

**Nutraceuticals** 

### **Investor Presentation**

September 2019 | Sydney, Australia

MO RE
SCIENCE







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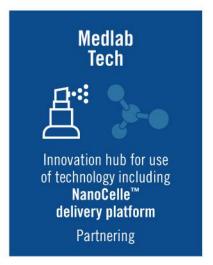
## Corporate Overview – Who is Medlab?

Medlab Clinical is a medical research and development company formulating and commercialising novel bio-therapeutics to improve patient health outcomes in early to moderate stage **chronic diseases**.

### Four Core Business Hubs











### **Executive Team**



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

Sean has over 20 years of experience in the Australian healthcare, food industries and early phase drug discovery in Australia and Asia. Sean is best known for building Australia's leading Practitioner-only brand, **BioCeuticals**.

**FIT-BioCeuticals** Limited was sold to Blackmores Limited early July 2012.



Alan Dworkin CA, ACSA, GAICD Chief Financial Officer & Company Secretary

Alan Dworkin is a chartered accountant with over 18 of years experience in the tax, retail, resources and nutraceutical/pharmaceutical sectors. Alan was the CFO and Company Secretary of FIT-Bioceuticals Limited for over six years and also has had experience in ASX listed companies within the resources sector.



Paul Vilner BSc MRes Director, Commercial Operations

Paul's diverse commercial experience include sales, marketing, New Business Development and licensing & acquisitions for **Abbott** and **Mylan**. Most recently as General Manager for **Tolmar** ANZ in the oncology arena.



Dr David Rutolo
Director of Science

David is renowned in the US for his specialised, patented delivery systems for nutraceuticals and pharmaceuticals. David was a Cofounder of **Micelle Laboratories, Inc.**, where he served for over 20 years as Executive Vice-President and as a Board Member.



Prof Luis Vitetta
Director of Medical Research

Luis has held senior posts in Australian Universities and has an international reputation as a rigorous academic and a scrupulous researcher. Luis heads a team whose applied research leads directly to product development.



## Department Heads



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

Tony is a Pharmaceutical executive with almost 30 years experience in both New Zealand and Australia.

Tony has been responsible for leading several successful sales and marketing teams such as Abbott.



National Sales Manager
Varun brings over 10 years of sales experience in the nutraceutical industry and has worked closely alongside Sean at FIT-Bioceuticals.



Medical Affairs Director

Jeremy has 18 years' experience in cancer research and notably predicted the presence of a completely novel type of cancer biomarker and invented (patented) an assay to detect it. This assay is a frontline research assay and has the potential to become a clinical diagnostic.

**Dr Jeremy Henson** 



Dr Patrick Mueller
Regulatory Affairs Manager
Prior to joining Medlab, Patrick worked as a premarket evaluation officer for the Therapeutic Goods
Administration in Canberra. Patrick has also worked as a Researcher in Microbiology and Virology at the Sydney University and UTS.



Director of Digital and Technology

A strategic executive with C level success in IT governance and Business Intelligence solutions, with 20 years of experience in Management. Ian served over 9 years as an Executive Team member of FIT-BioCeuticals.

Ian Curtinsmith



## **Corporate Achievements**

ASX:MDC.

Market Cap: \$103M.

Current share price \$0.48 as at 22 August2019.

Date Listed and IPO price: 14 July 2015 at

\$0.20.

Practitioner brand.

JUL 2012	Medlab secures Alexandria premise	AUG 2013	Medlab admitted to ASX (ASX: MDC) raising \$6.2m before costs	JUL 2015	Completes Rights Issue raising \$5.4m before costs	AUG 2016	Completes Phase 1 NRGBiotic™/ Depression Trial	NOV 2016	Ethics granted for Phase 2a NRGBIOTIC™/ Depression Trial
Sold BioCeuticals to Blackmores (ASX:BKL) for \$43M. BioCeuticals was Australia's leading	OCT 2012	Gov't certification for Alexandria lab	JUL 2015	Granted a Cannabis research licence	JUL 2016	Medlab and Aphria Inc executes Cannabis supply agreement	AUG 2016	Granted licence for the import of Cannabis	MAR 2017



# **Corporate Achievements**

JUN 2017	Granted 20 Year Australian Patent for its anti- depression product (NRGBiotic™)	JAN 2018	Completes over- subscribed placement raising \$24m before costs	MAY 2018	Recruitment commences for Phase 2a NRGBiotic™/ Depression Trial	AUG 2018	Medlab starts talks with the FDA and EMA for NanaBis™ Drug Registration	SEPT 2018	Successful completion of Stage 1 of NanaBis™ trial at Royal North Shore Hospital
Ethics granted for NanaBis™ and NanaBidial™ cannabis trials	SEPT 2017	Granted licences to sell or supply Cannabis in Australia	JAN 2018	NanaBis™ trial at Royal North Shore Hospital commences	JUL 2018	Ethics granted for new oncology trial (Mucositis)	SEPT 2018	Granted a licence to export Cannabis	OCT 2018



# **Corporate Achievements**

DEC 2018	Successful completion of NanoStat trial (Atorvastatin)	MAR 2019	Heads of Agreement for NanaBis™ executed with Pharmascience Inc	APR 2019	Heads of Agreement for NanaBis™ executed with Mega Lifesciences	JUN 2019	Heads of Agreement executed to expand nutraceuticals into USA	AUG 2019	to apply for AU Ethics approval to commence Phase 3 NanaBis™ Drug Trials, and then subsequently US.
Medlab expands into Europe	JAN 2019	Medlab expands into AU banner pharmacy	MAR 2019	Medlab achieves monthly revenue in excess of \$1m for the first time	MAY 2019	Ethics granted for second NanaBis™ Trial (Observational Study)	AUG 2019	Successful completion of NanaBidial Phase 1 Trial	APR 2020





Our aim, in the midst of today's chronic disease, is to provide More Choice.











## Why Chronic Disease?

Over 7 in 10 (73%) of deaths in 2013 were due to the 8 chronic diseases.

**More than 11 million** Australians (50%) reported having at least 1 of 8 chronic diseases in 2014-15.

**Around 1 in 3** (30%) problems managed in general practice in 2014-15 were associated with 8 chronic diseases.

**87%** of people aged 65 and over had at least 1 of 8 chronic diseases in 2014-15 compared with 35% of people aged 0-44.

**More than 1 in 3** (39%) of potentially preventable hospitalisation's in 2013-14 were due to the 8 chronic diseases.



# Why Chronic Disease?

**METABOLIC DISEASES** Type II Diabetes **USA** 30,000,000 & growing<sup>1</sup>

**CVD** Australia 1,200,000<sup>2</sup> **USA** 85,600,000<sup>3</sup>

**ONCOLOGY Advanced Cancer** Pain Australia - 130,000 new patients every

vear4

medlab.

**MENTAL HEALTH** 

**Depression** 5% of the world population<sup>5</sup>

### Scale of **Opportunity**

**Unmet needs** 

**Significant** market size

Uniqueness, **Patents, Solutions** 

> **Minimal** competition

<sup>1</sup>http://www.diabetes.org/assets/pdfs/basics/cdc-statistics-report-2017.pdf

<sup>2</sup>Australian Government, The Department of Health

http://www.health.gov.au/internet/main/publishing.nsf/Content/chronic-cardio

<sup>3</sup>American Heart Association <a href="https://www.heart.org/idc/groups/ahamah-">https://www.heart.org/idc/groups/ahamah-</a> public/@wcm/@sop/@smd/documents/downloadable/ucm 470704.pdf

4https://www.cancer.org.au/about-cancer/what-is-cancer/facts-and-figures.html

5https://www.healthline.com/health/depression/facts-statistics-infographic#1



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Fundamentally Different. Driven by Science.





Nutraceuticals







### The Medlab Difference

### Fundamentally driven by Science:

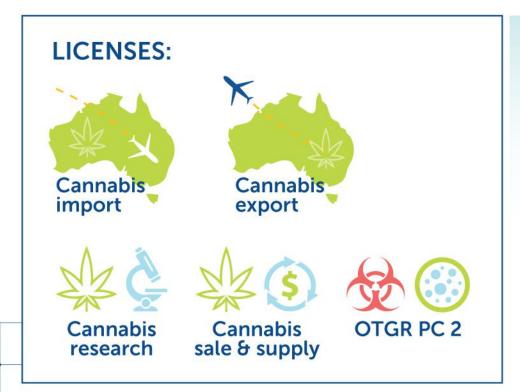
- ✓ We own a Government accredited lab.
- ✓ We work with some of Australia's best institutions.
- ✓ We work with Human Ethics departments to ensure our research is meaningful and publishable.
- ✓ All research is peer-reviewed.
- ✓ Extensive patent portfolio.
- ✓ As Researchers and Doctors, we are invited speakers at global conferences and authors in meaningful medical/scientific publications.
- ✓ We are revenue earning, via nutraceutical sales, compassionate access to drugs and contract work.
- Executing licencing agreements and significant interest in current work, promising future work.

#### **Extensive Patent Portfolio**





## Validated Research Agenda























Preeminent partners validate our scientific credentials and approach.

### **Science Matters**

Dr Sean Hall, CEO of Medlab stated that "Medlab is in a unique and privileged position, as one of a global few who possess proof via clinical studies that the Medlab patented pharmaceutical cannabis formulations are actually absorbed, what that absorption profile looks like, and how the product is utilised, metabolised and eliminated from the body over time... This is critical for approved claims & medical confidence."







Nutraceuticals

Commercialisation

Science driven / commercially focused

- Medlab Nutraceuticals
- Medlab Pharmaceuticals
- Medlab Tech
- 4. Medlab Lab Services











## Medlab Philosophy – Commercial Approach





Nutraceuticals

## Nutraceuticals

- 1. via our sales team into AU Pharmacy.
- 2. via global partnering.









## Major Deals

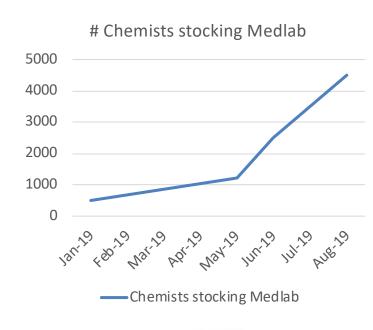
- Domestically, Medlab have signed deals with 2 major wholesalers.
- This gives access for Medlab products to over 4,500 pharmacies in Australia.



Symbion Wholesale, Good Price
Pharmacy, DoseAid, healthSAVE,
IntelliPharm, Minfos, Pharmacy Choice,
TerryWhite Chemmart, New Zealand
Wholesale, Ventura Health.



Priceline Pharmacy, Soul Pattinson Chemist, Pharmacist Advices, Club Premium, Pharmacy Best Buys.





### **Products**



- The Medlab product range now includes 34 premium formulations, many protected under patents.
- Medlab's nutraceuticals are scientifically validated, innovative and Professional recommended products that provide therapeutic support for various conditions.
- Global opportunities currently being evaluated with 1 HoA for US expansion signed.

AU Circa Market

AUD \$2.8B<sup>6</sup>

US Circa Market

**USD** \$32.7B<sup>7</sup>

Asia Circa Market

USD \$44B8





<sup>&</sup>lt;sup>6</sup>http://www.cmaustralia.org.au/resources/Documents/Australian%20Complementary%20Medicines%20Industry%20snapshot%202018\_English.pdf

<sup>&</sup>lt;sup>7</sup>https://www.ibisworld.com/industry-statistics/market-size/vitamin-supplement-manufacturing-united-states

<sup>8</sup>https://www.slideshare.net/Euromonitor/opportunities-for-vitamins-and-dietary-supplements-in-asia-pacific



Nutraceuticals

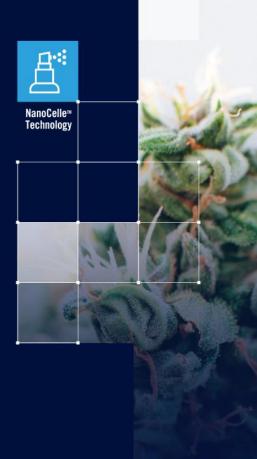
- Cannabis
  - 1. NanaBis™ (1 THC:1 CBD)
  - 2. NanaBidial™ (20 CBD:1 THC)
  - 3. NanoCBD™ (CBD only)













## NanaBis<sup>™</sup>

NanaBis<sup>™</sup> is in a robust trial at Royal North Shore Hospital led by Professor Stephen Clarke.

- Pathway to drug registration and global market access.
- ✓ Investigative use in <u>cancer pain management</u>.
- ✓ Accumulative data to date demonstrates opioid reduction, improved quality of life, safety, fast acting and superior to other cannabis products.

### **Observational study in AU underway.**

Phase III: trial design has now commenced.

Available under Government Special Access Scheme (SAS).





# NanaBis<sup>™</sup> Is Targeting Pain

### The Opioid Market

In 2018, overall deaths due to opioid misuse cost Australia \$4.7 billion, comprising \$1.0 billion in financial losses (forgone future income), and \$3.7 billion in reduced wellbeing.9

### The Chronic Pain Market

 According to Painaustralia, the total financial cost of chronic pain in Australia in 2018 is estimated to be \$73.2 billion AUD.

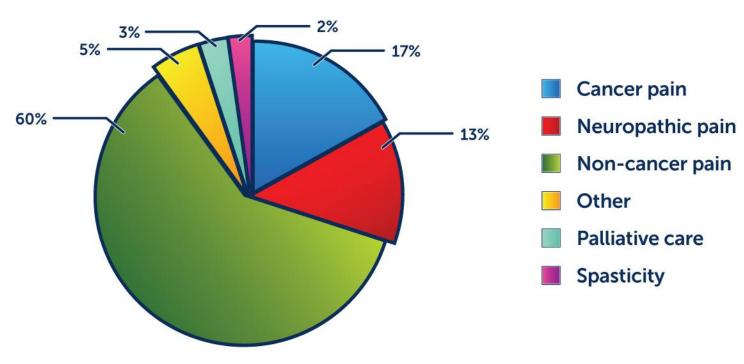


<sup>&</sup>lt;sup>9</sup> Deloitte. Access Economics, March 2019, Regional analysis and projections, Cost of opioid misuses, https://www.painaustralia.org.au/static/uploads/files/the-cost-of-pain-in-australia-final-report-12mar-wfxbrfyboams.pdf

<sup>&</sup>lt;sup>10</sup> Deloitte. Access Economics, March 2019 The cost of pain in Australia Painaustralia. https://www.painaustralia.org.au/static/uploads/files/the-cost-of-pain-in-australia-final-report-12mar-wfxbrfyboams.pdf

**In Market** 

# NanaBis™ Primary Illness Usage



Whilst NanaBis<sup>™</sup> targets cancer pain, clearly there are other areas of use.





## NanaBidial™

NanaBidial<sup>™</sup> is a new product containing 20mg/mL of Cannabidiol (CBD) and <1mg/mL of delta-9-tetrahydrocannabinol (THC), in a sub-micron spray (NanoCelle<sup>™</sup>) applied to the oro-buccal membrane.

- Safety trial conducted at Scientia Clinical Research, NSW completed.
- ✓ No safety issues have been reported.
- ✓ Indicated for seizures, CINV, mild anxiety.
- ✓ Available under Government Special Access Scheme (SAS).







### NanoCBD<sup>TM</sup> (New Product)

**Cannabis** 

NanoCBD™ is a formulation containing 16.67 mg/mL cannabidiol (CBD) as an active ingredient, in a sub-micron spray applied to the oro-buccal membrane. NanoCBD™ is a hemp-based product available soon in the United States. NanoCBD™ is not available yet in Australia however Medlab is working to make NanoCBD™ more widely available.

- NanoCBD™ is manufactured in a U.S. Food and Drug Administration (FDA) approved, Good Manufacturing Practice (GMP) licenced and Over The Counter (OTC) certified facility in California.
- Uses NanoCelle<sup>™</sup> patented delivery platform.
- Complies to US Farm Bill 2018.
- Expected Christmas 2019 (AU, HK & USA).





## Cannabis – Dual Track Approach

### The path to full registration is our absolute goal

 Registered drug pathway, long but highly lucrative on success.

# The short and medium term opportunity has also been executed

- Short-term opportunity maximisation via SAS compassionate use.
- Mid-term opportunity maximisation via global partnering.

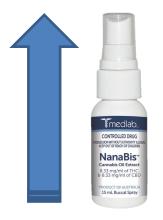
**GW Pharma** has the only registered form of drugs available under FDA or Euro approval. That drug is for a specific and limited treatment. Last quarter GW recorded revenues of \$70 million and GW has a market capitalisation of \$4.5 Billion USD (ticker GWP US)11



## Cannabis Commercial Pathways

### Short to Medium Term Opportunity

- Heads of Agreement signed, working through term sheets:
  - PharmaScience Inc.
  - Mega LifeSciences.
- Several early stage licensing discussions underway.
- Offering new NanoCBD™ product to global markets. NanoCBD™ has signed HoA for Hong Kong. Several others currently in discussion.
- 4. SAS Compassionate use in Australia.
  - Patients are de-identified according to strict medical standards.
  - Medlab have almost over 150 Specialists and GPs prescribing and over 3000 bottles dispensed.



Almost 700 approvals



Over 100 approvals



## **Cannabis Commercialisation Summary**









# Competitive Landscape

ASX	ASX Name		Product	June Quarter 4C ASX filing customer receipts	Licences
MDC Medlab Clinical Limited		100 Mill	Nutraceuticals and PATENTED Medical Cannabis – NanaBis in drug registration models. Products available via SAS and Export.	\$2.6 Mill	Import; Export; Manufacture; Research
AGH	Althea Group Holdings	182 Mill	CBD:THC Oil via SAS and UK focus / Seed to sale plans / Aphria Inc 25% shareholder	\$280 K	
AC8	AusCann	118 Mill	Products in planning / Cannopy Growth is an investor	-	
EXL	Elixinol	332 Mill	Hemp and MC plans	\$8.4 Mill	
CAN	Cann Group	245 Mill	Vertically integrated Medical Cannabis	\$1.5 Mill	
EOF	EcoFibre	850 Mill	Hemp and value added Hemp & CBD	\$12.3 Mill	
GW	GW Pharma (UK)	4.58 Bill	FDA Registered drug in narrow specific application	\$70 Mill USD (March Qtr)	





- Proprietary process developed inhouse with varied potential outcomes.
- Delivery platform is first material development.











## NanoCelle™ Commercialisation Opportunities

NanoCelle™ opportunity effectively delivering medicines with faster and greater absorption profiles.

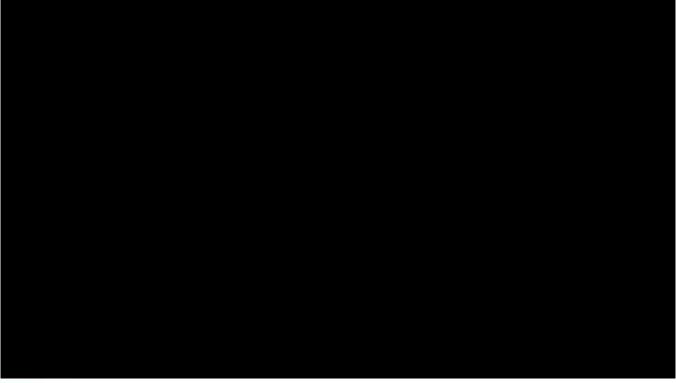
### Other revenue opportunities:

- Repurposing generic drugs.
- Repurposing stronger, poorly absorbed drugs.
- Cosmetics.
- Food additives.
- Reduction of side effects.

Global value of pharmaceutical delivery platforms at 1,244B USD (2018) at a CAGR of 6.4%.



### What is NanoCelle™ Delivery Platform?





**ABSORPTION** 



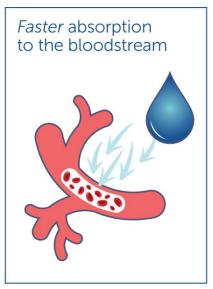


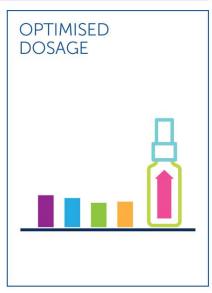




### NANGCELLE SIMPLIFIED







- NanoCelle™ International Patent "Transmucosal and transdermal delivery systems" #WO2016141069A1.
  - AUS #PCT/US2016/020468
  - Canada#2978179
  - EU#16759418.3
  - NZ#735138
- "Protection of plant extracts and compounds from degradation" #WO2017193169A1
  - AUS #2017261847
  - Canada#3023767
  - EU#17795190.2
  - NZ#748609

Singapore#11201809976P

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USA#15/555038

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- USA#16/300537
- HK#19122060.7



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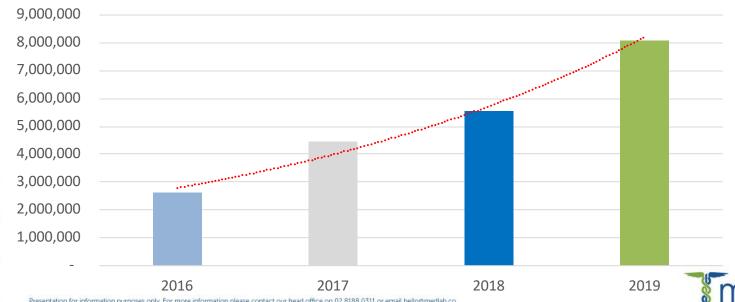
## Financial Highlights

Revenue up %46

June Qtr achieved \$3m in revenue

Cash collections increased by 24% Cash balance of \$11.442m

#### **Total Revenue**



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### **Nutraceutical Business**

### **Nutraceutical Sales**



Sales (net of discount but prior promotional costs) increase of 40% to \$5.794m.

Increase in expenses incurred as part of the launch in Banner Pharmacy.

### Pharmaceutical Division

- Initial Income of \$350k achieved.
- R&D tax incentive increase of 163% to \$2.027m as a reimbursement for research costs.
- Over 700 approvals have been given for NanaBis™ and over 2,500 bottles have been dispensed.
- Global partnering opportunities Heads of Agreements have been signed.



## Strong Balance Sheet

	2019	2018
Current Assets	19,089,829	23,814,746
Non-current assets	1,114,548	512,226
Total Assets	20,204,377	24,326,972
Current liabilities	4,983,487	2,349,791
Non-current liabilities	228,238	118,618
Total liabilities	5,211,725	2,468,409
Net Assets	14,992,652	21,858,563

- Net assets of \$15m.
- Increase in inventory from \$1.164m to \$2.218m as a result of acquiring more inventory to cater for the launch into Banner Pharmacy.
- Trade receivables increase from \$767k to \$1.799m (allowance for expected credit loss of only \$25k).
- Trade payables increase from \$990k to \$2.549m.
- Balance of debtor finance facility of \$930k. Total facility of \$2m. Helps significantly with cash flow management.



## Strong Cash Flow Management

	2019	2018
Operating activities	(10,316,577)	(4,775,366)
Investing activities	(340,323)	(96,477)
Financing activities	1,775,173	23,677,982
Net increase/(decrease)	(8,881,727)	18,806,139
Opening cash	20,332,694	1,497,600
FX adjustments	(8,992)	28,954
Closing cash	11,441,975	20,332,693

Cash balance of \$11.442m.

#### Operating Activities:

- Cash collections increased by 24% to \$5.832m.
- Receipts from R&D Tax incentive and other government grants of \$1.4m.
- Low administration and overhead costs.
- Increase in payments for Banner launch (marketing and inventory).

#### Financing activities:

- Net movements of borrowings of \$472k.
- Proceeds from conversion of options of \$1.3m.

### Thank You





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