	May avoid first pass metabolism, but may be ingested as well pending the medicine
Oral - Buccal	3-5 minutes	30% or more	Direct absorption into venous circulation. First pass metabolism is avoided
Rectal	5-30 minutes	30<100%	Less first pass metabolism than oral route
Inhalation	2-3 minutes	5<100%	Rapid Onset
Transdermal	Highly varied	80≤100%	Usually slow absorption, lack of first pass metabolism and prolonged duration of action

FAST AND EFFECTIVE ENTRY INTO TISSUE

NanoCelle® has been shown to effectively enter target tissue and release API.





Holotomography imaging overlayed with fluorescence showing Nile Red uptake into fibroblasts. Scale bar represents 5 µm

DEVELOPMENTAL STUDIES

Morphological Analysis with two formulations:
NB = CBD / THC
NBD = 20:1 ratio CBD to THC

- Dynamic light scattering
- Nano flow cytometry
- Atomic force microscopy

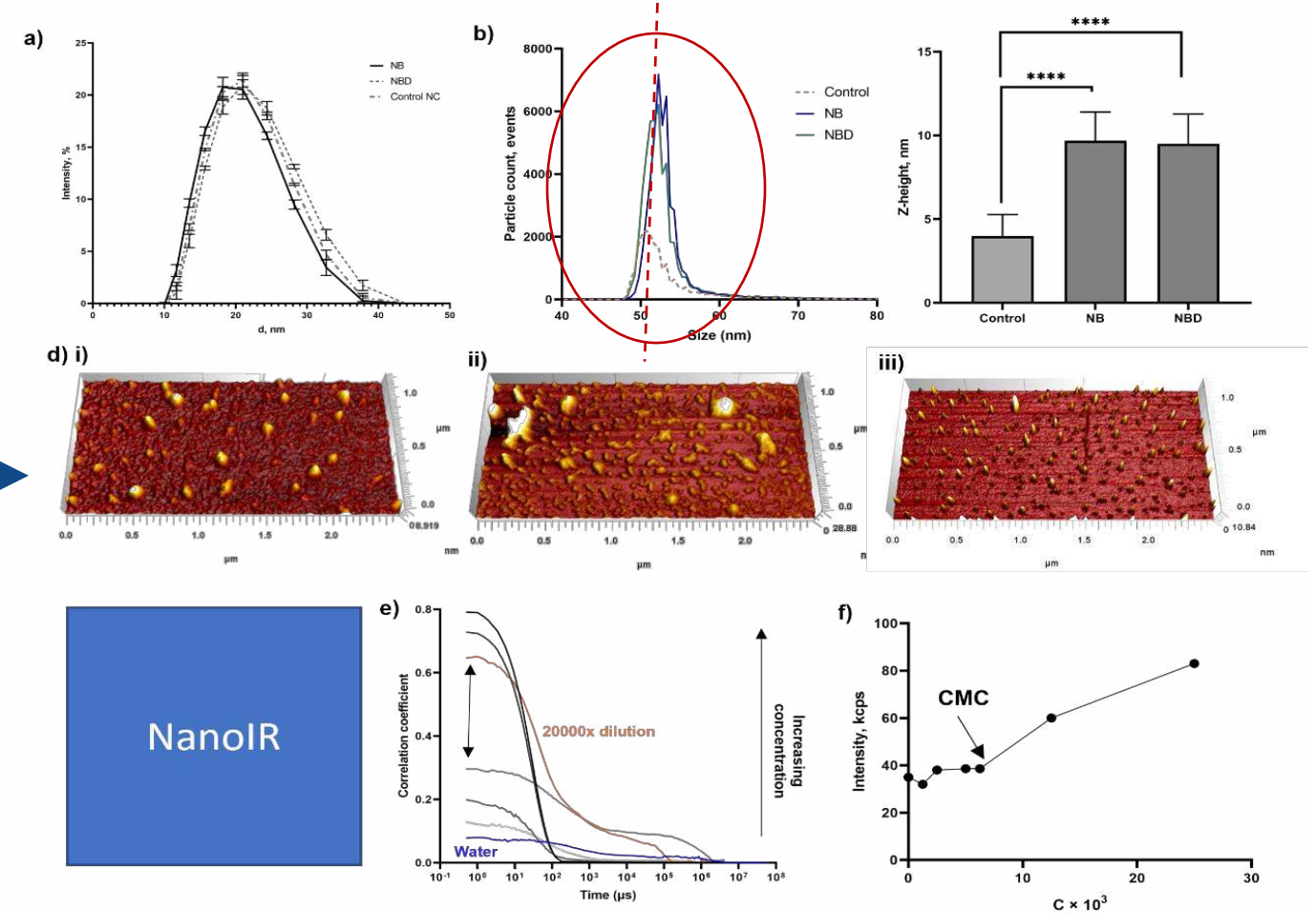


Figure 3: CAPTION

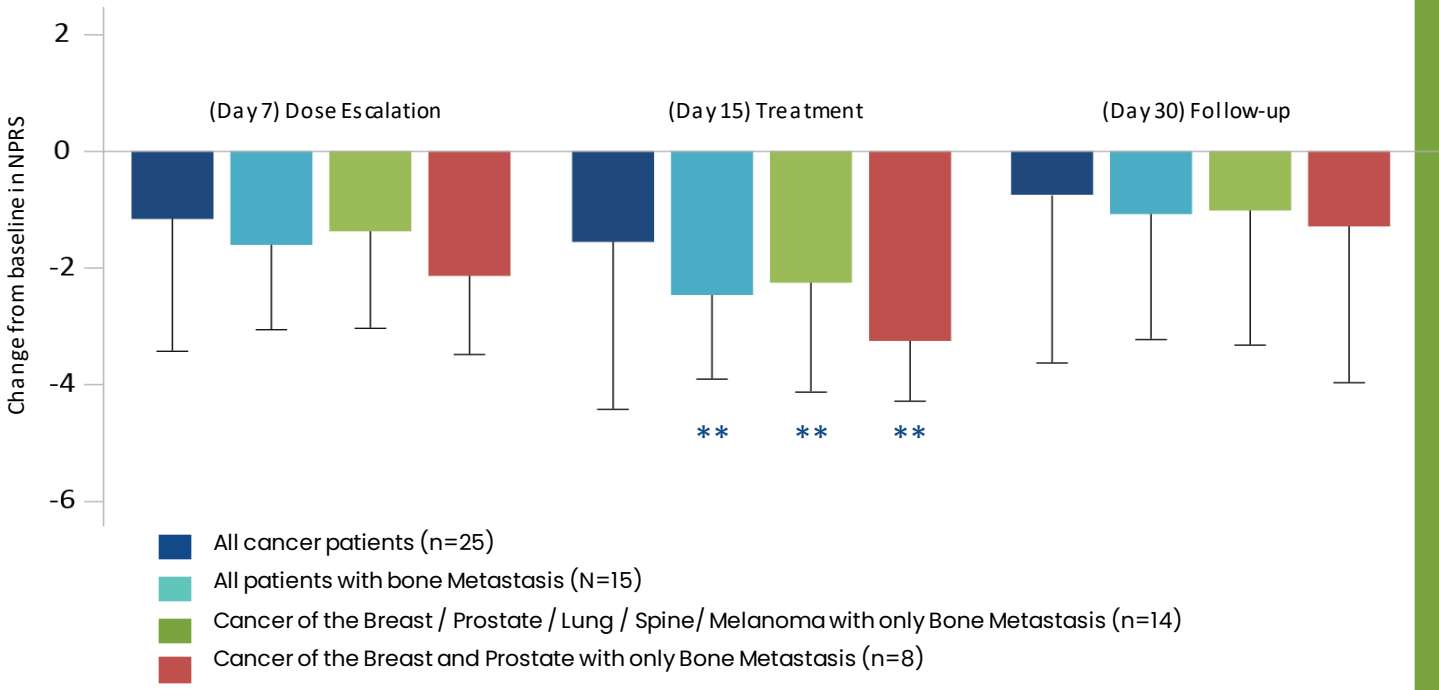
~ 52 nm for NB and NBD

NANABIS™ – ROBUST CLINICAL EXPERIENCE

Primary and 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 (to be confirmed in Phase III trial)
- Improvements in Quality of Life measures (emotional functioning and insomnia)
- MMEQ (morphine in milligrams equivalent) **significantly reduced**
  – quantifiable measure of efficacy

NanaBis™ significantly decreased MMEQ



Real world data replicates clinical data

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

Real-world data

could expedite path to market

Strong body of RWD could reduce the total number of patients required to be observed in clinical trials

1151 of 2000

Australian patients

Of which 15% in cancer-related pain, 85% in non-cancer-related pain

Median averages = dosage 4 sprays per day

Significant improvements in pain, QoL scores and Opioid Sparing

WHY AVOID FIRST PASS METABOLISM?

For cannabinoids, one problem with oral delivery is the high level of first pass metabolism resulting in systemic exposure to the metabolites rather than THC and CBD.

First pass metabolites may not be as effective (medicinally) as THC and CBD and may have more side effects. For example, the first pass metabolite of THC, 11-hydroxy-tetrahydrocannabinol (11-OH-THC) has worse psychiatric adverse reactions than THC.

Oro-Buccal NanoCelle® spray delivery of THC and CBD provides relative levels of first pass metabolite over 10-fold lower than with ingestion, sublingual delivery, or ethanol vehicle oral buccal spray.

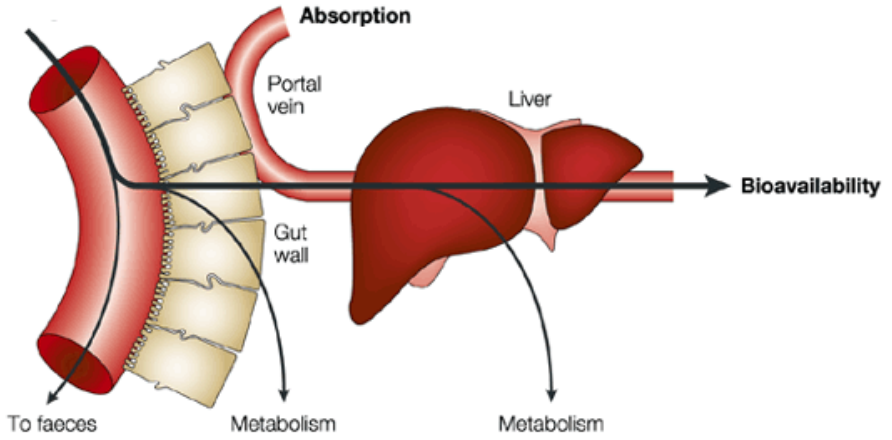
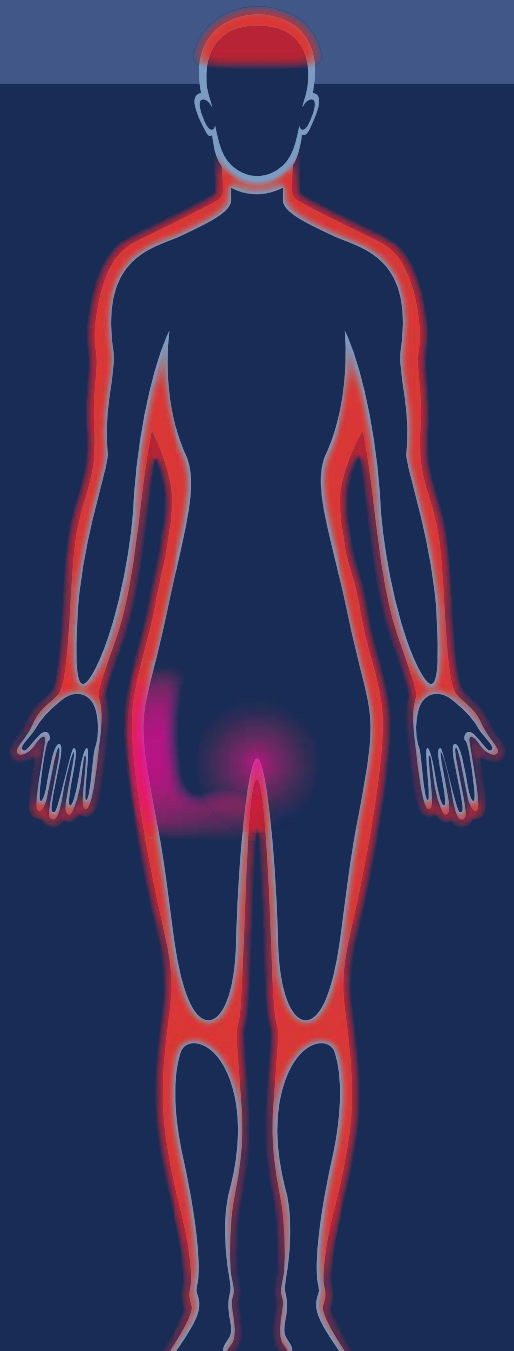


Image Credit: **Nature Reviews | Drug Discovery**

NanaBis™ PATIENT Case Report



Patient Initials	TB
Age	35
Sex	F
Indication	Epithelioid Sarcoma of the Vulva, Lymphedema

Medications pre-NanaBis™	**Dosage:**
Nortriptyline 10mg	1 tablet daily
Ibuprofen 200mg	2 tablets TDS PRN
Paracetamol 500mg	2 tablets QID PRN
Sertraline 100mg	1 tablet daily
Oxycodone 5mg	2 tablets QID PRN
Targin 10/5mg	1 tablet BD
Pregabalin 150mg	1 tablet BD

Date NanaBis™ Commenced	09/08/2021
NanaBis™ Initial Dosage	1 spray BD
Changes in current medications	**Dosage:**
Nortriptyline	ceased Oct 2021
Ibuprofen	ceased Nov 2021
Targin	ceased Dec 2021
Endone	ceased Dec 2021
Paracetamol	ceased Dec 2021
Sertraline	ceased Feb 2022
Paracetamol + Diphenhydramine introduced in Dec 2021 as PRN but rarely used	
Current NanaBis™ dose	6-8 sprays nocte before meals

Quote from the patient

I have chronic global and chronic pain as a result of epithelioid sarcoma. I had 5 excision surgeries in 4 months which all had no clear margins. 6 weeks radiation to vulva, right side groin and right bottom of pelvis. I have contact nerve pain and heightened central nervous system sensitivity where a small pain feels like my body is being crushed when the pain is at its worst. I do not sleep well and have PTSD.

Patient outcomes at time of writing

Currently **pain** has gone **down** from 10 out of 10 to **2 out of 10**

Comment from the patient

"This has been life changing for me and my family. I am now doing things I didn't think I'd ever be able to do again with my level of pain and despair I was in.

I am off all pain meds, no more Endone, Targin and pregabalin. No more feeling like my only choice was to throw myself into a brick wall so my body would focus on a different kind of pain.

My world is free of brain fog and feeling awful each day. I am now able to focus and think clearly and enjoy my days. I am sleeping so incredibly well which has been a massive blessing.

Our family and friends say I have colour back in my face and light in my eyes again.

I am incredibly grateful for this trial and the doctor who has guided me through the process."

Date data collected	26/07/2022
Continuing medication?	Yes

THE IMPORTANCE

EMA STEPWISE PAIN GUIDELINES

PAIN SCALE

Mixed Opioids and Adjuvants

10

Low Dose Opioids and Adjuvants

THC / CBD Therapeutic Entry Point

NSAIDs and other Non-Opioid Medications

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

- THC / CBD 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

NanoCelle® Particle Sizes PoC

Article	Particle Size (nm)	Concentration	Dosage
Ampicillin Sodium Salt (2162016AMP)-antibiotics	12.85	2 mg/mL	0.6 mg/0.3mL
Atorvastatin (1022015ATO)	11.41	10 mg/mL	3 mg/0.3mL
Atorvastatin (1232015ATO)	89.31	0.1 mg/mL	0.03 mg/0.3mL
Atorvastatin (03212017ATO)	14.4	8.3 mg/mL	2.49 mg/0.3mL
Atorvastatin (3152017ATO)	19.37	13.3 mg/mL	3.99 mg/0.3mL
Atorvastatin-25 (12142015ATO25)	14.62	1.67 mg/mL	0.5 mg/0.3mL
Atorvastatin-30 (12142015ATO30)	14.37	1.67 mg/mL	0.5 mg/0.3mL
Atorvastatin (2162016ATO)	12.71	10 mg/mL	3 mg/0.3mL
Beta-Estradiol (2162016EST)-hormones	16.43	1 mg/mL	0.3 mg/0.3mL
Fexofenadine (Telfast™)	10.6	4 mg/mL	1.2 mg/0.3mL
Dexamethasone (2162016DEX)-hormones	13.17	2.6 mg/mL	0.78 mg/0.3mL
Insulin (1022015INS)	3.843	15 IU/mL	4.5 mg/0.3mL
Perindopril Erbumine (2162016PER)-ACEi	12.7	7 mg/mL	2.1 mg/0.3mL
Progestogen (2162016PEO)-hormones	15.48	2 mg/mL	0.6 mg/0.3mL
Rosuvastatin (1022015ROS)-statin	12.19	2 mg/mL	0.6 mg/0.3mL
Rosuvastatin (1022015ROS)-statin	12.19	2 mg/mL	0.6 mg/0.3mL
Sertraline Hydrochloride (2162016SER)-SSRI	15.21	0.5 mg/mL	0.15 mg/0.3mL
Testosterone Propionate (123015TES)-hormones	14.31	15 mg/mL	4.5 mg/0.3mL
CoQ10 (2182916CoQ10)	32.3	100 mg/mL	30 mg/0.3mL
D3	86.3	3333 IU/ mL	5000 IU/0.3 mL
D3 & K2 (2182016D3K2)	28	3333 IU+150mcg/0.3 mL	1000 IU+45 mcg/0.3 mL
Melatonin (2182016MEL)	23	8.3 mg/mL	2.5mg/0.3mL
Cyanocobalamin B12	24.8	3333 IU/ mL	1000 IU/0.3 mL
MethylcobalaminB12 (2182016B12)	18.9	3333 IU/ mL	1000 IU/0.3 mL
NanaBidial™(<1:20 THC:CBD (20mg/mL CBD and less than 1 mg/mL THC)	20.13 nm	8.3 mg/mL	2.5mg/0.3mL
NanaBis™1:1 THC:CBD (8.33mg/mL THC 8.33mg/mL	33.33 nm	8.3 mg/mL	2.5mg/0.3mL
NanoCBD™(16.66 mg/mL CBD)	21.99	5mh/0.3mL	5mg/0.3mL
Chloroquine	31.5 nm	5mg/mL	-

SUMMARY – NANOCELLE®

As buccal spray, API's bypass first pass metabolism.

Convenient, easy to use and **PATENT** protected. NanoCelle® portfolio spread from early stage to late stage.

For use as buccal, nasal or topical delivery.

Strong, scalable & transferrable technology – targeting big markets with robust rationale, protection and differentiation.

THANK YOU

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