

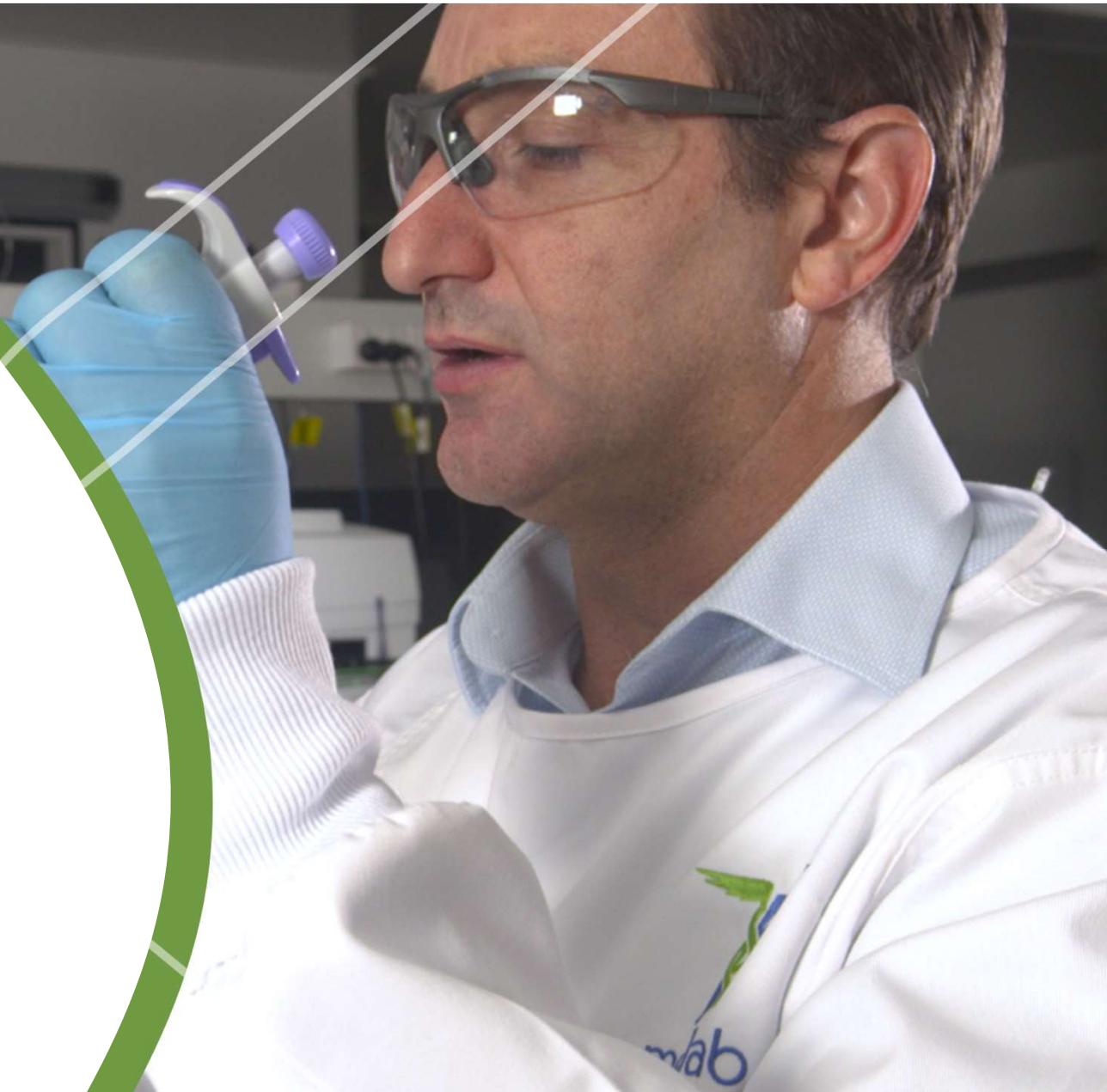


Medlab Clinical Ltd (ASX.MDC)  
*Scientifically optimised for a better life*

# Corporate Presentation

20<sup>th</sup> January 2021

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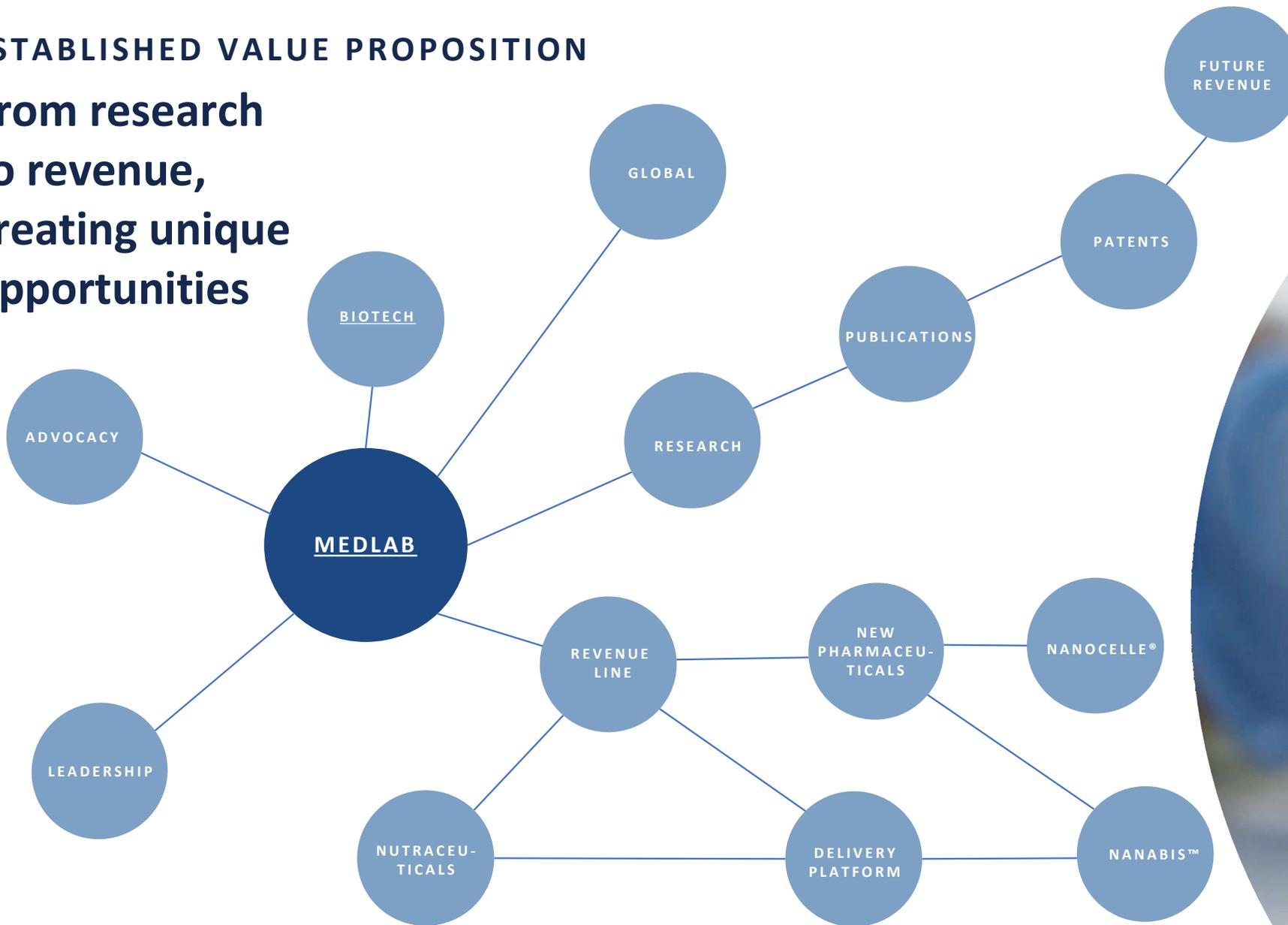
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## ESTABLISHED VALUE PROPOSITION

From research  
to revenue,  
creating unique  
opportunities



A close-up photograph of a microscope. A hand wearing a blue nitrile glove is adjusting one of the objective lenses. The microscope is metallic and has several lenses. The background is blurred, showing a laboratory setting. The text "COMMERCIALISATION AND PROGRESS" is overlaid in white, bold, sans-serif font in the center of the image. There are also some white curved lines on the right side of the image.

**COMMERCIALISATION AND  
PROGRESS**

## STRONG START TO 2021 WITH IMMEDIATE GLOBAL GROWTH

### Solid clinical and regulatory progress to bring commercial opportunities

Q1



- NanoCelle® **differentiated and innovative mode of action** recognised with the granting of an Australian patent. Further patents expected to follow.
- NanaBis™ Phase III trial signs CRO from George Clinical.

Q2



- **US FDA IND approval for NanaBis™ Phase III.**
- Other IND's to follow that may present compassionate use opportunities in USA.
- NanaBis™ UK **Phase III rollout receives third-party validation** with support from UK National Institute of Health Research (NIHR), one of the world's leading organisations delivering clinical research.
- Solid progress made in NanoCelle® development, advancing applications into diverse programs.

Q3



- Venture Valuations (independent) values NanaBis™ at \$97.6M USD (rNPV 14%) to \$120M USD (rNPV 14%) for cancer bone pain, demonstrating **confidence in market potential.**
- New York BD team currently focused on US NanaBis™ deals.
- Medlab Sydney facility completed installation of **new commercial vault.**
- Received NSW Health licences for Schedule 4 and Schedule 8 pharmaceutical supply and sale.

# REVENUE CREATION

Commercial potential accelerating as we drive further into global revenue models, advance partnering strategies and validate our products through research

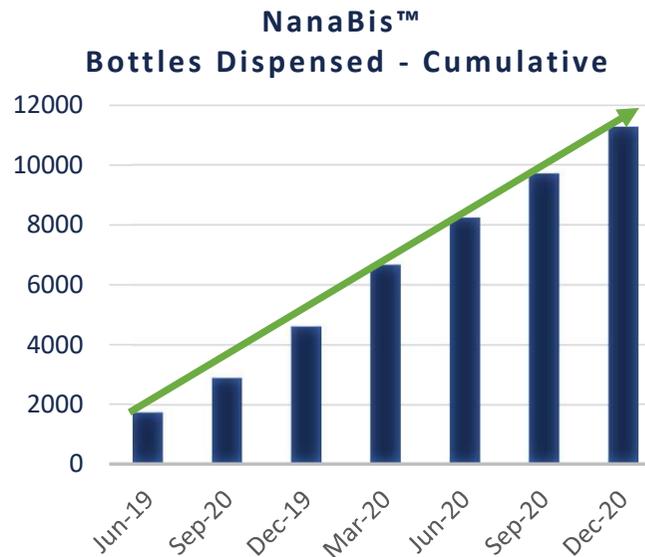


## Revenue streams today

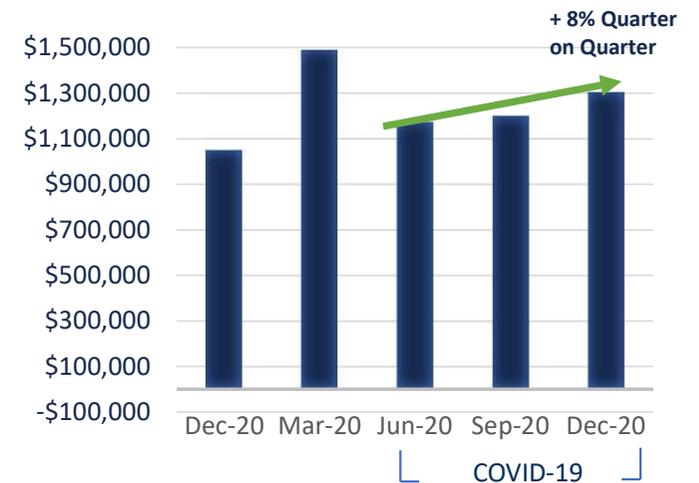
- Domestic compassionate-use sales for non-approved pharmaceuticals
- Sales of nutraceuticals (VMS) products
- Local Government Grants

## Revenue streams tomorrow

- Global pharma and NanoCelle® partnering
- Global grants
- US, UK compassionate-use sales for NanaBis™



## VMS Invoiced Sales (Pre-discount)



# MEDLAB'S R&D PORTFOLIO

Multiple options for partnering or in-house development

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

A person wearing a blue lab coat and blue nitrile gloves is holding a green cannabis plant. The plant has serrated leaves and a developing bud. The background is a blurred laboratory or cleanroom environment. The text "NANABIS™ PROGRAM" is overlaid in white, bold, sans-serif font across the center of the image. A thin white line curves around the plant and text.

# NANABIS™ PROGRAM

## NANABIS™ - OUR LEAD PHARMACEUTICAL CANDIDATE

### Scientifically optimised to perform better

- 1 to 1 ratio of CBD and THC delivering 2.5mg of each compound, in a nanoparticle (NanoCelle®) for improved bioavailability and absorption.
- Commercial strategy is to achieve drug registration for NanaBis™ for cancer bone pain, a US\$1.22B global market with up to 700,000 new patients annually in US, AU, Canada.
- Trial programs showing improvement in pain scores:
  - Robust completion of Phase I/II study with primary and secondary endpoints met, demonstrating safety, tolerability and efficacy.
  - Observational NanaBis™ study designed to gather real-world evidence continues; 668 of 2000 patients recruited, with 55% improvement in pain scores (as at last audit).
  - Demand via Special Access Scheme continues to grow, establishing proof of concept and generating early revenue.
- \*40% improvement in pain scores recorded in Phase I/II study

US FDA  
IND  
Approved

REDUCTION  
IN OPIOID  
DOSAGE

40%  
IMPROVEMENT  
IN PAIN  
SCORES\*

PATENTED



SAFE,  
TOLERABLE &  
EFFICACIOUS

## 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.

***“Taking cannabis oil to manage the side effects of the cancer has been very successful. I have regained the 20kg I lost, regained my appetite and I no longer have issues with sleep”***

- SAS NanaBis™ Patient



# WHY IS NANABIS™ IMPORTANT?

EMA STEPWISE  
PAIN GUIDELINES

PAIN SCALE

Mixed Opioids  
& Adjuvants

10

Low Dose Opioids  
& Adjuvants

5

NSAIDs & Other  
Non-Opioid Medications

0



NanaBis™  
Therapeutic  
Entry Point

**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

## SIGNIFICANT COMMERCIAL POTENTIAL

An independent valuation undertaken by Venture Valuations (Switzerland) highlights significant commercial potential of NanaBis™ for chronic pain associated with bone metastasis.

- Venture Valuations focuses on independent valuation of companies and products in pharmaceuticals, life sciences and technology.
- Valuation was performed strictly for chronic pain associated with bone metastasis, evaluating FDA approval as path to US market.
- NanaBis™ competition included both opioid and non-opioid analgesics, as well as non-steroidal, anti-inflammatory (NSAIDs) drugs.
- Valuation agreed potential to meet FDA regulatory filing by end 2023, with potential for secondary TGA and MHRA (UK) filing in parallel, with RoW following 12 months later.
- Probability of success (pre-IND application) was deemed as:
  - 67.4% - Phase III trial outcomes met
  - 84.8% for FDA approval
- NanaBis™ valued at \$97.6M USD (rNPV 16%) to \$120M USD (rNPV 14%) for chronic pain associated with bone metastases (FDA drug registration route).

NanaBis™ valued at US\$97.6M (rNPV 16%) - US\$120M USD (rNPV 14%) for chronic bone pain



# NANABIS™ ROUTE TO GLOBAL PATIENTS

Phase III trial initiation and filing for compassionate access well-established across three markets, paving way for an established patient base, clinical validation, early revenue and real-world data



## USA

Patient payable  
compassionate use –  
**APPLICATION PENDING**

Phase III trial  
progression –  
**IN PROGRESS**

**US FDA IND APPROVED**

## UK

Patient payable  
compassionate use –  
**UNDER INVESTIGATION**

Phase III trial  
progression –  
**IN PROGRESS**

**UK NIHR SUPPORTED**

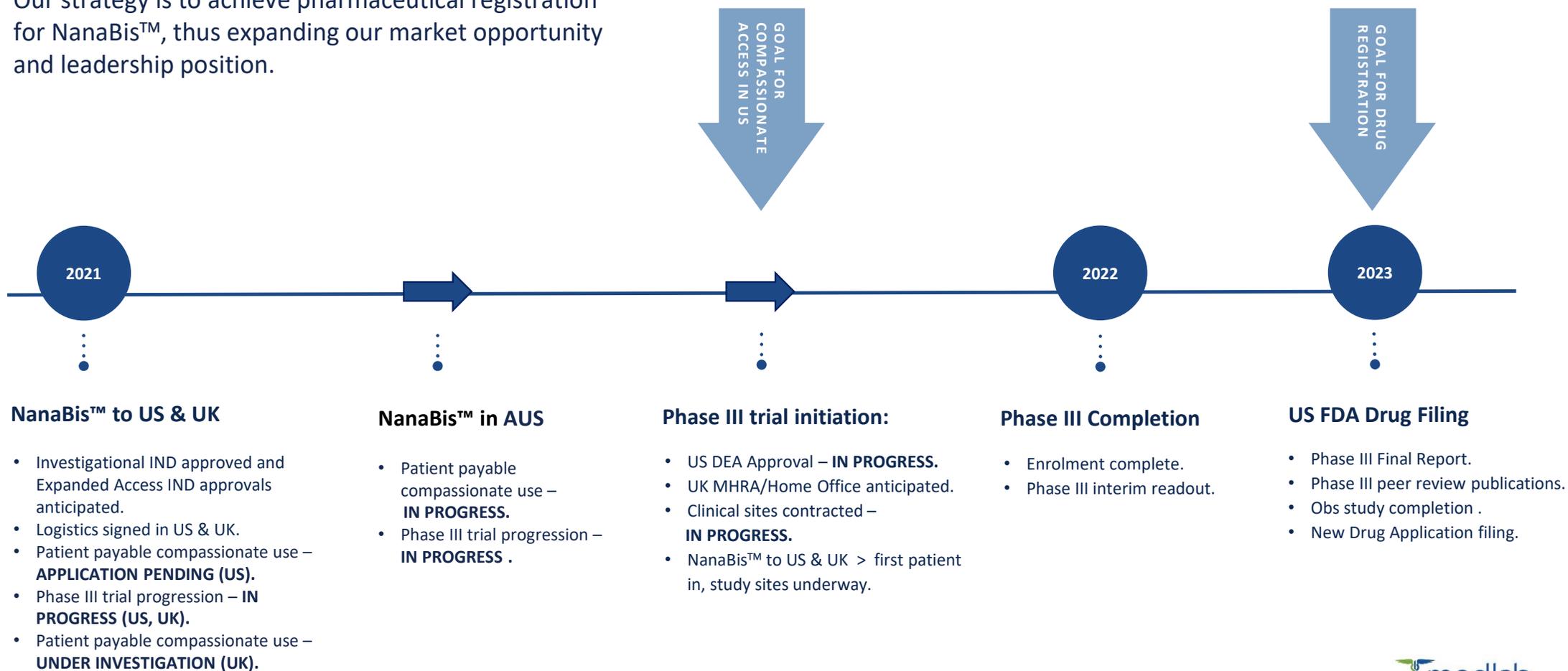
## AUSTRALIA

Patient payable  
compassionate use –  
**IN PROGRESS**

Phase III trial  
progression –  
**IN PROGRESS**

## NANABIS™ NEXT MAJOR STEPS

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



# 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

### Cancer Bone Pain

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

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



## FUTURE TARGETS

### Cancer Pain

**US \$5.28B** Global market opportunity (2017)

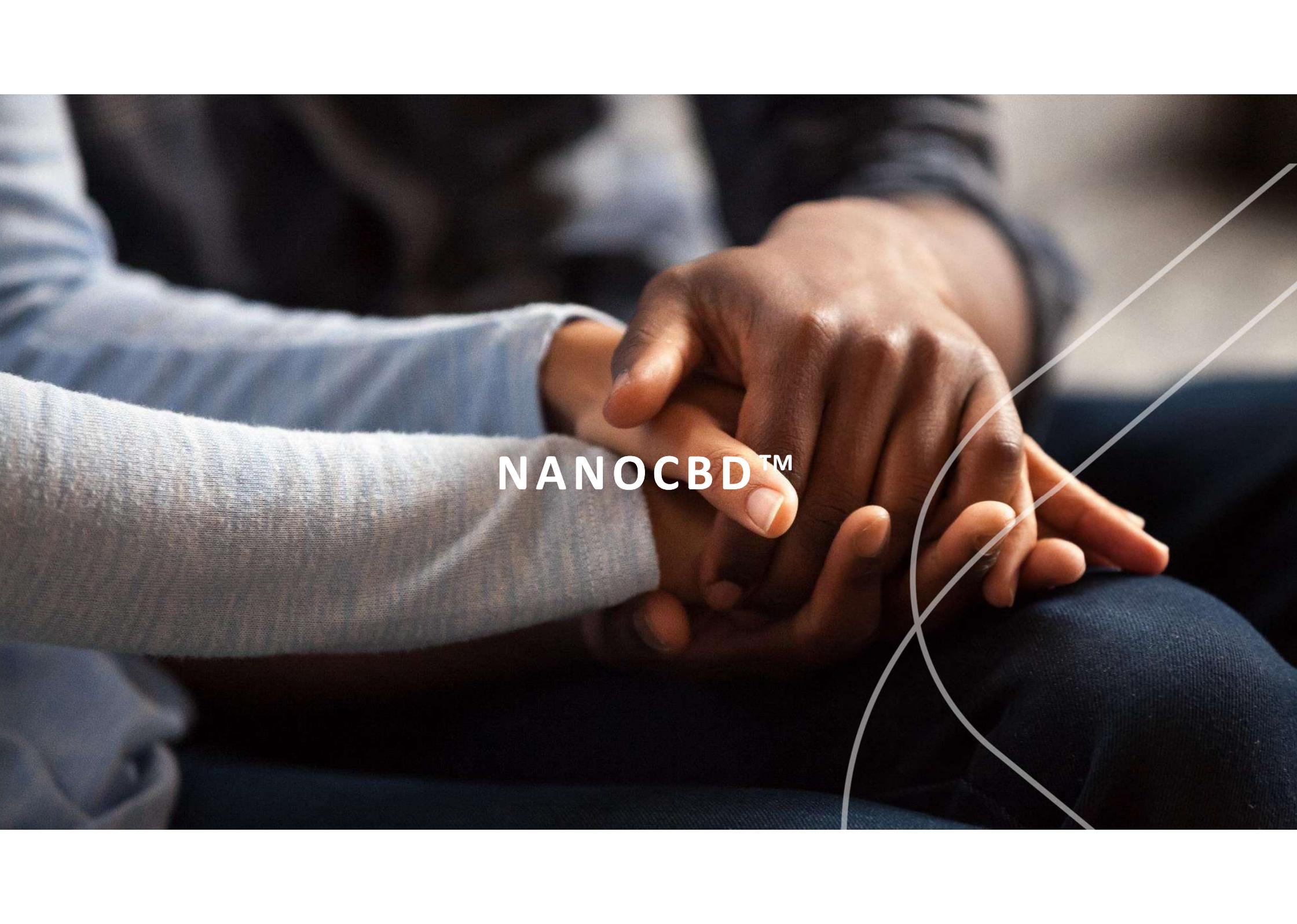
CAGR 4.5%, estimated to be US \$7.54B (2025)



### Chronic Pain

**US \$69.3B** Global market opportunity (2017)

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



NANOCBD™

## NANOCBD™ VALUE CREATION

# Targeting existing global markets and Pharmacy use in Australia

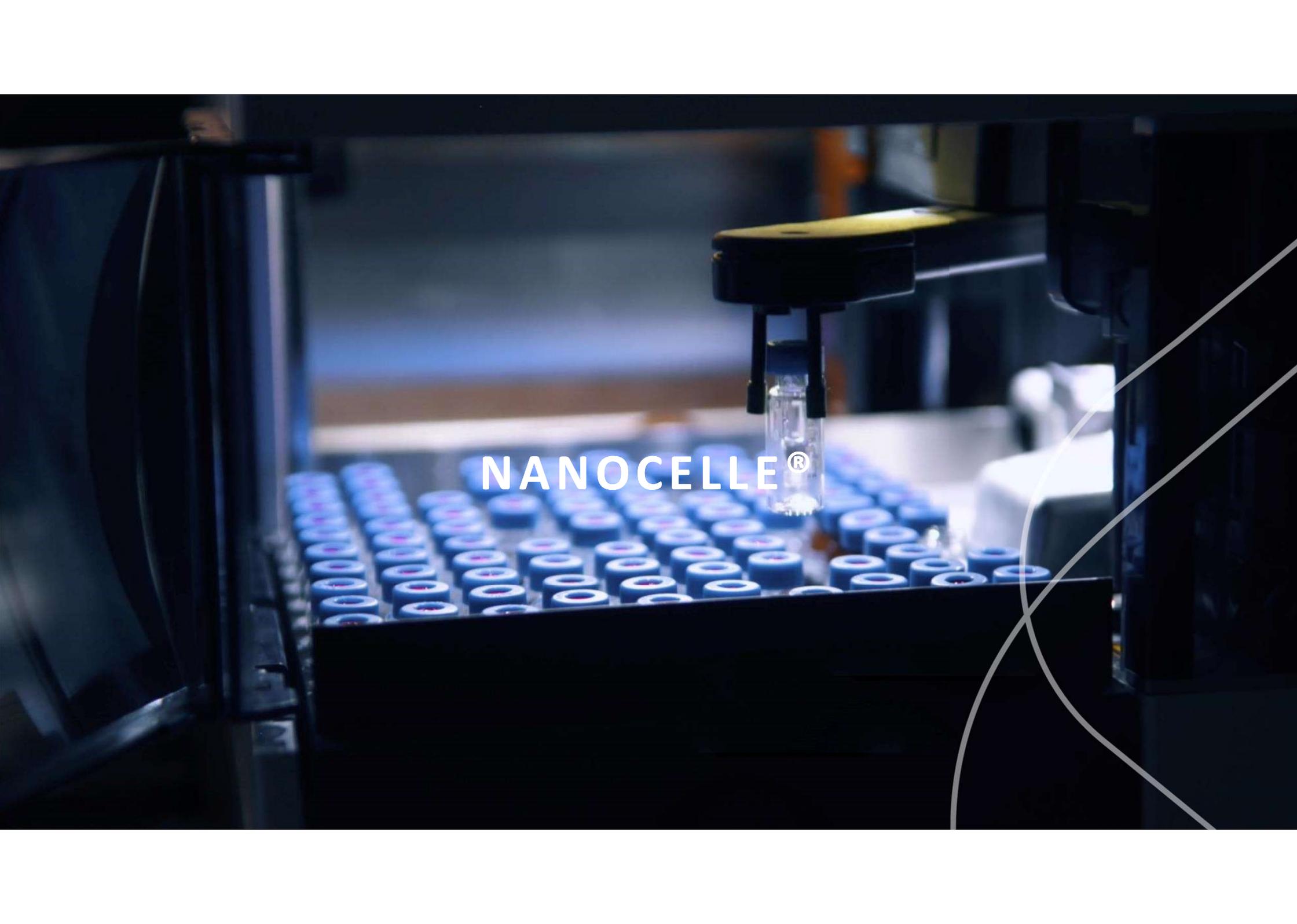
- NanoCBD™ is a highly refined cannabidiol (CBD) product, differentiated by our NanoCelle® delivery platform. Unlike other CBD preparations, NanoCBD™ does not contain ethanol.
- TGA has down-scheduled CBD-only products to Schedule 3 for Pharmacy sales.
- Sales of NanoCBD™ have commenced under SAS in Australia; first patient supplied in June 2020.
- Highly purified, standardised, strong CMC, GMP manufacturing – transferable from NanaBis™.
- Robust clinical trials in planning, with aim to achieve regulatory approvals and pharmaceutical registration.

Sales underway under SAS and via export agreement

Two clinical trials in design phase

Ability to surrogate CMC data from NanaBis™





NANOCELLE®

## MEDLAB'S PROPRIETARY DELIVERY SYSTEM

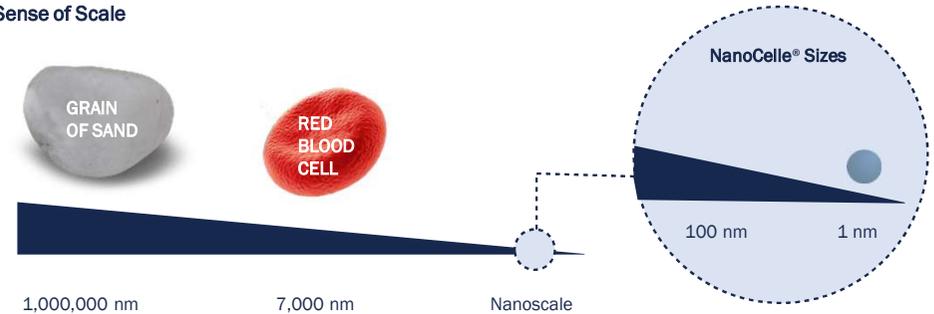
# NanoCelle® creates nano-sized water-soluble particles that enable optimised delivery of particles, overcoming issues with solubility and degradation

Meaning they can pass more easily into the bloodstream for faster absorption and metabolism whilst employing non-traditional routes of administration.

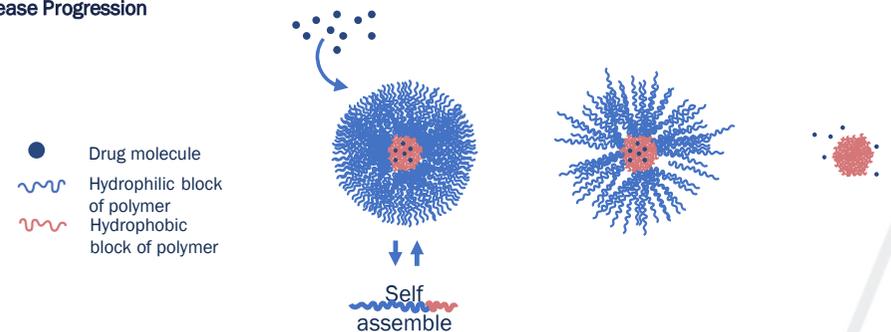
### HOW NANOCELLE® WORKS

- 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.

### Sense of Scale



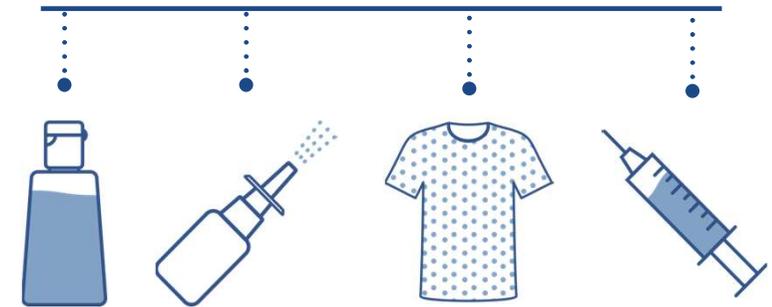
### Release Progression



## WHY NANOCELLE® OFFERS OPPORTUNITY

NanoCelle® underpins our growth strategy by offering near-term partnering opportunities whilst enhancing our pharmaceutical portfolio

# NANOCELLE®



### Innovative drug delivery

Enhanced pharmaceutical delivery system that vastly improves drug solubility issues and enables faster absorption and metabolism of active ingredients.

### Commercially viable to manufacture

Several in market. Easy and convenient to manufacture.

### Significant growth potential

Our R&D programs and strong partnerships provide a robust pipeline of opportunities to development and commercialisation.

### Multiple global markets for commercialisation

With patent protection in EU, US, Canada, Hong Kong, Singapore, Australia, New Zealand.



# NUTRACEUTICALS

## NUTRACEUTICAL BUSINESS – DRIVEN BY SCIENCE

Our innovative and evidence-based nutraceuticals portfolio consists of 21 formulations focused on fixing core issues and not just symptoms.



“ This is one of the best probiotics I've used. I find it's more effective than the other ones I've used in the past. It helps with my bloating and with my digestion. Highly recommend. - Katerina K ”

### Clinical

- Clinical progress delivered for NRGBiotic™, a probiotic formula combined with Coenzyme Q10 and Magnesium Orotate. Results expected Q3 FY2021.
- Results due Q3 FY2021 for MultiBiotic™ safety and efficacy study for prevention of intestinal ulcers.

### Partnering

- Commercial deals span across the US, Asia, UK & NZ.
- In UK market of new CBD and nutraceutical product, Mg Optima and CBD (export only).

### Sales

- Steady improvement in sales in FY2021 showing COVID-19 recovery; Q2 sales up 8% quarter on quarter vs Q1.
- Customer advocacy growing, with strong customer testimonials and rapidly increasing brand loyalty.



# INVESTMENT SUMMARY

## INVESTMENT SUMMARY

**An  
opportunity  
with  
significant  
global  
commercial  
potential**

- Lead candidate NanaBis™ targeting a global market for cancer bone pain, Phase I/IIa primary and secondary endpoints met, now advancing toward Phase III study and Investigational New Drug (IND) acceptance.
- Diverse product offering early revenues with potential for expanding both domestic and global footprints.
- US market a priority for NanaBis™ entry; New York business development team focused on US NanaBis™ deals.
- Expanded Access INDs pending for NanaBis™. Approval could see Medlab become one of the first companies to offer a cannabinoid therapeutic under compassionate use in the US.
- Focus on partnering for NanoCelle® with initial focus on Generics and New Chemical Entity.
- Increasing strategic opportunities for NanoCBD™, with TGA in Australia down-scheduling CBD-only products to schedule 3 for Pharmacy sales.
- Improvement in normalised cash burn, well capitalised to accelerate clinical and commercial activities.

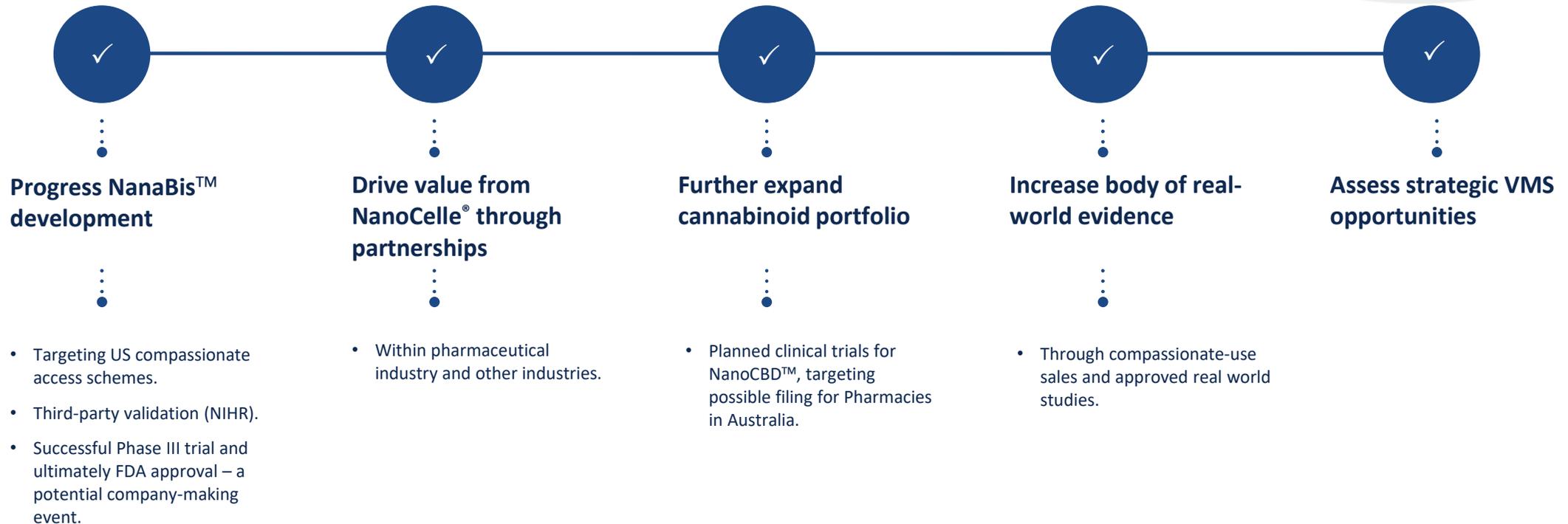
**46 Patents**

**80+ Publications**

**45 Conferences**

## GROWTH STRATEGY

# Clear opportunity for growth through clinical validation and partnering





CORPORATE

## COMPANY SNAPSHOT (ASX-LISTED AS MDC)

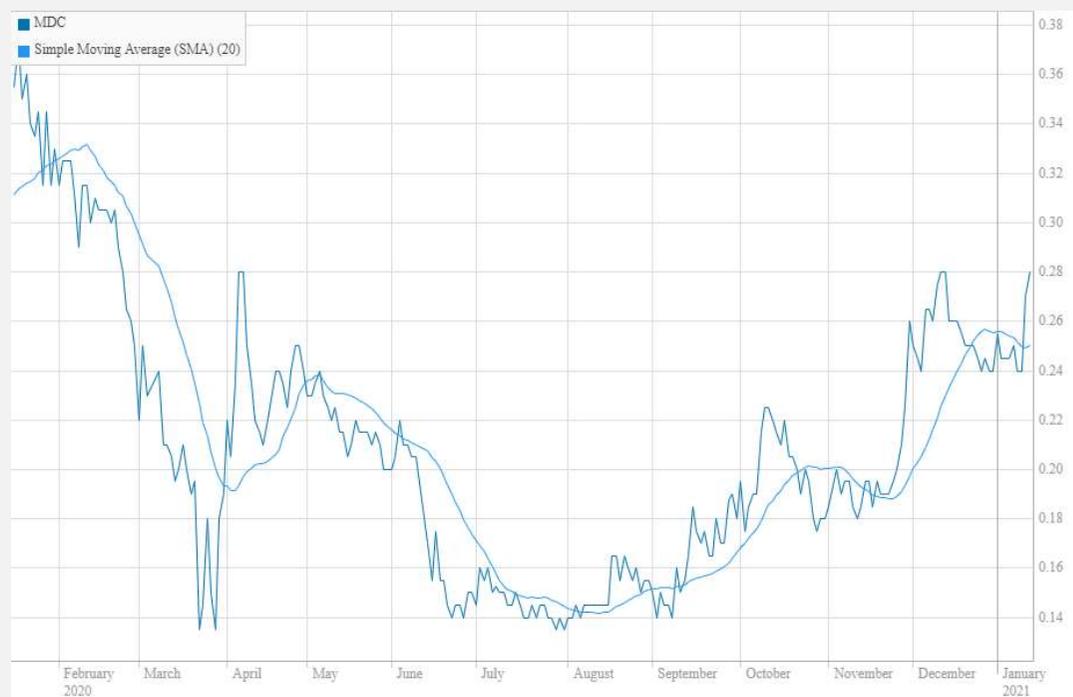
### SNAPSHOT

LISTED 2015	\$0.20
CURRENT PRICE	\$0.28
MARKET CAP	\$78M
AVERAGE DAILY TURNOVER	422K

### MAJOR SHAREHOLDERS:

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

### SHARE PRICE AND VOLUME – 12 MONTHS



## EXECUTIVE AND MANAGEMENT TEAM



**Dr Sean Hall**

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



**Prof Luis Vitetta**

BSc (Hons), PhD, MD, GradDip  
Nutr/Environ Med, Grad Dip Integ  
Med  
Director of Medical Research



**Alan Dworkin**

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



**Ian Curtin Smith**

AssocDip Technology, GAICD,  
Chief Information Officer



**Dr Patrick Miller**

Dr. rer. nat (PhD), MSC, BSc, Director  
of Pharmacovigilance  
& Regulatory Affairs



**Tony Potter**

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



**Dr Jeremy Henson**

MBBS PhD BSc (Hons) Medical  
Affairs Director



**Dr David Rutolo, Jr.**

PhD, JD, Director of Science

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MBBS MD PhD FRACP  
FChPM FAAHMS



**Ass Prof Wojciech  
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MSc, PhD, DSc



**Dr Andrew Mclachlan**

BPharm (Hons1 Medal), PhD,  
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**Dr Mathew Bambling**

PhD



**Dr Esben Strodl**

BS's (Hons), MPsucjClin, PhD

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PTY Ltd



**Benjamin L. England**

Regulatory Representation and  
Counsel - Founding Member/CEO  
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| FDAImports.com, LLC



ERA Consulting Group



Tasmanian Alkaloids

Manufacture, biomass supply,  
analytical



Agilex Biolabs Pty Ltd

Human Assay, pathology



Nitto Avecia

Analytical



## THANK YOU

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