



ASX Announcement

Medlab outlines opportunity for growth, supported by the clinical and regulatory strategy to the US and global investment community

SYDNEY Australia, 2 June 2021: Medlab Clinical Limited (ASX: MDC), the Australian company commercialising an enhanced drug delivery platform to maximise the efficacy of medicines has outlined its growth strategy for US and global investors at the prestigious annual Jefferies Healthcare Conference.

Medlab Clinical's Founder, CEO and Managing Director Dr Sean Hall told the conference, "The progress of our novel synthetic cannabinoid formulation for non-opioid pain has put Medlab at the forefront of the efforts to develop clinically validated non-opioid alternatives for cancer bone pain."

Dr Sean Hall said "Medlab's move to a synthetic compound for its pending Phase III trial brings greater certainty to the delivery of a pharmaceutical-grade product at industrial scale for global markets."

Dr Sean Hall said "Medlab was focused on achieving regulatory approval for its lead drug candidate NanaBis™ in the shortest time possible."

He shared with the audience that Medlab had identified multiple revenue generating partnering opportunities for its NanoCelle® drug delivery platform which can improve the efficacy of multiple medicines and therapeutics.

Dr Sean Hall, on behalf of Medlab, would like to thank Jefferies Financial Group Inc for the opportunity to present our vision to such an influential global audience.

The recording of Dr Sean Hall's presentation can be accessed via this link

<https://wsw.com/webcast/jeff174/mdc.ax/2053485>

A copy of Dr Sean Hall's presentation is attached.

ENDS

Authorisation & Additional information

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

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About Medlab – www.medlab.co

Medlab Clinical LTD (ASX: MDC) is pioneering the development and commercialisation of a 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 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.

Medlab – *better medicines, better patient care*



Delivering an Approved & Safe Solution for the Global Opioid Crisis

Presented by Dr Sean Hall, MD, CEO & Founder
Jefferies Healthcare Conference | 1st-4th June 2021

ASX:MDC

Scientifically optimised for a better life

ABOUT MEDLAB CLINICAL

Differentiated drug delivery company entering a pivotal period

- Medlab Clinical Ltd (ASX: MDC) is an Australian, publicly listed biotechnology company that is delivering new ways to **address unmet medical needs**, including the growing burden of suboptimal **cancer pain** management as well as **enhancing drug delivery using nanotechnology**
- Medlab is focusing on pharmaceutical candidates optimized by its delivery platform **NanoCelle®**
- Lead candidate **NanaBis™** is one of the world's most advanced, clinically validated medicinal cannabis therapeutics for cancer bone pain
- Medlab will focus on a **synthetic product pathway**, however, will continue to work on Botanical solutions to address global health agenda



ABOUT MEDLAB CLINICAL

Key investment highlights

- **Patented NanoCelle® drug delivery platform** offering near term partnering opportunities; total addressable market of platform is **\$260 Billion**
- Portfolio of **cannabinoid therapeutics** addressing global unmet need in oncology areas including **pain management**; transitioning to **synthetic APIs** in accordance with FDA guidance
- Lead candidate NanaBis™ met **Phase I/II primary and secondary endpoints** in bone cancer patients, **Phase III imminent** with clear drug pathway in US, EU and Australia
- Strong patent portfolio; patents **granted in AU, NZ, and EU; protection until 2036; patents filed for SG, HK, CA, and US**
- **Experienced Board and Management team with >150 years** combined experience in the life sciences space; experience at Novartis, Abbott, Sanofi and Medlab among others



A photograph of two scientists in a laboratory setting. On the left, an older man with glasses and a white lab coat is wearing blue gloves and holding a test tube with a yellow liquid. On the right, a younger man with safety glasses and a white lab coat is also wearing blue gloves and holding a test tube. They are both looking intently at the test tubes. The background shows laboratory shelves with various bottles and equipment. A large, white, curved line graphic is overlaid on the left side of the image.

NANABIS™ PROGRAM

OUR LEAD DRUG CANDIDATE

SIGNIFICANT MARKET OPPORTUNITY: 64% OF ALL BONE CANCER PATIENTS ARE NOT CURRENTLY SUPPORTED BY EXISTING THERAPIES

Aiming to reduce cancer-induced chronic pain

Cancer Bone Pain	\$1.22B Global market (2019) with CAGR of 5.4%	Cancer Bone Pain (primarily in Breast, Prostate and Lung) About 700,000 new patients (annually) in US, AU and Canada
Cancer Pain	\$5.28B Global market opportunity (2017)	CAGR 4.5%, estimated to be \$7.54B (2025)
Chronic Pain	\$69.3B Global market opportunity (2017)	CAGR 6.4%, estimated to be \$151.7B (2030)

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.

Addressing the opioid crisis

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
- 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

NANABIS™ - A VIABLE NON-OPIOID ANALGESIC TO TREAT BONE PAIN

Scientifically optimised to perform better: 1 to 1 ratio THC and CBD

- Robust clinical trials program with early clinical data pointing to improvement in pain scores; when used alongside opioids, could lead to **reduction in opioid dosage**
- Optimised by the **NanoCelle® drug delivery platform for buccal spray formulation**
- High bioavailability, smaller doses and **fast absorption into the bloodstream** enhances performance and efficacy
- **Clear plan outlined to transition from botanical extract formulation to synthetic APIs, in accordance with FDA guidance**

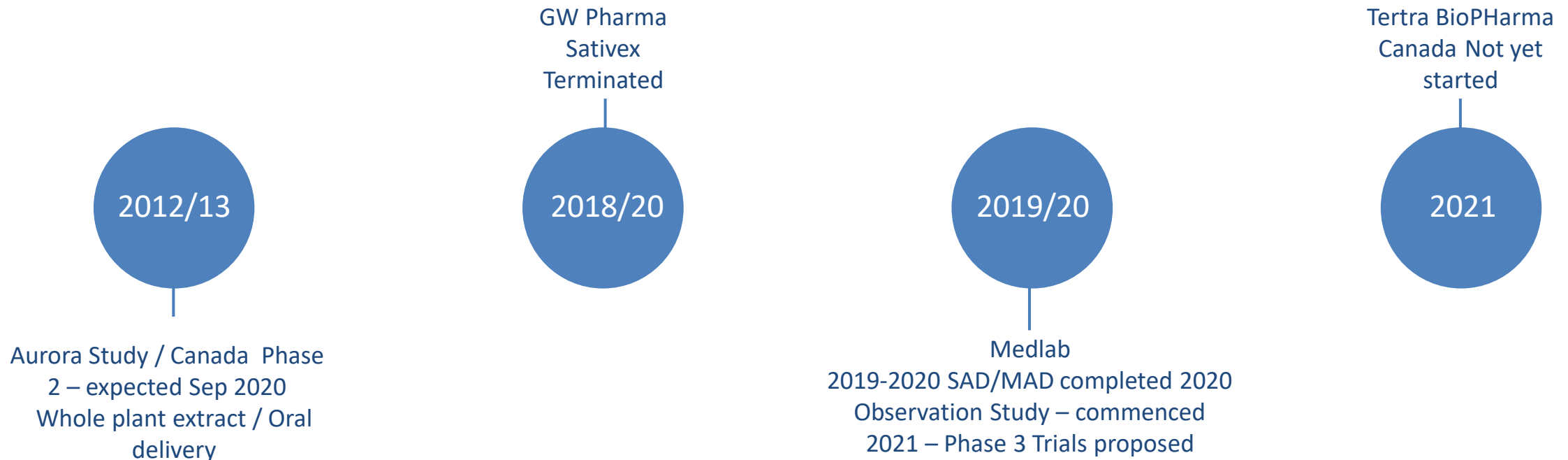
NanaBis™ provides a fast-acting and viable alternative to opioids, improving pain management and quality of life

NanaBis™ has potential to become the first FDA-approved THC therapeutic for analgesic use



NANABIS™ COMPETITIVE POSITIONING

- Currently 8 clinical Trials on clinicaltrials.gov for “Pain” and “Cannabis” that are active
 - Of the 8, NanaBis™ is the ***only cancer pain trial*** with an associated trademark for a finished product
 - 2 relevant market examples:
 - i. GWPH acquired by Jazz Pharma in 2021 for **US \$7.2 billion**; GWPH same MC as Medlab today with limited indication vs Medlab broader indication
 - ii. The Medicines Company, platform development company, acquired by Novartis in 2020 for **US \$9.7 billion**
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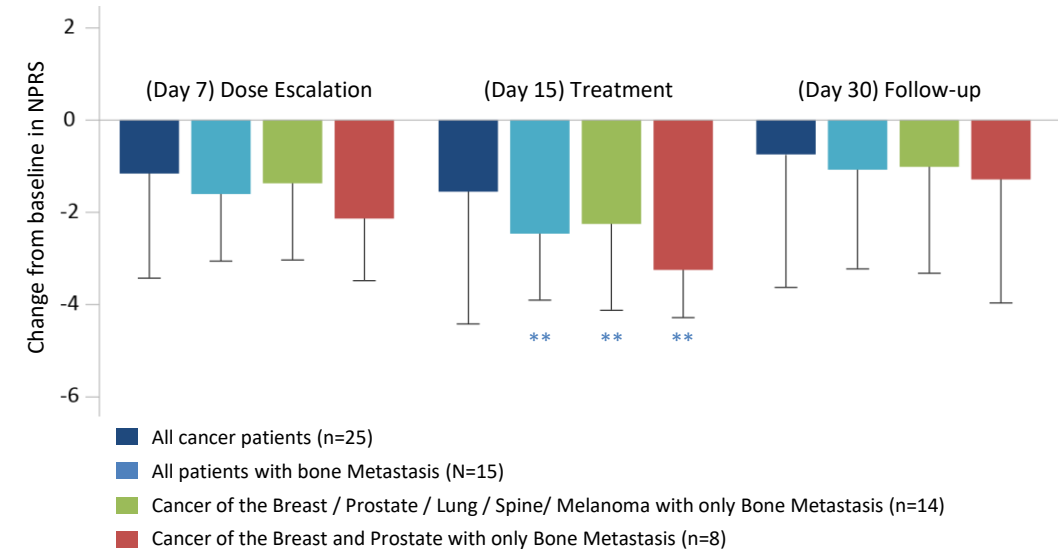


NANABIS™ ROBUST CLINICAL EXPERIENCE

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

805 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

TRANSITIONING FROM BOTANICAL EXTRACT TO SYNTHETIC APIs

'Next-gen' NanaBis™

- After discussions with the FDA Medlab has identified an opportunity to **switch to synthetic THC/CBD combination in NanaBis™**; This is due to recent technology advancement that materialized in Jan 2021
- Completion of Drug Master File (DMF) filing for so-called neat dronabinol, and CMC package expected to be 8-10 months - 2 Critical elements:
 - I. CBD already has a recognized DMF with the FDA
 - II. A 100% plant isomer
- This approach will be the **most efficient and favored by the FDA**



TRANSITIONING FROM BOTANICAL EXTRACT TO SYNTHETIC APIs

Benefits of synthetic drugs vs botanical extracts include:

- Precision and control in use of the manufacturing cycle of the drug;
- Minimised batch-to-batch variation;
- Minimised/non-existing adulteration in botanical extracts;
- Potentially lower manufacturing costs, easier to upscale and transfer manufacturing;
- Potential large pharma are used to synthetic drugs;
- FDA guidance received indicates strong preference for synthetic use.



PHASE III TRIAL – END POINTS

Primary

- Demonstrate that at the end of the 6-week study period the proportion of responders in the NanaBis™ treated group is significantly greater than the proportion of responders in the placebo group.
-

Secondary

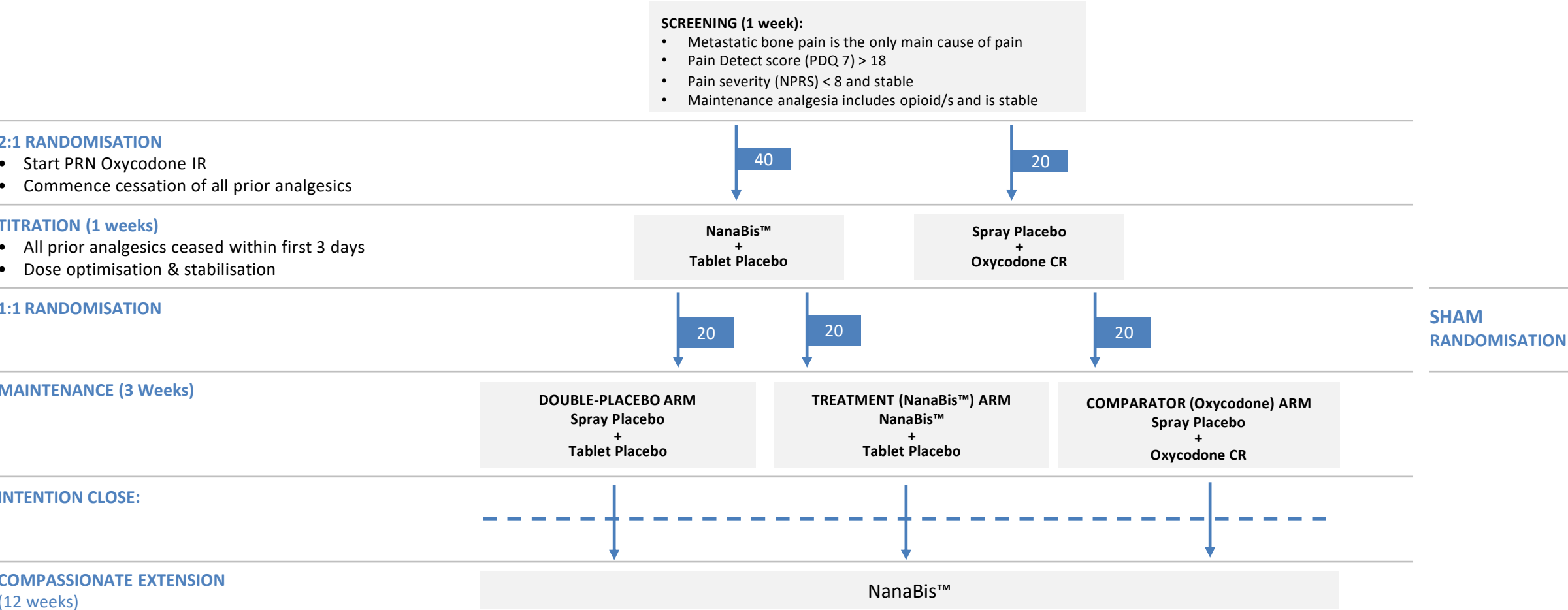
- Demonstrate that at the end of the 6-week study period the proportion of responders in the Oxycodone CR treated group is significantly greater than the proportion of responders in the placebo group (study validation).
- Demonstrate that at the end of the 6-week study period the proportion of responders in the NanaBis™ treated group is non-inferior to the proportion of responders in the Oxycodone CR treated group.
- Demonstrate that at the end of the 6-week study period the HR-QoL scores in the NanaBis™ treated group are significantly greater than in the Placebo group and non-inferior to the Oxycodone CR treated group.
- Demonstrate that NanaBis™ is safe and tolerable.
- Demonstrate that half or more of the NanaBis™ treated group preferred further treatment with NanaBis™ in the open label extension study (note that all participants will be offered open label extension if appropriate).



GLOBAL PHASE III SCHEMATIC (N=360)

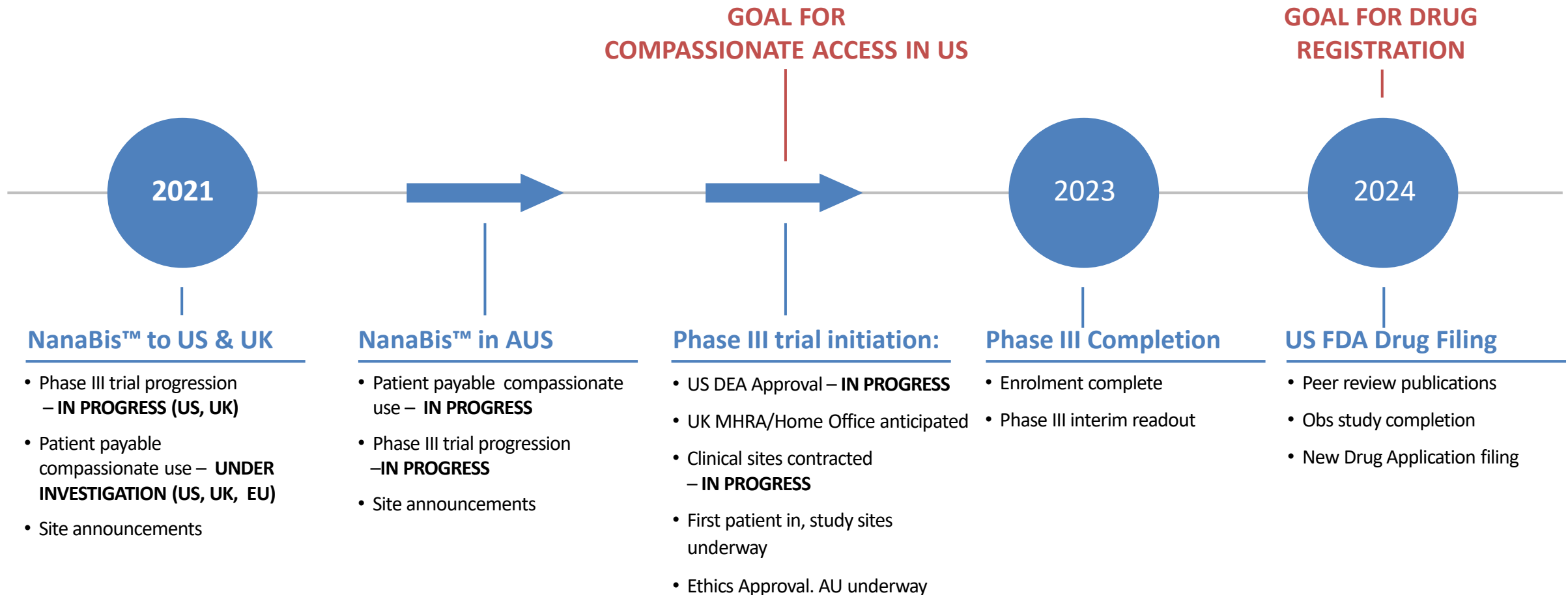
Understanding the NanaBis™ PIII Trial

Trial locations
locked in AUS,
UK & US



NANABIS™ NEAR-TERM CATALYSTS

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



The background image shows a laboratory setting with a robotic arm positioned over a multi-well plate containing numerous small blue vials. The scene is dimly lit with a blue color cast. A white curved line graphic is visible on the right side of the image.

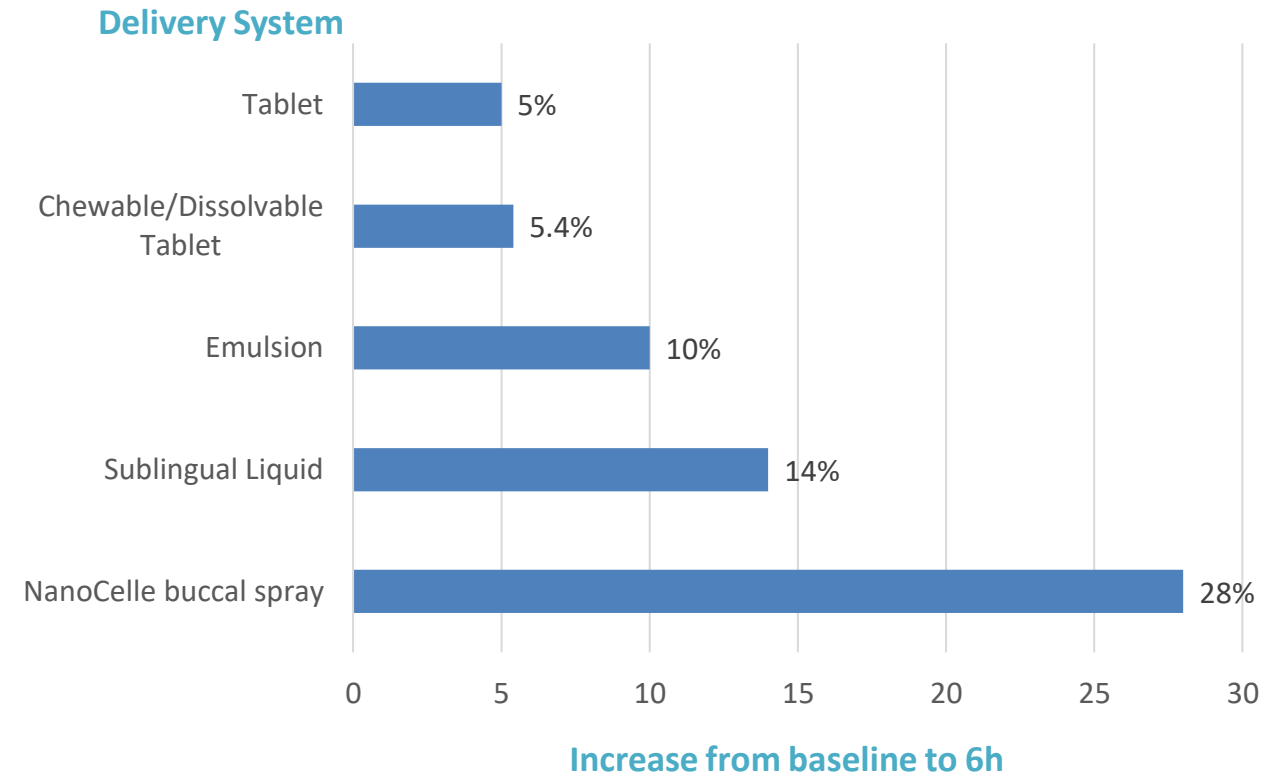
NANOCELLE®

NANOCELLE® OFFERS SIGNIFICANTLY BETTER NON-INVASIVE DELIVERY METHOD

Significantly better non-invasive delivery is needed

- Nanoparticles are characterized under 100nm in size, uniformed and validated
- Increased absorption by improving drug solubility
- Requires less API with simple, scalable manufacture
- By-passes 1st pass metabolism by buccal, nasal, topical or sub-cutaneous routes
- Unlike liposomes, no evidence of CAPRA
- Validate by University of Sydney, NanoScale Unit
- Patentable and primed for FDA 505(b)(2) pathway
- Convenient to use and simple to transport

NanoCelle® advantage vs other delivery methods



NANOCELLE®: UNIQUE DELIVERY PLATFORM ENABLING MORE EFFECTIVE ABSORPTION OF ACTIVE INGREDIENTS INTO THE BLOODSTREAM

NanoCelle® Highlights

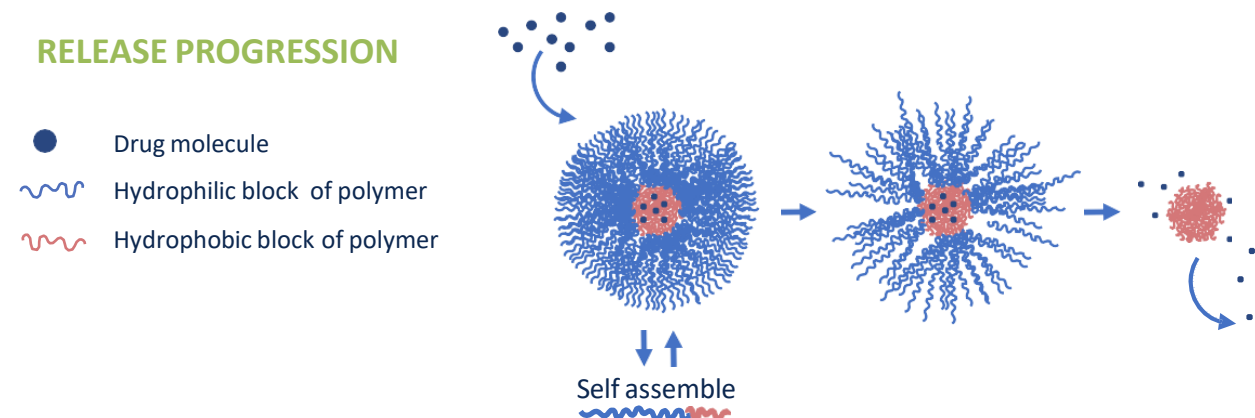
- **Innovative drug delivery**
Enhanced drug delivery system improves drug solubility issues and enables faster absorption and metabolism of active ingredients
- **Commercially viable to manufacture**
Consistently proven to meet the highest quality and safety standards; products are commercially viable and ready for manufacture
- **Significant growth potential**
R&D programs and strong partnerships provide a robust pipeline of opportunities to development and commercialization
- **Multiple global markets for commercialization**
With patent protection in EU, US, Canada, Hong Kong, Singapore, Australia, New Zealand

How it Works

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

RELEASE PROGRESSION



NANOCELLE® UNDERPINS MEDLAB'S OWNED R&D PORTFOLIO

Multiple options for partnering or in-house development

Name	Indication	Pre clin	Safety	P1	P2B	P3	Market potential		
Small molecule program – cannabis									
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™	Anxiety						US \$10.9B (2020)	CAGR 7.2%	
Small molecule program – other									
NRGBiotic™	Depression					PRELIM RESULTS		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%
Protease Inhibitors	Anti-viral							US \$46.5B (2019)	CAGR 5.0%
Textiles program									
Medicated Gauze	Antibiotic							US \$100M (2020)	CAGR 6.1%
Smart Clothing	Antibiotic							US \$100M (2020)	CAGR 6.1%

NANOCELLE® GROWTH CATALYSTS

NanoCelle® has a very broad market opportunity: Partnering, patent expansion, protease inhibitors, and opportunity to give second life to generic medicines

2021

Partnering Discussions

- Partnering discussions for the use of the NanoCelle® platform to increase delivery efficiency for a variety of medicines

Patent Expansion

- Currently approved territories include all of Western EU, AU, and NZ
- Patents submitted for Hong Kong, Singapore, US, and Canada

Protease Inhibitors

- Preferred due to relevance in immunotherapies
- Developed to delivered a by mouth solution, not injection
- This will deliver safer, easier and more convenient administration
- Potential platform for vaccines

Generic Medicine Improvements

- Peer review publications
- Program Updates

An aerial photograph of the New York City skyline, featuring numerous skyscrapers and a dense urban landscape. The image is overlaid with a semi-transparent blue filter. The text "SUMMARY AND CATALYSTS" is centered in white, bold, sans-serif capital letters. A white, curved, abstract line graphic is positioned on the right side of the image, partially overlapping the buildings.

SUMMARY AND CATALYSTS

NEAR-TERM PRIORITIES

Clear opportunity for growth through clinical validation and commercial partnering

- ✓ Global Agency engagement on synthetic solutions – FDA, MHRA & TGA
- ✓ Strongly engaged in global partnering
- ✓ Continue patent focus execution beyond the existing 36 patents granted to date (NanaBis™ & NanoCelle® protection until 2036)
- ✓ NanoCelle® opportunities in both “generic plus” and non-injectable immunotherapies / vaccines products in pipeline
- ✓ Depression study ongoing to address this significant & growing market
- ✓ Optimising the financial outlook of the Nutraceutical business
- ✓ Restructuring and investing in the Company & Medlab brand to enable greater US & EU facing engagement



THANK YOU

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CEO & Managing Director



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B.Com, CPA Non-Executive
Chairperson



Drew Townsend

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Cheryl Maley

Non-Executive Director

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Dr Patrick Miller

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