



ASX Announcement

## **Biotech Investor Conference – Emerging Biotech Conquering Global Markets**

**SYDNEY, August 17, 2022**

Medlab Clinical Ltd (**ASX:MDC**) and Genetic Technologies Ltd (**ASX:GTG**) are pleased to co-present at the “Biotech Investor Conference”, held at FB Rice: Patent and Trademark Attorneys in Melbourne 5.00pm on Wednesday 17<sup>th</sup> August 2022.

The event is proudly sponsored by FB Rice.

### **About the Event:**

Australian biotechnology companies are increasingly offering technology that show promise via the clinical and non-clinical trial path.

This event provides a great opportunity for biotech’s to showcase progression and plans to investors and shareholders.

The conference is designed to allow investors to become more knowledgeable in the role of Biotech work happening in Australia, and the potential to change global ecosystems by looking at biotech from its core and getting a better understanding.

A copy of Medlab’s presentation on the day can be found attached.

**- ENDS -**

### **Authorisation & Additional information**

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

### **About Genetic Technologies:**

Genetics Technologies Ltd is an established Australian-based molecular diagnostics company, specialising in the development of integrated genetic risk testing.

Through its revolutionary proprietary technology, GeneType predicts an individual’s risk of developing chronic disease and enables physicians to proactively manage patient health. For more information, please visit [www.genetype.com](http://www.genetype.com)

### **About Medlab Clinical:**

Medlab Clinical Ltd is an Australian biotechnology company, developing therapeutics using its proprietary delivery platform NanoCelle®.

Its most advanced program is in cancer pain management with lead drug candidate NanaBis™, a medical cannabis product for cancer-related bone pain. For more information, please visit [www.medlab.co](http://www.medlab.co)

*Medlab – better medicines, better patient care*

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ASX:MDC

# COMPANY UPDATE

## Understanding the value indicators

“ The NanoCelle® drug enhancement and bio-delivery technology; applicable to a vast range of new and existing medicines, with initial targets in pain and mental health medication. ”

CONFIDENTIAL

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# Welcome to Medlab

Medlab Clinical Ltd is a globally recognised Australian Biotech company, built on a proprietary drug processing and bio-delivery technology – NanoCelle® - that enhances the effectiveness, safety and reaction speed of new and existing medicines. Our initial therapeutic focus includes pain and mental health.

**NanoCelle®: Our validated delivery platform is patented and protected in all western regions until 2036**

**Scientifically optimized portfolio of cannabinoid therapeutics**





# What We Do

Our NanoCelle® R&D portfolio consists of:

## **Cannabinoid Development**

- Cancer Bone Pain
- Non-cancer pain
- Stress

## **Generics Plus**

- Depressive disorders
- Cholesterol lowering
- Pain
- Allergy
- Large bowel cancer

## **Large Molecule Program**

- Insulin
- Covid-19 Vaccine

## **Textile Program**

- Antibiotics

# NanoCelle® - Benefits and Advantages

The **NanoCelle®** patented technology involves the novel formation of a true micelle nanoparticle that provides enhanced bioavailability, flexibility, versatility, physical stability, efficiency in processing and simplicity, and cost effectiveness in manufacturing. These properties provide a significant advantage over other nanoparticle delivery systems.

The nanoparticle description (morphology and particle size), enhanced bioavailability, and chemical stability data are provided earlier in this presentation. A reduction in the amount of an API need for efficacy due to enhanced bioavailability could result in a cost savings.

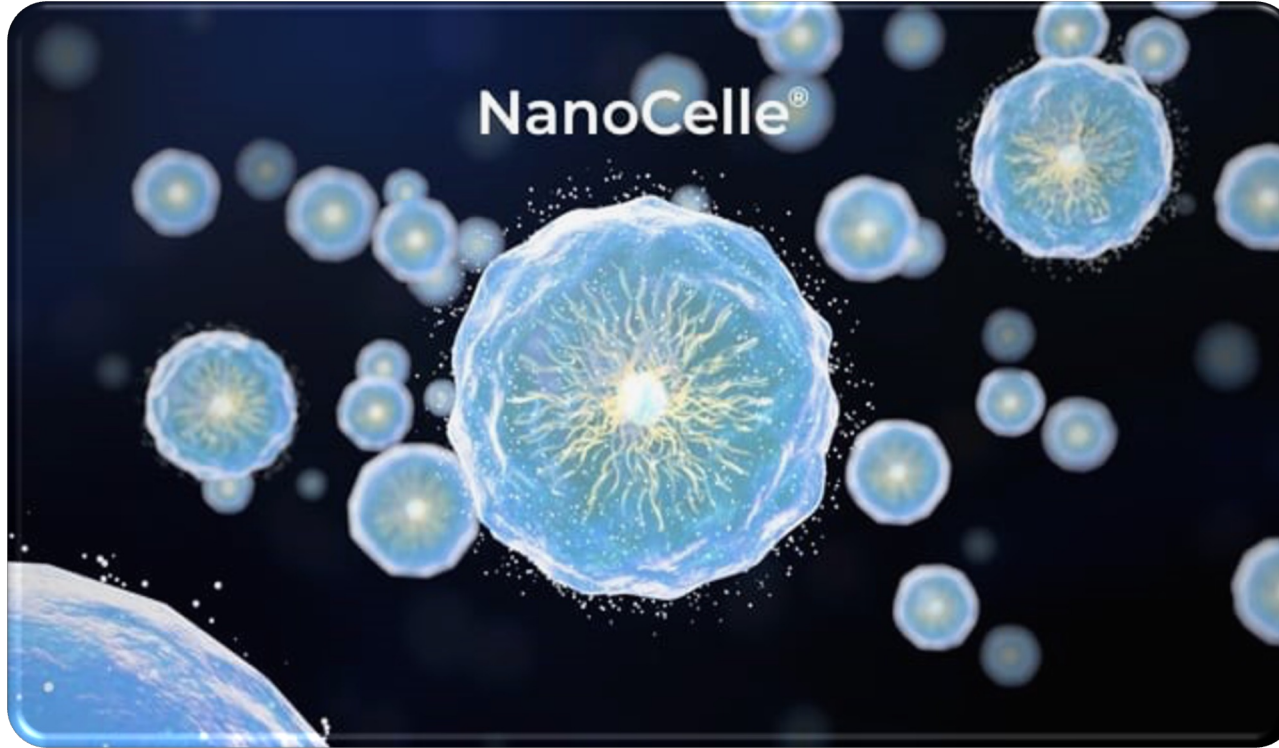
## Physical Stability

The **NanoCelle®** formulations are clear, aqueous solutions and they can maintain this stability for over two years without special handling. Chemical stability of specific formulations may require special storage conditions.

## Flexibility in Application

- Due to the stable, clear, aqueous solutions, there are a wide variety of dose applications.
- Oro-buccal Sprays
- Oral Muco-adhesive Gels
- Nasal Sprays
- Topical Sprays
- Topical Gels, Lotions, Creams
- Ocular Solutions
- Dermal Patch Applications
- Adsorption onto Carrier Agents

# What Is NanoCelle® and Why Is It So Important



<https://vimeo.com/611215328>

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

1

**NanoCelle®** is the registered name of our clinically validated, patent protected delivery platform, that uses nanoparticles to significantly enhance medicines. Medicine delivered by oral buccal mouth, topical or nasal spray.

2

**NanoCelle®** bypasses the gastrointestinal tract, known as 1<sup>st</sup> pass metabolism, this means we can administer a lot less of a medicine, vastly reduce the patient's exposure to harmful side effects, whilst conferring the intended therapeutic benefits.

3

**NanoCelle®** is a key differentiator to our programmes, such as the cannabinoid cancer pain program - **NanaBis™**.

4

The **NanoCelle®** technology optimises the bioavailability of medicines, making compounds more easily and rapidly absorbed by the body.

5

The **NanoCelle®** process can additionally **improve** the **stability** of medicines, such as removing the expensive requirement of storing vaccines at sub-zero temperatures.



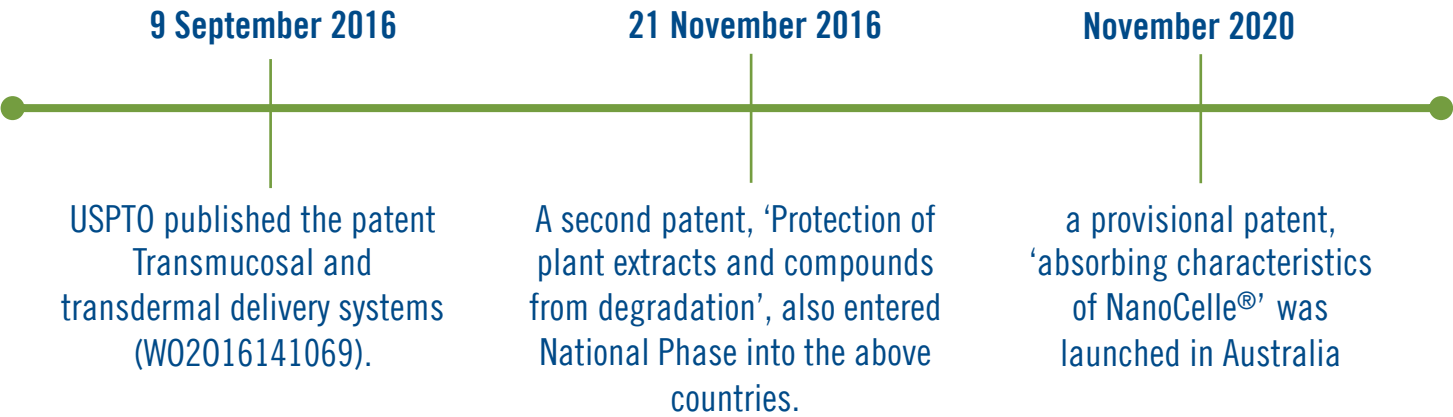
# Innovative Patented Technology

NanoCelle®  
57 patents  
worldwide



Our research into nano-sized particles has spanned years of rigorous development.

The science behind the unique NanoCelle® delivery system was validated with an Australian patent granted in September 2020, providing protection until March 2036.



- |                  |                  |                   |
|------------------|------------------|-------------------|
| Australia        | ▪ Estonia        | ▪ Monaco          |
| Canada           | ▪ Spain          | ▪ North Macedonia |
| United States    | ▪ Finland        | ▪ Malta           |
| Europe           | ▪ France         | ▪ Netherlands     |
| ▪ Albania        | ▪ United Kingdom | ▪ Norway          |
| ▪ Austria        | ▪ Greece         | ▪ Poland          |
| ▪ Belgium        | ▪ Croatia        | ▪ Portugal        |
| ▪ Bulgaria       | ▪ Hungary        | ▪ Romania         |
| ▪ Switzerland    | ▪ Ireland        | ▪ Serbia          |
| ▪ Liechtenstein  | ▪ Iceland        | ▪ Sweden          |
| ▪ Cyprus         | ▪ Italy          | ▪ Slovenia        |
| ▪ Czech Republic | ▪ Lithuania      | ▪ Slovakia        |
| ▪ Germany        | ▪ Luxembourg     | ▪ San Marino      |
| ▪ Denmark        | ▪ Latvia         | ▪ Turkey          |

Hong Kong Singapore	Registration of Grant requested Under Examination	New Zealand	Accepted
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# Global Research Analysis

**EDISON**

## Medlab Clinical

Novel drug delivery and cannabinoids against pain

Initiation of coverage

Pharma & biotech

12 July 2021

**Price** A\$0.16

**Market cap** A\$55m

Net cash (A\$m) at end of calendar Q1'21 13.8

Shares in issue 342.2m

Free float 90%

Code MDC

Primary exchange ASX

Secondary exchange N/A

Medlab's proprietary platform, NanoCelle, is a patented nanomicellar formulation that can improve the delivery of drugs. Medlab's lead product is NanaBis, a combination of THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, which enable a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, which will allow it to move away from a botanical extract. Once the product reformulation is completed (guidance is eight to 10 months), NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug optimised with proprietary delivery technology aimed at a vast market. Our valuation of Medlab is A\$201m or A\$0.59/sh.

**BLUE OCEAN** EQUITIES

**MEDLAB CLINICAL LTD (MDC)**

Analyst Philip Pape philp@blueocean.com.au +61 2 8072 2921 1 September 2021

Thomas Brunton thomas@blueocean.com.au +61 2 8072 2920

We say **BUY**

Share Price 0.175

Price Target 0.55

MDC is well positioned to potentially become a first mover within the cannabinoid cancer pain medication market. Assuming Phase III NanaBis trials are successful, we expect MDC to benefit from the growth of the global cannabinoid market, which is projected to surpass US\$45b in the USA alone by 2025. Further, the GW Pharmaceuticals takeover suggests a material valuation uplift is on offer should MDC successfully complete its Phase III trials. We initiate with a BUY rating, PT \$0.55/s.

SHARE PRICE CHART MDC SALES POTENTIAL COMPANY DATA & RATIOS

**EDISON**

## Medlab Clinical

Transforming into a pure-play biotech

Company update

Pharma & biotech

27 January 2022

**Price** A\$0.13

**Market cap** A\$44m

Net cash (A\$m) at end-November 2021 (after the completion of the transaction) 13.0

Shares in issue 342.2m

Free float 90%

Code MDC

Primary exchange ASX

Secondary exchange N/A

In its former shape, Medlab used the cash flows from selling innovative nutraceuticals to fund pharmaceutical research. With lead product NanaBis (NanoCelle encapsulated 50:50 THC:CBD for pain) preparing to enter a Phase III trial in pain, management has decided to fully focus on therapeutics development and divested its nutraceuticals portfolio in November 2021. As a pure-play biotech, Medlab is also focused on optimising its R&D portfolio, which has many initiatives. Historically, Medlab has explored its proprietary drug delivery technology NanoCelle in combination with various generic active pharmaceutical ingredients (APIs), extracts and other products. The management is now prioritising the likely winners, with NanaBis leading the pack. Our valuation has increased to A\$239m or A\$0.70 per share.

**morgans**

Equity Research | Wealth Management | Sustainability

## Medlab Clinical

Earnings guidance and result expectations

Earnings guidance/outlook provided: No guidance.

Result expectations: Financial results largely guided to in 4Q21 cashflow statement.

Earnings forecasts

(A\$m)	1H20A	2H20A	FY20A	1H21A	2H21F	FY21F	2H21F % chg on pcp	FY21F % chg on pcp
Revenue	1.3	1.5	2.8	2.0	2.7	4.7	74.9%	65.0%
Gross profit	-1.5	-0.2	-1.7	0.1	-0.1	0.0	72.3%	99.4%
Gross profit margin (%)	-1.1	-0.1	-0.6	0.0	0.0	0.0	125.6%	587.2%
Operating expenses	6.9	6.7	13.6	6.7	6.1	14.8	20.9%	9.1%
Open % of rates	522.6%	437.9%	477.1%	332.0%	302.6%	316.3%	-135.0%	-161.8%
EBITDA	6.6	5.8	12.3	4.8	6.3	11.1	-8.0%	10.0%
EBITDA margin (%)	-497.4%	-377.1%	-432.9%	237.0%	236.1%	236.2%	1420.7%	1967.7%
EBIT	7.8	4.3	13.3	5.3	5.9	11.2	6.1%	16.7%
EBIT margin (%)	-532.3%	-409.9%	-460.7%	269.2%	222.4%	239.3%	1875.0%	2338.9%
Underlying NPAT	7.1	4.3	13.4	5.3	5.7	11.0	8.4%	17.9%
EPS (cps)	-3.3	-2.7	-5.9	1.9	-5.5	-3.6	-106.8%	39.4%
DPS (cps)	0.0	0.0	0.0	0.0	0.0	0.0	n/a	n/a

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Analysis(s) own shares in the following stock(s) mentioned in this report: N/A

Source: Morgans research, company

- Multiple research reports from US and AUS see the nutraceutical divestment of the small Australia-only division to PharmaCare as an intelligent move. It uncomplicates our messaging, makes more efficient use of resources, and positions Medlab as a pure play biotech
- Research reports available on request identify strong upside with different positive valuations, and provide a deep dive into NanaBis™ as our investigative drug for cancer pain
- Research reports clearly state that beyond the obvious scientific validation, partnering is a critical validation model for commerciality
- Email us for a copy of reports – [investor@medlab.co](mailto:investor@medlab.co)

## IN SUMMARY

A globally recognised Biotech company addressing significant unmet patient needs; an ethical investment with vast global revenue opportunities in:

Name	Indication	Market potential	
NanaBis™	Cancer bone pain	US \$1.22B (2010)	CAGR 5.4%
NanaBis™	Non-cancer pain	US \$69.3B (2017)	CAGR 6.4%
NanoCBD™	Stress	US \$10.9B (2020)	CAGR 7.2%
MDC2000 (NRGBiotic™)	Depression	US \$11.67B (2019)	CAGR 2.9%

# It's Not Just Investment Research Analysis

One of our potential Partners recently undertook an in-depth and significantly expensive Due Diligence and subsequent Independent Expert analysis on **NanaBis™** suited to their potential territories.

What we can share at this time is:

- Due Diligence focused on Europe with the EMA as the central regulatory agency
- **NanaBis™** is much needed and would be well received
- The time to peak sales is shorter than expected and volumes are hugely significant
- Pricing placed **NanaBis™** in the early 200€ a bottle
- **NanaBis™** subject to re-imburement in given territories



Battling anxiety and depression, as well as pain, can be exhausting. The right treatment can offer a new outlook on life, as in Jinhee's case. [Read Jinhee's story..](#)

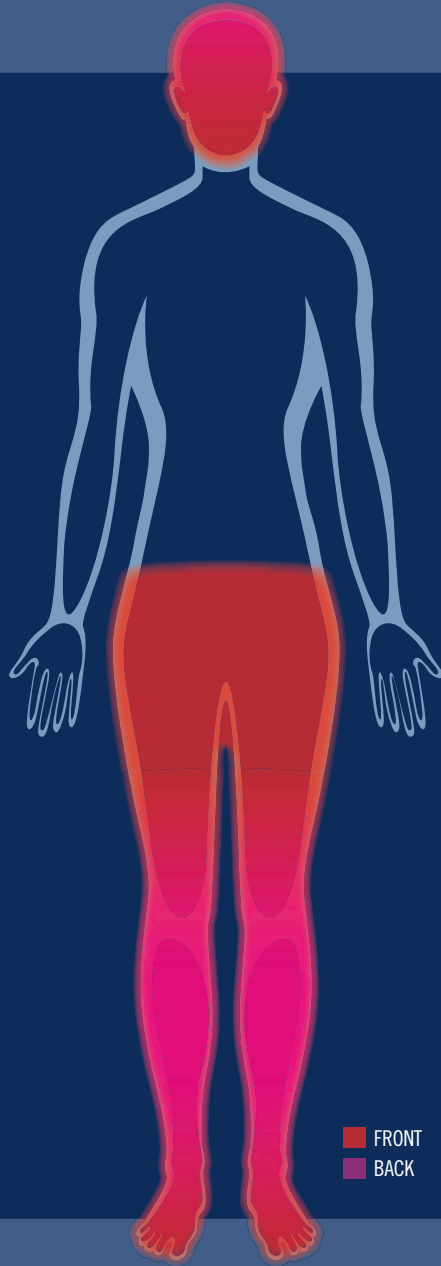


For Catherine, Endometriosis presented as intense pelvic pain, nausea and light-headedness/ dizziness leading up to her period. [Read Catherine's story..](#)



When prostate cancer spreads, it most frequently goes to the bones and this is what happen in Josef's case. [Read Josef's story..](#)





**Patient Initials** FA  
**Age** N/A  
**Sex** F  
**Indication** Fibromyalgia, Restless Legs and chronic migraines

Medications pre-NanaBis™	Dosage:
Gabapentin	1500mg daily
Endep	75mg daily
Topamax	50mg daily
Paxam	0.5mg daily (anxiety)
Anafrani	25mg daily (depression)

<b>Date NanaBis™ Commenced</b>	15/10/2019
<b>NanaBis™ Initial Dosage</b>	N/A
<b>Medications post-NanaBis™</b>	<b>Dosage:</b>
Gabapentin	600mg daily
Endep	25mg daily
Paxam	0.5mg daily
(ceased Topamax, Anafranil)	
<b>Current NanaBis™ dose</b>	3 sprays afternoon, 4-5 sprays night

## Symptoms of the patient before NanaBis™ treatment



**Fibromyalgia and Restless legs. Chronic migraines daily. Disturbed sleep - waking up 6 times a night due to pain.**

## Patient outcomes at time of writing



**Chronic migraines daily prior to NanaBis™**

After NanaBis™  
**migraines are rare**  
 (maybe once a month)

May have headaches sometimes but no where near the intensity as a migraine



Was **waking up to 6 times a night** due to pain - now able to **sleep through the night**

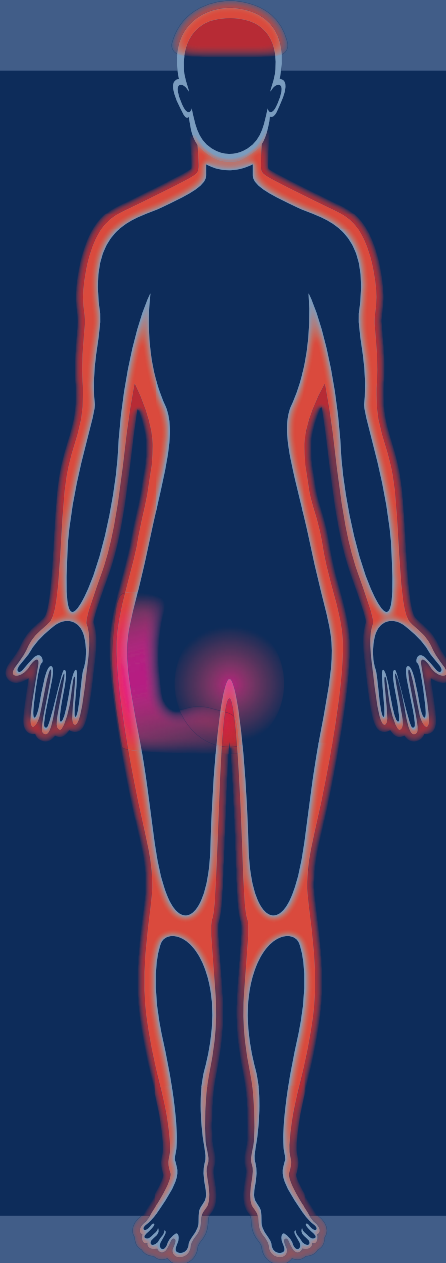


Currently **pain** has gone **down** from 10 out of 10 to **1-1.5 out of 10**  
 If no NanaBis™ (ran out for 3 days) = 7-8



Was initially prescribed **Tilray CBD 25mg**, **not effective at all**. Besides slight drowsiness, no other adverse events

**Date data collected** 10/03/2020  
**Continuing medication?** YES



**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

<b>Date NanaBis™ Commenced</b>	09/08/2021
<b>NanaBis™ Initial Dosage</b>	1 spray BD
<b>Changes in current medications</b>	<b>Dosage:</b>
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	
<b>Current NanaBis™ dose</b>	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

# Financials and Corporate Performance

As at end of 30 June 2022, Medlab **cash in the bank was \$5.2M**, with a \$3.4M cash burn for the quarter. Operating revenue for the quarter amounted to \$1.2M.

Expected future monthly cash burn rate to be less than \$1M, as we optimise savings from divesting / licencing out the AU nutraceuticals business.

Majority of the expenditure, including salaries, are R&D related and hence subject to rebate claimable R&D Grants.

Revenue already confirmed for the balance of 2022 includes:

- \$3.5M R&D Grant income in September
- \$0.25M Pharmacare Licence Royalty in November
- \$0.2M Amortised Service Income – July to December

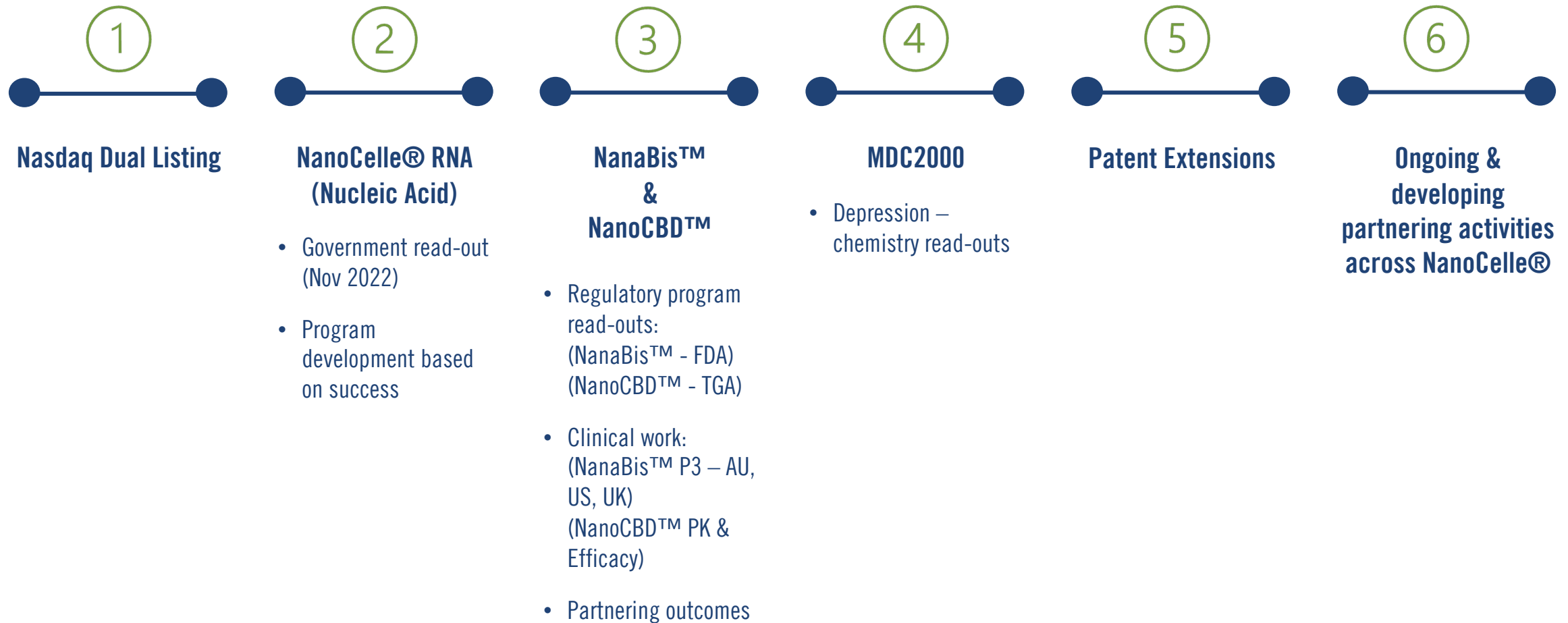
This is short of any potential partnering deals Medlab is currently working on.

By continuing to generate revenues and optimise costs Medlab can focus its core Pharma strategies. Future spend on R&D Claim (to include international costs) is approved for NanaBis™ development with circa \$12M cash back annualized over 3 years against future expenses of the program.





# Understanding the Future Short-Term Catalysts



# Nasdaq

We intend to dual list on Nasdaq, as common shares (not ADRs), we are doing this to access the largest global biotech market. A number of our programs are already US facing.

An investor will be able to trade on either the ASX or Nasdaq. The Company will not be relocating to the US for the foreseeable future.

A sophisticated CapRaise will coincide with the Nasdaq uplift. Because of the nature of this CapRaise, the Board and management team are recused from participation.

Use of funds will be primarily be used to fund the NanaBis™ program.





# THANK YOU

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**APPENDIX I:**  
**SYNTHETIC NANABIS™ &**  
**NANOCBD™**

## APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

### NanaBis™ Synthetic Importance & Progression

Our planned development for NanaBis™ Synthetic is well underway, with expectations of being back with the FDA in a few months. The synthetic program for NanaBis is key for us at a regulatory level as both the FDA and the EMA have expressed a preference for synthetic compounds due to the unavoidable impurities and inherent chemical variations from one batch to another in botanicals.

#### Why did we start in botanical and then move to synthetic THC?

2 significant reasons;

- First a 100% Dronabinol (the synthetic name for THC) was not technically possible to produce or commercially available until last year.
- Second, when we started we modelled work from GW Pharma (the only company globally that has to date received FDA approval for a cannabinoid product); we had purified botanicals to 97% and in our FDA IND meetings it was recommended that we do one of 2 things; either increase the purity of the botanical to minimum 98% purity or better yet, move to 100% pure synthetics for absolute purity control.

We embarked on a 2 pronged approach - searching for capabilities to create the 100% Dronabinol, whilst continually improving the purity index for botanicals. From the botanical aspect, this directly translated to more work and expense at every level of manufacturing and chemistry work; more time and increased costs.

During 2021 we (with the help from our biosynthetic partners) developed the 100% Dronabinol synthetic, and today we have what is known as Drug Master File (DMF) recognition at the FDA for both a 100% CBD and a 100% Dronabinol (THC). From a regulatory step, this is significantly superior to what we had in the botanicals – additionally, yields vastly improved, impurity issues no longer existed, and production risks were negated. We cannot overstate the value and importance of acquiring these DMFs for the progression of our NDA application.

What we have developed over the course of 2021 is a stronger Chemical, Manufacturing and Controls (known as a CMC) package. This CMC package is common to all western regulatory authorities and is absolutely fundamental in a new drug application.



## APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

### NanaBis™ Synthetic Importance & Progression (continued)

It's important to know that a drug application is traditionally made up of 5 key modules:

- Module 1 is region specific, and addresses why the product is needed.
- Module 2 is summary data with an emphasis on quality (driven from the CMC package and essential for regulatory approval).
- Module 3 is the CMC package itself
- Module 4 is the non-clinical data (elements of the CMC package are also present here) .
- Module 5 is the clinical reports (as in clinical trials and the final phase 3 endpoints report)

All 5 modules come together to make what is referred to as a Common Technical Document of Drug Dossier (<https://www.ich.org/page/ctd>) - the huge and ultimate application document required to apply for any pharmaceutical drug registration and subsequent commercialisation.

The point we are wanting to highlight is that too often the focus in biotech and New Drug Applications is on the clinical trials – and to some extent that makes sense simply because of the visibility in medical journals and the broader commercial pharmaceutical market. What we are demonstrating from the above is that there is a significant amount of work that is required in addition to the final clinical trials in order to format a final drug registration package.

Since COVID presented real risks and legitimate public health barriers to accessing patients which prevented us from initiating our Phase 3 trial, we have instead focused heavily on developing the other larger areas of the drug application dossier.

## APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

### NanaBis™ Synthetic Importance & Progression (continued)

#### So how detailed is a CMC package?

In short it is a huge, detailed document – in order to provide a sense, please review the FDA link:

[www.fda.gov](http://www.fda.gov)

We have leveraged the NanaBis™ CMC package work, both current and future so that NanoCBD™ shares significant process optimisation, production efficiencies and cost reductions, including US FDA recognised Drug Master Files (DMF), US manufacturing and Packaging components and CMC components - this reduces time and money in the development of the drug.

We learnt a lot from the Botanicals, they gave us our fundamental evidence that provides confidence in moving forward; and our Botanical based products continue to be available to compassionate markets for ethical use.

As for clinical development for both programs, we have a good line of sight on the future and both programs are currently in due diligence for our partnering discussions. Clearly, we can't talk too much about partnering as we are under confidentiality, but we can disclose that these negotiations are active and progressing rapidly now that full patent protection has been granted across all major western markets.