



ASX ANNOUNCEMENT

MEDLAB PRESENTS AT THE JEFFERIES LONDON HEALTHCARE CONFERENCE

SYDNEY, November 16, 2021 - Medlab Clinical Ltd (ASX: MDC) a delivery platform development company, is pleased to announce that it is presenting at the Jefferies London Healthcare Conference starting today and concluding Friday 19 November 2021.

During the 30-minute Presentation, Medlab outlines both its near-term goals and program optix. A Summary presentation is attached to this announcement.

Dr Sean Hall, CEO of Medlab says “we have had an overwhelming response for initial partnering discussions, all of which represent new opportunities, and from a cursory view, appears driven from the granting of NanoCelle® patents.”

Medlab will offer a presentation replay at **12:00pm on Monday 22nd November 2021 (AEDT)**. To register for this 30-minute webinar, please register [here](#).

ENDS

Authorisation & Additional information

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

About Medlab Clinical:

Medlab Clinical Ltd (ASX: MDC) is pioneering the development and commercialisation of a pharmaceutical delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab’s pipeline comprises a number of small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies. Patented lead drug candidate NanaBis™ has been developed for cancer bone pain as a viable alternative to opioid use. Data to date, strongly suggests NanaBis™ may be equally effective in non-cancer neuropathic pain. NanoCelle®, the patented delivery platform is wholly owned by Medlab and developed in Medlab’s owned OGTR (Office of the Gene Technology Regulator) Registered Laboratory. NanoCelle® is designed to address known medication problems, addressing global unmet medical needs. Medlab operates in Australia (Head Office), USA, and the UK. For more information, please visit www.medlab.co

Medlab – better medicines, better patient care

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MEDLAB CLINICAL LTD

Summary of Video Presentation for
Jefferies London Healthcare Conference
November 2021

Presenters:

- Dr Sean Hall | CEO & Managing Director
- Prof. Luis Vitetta | Director of Medical Research
- Dr Jeremy Henson | Medical Affairs Director
- Dr Michelle Quezada | Research & Development Technical Scientist
- Mr Kerem Kaya | CFO

ASX:MDC

Scientifically optimised for a better life

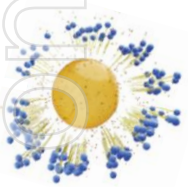
Contact Us



WHO IS MEDLAB

Medlab Clinical Ltd (ASX:MDC) is an Australian Biotech specialising in delivery platforms. Medlab is undertaking development for several drug registrations and pursuing revenue partnering opportunities.

NanoCelle® Delivery Platform



- Proprietary, patented delivery platform.
- Several branded molecules moving through clinical evidence for drug registration.
- Partnering underway for multiple different molecules.

NanoCBD™ Targeting Stress



- Enhanced by NanoCelle® delivery platform
- TGA Pathway understood for OTC registered Medicine.
- Similar to NanaBis™ - without THC.
- In Partnering Discussions.

NanaBis™ Targeting cancer bone pain



- Enhanced by NanoCelle® delivery platform
- Safe, Tolerable, Efficacious.
- PI/II Complete – 900+ AU patients under clinical observation.
- Preparing for N=360 AU, UK & US PIII – (Estimated May 2022).
- NDA Estimated 2024.
- DMF for CBD & THC, working on robust CMC.
- In partnering discussions.

Nutraceuticals



- Divested AU operational Model.
- Medlab reserves Global rights and ownership of R&D and IP and ability for future licencing.
- Pursuing global trade opportunities.

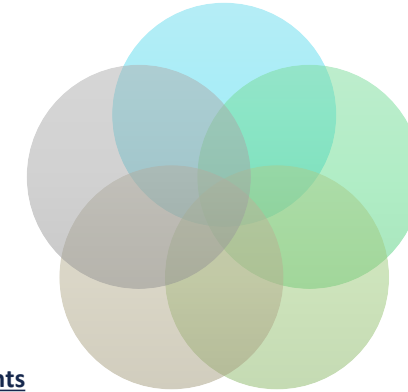
COMMERCIAL APPROACH

Exploring Variety of Partnering Models

Royalties, Joint Ventures & Asset Sales

Expanding Global Leadership Team

Worldwide Presence
Increased IR Focus



Securing US & AU Grants

In House Commercialisation Teams

Global BD & MSL Teams

48 Global Patents



[Click or scan to watch Medlab Channel 7 Interview](#)

INVESTMENT HIGHLIGHTS

- **Patented NanoCelle® drug delivery platform** with total addressable market of platform is **\$260 Billion**
- **Partnering activities underway** globally offering near term and future revenue
- Portfolio of therapeutics, including **cannabinoid therapeutics** addressing global unmet need in oncology areas including **pain management**; transitioning to **synthetic APIs** in accordance with regulatory guidance
- Lead candidate NanaBis™ met **Phase I/II primary and secondary endpoints** in bone cancer patients, **RWE continues to provide strong, positive signals, prepping for global P3**
- Strong **global patent** portfolio.
- **Experienced Board and Management team with >150 years** combined experience in the life sciences space; experience at Novartis, Abbott, Sanofi and Medlab among others

STRONG MOMENTUM IN 2021

	NOV 21	NanoCelle® US Patent Granted
	NOV 21	PharmaCare purchases Medlab's AUS Nutraceutical Business
	OCT 21	Orotate US Patent Granted
	OCT 21	NanoCelle® issued notice of allowance by US patent office
	AUG 21	NanaBis™ Phase III Trials approved in Australia
	JUL 21	Master Services Agreement (MSA) in UK – NanaBis™
	JUL 21	Granted Ethics for NanaBis™ Phase III Trials in Australia
	JUL 21	Strong NRGBiotic™ results achieved
	JUN 21	Europe & Canada NanoCelle® patent granted
	MAY 20	Synthetic introduction to phase III NanaBis™ announced
	NOV 20	UK NanaBis™ NIHR Trial collaboration
	JUN 20	Australian NanoCelle® Patent Granted



Scan QR Code to email us with any questions,
or email us at jefferies_questions@medlab.co

EXECUTIVE AND MANAGEMENT TEAM



Prof Luis Vitetta

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



Dr Patrick Miller

Director of Pharmacovigilance
& Regulatory Affairs



Kerem Kaya

Chief Financial Officer &
Company Secretary



Ian Curtin Smith

Chief Information Officer



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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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NANOCELLE®

OUR LEAD DRUG DELIVERY PLATFORM

Patent, novel sub-micron delivery platform that enhances medicines, improves solubility & by-passes first pass metabolism

NanoCelle® Global patent Protection to 2036 includes:

Jurisdiction	Application	Status
Europe (37 Countries)	16759418.3	Granted
Australia	2061226280	Granted
Canada	2978179	Granted
United States	15/555038	Granted
Hong Kong	18103321.4	Registration of Grant requested
Singapore	11201707068X	Under Examination
New Zealand	735138	Accepted

NANOCELLE® - HOW IT WORKS

[Click here to learn more about NanoCelle®](#)

NanoCelle®: a unique delivery platform enabling more effective absorption of active ingredients into the bloodstream

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

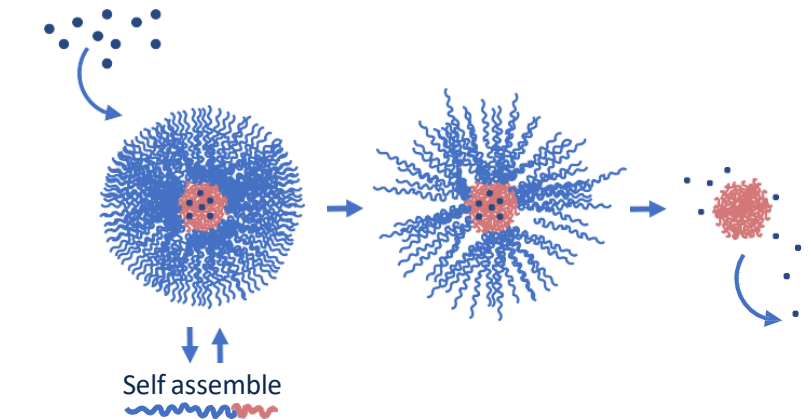


Figure 2a: NanoCelle™ fat-soluble beta-carotene (left) dispersed and soluble in an aqueous phase versus fat-soluble beta-carotene (right) insoluble in water sits on the surface of water phase.



Figure 3b: NanoCelle™ fat-soluble beta-carotene at a concentration of 1.5 mg/mL (right) dispersed and soluble in an aqueous phase versus fat-soluble beta-carotene (left) insoluble in water sits on the surface of the water phase.

RELEASE PROGRESSION



- Drug molecule
- ~ Hydrophilic block of polymer
- ~ Hydrophobic block of polymer

WHY NANOCELLE® OFFERS OPPORTUNITY

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



Innovative drug delivery

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



Commercially viable to manufacture

Consistently proven to meet the highest quality and safety standards, our products are commercially viable and ready for 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 global western territories



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NANOCELLE® R&D PORTFOLIO

Medlab's current NanoCelle® development work is comprised of:

Name	Indication	Pre clin	Safety	P1	P2B	P3	Market potential
Cannabinoid Development							
NanaBis™ (Botanical)	Cancer bone pain					UNDERWAY	US \$1.22B (2010) CAGR 5.4%
★ NanaBis™ (Synthetic)	Cancer bone pain					PIVOT	US \$1.22B (2010) CAGR 5.4%
NanaBis™ (Botanical)	Non-cancer pain			UNDERWAY			US \$69.3B (2017) CAGR 6.4%
NanaBis™ (Synthetic)	Non-cancer pain			PIVOT			US \$69.3B (2017) CAGR 6.4%
★ NanoCBD™	Stress						US \$10.9B (2020) CAGR 7.2%
Generics Plus							
★ NRGBiotic™	Depression						US \$11.67B (2019) CAGR 2.9%
NanoStat™	Cholesterol lowering						US \$16.3B (2010) CAGR 7.26%
Lidocaine	Pain						US \$69.3B (2017) CAGR 6.4%
Loratadine	Allergy						US \$24.65B (2017) CAGR 6.3%
Mesothelioma	Large bowel cancer						US \$338M (2017) CAGR 7.5%
Large molecule program							
NanUlin	Insulin						US \$21.6B (2018) CAGR 3.8%
★ mRNA	COVID-19 Vaccine						US \$1176.3M (2020) CAGR 8.7%
Textiles program							
Medicated Gauze	Antibiotic						US \$100M (2020) CAGR 6.1%
Smart Clothing	Antibiotic						US \$100M (2020) CAGR 6.1%

★ Medlab's priority Developments

NANABIS™ PROGRAM

OUR LEAD DRUG CANDIDATE

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A VIABLE NON-OPIOID ANALGESIC
TO TREAT CANCER BONE PAIN

THE OPIOID EPIDEMIC BY THE NUMBERS



70,630

people died from drug overdose in 2019²



10.1 million

people misused prescription opioids in the past year¹



1.6 million

people had an opioid use disorder in the past year¹



2 million

people used methamphetamine in the past year¹



745,000

people used heroin in the past year¹



50,000

people used heroin for the first time¹



1.6 million

people misused prescription pain relievers for the first time¹



14,480

deaths attributed to overdosing on heroin (in 12-month period ending June 2020)³



48,006

deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending June 2020)³

SOURCES

1. 2019 National Survey on Drug Use and Health, 2020.
2. NCHS Data Brief No. 394, December 2020.
3. NCHS, National Vital Statistics System. Provisional drug overdose death counts.



THERAPEUTIC INDICATIONS

MAIN:

- Cancer Bone Pain

ADDITIONAL

- Cancer Pain
- Chronic Pain

STATUS

- Phase III US Clinical Trial Number NCT04808531
- Phase III AU Ethics Approved HREC Approval ID: 2021-01-001/AA
- ANZ Clinical Trial Number assigned (ACTN) # ACTRN12621001302842
- Phase III AU TGA notification: CTN-03253
- USA FDA DMF's Synthetic CBD & THC
- Bridge determination

MAIN INGREDIENTS

- Synthetic CBD & THC
- Botanical CBD & THC

DELIVERY PLATFORM

- NanoCelle® Delivery Platform

MANUFACTURING

- Australia Botanical – for ethical compassionate programmes
- USA Synthetic – for clinical trials

AUTHORISED COMPASSIONATE USE

- Botanic Material – Australian Markets
- Botanic & Synthetic Material – UK Markets (Jan 2022), EU4 markets (April 2022)

NEXT STEPS

- Available as Compassionate Use in Australia and United Kingdom (coming Jan 2022)
- Ethical Compassionate Use in EU4
- Anticipated US FDA application 2024

METHOD OF ADMINISTRATION

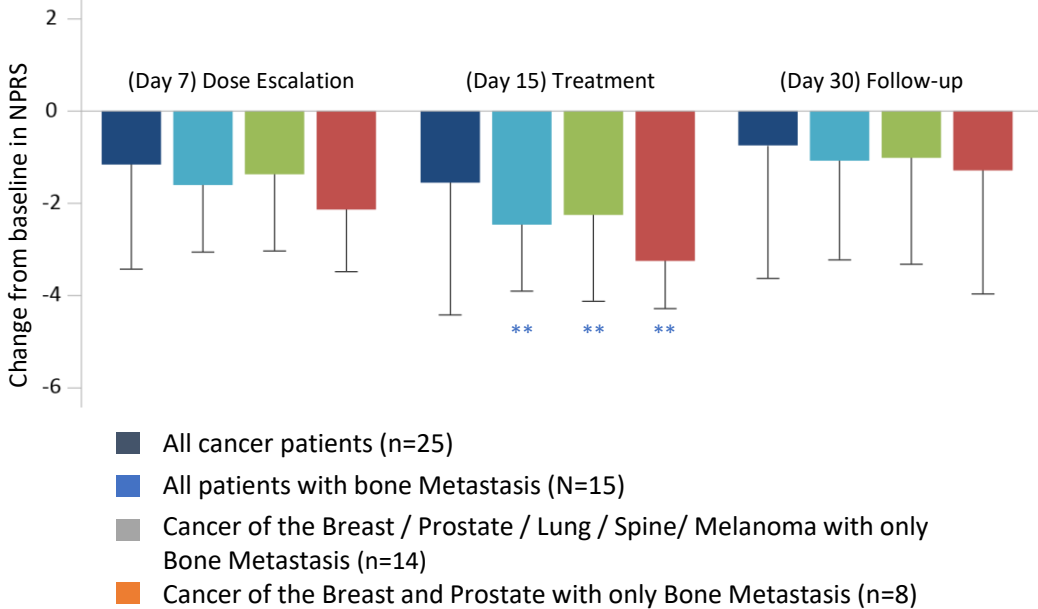
- Oro-buccal Spray

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 RWE could reduce the total number of patients required to be observed in clinical trials

961 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

NANOCBD™ PROGRAM

CBD DRUG CANDIDATE



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FOR TEMPORARY RELIEF OF STRESS

Prevalence of Stress

- More than three-quarters of adults report symptoms of stress, including headache, tiredness, or sleeping problems. (APA 2019)
- About one-third of people around the world reported feeling stressed, worried, and/or angry in 2019 (Gallup)
- It's estimated that job stress costs U.S. industry more than \$300 billion a year in absenteeism, turnover, diminished productivity, and medical, legal, and insurance costs (The American Institute of Stress)
- Stress costs businesses an estimated \$125 billion to \$190 billion in additional health care expenditures per year (Management Science, 2016)

Size of Market: USD 7.01 billion

- The global workplace stress management market size was valued at **USD 7.01 billion** in 2018 and is expected to grow at a **CAGR of 8.4%** over the forecast period. With the rising competition, the employees work under a lot of pressure and excessive demands.
- The Global Workplace Stress Management Market size is expected to reach **\$11.3 billion by 2025**, rising at a market growth of **8.5% CAGR** during the forecast period.

Source:
<https://www.grandviewresearch.com/industry-analysis/workplace-stress-management-market>
<https://www.apa.org/news/press/releases/stress/2020/report>



MAIN THERAPEUTIC INDICATIONS

- Temporary Stress relief
- OTC Registered Medicine

STATUS

- Product Development stage
- Drug Substance Synthetic CBD, US FDA recognised Drug Master File (DMF)

MAIN INGREDIENTS

- CBD Synthetic (No THC)

DELIVERY PLATFORM

- NanoCelle® Delivery Platform

MANUFACTURING

- Australia Botanical – for ethical compassionate programmes
- USA Synthetic – for clinical trials

Authorised Compassionate Use

- Botanical Material – Australian Markets
- Botanical & Synthetic – UK Markets (Jan 2022), EU4 (April 2022)

NEXT STEPS

- Strengthening the Chemistry Manufacturing and Controls (CMC) package for Synthetic for TGA drug application.
- Like NanaBis™, open the global availability to all fit for purpose, ethical patient payable, compassionate use programs.
- Work with existing partners for joint development and registration of an approved product.
- Anticipated AU TGA application 2024

METHOD OF ADMINISTRATION

- Oro-buccal Spray

NRGBIOTIC™ PROGRAM

INVESTIGATIVE PROBIOTIC FORMULATION

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A VIABLE ADJUNCTIVE THERAPY TO
ANTIDEPRESSANT MEDICATIONS

Depression is a common mental disorder - approximately 280 million people in the world have depression.

Depression is a leading cause of disability worldwide and is a major contributor to the overall global burden of disease.

Although there are known, effective treatments for mental disorders, more than **75% of people** in low- and middle-income countries **receive no treatment**. Barriers to effective care include a lack of resources, lack of trained health-care providers and social stigma associated with mental disorders.

In countries of all income levels, people who experience depression are often **not correctly diagnosed**, and others who do not have the disorder are too often **misdiagnosed** and prescribed antidepressants.

1. Institute of Health Metrics and Evaluation. Global Health Data Exchange (GHDx). <http://ghdx.healthdata.org/gbd-results-tool?params=gbd-api-2019-permalink/d780dffbe8a381b25e1416884959e88b> (Accessed 1 May 2021).

2. Evans-Lacko S, Aguilar-Gaxiola S, Al-Hamzawi A, et al. Socio-economic variations in the mental health treatment gap for people with anxiety, mood, and substance use disorders: results from the WHO World Mental Health (WMH) surveys. *Psychol Med.* 2018;48(9):1560-1571.

ABOUT NRGBIOTIC™



KEY FEATURES

- Supports healthy mood balance and reduces symptom occurrence of mild depression.
- Aids the synthesis of neurotransmitters and supports nervous system health.
- Helps balance the gut-brain axis.
- Enhances energy levels.
- Promotes healthy muscle function, improves exercise performance and post exercise recovery.

STATUS

- The Phase 2a trial met primary and secondary endpoints and has shown keen insights to optimise the product to a simpler and more cost-effective formulation.

ACTIVE INGREDIENTS

- | | |
|---------------------------------------|-----------------|
| • Magnesium orotate | 400mg |
| • Ubidecarenone (Coenzyme Q10) | 37.5mg |
| • Lactobacillus acidophilus (Med 27) | 2.5 billion CFU |
| • Bifidobacterium bifidum (Med 11) | 1 billion CFU |
| • Streptococcus thermophilus (Med 51) | 1.5 billion CFU |

DELIVERY PLATFORM

- Probiotic

PATENTS

Jurisdiction	Patent No.	Status	TGA #
Australia	2015202755	Granted	328697
Canada	2964971	Requested	
Europe	15854029.4	Under Examination	
New Zealand	731151	Granted	
Singapore	11201703193X	Under Examination	
United States	15/523271	Granted	
Hong Kong	17109856.5	Filed	

NUTRITION

- Vegetarian
- Gluten Free
- Dairy Free

NEXT STEPS

- Optimise the drug substance – keen insights demonstrated in above trial.
- Consult regulation on final formulation and possible next steps ultimately leading to drug application.

METHOD OF ADMINISTRATION

- Soft Shell Capital




CORPORATE & FINANCIALS


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FINANCIALS & CORPORATE PERFORMANCE



Medlab's **total sales revenue for FY21** was \$4.4M, being +54% from last year, with a net loss after tax of \$12.3M. Normalising the average monthly cash burn was critical to ensure available funds for Medlab's high value programs. Last financial year the Australian Government's R&D tax incentive was \$2.4M, with this year estimated in annual report to be \$2.2M, actual refund to \$3M.



Medlab divested **AU only nutraceuticals business** to PharmaCare, for total \$2.1M consideration (\$1.6M upfront & inventory \$0.5M over next two years). The sale of the consumer business allows Medlab to focus its core Pharma strategies, while providing annual opex / cash savings of ~\$2M



In March/April 2021, Medlab **secured a placement** of \$15.5M net. This placement was predominantly taken by several new institutional bankers, based on the average current cash burn and before any Government cash or rebate initiation, this is projected to last 15 months from date of placement.



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CURRENT FINANCIALS SNAPSHOT

Direct P&L	FY Jun 2020	FY Jun 2021
Revenue	6,319,536	5,978,909
Disc/Rebates/Credits	3,471,142	1,579,498
Net Revenue	2,848,394	4,399,412
COGS	2,804,877	2,939,794
Gross Profit	43,517	1,459,617
Other Revenues		
- R&D Tax Incentive	2,444,685	2,265,000
- Interest Income	76,143	25,198

Balance Sheet	FY Jun 2020	FY Jun 2021
Cash	9,063,044	13,434,762
Accounts Receivable	783,501	1,044,467
Inventory	1,473,136	792,371
Other Assets	6,468,842	5,374,705
Liabilities	6,533,232	5,740,454
Net Assets/Equity	11,255,291	14,905,851

- Net revenue increased by +54% to \$4.4m, with a net loss after tax down by +8% to \$12.4m in FY2021.
- Revenues are predominantly from sales in Nutraceutical products.
- Significant reduction on Nutraceutical CO-OP spend (+1.4m YoY) main driver of sales deductions improvement in 2021.
- Recent optimisation project seeing a rapid turnaround in gross margins.
- Divestment of Nutraceuticals currently in progress, improving cashflow and re-optimizing spend on Pharma Strategic imperatives.
- Diluted loss per share fell 30% to 4.18 cents, with net tangible assets per share up 5% to 4.36 cents.
- R&D Tax Claim of \$3.1M cash back expected November 2021.
- Future R&D Claim approved for NanaBis™ development circa \$12M cash back annualized against future expenses of the program.

MEDLAB CATALYSTS | 6-9 MONTHS



USA/Europe Partnering (various assets) – provides for early revenues



NanaBis™ US c-IND status and potential bridge determination



NanaBis 1st patient in



NanoCBD™ PK and ToxiCol packages



Compassionate (ethical) Programmes – UK and EU4 launches, US EA-IND application



3rd NOV 2021 - The Australian Government awards an 'Advanced and Overseas Finding' for the NanaBis™ development program for the expected 3 year period of circa AU\$27M, allowing for a approx. 43.5% expected cash rebate for the associated activities.



4th NOV 2021 - USPTO upgrades NanoCelle® patent from **allowed** to **granted** with expiry of 2036.



Scan QR Code to email us with any questions,
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THANK YOU

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APPENDIX I: CORPORATE INFORMATION

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BOARD OF DIRECTORS



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



Laurence McAllister

Executive Director



Cheryl Maley

Non-Executive Director

MEDICAL & SCIENTIFIC CONSULTING TEAM



Prof Stephen Clarke

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FACHPM FAAHMS



Ass Prof Wojciech Chrzanowski

MSc, PhD, DSc



**Prof Andrew
Mclachlan**

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



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PhD



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Margot Rothwell

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Consultant - MBA (Clin Pharm
Mgt), Executive Director at
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