# **\***AusCann

Developing high quality, cost effective cannabinoid medicines

Investor Presentation March 2019

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### **Investment Summary**

AusCann is an Australian Pharmaceutical Company focused on the development, production and sale of cannabinoid pharmaceuticals within Australia and internationally.

- Fully integrated pharmaceutical cannabinoid company with capabilities and established channels across raw material supply, product development, manufacturing and distribution & sales.
- Clear strategy to address major market need chronic pain.
- Industry leading intellectual property with all required Australian licences to produce final dose cannabinoid pharmaceuticals, proprietary final dose form capsules developed, and advanced R&D and new product development facility under construction.
- Strong strategic partnerships and experienced production team place AusCann at the forefront of the industry:
  - World leading expertise from Canada, Chile and Australia.
  - Leader in cannabinoid medicine training in Australia.
  - Access to established licensed manufacturing facility in Australia.
- Well funded into CY2019 with over \$41m in cash as at 31 December 2018.
- First Australian cannabinoid pharmaceutical product to be released for clinical trials during 2019.



### AusCann strategy

- Develop and produce cannabinoid pharmaceuticals which address the medical needs of doctors and their patients.
- Focus initially on capsule-based pharmaceuticals for management of chronic pain (including neuropathic pain) using extracted cannabinoids as the API (active pharmaceutical ingredient).
  - AusCann hard shell capsule addresses the critical unmet need for providing consistent and stable dosages.
  - Known dose form in user friendly format what doctors and patients want.
- Distribute throughout Australia via established:
  - pharmaceutical distribution channels; and
  - unregistered product pathways (Authorised Prescriber and Special Access Schemes).
- Aim to have cannabinoid pharmaceuticals for chronic pain indications registered on the ARTG (Australian Register of Therapeutic Goods) and ultimately covered under PBS (Pharmaceutical Benefits Scheme) reimbursement.





## Significant recent developments

#### Leadership transition

- Experienced global pharmaceutical executive Mr. Ido Kanyon appointed to lead the company through the next stage of its development as a pharmaceutical company.
- Structured CEO transition process minimised disruption to business and product development activities.

#### Product development

- Successful Pilot Study of final dose cannabinoid capsules solving problem of stability of medical cannabis products currently on market.
- Announced the acquisition and re-development of AusCann R&D facility in WA to build and develop product pipeline.
- 7,300m<sup>2</sup> site acquired. Existing facilities will be upgraded and customised.

#### Raw material supply

- Cannabis raw material supply channel diversified: new agreement with MediPharm and DayaCann's first cultivation activity with Khiron.
- MediPharm cannabis resin to be used in manufacture of AusCann hard shell capsules.

#### Path to market

• Appointed TGA licensed PCI Pharma to manufacture and release AusCann's first medicinal cannabis product line.



## FY19 Focus / Priorities

#### First Capsules to Market

- New proprietary solid hard shell capsules to treat chronic pain expected release for clinical trials during 2019.
- Manufactured under contract by PCI Pharma.

#### **Raw Materials Supply**

- Continue to diversify and increase cannabis raw material supply base.
- DayaCann to continue to pursue export licenses from Chile.

#### **Product Development**

- Progress the development of new AusCann R&D facility in WA.
- Site to encompass cultivation, extraction and new product development.
- Expected to invest further capital of up to \$6m over time to customise and fit out site to purpose.

#### **Disciplined Capital Management**

• Focus on product development and quickest path to market – outsource capital intensive production and distribution activities.



## Leadership transition

#### • Leadership transition in line with strategy

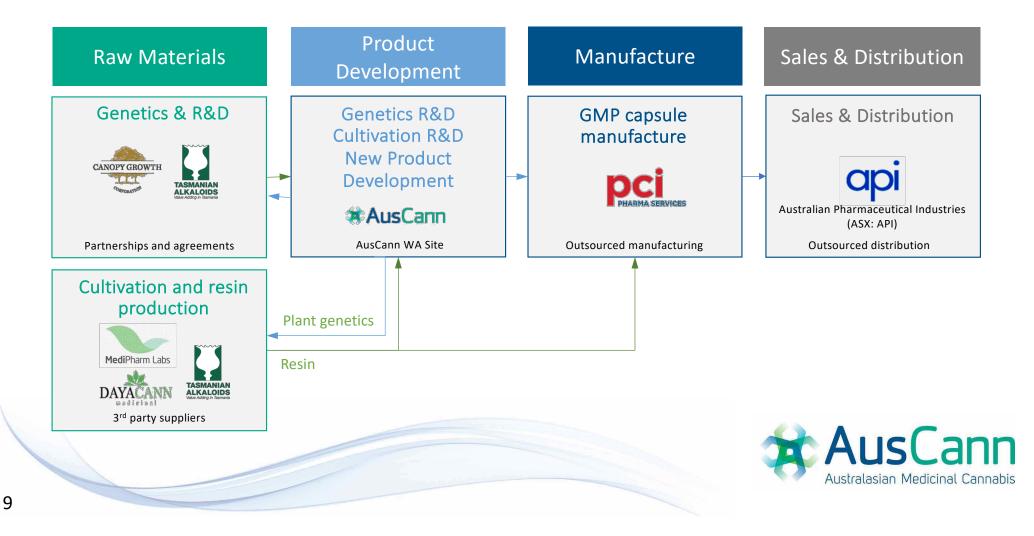
- Transition initiated following rapid growth and success in AusCann's initial phase as medicinal cannabis start-up
- Designed to align AusCann's management with the next phase of AusCann's development as a pharma manufacturing and sales business
- Thorough and extensive executive search
  - Led by Dr Paul MacLeman, AusCann Director with extensive pharma and senior management experience
  - Carefully managed to minimise disruption to AusCann's business and product development activities

#### • Appointment of Mr Ido Kanyon as new CEO

- Commencing May 2019
- More than 15 years experience in the pharmaceutical industry
- Most recently at NYSE listed Teva Pharmaceutical Industries, the world's largest generic pharma company with FY17 revenue of over US\$22 billion
- Significant experience in product pipeline development and product commercialisation



### Partners and capabilities across the supply chain



## **Raw Materials: Partnerships**

### **MediPharm Labs**

- Agreement to supply cannabis resin to be used primarily for AusCann's hard shell capsules.
- Canada's largest and most experienced supplier of purified, pharmaceutical grade cannabis extracts.

### **Canopy Growth Corp**

- 11% equity in AusCann, Founder and CEO, Bruce Linton Director of AusCann.
- Pursuing opportunities for suppling medical cannabis products into Australia.

### DayaCann (in Chile)

- JV between AusCann and Fundación Daya, only entity licensed for cannabis cultivation in Chile.
- Agreement with Khiron Life Sciences Corp to supply medical cannabis for patients in Chile.

#### Jade Cannabis

• Worked with Jade to develop and optimise AusCann's cultivation system.

### **Tasmanian Alkaloids**

- Licensing in place for cannabis cultivation and manufacturing cannabinoid APIs.
- Established facilities for extraction of pharmaceutical grade products.











## Product Development: AusCann WA Site

- Establishment of new AusCann Research and Development Facility
  - **Consistent with strategy:** New product development is a key pillar of AusCann's strategy and growth plans, with R&D facility providing flexibility for the Company to develop its own next generation products
  - Cost effective suitable site acquired: 7,300m<sup>2</sup> site acquired in Western Australia for \$5.25m
  - Facility to be state of the art, and fully integrated supporting R&D and product development activities across the key areas of genetics, cultivation, extraction, and clinical trial production.
  - Capex to be managed through the use and conversion of existing buildings and facilities on site
  - Will focus on Auscann's cannabinoid pharmaceutical product pipeline, supporting development of both innovative formulations and dose forms
  - A key point of difference in the market compared to other cannabis producers and will position AusCann at the forefront of the medicinal cannabis industry





### **Product Development: Proprietary Capsules**

- Unique proprietary **final dose form capsule** to solve stability and dosing problems that exist with current oils and capsules on market.
- Oil/soft gel capsule cannabinoid medicines that are currently in the market can suffer from:
  - An unreliable dosage;
  - Difficult to administer; and
  - Unstable (cannabinoids degrade over time).
- Clinicians express preference for capsules:
  - Easy to administer to patients;
  - Familiar; and
  - Enables controlled dose titrations to best manage pain with low side effects.





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## Product Development: Expertise and capability

### The AusCann management team has extensive experience in the pharmaceutical sector

Personnel		
Ido Kanyon	Incoming Chief Executive Officer	More than 15 years experience in the pharma industry including product development and commercialisation
Paul MacLeman	Executive Director	20 years experience in the pharmaceutical and life sciences sector including MD of IDT Australia
Sheena Emslie	Quality Manager	16 years in pharmaceutical manufacturing. 8 years in Quality Management under GMP, audited by TGA, FDA, WHO and MCC. 10 years with Aspen SVP/Aspen Pharma Pty Ltd
Cameron Scadding	Extraction and analytics	Forensic and Analytical Chemist, founder and CEO of TSW Analytical
Phil Wykes	Infrastructure	Prior Director of Infrastructure, IDT Australia Ltd. Over 20 years of providing engineering expertise to the food, agri and pharma sector
Dr Melinda Thompson	Director of Regulatory Affairs and Research	Biochemist with over 10 years experience in research and development management, with a focus on governance frameworks and operational processes
Dr Musa Mavlianov	Product Development	Formulation specialist, extensive experience across the pharmaceutical sector including 10 years as Production & Product Development Manager for Swisse Wellness Pty Ltd
Darren Bampton	Clinical and Regulatory Manager	16 years experience in the prescription medicine industry. Prior Director of Regulatory Affairs and Clinical Development for Progen Pharmaceuticals Ltd



## Manufacture, distribution and sales

#### • Manufacturing agreement with PCI Pharma

- US based global provider of manufacturing services to the healthcare sector.
- TGA licensed manufacturer in Australia, utilizing Australian facilities.
- AusCann's proprietary solid hard shell capsules scheduled for release to clinical trials towards mid 2019.
- Distribution agreement in place with Australian Pharmaceutical Industries (ASX:API)
  - Australia's largest pharmaceutical distributor the parent company of Priceline Pharmacy, Soul Pattinson Chemist, and Pharmacist Advice.
  - Access to an Australia wide retail pharmacy network (~7,000 pharmacies).
- AusCann overseeing distribution and sales
  - 3 person team of Medical Liaison Managers currently training and educating Australian doctors.
  - Overseen by Chief Medical Advisor Dr Danial Schecter who established some of the first medical cannabis clinics in Canada.





## Medicinal Cannabis: Australian opportunity

• **Regulatory** - three key Federal Government changes:

2016: Rescheduling of cannabis allowing doctors to prescribe.

2016: Implementation of regulatory framework enabling the cultivation and manufacture of cannabis products in Australia.

2018: Australian Federal Government approved manufactured cannabinoid medicines to be exported from Australia.

- **History** Australia has a long history of producing pharmaceutical grade medicines from plants and still produces >40% of the world's pharmaceutical opiates.
- Momentum the transition to using cannabis derived products for medical purposes is gaining significant momentum:
  - Importation of cannabis products until local production is up and running.
  - Processes to provide patients with access.
  - Opening up of export opportunity.







### Initial focus on Chronic pain and cannabinoids

- Around 72% of Canadian cannabinoid prescriptions are for pain management.<sup>2</sup>
- 10,000 international studies reviewed to assess the use of medical cannabis as a therapeutic treatment - 2017 US NAS Report 'strong and conclusive evidence' for treatment of chronic pain in adults.
- Canadian Pain Society treatment guidelines currently 3<sup>rd</sup> line treatment and potential to move to 2<sup>nd</sup> line.
- TGA treatment guidance on use in chronic neuropathic pain –

'patients who used medicinal cannabis for non-MS related neuropathic pain were more likely to experience a 50% reduction in pain and a reduction in pain scores compared with patients taking a placebo'<sup>3</sup>





### Australian market opportunity for Chronic pain

Key Opportunity: Chronic neuropathic pain (nerve pain) Incidence in Australia: 1.9m (8% of population)<sup>4</sup>

- Current treatment options for neuropathic pain lacking:<sup>5</sup>
  - Anticonvulsants gabapentin and pregabalin no significant difference to placebo with increased risk of depression and suicide.
  - Antidepressants no first or second tier evidence "only a minority of people will achieve satisfactory pain relief".
  - Benzodiazepines and opiates (e.g. oxycodone) low or no evidence of efficacy.
- Opioid sparing:
  - Around 750,000 Australians are dependent.<sup>6</sup>
  - Between 2011 and 2015 2,145 Australians died from *prescription* opioids.<sup>7</sup>
  - 44% and 65% reduction in opioid use by patients using cannabinoids cited in US and Canada.
  - 25% reduction in deaths from prescription opioids in US states with access to cannabinoids.
- In 2013 more than 27 million packs of codeine were sold.<sup>8</sup>
- Since 2009 there has been an increase in opioid prescriptions from about 10M to 14M annually in Australia.<sup>9</sup>
- The average spend on pain treatments in 2017 was \$473 per month.<sup>10</sup>



### **Export opportunity**

- Australia allows the export of cannabis-based pharmaceutical products.
- Australia's Health Minster, Greg Hunt, stated:

'We would like to be the world's number one medicinal cannabis supplier' <sup>9</sup>

- Australia is well positioned to achieve this as:
  - Respected international supplier of pharmaceutical products using plant-derived actives.
  - Large number of countries allow use for medical purposes but have not established legal frameworks for production.
    - German market, which has 3 times population of Canada, is still finalising the issue of licences to producers.
  - Current cannabinoid medicines are generally flowerbud or extracted oils from Canada or Netherlands.
  - Many producers do not operate under international GMP standards required for pharmaceuticals in most countries.
- AusCann is developing one of the first final dose form capsules that are compliant with international quality standards.



### info@auscann.com.au

### Developing high quality, cost effective cannabinoid medicines for patients

March 2019



### Board



#### Dr Mal Washer Founding Chairman

- Medical doctor
- Previous member of the Australian House of Representatives
- Former chair of the Alcohol and Other Drugs
   Council of Australia



#### Bruce Linton Non-executive Director

- Founder, Chairman and CEO of Canopy Growth Corporation
- Previous work with the World Bank and the Asia Development Bank



#### Dr Paul MacLeman Executive Director & Interim CEO

- · Experienced pharmaceutical executive
- Over 25 years' board and executive experience for commercialisation of pharmaceutical products spanning ASX, TSX and NASDAQ capital markets
- Chair of AdAlta Limited, Livac Pty Ltd, and Director of Sypharma Pty Ltd and Nextleaf Solutions Inc.



#### Hon Cheryl Edwardes Non-executive Director

- Former Attorney-General for Western Australia
- Former Minister for the Environment
- Prior Executive General Manager for External Affairs, Government Relations and Approvals at Hancock Prospecting



#### Bruce McHarrie Non-executive Director

- Experienced senior executive with a background in the life science industry
- Former Chief Operating and Financial Officer at WA's Telethon Kids Institute
- Former Assistant Director at Rothschild Bioscience Unit, London



### Australian Regulatory bodies



Regulates quality standards and supply of pharmaceuticals

Ensures patients have access to safe, effective and medical-quality therapeutic products



Regulates security of production and supply to prevent diversion



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