ASX:MDC

# Annual General Meeting

30 September 2022

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# Chairman's Address

Delivered by Drew Townsend

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

# Resolutions

- **Ordinary Resolution 1** - Adoption of Remuneration Report
- **Ordinary Resolution 2** - Re-election of Mr. Drew Townsend as Independent Director
- **Ordinary Resolution 3** - Appointment of Mr. Mohit Gupta as Independent Director

# CEO Update

**Delivered by Dr Sean Hall**

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

**Medlab** is a disruptive, Australian headquartered, Biotechnology company currently listed on the ASX, whilst undergoing dual listing to Nasdaq.

# Key Strategic Achievements & Milestones

## Over the past year, we have made several key strategic achievements and milestones, including:

1. Partnered with a United States-based biosynthetic partner for FDA-recognised DMFs for the two cannabinoids, CBD, and THC (Dronabinol).
2. Partnered with a strategic United States-based manufacturing company for (1) Chemistry, Manufacturing, and Controls (CMC) development for the cannabinoid programs; (2) manufacturing optimisation and scale; and (3) future commercial scale manufacture.
3. Strengthened our datapoints from our Australian data bank to understand sustainability of the NanaBis™ program over time (6-12 months), and safety as it relates to adverse events and in relation to other opioid medications.
4. Secured global patents in all several territories, including Australia, Canada, several European Union countries, New Zealand, the United States and Hong Kong for the NanoCelle® delivery platform until 2036.
5. Entered agreements with United Kingdom partners for Compassionate Use of the cannabinoids to at-risk patients.
6. Entered agreements with Macquarie University and University of New South Wales for the joint development of NanoCelle® as a nasal delivery for vaccines.

# FY22 Announcements

## 16 ASX Announcements:

Three Commercial Deals

Two Grant Fundings

Two Patent Approvals

Four Clinical Developments

Nasdaq Filing

# FY22 Financial Summary

Cash management focus, with planned US Nasdaq capital raising requirements to accelerate clinical and commercial activities.

- Increase in R&D investment in FY2022 including NanoCelle® development, progression of cannabinoid portfolio and pre-clinical, results in **$3.6M in R&D cash grant from AU Govt.**
- Revenue for FY2022, which included divestment of AU nutraceuticals business and under accrual of prior year R&D revenue, **increasing by 35% vs PY.**
- FY2022 net loss after tax of **$7.2M, improvement vs. 2021 by +42%.** Improvements in bottom line generated from Opex efficiencies, product development costs phased into 2023 and removal of non-productive fixed costs.
- Expecting future revenue streams from partnering and licencing agreements, Pharmacare royalty payment of A$250K in November 2022, and circa A$4M for R&D rebate income for 2023 (as part of $12M funding over 3 years, which includes US incurred R&D expenditure).
- Medlab completed a share consolidation, in early August 2022, in preparation for the upcoming Nasdaq listing and US capital raise.

**$5.2M**

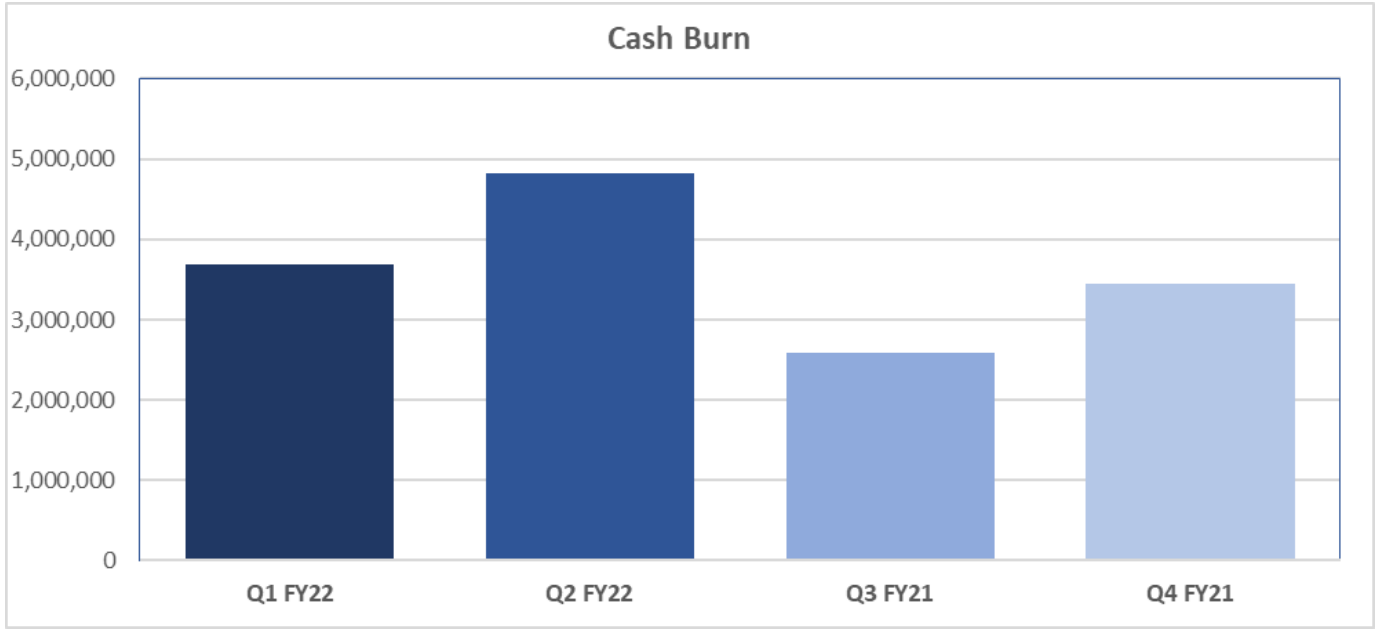
Cash position as of 30 June 2022

**$6M**

FY2022 revenue +35% vs PY

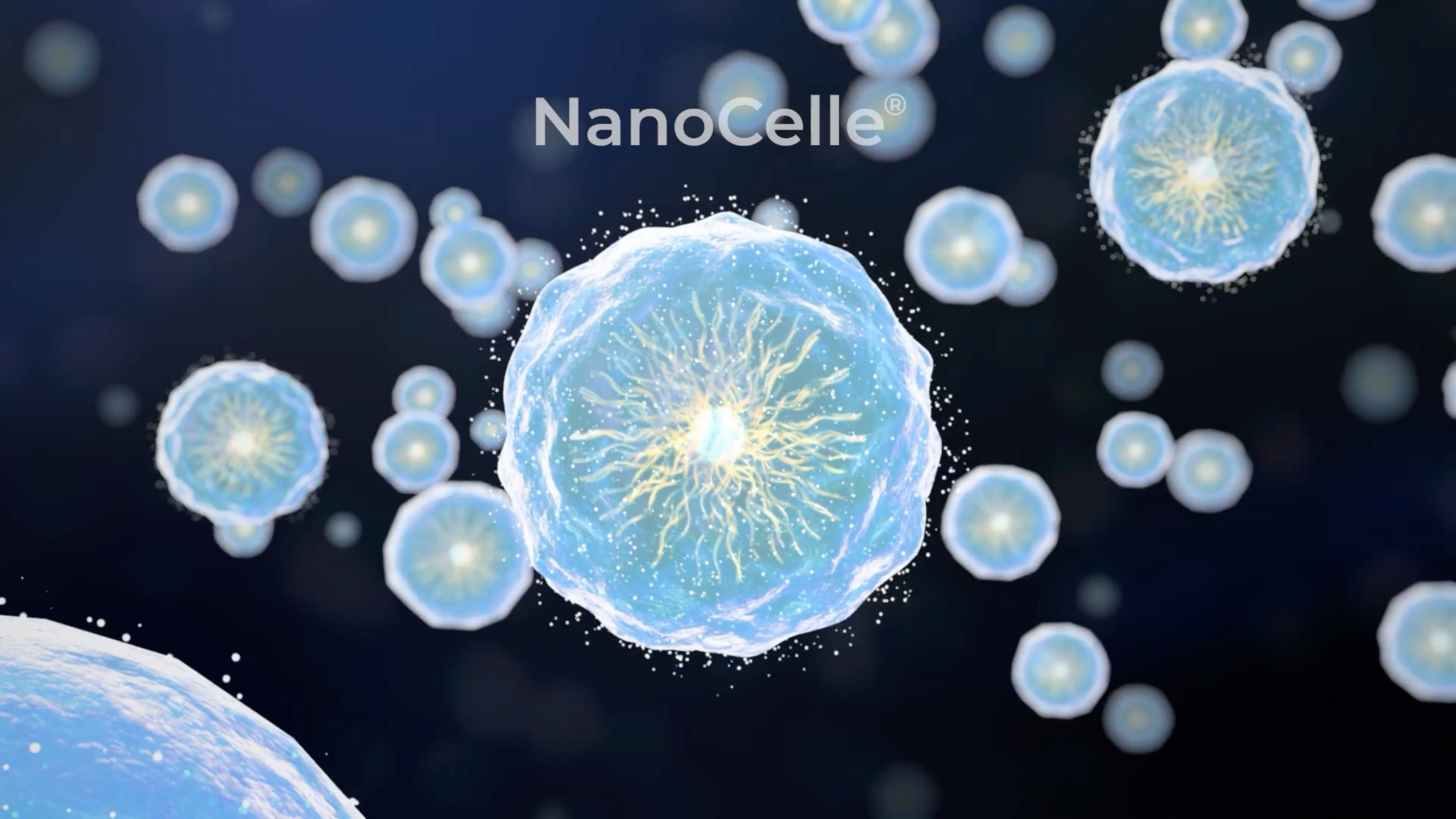
**$7.2M**

FY2022 after tax loss 42% improvement vs PY



# Business Overview

| NanoCelle® | PRIMARY Drug Development | SECONDARY Drug Development |
|---|---|---|
| **Core product offering**<br>Alternative, more effective method of consuming medical products, compared to the traditional methods, which include intravenous, intramuscular, subcutaneous, oral, rectal, inhalation and transdermal. | **NanaBis™**<br>Cannabinoids (THC+CBD) with FDA recognized API DMF's for proposed indication of cancer bone pain (bone METs) + larger neuropathic pain populations. Regulatory Filing expected late 2024. | **NanoCBD™** - Cannabinoid (CBD) with a FDA recognised API DMF for proposed indication of occupational stress, + mild, chronic pain populations.<br><br>**MDC2000** - Proposed FDA program using earlier, approved drug substance for depression.<br><br>**Nasal RNA** - Nucleic Acid collaboration with Woolcock Institute at Macquarie University and UNSW in pre-clinical stages for a nasal vaccine delivery utilising nucleic acid leading to new vaccine and/or anti-viral technologies. |


NanoCelle®

# NanoCelle® BYPASSES First Pass Metabolism – SUPER IMPORTANT

Tablets and Capsules →

NanoCelle® →

| 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 |

Bioavailability and characteristics of different routes of administration include:
* Unless otherwise indicated, source is howMed, 2015

# NanoCelle® superior delivery for speed and absorption

# NanaBis™ - *investigational new drug targeting Cancer Pain*

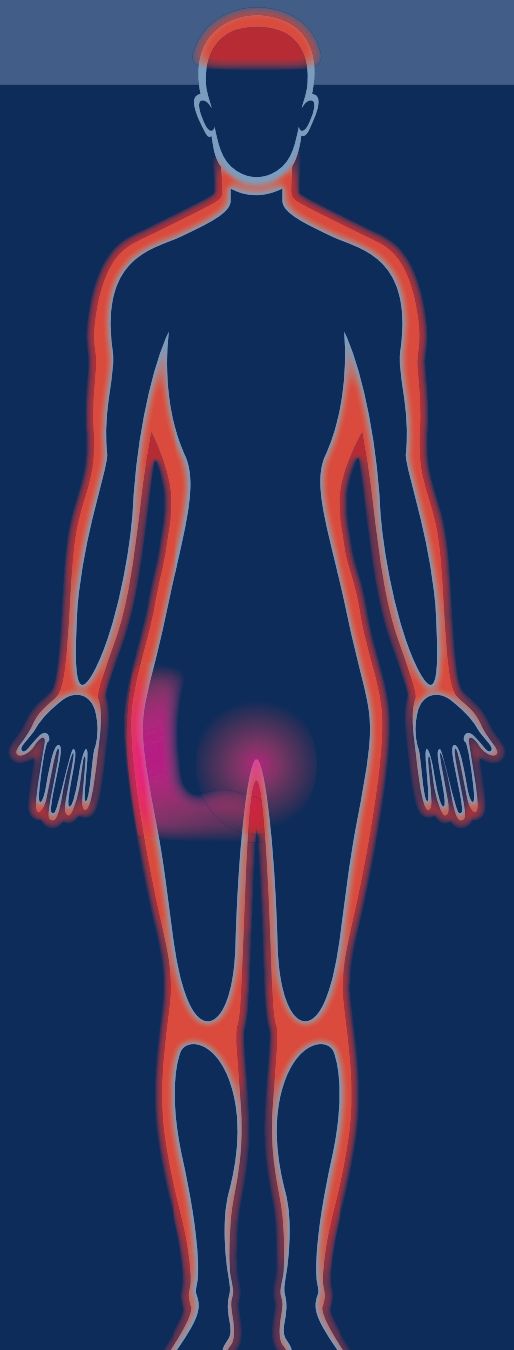
**1:1 mixture of Cannabidiol (“CBD”) and delta-9-trethydrocannabinol (“THC”) in a 1:1 ratio of 9.62 mg/mL CBD to 9.62 mg/mL THC.**

- A new, viable, multi-jurisdictional patent protected non-opioid pain management and reducing the reliance on opioids, directly competing against the US$ 42 billion opioid market.
- Available for Compassionate Use outside the clinical investigation on an approved named patient basis.
- In the NanoCelle® patented delivery platform optimised for buccal delivery.
- Drug Master Files done, a.CMC near completion, accelerated clinical returns 2023 for FDA regulatory 505(b)(2) application expected late 2024.
- Target indication = Cancer induced bone pain (CIBP)


## What is Pain?

Classified as a chronic illness, including indirect costs with lost economic productivity costs the United States approximately US$3.7 trillion each year, per the American Action Forum. In 2010, the National Academy of Sciences estimated that more than 100 million American individuals suffered from pain, resulting in estimated costs from health care and missed work time of approximately US$3.7 trillion per year. Traditionally, pain management has centered around opioid use. Over 81,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, the highest number of overdose deaths ever recorded in a 12-month period, according to recent provisional data from the Centers for Disease Control and Prevention.

# 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 |

# Adverse Events (AE)

Via the RWE (n=1186), NanaBis™ reports a 12.3% non-serious AE profile and a 1.3% serious AE profile.

JPSM, “The burden of opioid AE & the influence of cancer patients’ symptomatology” May 2019 reports a n=498 cohort over a 28-day follow-up were analyzed to which only 17% had no adverse event and 48% had 4 or more.

https://www.sciencedirect.com/science/article/pii/S0885392419300600 oncomitant AE’s.

# Backed by Australian R&D Grant

In November 2021, we announced that we received an award of approximately AU$12 million from an “Advanced and Overseas Finding” award from Australia’s Federal Government’s research and development tax incentive program for the further development of NanaBis™.

# NanoCBD™ *- investigational new drug targeting Stress*

**16.67 mg/mL synthetic CBD.**

- Pre-clinical phase.
- Shares the same components (inclusive of the DMF) used in **NanaBis™.**
- Manufactured in the same facility as **NanaBis™.**
- Available for Compassionate Use outside the clinical investigation on an approved named patient basis.
- In the NanoCelle® patented delivery platform optimised for buccal delivery.
- Expectations are this will be co-developed with an industry partner.


## What is Stress?

Historically, occupational stress was a term used to describe “an undesired factor causing discomfort for healthcare workers,” and stress within any workplace being mental, physical and/or emotional. Over the last few years, stress has been applied to scenarios beyond the workplace to include loss of income, loss of home, loss of life, and incarceration. The global stress management treatments market is expected to reach $20.6 billion by 2024 from $17.2 billion in 2019 at a compound annual growth rate of 3.7% for the forecast period of 2019 to 2024.

# Current “in-Market” Products

## The size of either US or Global Markets

| Medlab Drug Product Name | Availability Status | Target Market | Estimated Size of Target Market | Estimated global dollar value of potential demand for product |
|---|---|---|---|---|
| **NanoCelle® D3** | Listed with TGA | Immunity and Bone health | An estimate of 1 billion people globally have low Vitamin D3 levels<br>Source: Harvard.edu, 2022 | US$ 1.1 billion with potential to reach US$ 1.6 billion by 2025<br>Source: marketandmarkets.com, 2022 |
| **NanoCelle® B12** | Listed with TGA | Reduce homocysteine levels and support nervous system | Approximately 15% of global population is deficient in absorption of vitamin B12<br>Source: Harvard.edu, 2022 | US$ 276 million<br>Source: marketandmarkets.com, 2022 |
| **NanaBis™** | Distributable pursuant to United Kingdom and Australian Compassionate Use program | Opioids | 100 million in United States<br>Source: Smith, T. et al. JAMA, Health Policy, The Cost of Pain, April 2019 | US$ 70 billion<br>Source: ww.apa.org, 2022 |
| **NanoCBD™** | Distributable pursuant to United Kingdom and Australian Compassionate Use program | Stress | 67% of the United States<br>Source: www.apa.org, 2022 | US$ 17.2 billion (Global)<br>Source: BCC Research, Stress Management Industry: GlobalTrends, March 2020 |

# Our Goals (0-12 months)

| Projects | |
|---|---|
| **NANABIS™ – Synthetic**<br>• Completion of a.CMC data<br>• IND<br>• Clinical work delivery (commencement)<br>• Compassionate Use | **NANABIS™ – Botanic**<br>• Compassionate Use for data points and KoL identification and development |
| **NANOCBD™ – Synthetic**<br>• Completion of a.CMC data<br>• Commercial deal collaboration on clinical and regulatory (AU at present) (commencement)<br>• Compassionate Use | **NANOCBD™ – Botanic**<br>• Compassionate Use for data points and KoL identification and development |
| **MDC2000**<br>• Determination on NanoCelle® Lithium<br>• If successful (NanoCelle® Lithium) US FDA 505(b)(2) Regulatory development | |
| **RNA**<br>• PoC validation (success or failure)<br>• AU Gov't readout<br>• Planning next steps:<br>  • Future Gov't funding?<br>  • Continued Uni involvement? | |

| Confirmed immediate Conferences | | |
|---|---|---|
| Date | USA/Canada | UK/EU4 |
| **Nov 2022** | | • Jefferies Healthcare (Speaker, 1:1)<br>• CPHI – (1:1) |
| **Jan 2023** | • JP Morgans (1:1) | |

# NASDAQ Progression Summary

- Symbol Reserved NASDAQ:MDLB
- Filed FINRA
- Filed SEC
- Filed NASDAQ

# Thank You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**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

**Cheryl Maley**

Non-Executive Director

**Mohit Gupta**

Non-Executive Director

# Executive & Management Team

**Kerem Kaya**

Chief Financial Officer &
Company Secretary
B.Com, CPA

**Dr. Patrick Mueller**

Director of Pharmacovigilance
& Regulatory Affairs

**Dr. David Rutolo, Jr.**

PhD, JD, Director of Science

**Ian Curtinsmith**

Chief Information Officer

**Dr Jeremy Henson**

MBBS PhD BSc (Hons) Medical Affairs
& Research Director

**Tony Potter**

BSc (Hons), Dip Management
GM Pharma, Commercialisation
& Education

# Scientific Consulting Team

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MBBS MD PhD FRACP FAChPM FAAHMS

**A/Prof Wojciech Chrzanowski**

MSc, PhD, DSc

**Dr Andrew Mclachlan**

BPharm (Hons1 Medal), PhD, FPS, FACP, McPA, MSHPA

**Dr Mathew Bambling**

PhD

**Margot Rothwell**

Commercialisation and Business Consultant - MBA (Clin Pharm Mgt), Executive Director at BioAdvantage PTY Ltd

**Dr Esben Strodl**

BS's (Hons), MPsucjClin, PhD