



medlab[®].co[®]

February 2023 Presentation

ASX: MDC

NASDAQ (reserved): MDLB

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The Company

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

INDUSTRY:	Biotechnology
REV MODEL:	Partnering
ASX:	MDC (2015)
NASDAQ:	MDLB (reserved)
EMPLOYEES:	36

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.

OF PEOPLE DIAGNOSED WITH MENTAL HEALTH ILLNESS

AU versus US

8.6M¹ versus 50M²

OPIOID PRESCRIPTIONS

AU versus US

3.1M³ versus 191M⁴

¹AHW - <https://www.aihw.gov.au/mental-health/overview>

²U.S. Behavioral Health Market Share & Growth Analysis [2029] - <https://www.fortunebusinessinsights.com/u-s-behavioral-h-health-market-105298>

³<https://www.aihw.gov.au/reports/illegal-use-of-drugs/opioid-harm-in-australia/summary>

⁴<https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>



NANOCELLE®



NANOCELLE®

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.



IN-MARKET AND IN-DEVELOPMENT

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



IN-DEVELOPMENT

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.



PATENTS & PUBLICATIONS

PATENTS – 67 granted Patents into 9 patent families.

PUBLICATIONS - 133



Key Strategic Achievements & Milestones



NANOCELLE®

Strong global 15 year patent protection

Supplied over 350,000 NanoCelle® units to Australians

NanoCelle® D3 and B12 approved as listed medicines

Core to our therapeutic offerings

Demonstrated nanoparticle opportunities



NANABIS™

Strong study data shows:

- Pain reduction
- Improvements in quality of life
- Opioid reduction
- Acceptability and sustainability

AU and UK compassionate use

US manufacturing in accordance with FDA regulations

Drug master files, device master files – US FDA

Published data



OTHER

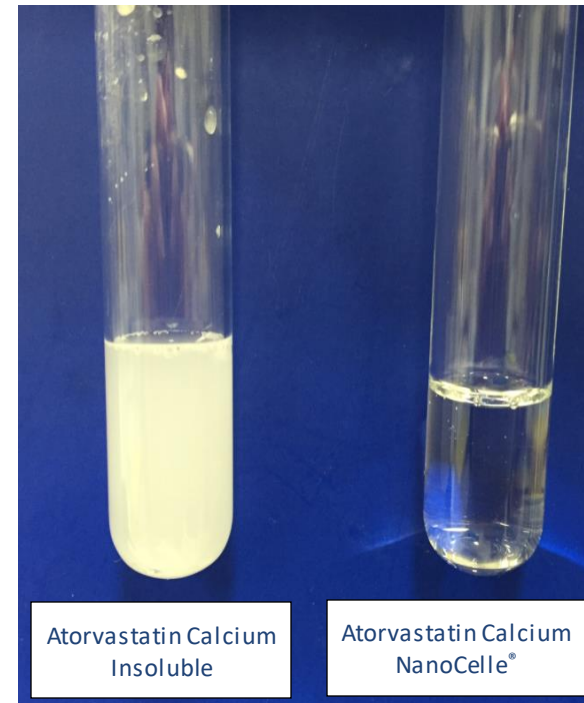
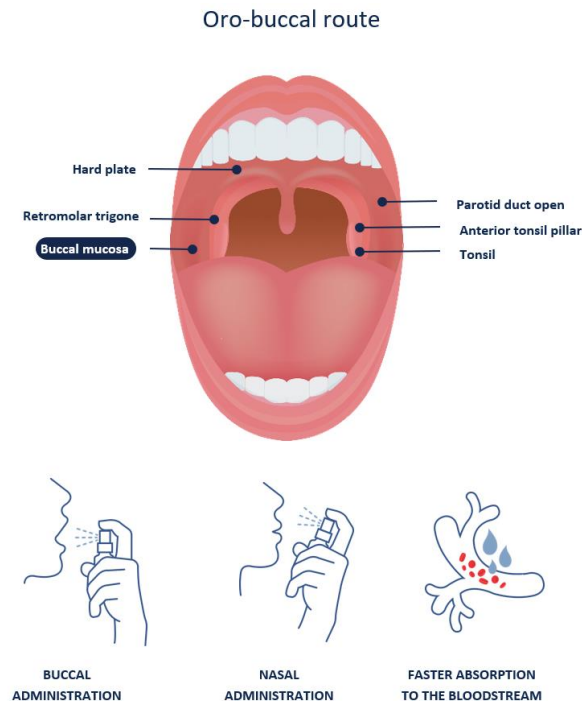
Lab co-located with University of New South Wales

AU Government provides for overseas costs for NanaBis™ for up to AU\$12M under the R&D Program

Nasdaq Ready – reserved symbol MDLB

The Platform Technology – NanoCelle®





NanoCelle® - allows medicines to be delivered via multiple routes that bypass first-pass metabolism, allowing for quicker absorption, greater drug bioavailability and superior efficacy. By bypassing the gastrointestinal environment, the drug substance is not subject to extensive degradation as found in other ingestible medicines.



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.

 ROUTE	 SPEED	 BIOAVAILABILITY*	 CHARACTERISTICS
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%	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

Source: Pharmawiki.in,

Source: National Library of Medicine, 2012

Tablets and Capsules →

NanoCelle®
NanoCelle® superior delivery for speed and absorption →

NanoCelle®
BYPASSES First Pass Metabolism

NanaBis™ Update

PUBLISHED - 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
- Improvements in Quality of Life (QoL) measures (emotional functioning and insomnia)
- MMEQ (morphine in milligrams equivalent) **significantly reduced** – quantifiable measure of efficacy

Real World Data Replicates Clinical Data

12-month observational (MEDCARE) study – n=1172, interim readout

Safety and Tolerability

Only 12.4% of patients experienced a non-serious AE and 1.3% experienced a SAE.

Indication

98.5% chronic pain; 85% non-cancer pain; 55% neuropathic pain

Dosage

Median Daily Dose = 6 sprays/day (7.5 mg each of THC and CBD/day)

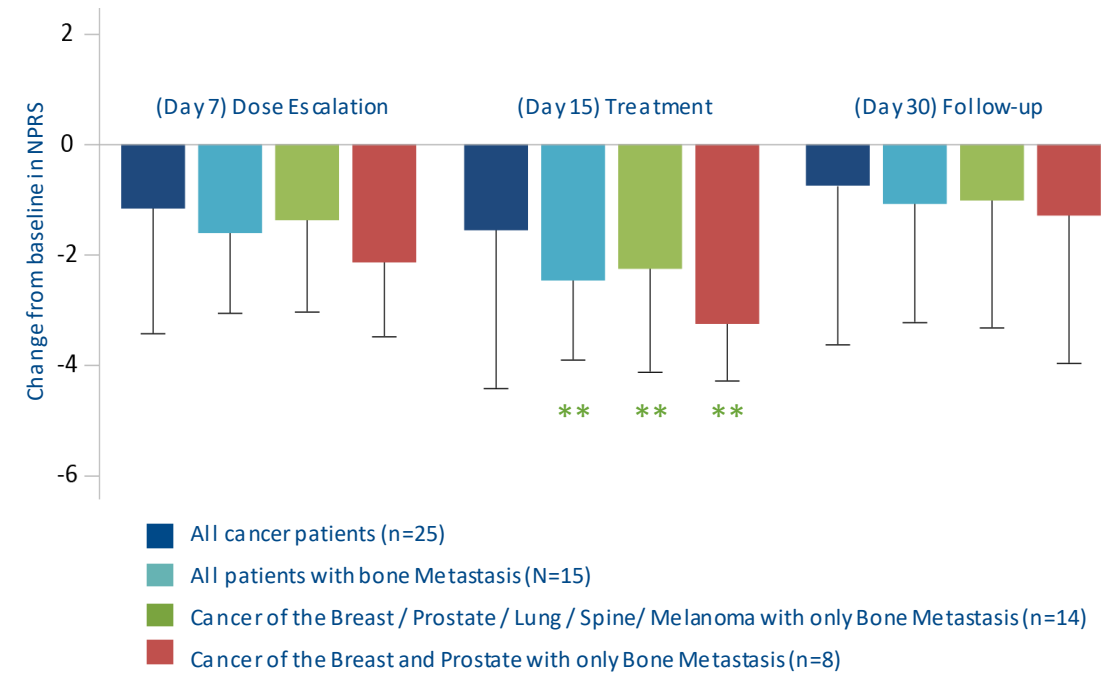
Cancer Bone Metastasis Participants at 12 Months

- 45% decrease in pain severity (BPI severity score); $p < 0.008$
- 79% improvement in pain relief ($p < 0.001$)
- 64% improvement in Quality of Life (BPI Pain Interference Score; $p = 0.001$)

All Participants at 12 Months

- 27% decrease in pain severity (BPI severity score); $p < 0.0001$
- 51% improvement in pain relief ($p < 0.00001$)
- 35% improvement in Quality of Life (BPI Pain Interference Score; $p < 0.0001$)
- 75% of participants reduced their opioid use (60% had a > 50% reduction)

NanaBis™ significantly decreased MMEQ



Financial Highlights

REVENUE

A\$1.5M in FY2022 from continuing operations
Divested nutraceuticals business in November 2021.

CASH POSITION

A\$5.2M as of June 30, 2022, Financial Year End. FY 2022 expenditures predominantly spent on salaries, are R&D related and hence subject to future rebate claimable R&D grants.

AFTER TAX NET LOSS

A\$7.2M in FY2022, decreased by \$5.2M, or 42%. This was mainly the result of improvement in operational expenditure outgoings, and reversal of provisions.



**FY 2022 Revenue growth
+110% vs. prior year**



**FY 2022 Net Loss
decreased 42%
vs. prior year**



**R&D CASH GRANT
RECEIVABLE**
A\$3.5M, as at June 2022



Summary

1

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

2

NanoCelle[®] research and development portfolio spread from early stage to late stage.

3

Significant future revenue potential.

4

Convenient and easy to use for patients and their lifestyle.

5

NanaBis[™] datapoints are compelling, available in AU and UK Compassionate use





THANK YOU

CONTACT INFORMATION

HEAD OFFICE	CALIFORNIA OFFICE (USA)	INVESTOR RELATIONS
<p><u>Medlab Clinical Limited</u> Units 5 & 6, 11 Lord St, Botany NSW 2019, Australia P +61 2 8188 0311 E sean_hall@medlab.co</p>	<p><u>Medlab Clinical US, Inc</u> 30021 Tomas Suite 150 Rancho Santa Margarita, CA 92679, USA P +1 949 202 1088</p>	<p><u>Edison Group</u> Laine Yonker 1185 Avenue of the Americas, 3rd Floor New York, NY 10036 P +1 646 653 7026</p>



Where are we with the NASDAQ?

In short, we are ready to go. Our bankers, EF Hutton, are holding off because of market conditions, at the start of this week they shared a document showing only five (5) healthcare IPOs got off and were crucified in deal terms and post market valuations.

Secondly, because of new rules (OCT last year) with NASDAQ on dual listing, Hutton's syndicate list is not fully pre-approved with Nasdaq.

If you recall, we had an EGM several months ago and passed resolutions supporting the NASDAQ and the scope of the deal. Unfortunately, the market has significantly worsened since then, and our ASX waiver on those resolutions expire 27 Jan 2023.

Because of these, we are delaying Nasdaq until such time as the market demonstrates improvements. Right now, we are (as we have been told) 1 of 71 IPOs awaiting friendlier market conditions.



Board of Directors



Michael Hall

Bachelor of Commerce, CPA
Non-Executive Chairperson



Cheryl Maley

Non-Executive Director



Drew Townsend

Bachelor of Commerce, CA, MAICD,
Non-Executive Director



Mohit Gupta

Non-Executive Director



Executive & Management Team



Dr Sean Hall

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



Kerem Kaya

Chief Financial Officer & Company Secretary
Bachelor of Commerce, CPA



Dr. David Rutolo, Jr.

PhD, JD, Director of Science



Ian Curtin Smith

Chief Information Officer



Dr. Patrick Mueller

Director of Pharmacovigilance
& Regulatory Affairs



Dr Jeremy Henson

MBBS PhD BSc (Hons) Medical Affairs &
Research Director

