AusCann
Australasian Medicinal Cannabis

We believe Australian patients have the right to high quality, cost effective and clinically validated cannabinoid medicines

R&D commercialisation strategy statement
January 2017

Table of Contents

1. Background

The board and management of AusCann believes that patients have the right to high quality, economical and clinically validated cannabis medicines.

AusCann has the ability to deliver these medicines by:

(i) having access to expertise and relevant intellectual property in respect of:

  (A) plant genetics and breeding;

  (B) cultivation and production techniques;

  (C) manufacturing techniques;

  (D) cannabis medicines that are currently being prescribed for patients for a range of conditions internationally; and

  (E) undertaking clinical studies in Australia;

(ii) having the expertise to operate under Australia's cultivation and manufacturing requirements; and

(iii) being able to supply full spectrum plant extracts.

Our business model is based upon:

(iv) securing access to leading medicinal cannabis plant genetics and establishing a genetics breeding program to develop further strains;

(v) securing access to leading cultivation, production and manufacturing expertise and developing best practice in respect to full spectrum plant extracts; and

(vi) partnering with leading researchers for ongoing evaluation of the efficacy of AusCann's products for a range of medical conditions.

With this in mind, our main objectives are:

(vii) undertaking research into, and development of, new medicinal cannabis strains, cultivation and extraction techniques;

(viii) undertaking research into the clinical efficacy of medicinal cannabis products and delivery mechanisms for various medical conditions;

(ix) obtaining relevant licensing for the cost effective cultivation and manufacture of high quality, clinically effective medicinal cannabis in Australia; and

(x) the provision of relevant information to establish the Australian medical community's trust and confidence in the prescription of AusCann's medicinal cannabis products.

2. Research activities to drive future earnings

2.1 Overview of activities

AusCann's research activities include:

(i) Clinical studies in the areas of chronic pain, chronic neuropathic pain and treatment resistant epilepsy; and

(ii) Cultivation research and development.

AusCann's current commercial activities include:

(iii) Joint venture cultivation and production in Chile.

AusCann's potential future commercial activities include:

(iv) Supply of Canadian products to Australian authorised prescribers and third party clinical studies; and

(v) Cultivation, manufacture and supply of Australian medicinal cannabis products to Australian authorised prescribers

The AusCann team is well positioned to undertake all of the activities above as it has access to required intellectual property, the relevant skill-sets, experience and networks as outlined in Annexure B.

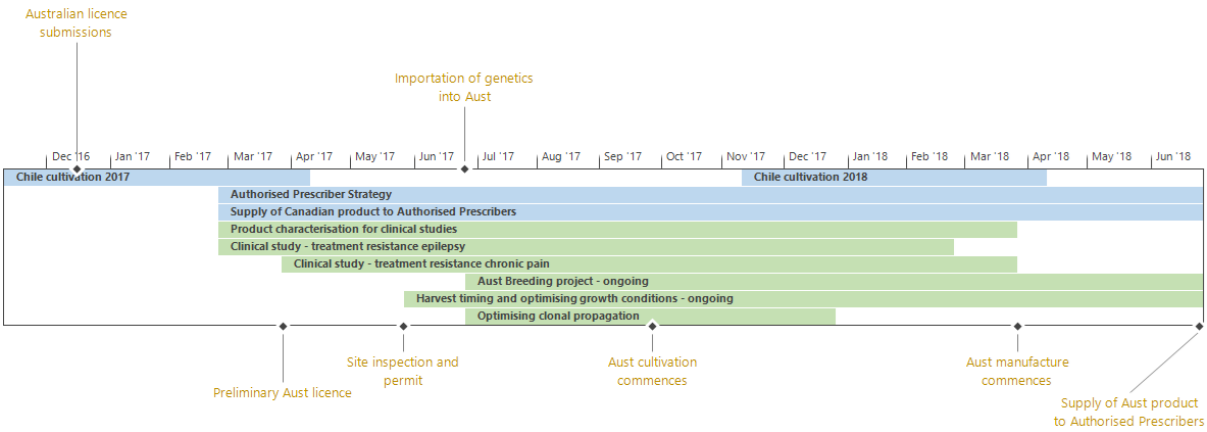
Results and knowledge gained from AusCann's research activities are to continuously feed into current and potential commercial activities to optimise revenue and profit from these commercial activities.

The clinical studies are to assist in developing demand for supply to Australian authorised prescribers resulting in an increase in revenue from sale of imported product initially and locally product products.

The cultivation research and development activities are to support and assist cultivation and production activities in Chile and proposed future activities in Australia. This will improve revenue outcomes by improvements in yields by improving genetics, optimising growing conditions and harvesting timing. This increase in yields in not only in raw material but also the levels of active compounds within the raw material in the end products.

Additionally cultivation infrastructure designed and constructed under the cultivation research and development projects may also be used for Australian commercial cultivation activities when permitted.

2.2 Timeline of activities



Estimated timeline of activities from mid November 2016 through to 1 July 2018.

Commercial activities are shown in blue and research and development activities in green.

2.3 Commercial activities – revenue streams

The Authorised Prescriber Strategy is outline in Annexure A. This outlines how the commercial supply of product to Australian authorised prescribers is to be driven.

Conservative estimated levels of demand are as follows. The rational for these figures is also provided in Annexure A.

	Q3 2017	*Q4 2017*	*Q1 2018*	*Q2 2018*	*Q3 2018*	*Incidence in Australia*
Chronic Neuropathic pain patients	180	270	360	455	550	1.8m
Amount required in grams – dosage based on average of 1.2 g/day	19,710	29,565	39,420	49,822	60,225	
Chronic pain patients	50	100	150	200	300	3.2m
Amount required in grams – dosage based on average of 1.2 g/day	5,475	10,950	16,425	21,900	32,850	
Treatment resistant epilepsy patients	50	75	100	125	150	82,000
Dried product equivalent in grams for median dosage of 15mg CBD/kg/day	37,641	56,461	75,281	94,101	112,922	
Total amounts (grams)	**62,825**	**94,238**	**125,651**	**157,612**	**189,572**	

As noted above, prior to AusCann being able to cultivate and manufacture Australian, AusCann intends to import product suitable for chronic neuropathic pain, chronic pain and treatment resistance epilepsy from its Canadian partner Canopy to meet demand.

The average prices per gram of product in Canada ranges between CAD$5 -$12. An average cost of production per gram in Canada is approx. CAD$2.88.

AusCann's revenue streams from these expected levels of Australian demand is being determined.

2.4 Funding of research and development activities

Following is the research and development expenditure provided for in the replacement prospectus:

Funds available	Minimum subscription ($3,000,000)	Percentage of funds (%)	Maximum subscription ($5,000,000)	Percentage of funds (%)
Source of funds				
Company existing cash reserves[1]	$370,270	6%	$370,270	4%
AusCann existing cash reserves[1]	$2,960,890	47%	$2,960,890	36%
Funds raised from the Public Offer	$3,000,000	47%	$5,000,000	60%
Total	**$6,331,160**	**100%**	**$8,331,160**	**100%**
Allocation of funds				
Horticultural R&D (incl. breeding, sourcing varieties)[2]	$1,200,000	19%	$1,800,000	22%
Chilean joint venture[3]	$1,350,000	21%	$1,350,000	16%
Analytical testing[4]	$300,000	5%	$330,000	4%
Clinical trials[4]	$1,811,160	29%	$2,771,160	33%
Medical Education	$240,000	4%	$330,000	4%
Licence applications[5]	$100,000	2%	$150,000	2%
Licence fee	$65,911	1%	$65,911	1%
Termination fee	$200,000	3%	$200,000	2%
Costs of the Offers[6]	$482,620	8%	$604,620	7%
General working capital[7]	$581,469	9%	$684,089	9%
Total	**$6,331,160**	**100%**	**$8,331,160**	**100%**

Expected timing of the proposed research and development expenditure is outlined below.

AusCann R&D expenditure	Q1 2017	Q2 2017	Q3 3017	Q4 2017	Q1 2018	Q2 2018	Q3 Q4 2018	TOTAL
Cultivation R&D								**$1,800,121**
Murdoch University staff expenses	$11,121	$15,000	$15,000	$15,000	$15,000	$15,000	$30,000	$116,121
Plant import expenses		$10,000						$10,000
Greenhouse facilities		$150,000	$150,000					$300,000
Clonal propagation facility		$1,045,000						$1,045,000
Leasing of site	$12,500	$37,500	$37,500	$37,500	$37,500	$37,500	$75,000	$275,000
Materials		$30,000	$6,000	$6,000	$6,000	$6,000		$54,000
Clinical Studies								**$2,778,614**
Clinical trial insurance	$25,000	$25,000						$50,000
Biostatistical modelling and analysis	$30,000							$30,000
Product importation expenses	$50,000							$50,000
Childhood epilepsy study	$126,335	$126,335	$126,335	$126,335				$505,340
Chronic pain study - CRO managed		$721,637	$721,637	$700,000				$2,143,274

The capital raised under the prospectus will fund all of the proposed clinical studies, the establishment of the infrastructure for the cultivation research and development projects, which can also be utilised for commercial activities, and ongoing monthly research and development expenses until the end of 2018. At this point the proposed commercial activities of supply of Canadian product to authorised prescribers; and the potential supply of Australian product to authorised prescribers can fund these expenses going forward.

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4. Annexure A – Authorised Prescribers Strategy

The main reasons why Canadian patient registrations have tripled in the last 12 months is due to clinician education on the therapeutic benefits of cannabis and an associated decrease in the historical stigma associated with cannabis use.

A key objective of AusCann is to provide relevant information to the Australian medical community to establish trust and confidence in the prescription of AusCann's medicinal cannabis products. This program will be formulated based upon the learnings and information of Canopy's medical outreach team. The program is to commence in Q2 2017 and will include amongst other activities:

(i) the provision of educational material; and

(ii) bringing in Canadian prescribers and researchers who have experience in either: the prescription of medicinal cannabis for their patients; or undertake research in the field, to conduct education seminars.

The initial focus of these education seminars for the first half of 2017 will be Perth, Sydney, and Brisbane with other Australian cites being added to the program as favourable state government access programs are developed. Education material is to be provided nationally to relevant specialists, in a manner that is compliant with the relevant Therapeutic Goods Administration (**TGA**) regulations in respect to the promotion and advertising of products not on the Australian Register of Therapeutic Goods as discussed further below.

(A) CANADIAN MODEL

The Canadian access model is a useful precedent to determine how demand may develop in Australia given the similarities in demographics. There are differences between the access regimes in the 2 countries that need to be taken into account however. The population of Canada is around 35 million in contrast to Australia's 24 million. The current Canadian model does not require prescribers to go through an approval process, they do however have reporting obligations. In Australia prescribers are to be authorised under the TGA Authorised Prescriber Scheme or Special Access Scheme and their relevant state government access program. Additionally there are less restrictions on Canadian producers in respect to advertising and promotion of their products to prescribers. In both countries there are prohibitions on advertising to the general public. Details on advertising and promotion regulations are discussed further below.

In 2001, Canada became the second country in the world to implement a government-run program for medical cannabis access. That program, the Marihuana Medical Access Regulations (**MMAR**), permitted home grown production of marijuana for personal use or by a designated individual. Between 2001 and 2014, the program registered approximately 40,000 patients.

The MMAR program was effectively replaced by the Marihuana for Medical Purposes Regulations (**MMPR**) which came into force in June 2013. The regulations created conditions for a commercial industry that is responsible for the production and distribution of cannabis for medical purposes. They also make sure that Canadians with a medical need can access quality controlled cannabis grown under secure and sanitary conditions. Under the program, cannabis is produced and sold by Licensed Producers (**LP**) with delivery to patients by direct courier. Under the MMPR, LPs are not permitted to supply storefront dispensaries. Licensed cannabis production and sales under the MMPR began in earnest in the first half of 2014, and by June 2016, Health Canada reported that over 75,000 patients had registered.

As of August 24, 2016, MMPR was superseded by the Access to Cannabis for Medical Purposes Regulations (**ACMPR**). Under this new access regime authorised Canadian patients will continue to have access to cannabis from one of the 34 LPs, but will also be permitted to cultivate a limited amount of cannabis for their own medical purposes, or have someone produce it on their behalf. 98,460 Canadian patients registered to buy medicinal cannabis from licensed producers by Sept. 30, 2016 (see Table 5.1 below). 1,161 patients registered with Health Canada to grow their own medicinal cannabis or have someone else do it for them between August and the end of October 2016 under the ACMPR. It is noted that 28,000 people have retained the right to possess or grow medicinal cannabis for themselves or others under the original MMAR program. And many thousands more people are bypassing the legal system and buying cannabis at illegal dispensaries across Canada. One dispensary umbrella group estimates that more than 300,000 Canadians shop at them (Miller, 2016). This may be credible given that a federal survey in 2011 found that 420,000 Canadians said they used cannabis for medical reasons (Health Canada Survey, 2016). This equates to around 1.2% of the Canadian

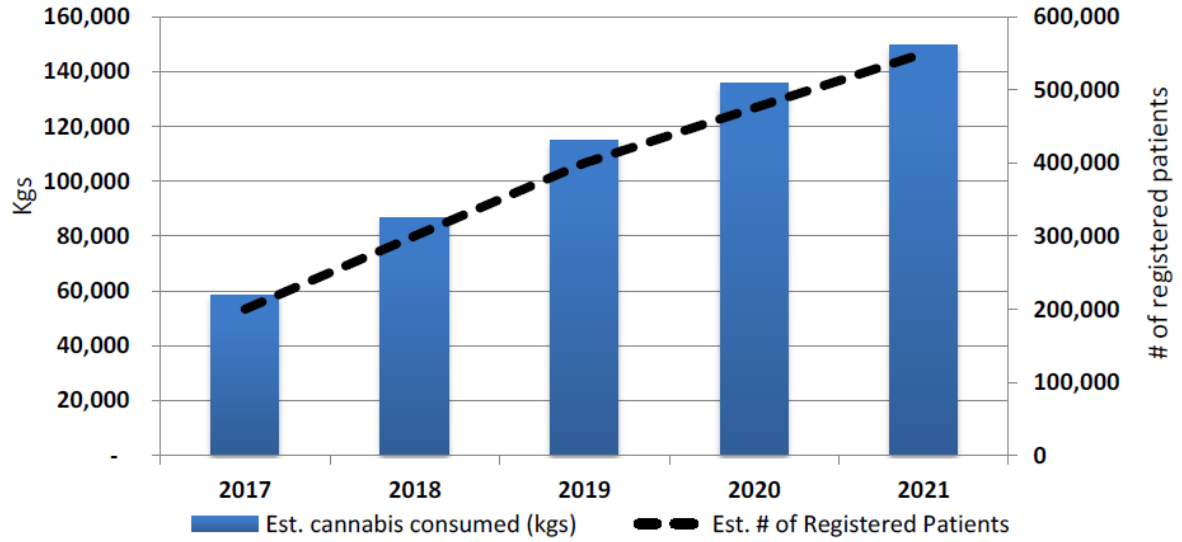
population. Around 72% of patients are taking medicinal cannabis products for pain management. (Capler, Patient Experiences with Cannabis Access in Canada - CANARY Study, 2016)

The prescription of the pharmacologic cannabinoid products nabilone and nabiximols are not included in the Health Canada figures cited in the table below (Health Canada, 2016).

	Q3 2015	*Q4 2015*	*Q1 2016*	*Q2 2016*	*Q3 2016*
Patients registered	30,537	39,668	53,649	75,166	98,460
Amount sold – dried (kg)	1,873	2,481	3,082	4,037	4,773
Amount sold – oils (kg)	n/a[1]	n/a[2]	584	1,500	2,420
Average amount per patient shipment(g/day)	1.12	1.12	1.03	0.96	0.89
Average amount authorised per patient (g/day)	3.0	2.9	2.8	2.7	2.6

A recent research report by capital markets group Cannaccord Genuity, indicates that there will around 500,000 registered patients in Canada using medicinal cannabis by 2021.

An estimation of the number of patients and consumption is provided below from (Bottomley & Maruoka, 2016)



Canopy's September 2016 financial report provides Health Canada estimates that the number of patients using medical marijuana will grow to 450,000 by 2024, creating a medical marijuana market worth an estimated $1.3 billion.

Under the ACMPR physicians enable patients to access a legal supply of marijuana by completing a medical document that functions like a conventional prescription. This document provides the daily quantity that the

[1 and 2] Production of oils not permitted by Health Canada at this time.

practitioner authorises for the person and the period of use. There is a maximum 30 day limit that applies and a maximum prescription of 150g (average of 5g per day) dried cannabis or its equivalent.

In Canada the regulatory instruments relevant to the advertising or promotion of medicinal cannabis are:

(i) the Access to Cannabis for Medical Purposes Regulations (ACMPR),

(ii) Food and Drugs Act (FDA); and

(iii) Narcotic Control Regulations (NCR).

These instruments define advertisement to include any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a drug (in the case of the FDA) or a narcotic (with respect to the NCR). Both the FDA and the NCR contain general prohibitions against the advertising of cannabis that licensed producers are required to comply with, including but not limited to:

(iv) FDA s 3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A (includes convulsions such as those associated with treatment resistant epilepsy but, does not include chronic neuropathic pain).

(v) FDA s 9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(vi) NCR s 70. No person shall (a) publish or cause to be published or furnish any advertisement respecting a narcotic unless the symbol "N" is clearly and conspicuously displayed in the upper left-hand quarter thereof or publish or cause to be published or furnish any advertisement to the general public respecting a narcotic.

In contrast the regulatory instruments relevant to the advertising or promotion of prescription medicines in Australia are:

(vii) Therapeutic Goods Act 1989 (TG Act) and the Therapeutic Goods Regulations 1990 (TG Regulations);

(viii) Therapeutic Goods Advertising Code;

(ix) Medicines Australia Code of Conduct (MA Code); and

(x) Competition and Consumer Act 2010

Under the TG Act, advertising directly to the general public is not permitted. (This is similar to the Canadian NCR prohibition of advertising to the general public). Advertising to health professionals is permitted, however prescription medicines not included in the Australian Register of Therapeutic Goods (ARTG) are considered unregistered therapeutic goods and may not be advertised in Australia to healthcare professionals. Section 3 of the TG Act provides an advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Where advertising to health professionals is permitted, it is regulated by the MA Code of Conduct which is a self-regulatory scheme. Section 1.4 of the MA Code also provides that a product or indication that has not been approved for registration in Australia by the TGA must not be promoted. Where a company has been formally advised by the TGA that a product has been entered on the ARTG and its Product Information containing the approved indications has been finalised, it is considered approved for registration for the purpose of the Code.

(B) CALCULATION OF EXPECTED AUSTRALIAN DEMAND

By undertaking clinical studies to provide prescribers with Australian efficacy and safety data combined with the Authorised Prescriber strategy we believe AusCann may be in a position where we are supplying the following minimum amounts by mid-2018. These figures reflect a potential 20 authorised prescribers with 50 patients each - 17 pain specialists and 3 neurologists - prescribing AusCann's products. These figures indicate conservative growth in contrast to our Canadian partner, Canopy's figures of over 24,400 registered patients at September 30 2016 compared to over 16,600 at July 2016 and over 6,200 at September 30 2015.

	Q3 2017	*Q4 2017*	*Q1 2018*	*Q2 2018*	*Q3 2018*	*Incidence in Australia*
Chronic Neuropathic pain patients	180	270	360	455	550	1.8m
Amount required in grams – dosage based on average of 1.2 g/day	19,710	29,565	39,420	49,822	60,225	
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As noted above, prior to AusCann being able to cultivate and manufacture Australian, AusCann intends to import product suitable for chronic neuropathic pain, chronic pain and treatment resistance epilepsy from its Canadian partner Canopy.

(C) AUSTRALIAN ACCESS REGULATORY FRAMEWORK OVERVIEW

Australian medical practitioners need approval from the Therapeutic Goods Administration (**TGA**) to prescribe medical cannabis. The most appropriate approval process would be the Authorised Prescriber Scheme (**APS**). Under this scheme the medical practitioner becomes an 'Authorised Prescriber' and can prescribe a particular medicine for specific conditions to individual patients in their immediate care without further TGA approval.

Under the APS the medical practitioner must have appropriate qualifications and/or expertise for the proposed indication(s) relevant to the product being proposed for use. If the medicinal practitioner is not a specialist in the condition to be treated with the medicinal cannabis product, then the TGA would expect a specialist report from an appropriate specialist on the use and suitability of the product for the particular indication for the patient.

Medical practitioners also require authorisation from their relevant state or territory government in addition to TGA approval. Some of these states may require the prescriber to be a specialist.

(i) New South Wales
Approval process in place now. Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation 2016 (under the Poisons and Therapeutic Goods Act 1966) enabled the prescription of cannabis products by clinicians in NSW from 1 November. In NSW there is to be no limitation on the conditions for which a cannabis-based product may be prescribed. Each application from a prescribing doctor for approval to prescribe will be considered on its merits. Applications must be accompanied by clinical evidence about use of the product to allow for an assessment of potential benefits and harms. It will also be expected that approved standard medicine or non-medicine treatments have already been utilised for the patient. The requirements for approval are the similar to that required by the TGA under the APS. See - http://www.health.nsw.gov.au/pharmaceutical/pages/cannabis-products.aspx

(ii) Victoria

Initially treatment is to be restricted to treatment resistance epilepsy, however Victoria has established an independent medical committee led by Professor James Angus AO as Chairperson, to provide advice to the Victorian Government on the types of medicinal cannabis products that should be available to Victorian patients, and the expansion of eligibility to include other patient groups. The Committee includes a range of specialist physicians in neurology, cancer and pain management as well as other experts in pharmacology, HIV/AIDS, medical research, medical ethics, drug safety, nursing and a consumer representative. See - https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis

(iii) Queensland

The Public Health (Medicinal Cannabis) Act 2016 commences on 1 March 2017. This access regime does not specify particular conditions or symptoms and the requirements for approval are similar to that required by the TGA, ie the patient has already tried the conventional treatments available and these have failed and the provision evidence that medicinal cannabis is effective for the particular condition or symptom. See - http://health.qld.gov.au/system-governance/legislation/reviews/medicinal-cannabis/default.asp

(iv) WA

A committee is to be established by the WA Health Minister to assist decision makers in providing approval under the Poisons Regulations. This access regime does not specify particular conditions or symptoms and the information to be provided for approval are similar to that required by the TGA. See - http://ww2.health.wa.gov.au/Articles/J_M/Medicinal-cannabis

(v) Tasmania

Developing the Controlled Access Scheme to commence in 2017. The VIC Department of Health and Human Services will establish an Expert Panel of clinicians to assess applications. Guidelines were to be released later this year. We can update you once they are released. See - https://www.dhhs.tas.gov.au/__data/assets/pdf_file/0012/217110/Medical_Cannabis_Fact_Sheet.pdf

(vi) Australian Capital Territory

A Medicinal Cannabis Scheme is expected to be in place by 2017. A Medicinal Cannabis Medical Advisory Panel is to develop clinical guidelines for prescribers.

(vii) South Australia

Access scheme yet to be developed. Their website provides that once all necessary national changes have been made by the Australian Government, South Australian laws will allow medicinal cannabis to be prescribed by certain specialist doctors and dispensed by pharmacists. It also provides that the South Australian Government will work with medical practitioners and other experts to develop the details of an access scheme. As the necessary national changes have been made they should be in a positon to implement the scheme. See – http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+topics/health+conditions+prevention+and+treatment/medicines/medicinal+cannabis

5. Annexure B - AusCann team

AusCann is well positioned to cultivate, manufacture and supply medicinal cannabis products as we bring together a strong team with relevant and complementary skill-sets, experience and networks.

5.1 Corporate - Board

Dr Mal Washer - Founding Chairman

Dr Washer was a Liberal member of the Australian House of Representatives from 1998 to 2013. He was a medical doctor before entering politics & established a number of prominent medical centres in Western Australia. Mal was also past chair of the Alcohol and Other Drugs Council of Australia. He has extensive experience in agricultural and horticultural activities and currently operates a commercial avocado plantation in Western Australia bringing highly relevant medical and horticultural expertise and experience to AusCann.

Elaine Darby - Founder & Managing Director

Elaine holds a Bachelor of Science in Biochemistry & Microbiology, Honours in Molecular Biology and a Bachelor of Laws. Previous roles have included as a lawyer with corporate law firm Clayton Utz, Media and Communications Officer for an Australian Federal Member of Parliament, Managing Director and Senior Winemaker of Aquila Estate Winery, and Project and Clinical Trials Manager for diabetes medical device company Firefly Health Pty Ltd.

Hon Cheryl Edwardes AM - Non-executive Director

Cheryl was the former Attorney-General for Western Australia and Minister for the Environment. Cheryl was most recently Executive General Manager for External Affairs, Government Relations and Approvals at Hancock Prospecting.

Cheryl has extensive experience of successful negotiations to ensure that critical primary agreements and government approvals are obtained in a timely fashion. Such agreements and approvals include the the Railway (Roy Hill Infrastructure Pty Ltd) Agreement Act 2010 (WA) and the Special Railway Licence; port lease and licence; native title agreements; environmental approvals, State and Federal; and many other critical approvals for Hancock Prospecting Pty Ltd and Roy Hill Iron Ore and Infrastructure.

Bruce Linton - Non- executive Director

Mr Bruce Linton is the founder, Chairman and CEO of Canopy Growth Corporation, one of the world's leading medical cannabis companies. Canopy Growth, through its subsidiaries Tweed and Bedrocan Canada, is the world's largest producers of legal cannabis and recently entered into a strategic partnership with AusCann.

Bruce has more than ten years of senior executive experience in the high-tech sector as a founder, executive and board member. He has a proven track record of international success, working extensively with the World Bank and the Asia Development Bank. Bruce enjoys a high profile in the global medicinal cannabis sector and has a demonstrable track record of raising the capital required to build large scale cannabis businesses.

Bruce McHarrie - Non-executive Executive Director

Bruce is an experienced senior executive with a background in the life science industry focussed on finance, operations, business and investment management, and strategic planning. He is a non-executive director of Adherium Limited, an ASX listed digital health technology company, Chairman of the Animal Ethics Committee of the Telethon Kids Institute, and undertakes corporate consulting activities.

Bruce is a Fellow of the Institute of Chartered Accountants (Australia and New Zealand) and a Graduate of the Australian Institute of Company Directors. Mr McHarrie resides in Australia.

Harry Karelis- Founder & Executive Director

Harry is the founder of Titan Capital Partners and has in excess of 24 years diversified experience in the financial services sector including specialist med-tech private equity investing. Harry has acted as a Director on several public and private companies in Australia, Singapore and the United Kingdom.

5.2 Commercial Operations - Key Management

Dr Melinda Thompson – Research & Quality Assurance Manager

Melinda has a PhD in metabolic biochemistry and postdoctoral experience in genetic influence on metabolism. She has held several senior roles in research and development management, with a focus on governance frameworks and operational processes, including the development of bespoke research management systems, contractual frameworks and risk assessment of research activities including clinical trials. Melinda has worked in State Government, CSIRO, several biotechnology companies, and several universities.

5.3 Partners

AusCann has partnered with key players in the international medicinal cannabis field.

(A) CANOPY GROWTH CORPORATION

The team includes Canopy Growth Corporation (**Canopy**). Canopy was the first publically traded, federally regulated cannabis producer in North America and remains the largest and most diversified. Listed on the TSX Venture Exchange, Canopy has a market capitalisation in excess of CAD$1 billion. Core brands under Canopy are Tweed (a highly recognised cannabis brand) and Bedrocan Canada (a producer and seller of genetically standardised cannabis varieties). Canopy operates two indoor production facilities and a large greenhouse with more than 46,400 square metres of production capacity. Canopy is dedicated to educating healthcare practitioners, providing consistent access to high quality medication, conducting robust clinical research, and furthering the public's understanding of how marijuana is used for medical purposes.

As of 30 September 2016 Canopy had over 24,400 registered Canadian patients.

AusCann and Canopy have a strategic partnership that provides AusCann with royalty free access to Canopy's expertise and intellectual property in the cultivation, manufacture and supply of high quality medicinal cannabis products. Canopy's founder, Chairman and CEO is a director on the AusCann board.

Tweed Farms greenhouse facility

(B) PHYTOPLANT RESEARCH SL

Established in 2008, Phytoplant Research SL (**Phytoplant**) is a private Spanish company which is internationally regarded for producing high quality, proprietary medicinal plants. Phytoplant specialises in techniques for the selection and genetic improvement of medicinal plants, under the standards of Good Agricultural Practice. In addition, Phytoplant has expertise in the extraction, isolation and purification of bioactive plant components to the standards of Good Manufacturing Practice. In addition, Phytoplant has expertise in the extraction, isolation and purification of bioactive plant components.

Our agreement with Phytoplant focuses on securing plants with desired chemotypes which also display environmental compatibility with Australian conditions, and drawing upon expertise to produce commercially viable, quality products.

Under the agreement, AusCann is granted exclusivity in the Australian market over certain strains of interest to it including but not limited to high yielding strains containing particular cannabis compounds of medical interest. AusCann is also granted exclusivity in the Australian market for any relevant intellectual property and know-how in terms of extraction protocols that Phytoplant has developed. The parties will also collaborate on a joint breeding program under which AusCann will provide suitable growing conditions and analytical laboratories.

(C) MURDOCH UNIVERSITY AND THE WA SABC

Based in Western Australia, Murdoch University undertakes world-class research in agricultural sciences, including genetics and biotechnology. The University is home to the Western Australian State Agricultural Biotechnology Centre (**SABC**) which has platform technologies, world-class facilities for, and world-class researchers in, agricultural research. AusCann has entered into a research and development collaboration agreement, focussed on cultivation and development of targeted medicinal cannabis strains for the effective treatment of various medical conditions, which are suited to Australian growing conditions.

(D) ZELDA THERAPEUTICS PTY LTD

Zelda Therapeutics Pty Ltd (**Zelda**) was established in August 2015 as a special purpose vehicle that has secured an exclusive, global licence to a set of human patient data being treated with cannabinoid-based medicines. This data has been generated by a Californian group, Caziwell Inc, incorporating the activities of Aunt Zelda.

The focus of Zelda is to design certain human clinical trials leveraging the already existing anecdotal patient data.

Under the agreement AusCann is to be Zelda's preferred supplier of cannabinoid-based medicines required for research and clinical activities conducted by Zelda in the Australian market. Zelda also intends to source medicinal cannabis plant and extract material for its international clinical trials from AusCann's Chilean joint venture entity DayaCann or from Australia once regulations permit.

(E) FUNDACIÓN DAYA

Fundación Daya (**Daya**) is a medical cannabis organisation based in Santiago, Chile. Daya are the only group to have ever held a licence to grow medical cannabis in Chile and was the first group in South America to receive such approvals in 2014 with subsequent licences being granted in 2015 and 2016. Daya has a strong social focus on educating clinicians and patients on the suitability and benefits of medical cannabis. Daya enjoys a very high profile in the region and has an extensive set of networks and relationships and is an excellent partner for AusCann.

AusCann and Daya are forming a 50/50 joint-venture company DayaCann to focus on becoming South America's leading medical cannabis group and a key player in the global supply chain operating from a very stable, progressive and low cost base. A number of groups have already expressed interest in accessing plant material for a range of uses providing a strong base from which to grow future crop size and revenues.

All necessary infrastructure is already in place from previous year's activities. Planting of the crop commenced in November 2016 with harvesting expected in May 2017. This plant material will be sold to several groups conducting research, clinical trials and developing products where AusCann and Daya have long-standing relationships.

6. Annexure C – Research and Development activities

6.1 Clinical studies

The key objectives of the clinical studies being undertaken by AusCann are to:

(i) provide Australian clinicians with Australian efficacy and safety data in respect to cannabis medicine formulations suitable for the treatment of chronic pain, chronic neuropathic pain and treatment resistant epilepsy symptoms; and

(ii) undertake research into the clinical efficacy of various modes of delivery.

The purpose of providing quality Australian evidence of the safety and efficacy of AusCann's medicinal cannabis products is to assist in the development of the medical community confidence to prescribe these products. The targeted medical conditions being chronic neuropathic pain, chronic pain and treatment resistance epilepsy.

AusCann has engaged Australian clinical research organisation Datapharm Australia Pty Ltd to assist in the management of these studies.

AusCann will undertake chemical analysis of the medicinal cannabis products to support its clinical investigations. This analysis will be undertaken using AusCann analytical equipment and Murdoch University expertise and facilities under the research collaboration.

Prior to AusCann being licensed to cultivate and manufacture in Australia, AusCann intends to import product suitable for the treatment of chronic neuropathic pain, chronic pain and symptoms of treatment resistance epilepsy from its Canadian partner Canopy.

The products to be imported will already have some efficacy and safety data from use in the Canadian patient population to ensure appropriate formulations are utilised in the clinical studies.

The key reason for the selection of chronic pain and chronic neuropathic pain is the amount of good quality clinical evidence and patient data to support the use of particular medicinal cannabis formulations. It has been cited that the main use of medicinal cannabis internationally is for the treatment of chronic pain. In Canada, around 72% of registered patients are taking medicinal cannabis products for pain management. (Capler, Patient Experiences with Cannabis Access in Canada - CANARY Study, 2016). Upon review of the relevant clinical evidence to determine potential therapeutic uses of medicinal cannabis, The American National Academies of Sciences found that there was conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults (National Academies of Sciences, Engineering, and Medicine, 2017).

Chronic neuropathic pain is difficult to treat. Regardless of aetiology, chronic neuropathic pain persists despite attempts at management with opioids, NSAIDs, anticonvulsants (gabapentin), anti-inflammatory agents, antidepressants and complementary medicine approaches.

For these reasons chronic pain and neuropathic chronic pain are key focus areas for AusCann. Treatment resistance epilepsy is also a focus area given the evidence available and the current level of interest and demand.

The following table provides the incidence of AusCann's key focus areas

	Incidence in Australia population 24m (Australian Bureau of Statistics, 2016)
Chronic neuropathic pain	7-8% (Pollack, Harrison, Henderson, & Britt, 2013) 1.8m
Chronic pain	3.2m (Access Economics Pty Limited, 2007)
Treatment resistant epilepsy	82,000 (Kwan & Sander, 2004)

AusCann will initially import product for:

(i) use in clinical studies AusCann is undertaking in chronic neuropathic pain;

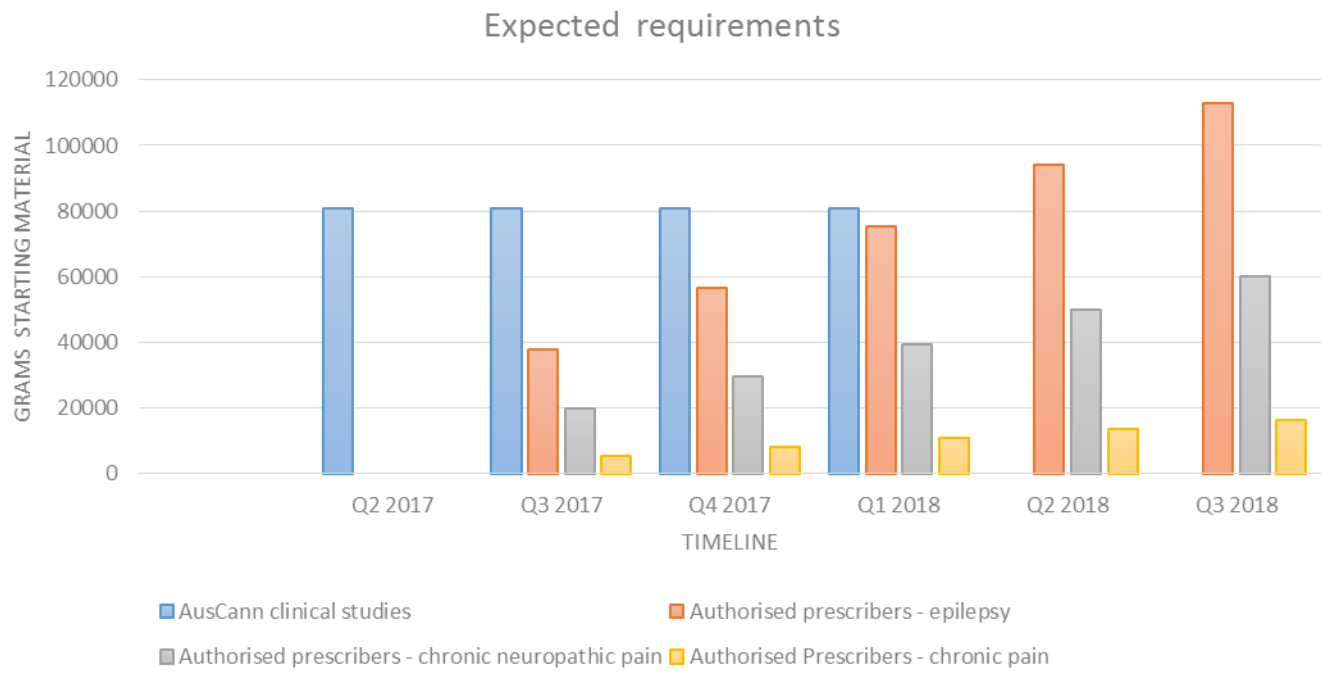
(ii) supplying treatment resistance epilepsy clinical studies being undertaken jointly;

(iii) supplying 3rd parties such as Zelda Therapeutics for their clinical studies; and

(iv) supplying product to authorised prescribers for the treatment of chronic neuropathic pain, chronic pain and treatment resistance epilepsy.

Demand from authorised prescribers will predominately stem from of AusCann's medical education program under its Authorised Prescriber Strategy outlined in Annexure A and results from its clinical studies.

The following graph is an indication of expected requirements for product based upon AusCann's Authorised Prescriber Strategy and its clinical studies as outlined in Annexure A and below.



The relevant Australian clinical study regulatory framework is outlined in Annexure D.

(B) REFRACTORY EPILEPSY STUDY

This investigator led study is to involve 50 patients aged up to 16 years over 12 months. The dosage range of cannabidiol in a medicinal cannabis full spectrum extract in a childhood epilepsy study may be up to 30 mg/kg/day (Porter & Jacobson, 2013).

This study is expected to commence in late Q1 2017.

(C) CHRONIC PAIN AND NEUROPATHIC PAIN

AusCann is particularly interested in the potential for better chronic neuropathic pain symptom management combined with a reduction in opioid use leading to measurable better quality of life outcomes (as seen in the long term study undertaken by the Pain Relief Unit, Hadassah-Hebrew University Medical Centre in Jerusalem, Haroutounian et al., 2016).

This sponsor initiated study is to involve 100 adult patients over a 12 month period. Based upon other studies the dosage of tetrahydrocannabinol (THC) in a medicinal cannabis full spectrum extract for chronic neuropathic pain study the dosage for this study will be up to 130 mg /day THC (Rog, Nurmikko, Friede, & Young, 2005). We note that the Health Canada dosage fact sheet provides doses of vaporised dried cannabis ranging up to 256 mg/day THC (Health Canada, 2016) and higher dosage may be required for some patients.

This study is expected to commence in late Q1 2017.

6.2 Cultivation Research and Development

Under the research alliance with Murdoch University, AusCann intends to undertake various research projects as follows.

Information and any intellectual property obtained from these research projects are to assist AusCann with its ongoing cultivation and production activities in Chile and in future, Australia.

(A) OPTIMISING CLONAL PROPAGATION

AusCann and Murdoch University intend to undertake research to optimise clonal propagation techniques of Cannabis species. Cultivation of clonal propagation medicinal cannabis material is required for the manufacture of full spectrum medicinal cannabis. To meet acceptable quality standards, phytomedicines have to undergo a standardisation process, this being "the establishment of reproducible pharmaceutical quality by comparing a product with established reference substances and by defining minimum amounts of one or several compounds or groups of compounds (or in some cases) a maximum and minimum amount" (Heinrich, Barnes, Gibbons, & Williamson, 2004).

Studies have shown that when the ratios of cannabinoids in seed-sown and cloned plants were compared, the chemical profile of seeds-sown plants was significantly more variable than that those raised from cuttings. Statistical analysis showed certain cannabinoids to be significantly more variable in plants grown from seed. The conditions for the importation of cannabis seeds and other germplasm, such as cuttings and cultural plant tissue, are established in the Biosecurity Import Conditions System of the Commonwealth Department of Agriculture and Water Resources (DAWR). Murdoch University has relevant facilities and expertise in this space given their quarantine containment level 2 facilities and their participation in the Plant Biosecurity Cooperative Research Centre, coupled with the fact that they have DAWR Quarantine Approved Persons on staff, and are leaders in plant pathogen diagnostics.

Once AusCann has the necessary research and development licence for cannabis species the appropriate plant genetics will be imported into Australia from our partners Phytoplant in Spain and Canopy in form of cuttings and/or tissue culture to clonally reproduce.

(B) OPTIMISING GROWTH CONDITIONS

Working with Phytoplant and Murdoch, AusCann intends to research optimum growth conditions for yield of medical cannabis compounds.

AusCann is investigating combining the benefits of outdoor and indoor grow by utilising automated retractable roof greenhouses that can optimise growing conditions whilst protecting in-ground crops from adverse weather events. Weather stations and specially designed computer systems can automatically regulate the roof and wall positions to help prevent losses which can naturally occur in the open field due to extreme weather conditions.

The automated roof system will also enable them to control temperature and daylight hours to optimise yield and harvesting times.

The greenhouses and systems designed and constructed for this R&D project may also be used for commercial cultivation activities once licensed.

(C) HARVEST TIMING

Cannabis is generally a 'short day plant' that by definition only commences to flower late in summer, once the day length starts to reduce (Clarke, 1981). When the critical day length is reached floral development is stimulated. More correctly, the plant is responding to the increasing length of the night, during which time a light-sensitive phytochrome protein slowly dimerises (combines with a smaller molecule) to a different form. Within seconds of light exposure, the protein reverts back to the original structure. It is only when the night time is sufficiently long that a required balance of the dimers is reached to signal commencement of flowering (Halliday & Fankauser, 2003). To reliably induce flowering in most varieties of cannabis, the night-length must be greater than the critical day length. The critical day length for an individual variety is greatly affected by its geographical origin and would generally be greatest in those plants derived well away from the equator (de

Meijer & Keizer, 1994). Exceptions to this response occur in plants adapted to grow in equatorial regions, where there is minimal variation in day length. Flowering in tropical cannabis plants is more closely related to plant age. In contrast, rapid flowering ecotypes are found at latitudes of 60º or more (Callaway, 2002). These have typically adapted to survive in the very short growing season, and commence flowering early in the season irrespective of the day length.

In an outdoor grow environment with variable day length between summer and winter, there is generally one harvesting time which may yield between 451 – 728 g/m2 depending upon the strains and region. This can be contrasted to an indoor grow environment where a crop may be grown and harvested in a 12-14 week period and provide a yield of 494 – 515 g/m2 (Potter, 2006).

(D) BREEDING PROJECT

AusCann, Murdoch University and Phytoplant are to undertake a plant breeding collaboration to develop improved medicinal cannabis varieties. A key component of this research will be analytical techniques for resolution of the chemical components of the varieties, for profile characterisation and consistency.

(E) PRODUCT CHARACTERISATION FOR CLINICAL STUDIES

Building upon the chemical characterisation expertise for the chemotyping of plants, AusCann will undertake chemical analysis of produced and sourced medicinal cannabis extracts to support its clinical investigations.

7. Annexure D - Australian clinical study regulatory framework

To undertake a clinical study with schedule 8 substances, such as full spectrum cannabis plant extracts as proposed by AusCann, a State poisons permit is required under section 25 of the Poisons Act 1964 (WA). This is applied for using a prescribed form.

Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research involving humans. The HRECs review research clinical study proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. There are more than 200 HRECs in institutions and organisations across Australia that can review and provide the necessary approval for a study to proceed.

As Australian medicinal cannabis will be unavailable until sometime in 2017, product would need to be imported into Australia under the Customs (Prohibited Imports) Regulations 1956 (Cth) for any clinical studies undertaken prior to this time. A copy of the State poisons permit is required for inclusion in the application to the Office of Drug Control for a licence and permit to import.

The study also needs to be registered with the TGA using either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes, as with all clinical studies. Whether the CTN or CTX scheme is used is a consideration of the sponsor of the study (such as the Company) and the HREC that reviews the protocol. A determining factor for a HREC may be whether the committee has access to appropriate scientific and technical expertise in order to assess the safety of the product.

To conduct a clinical trial in Australia, the trial must have an Australian sponsor. The sponsor may be an individual (for example a medical practitioner), a body or organisation (for example hospitals, area health services, non-government organisations), or a company (for example, AusCann or a Contract Research Organisations, CROs). The TGA would deal directly with the Australian sponsor on all matters relating to the trial.

The CTN Scheme is a notification scheme and the TGA does not review any data relating to the clinical trial. All material relating to the proposed trial, including the trial protocol is submitted directly to the HREC and the HREC is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and for approval of the trial protocol. The institution or organisation at which the trial will be conducted gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

The CTX Scheme is an approval process and a sponsor submits an application to conduct clinical trials to the TGA for evaluation and comment. A TGA delegate decides whether or not to object to the proposed usage guidelines for the product. The sponsor may conduct any number of clinical trials under the CTX application without further assessment by the TGA, provided use of the product in the trials falls within the original approved usage guidelines. The TGA must be notified of each trial conducted.

Access to unregistered medicines for clinical trials requires seeking the approval of a HREC and notifying the TGA, or seeking approval of both a HREC and the TGA, depending upon the risks associated with the clinical trial proposal.