

Leveraging anecdotal patient data by funding clinical trials with world leaders to demonstrate the effectiveness of medicinal-cannabis based therapy

December 2015

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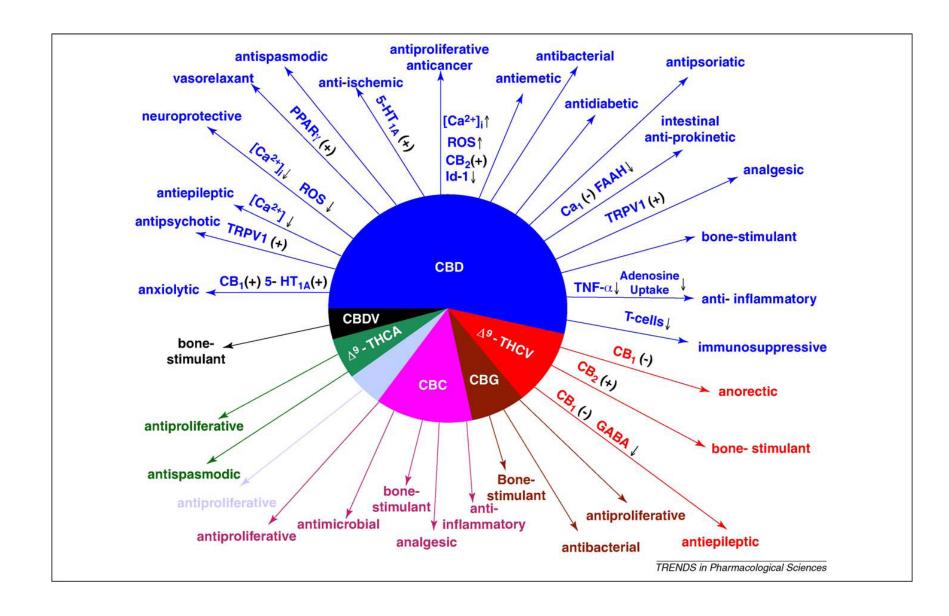
Overview

- > Zelda Therapeutics Pty Ltd ("Zelda") has been established to exploit the emerging global opportunity in the medical cannabis sector
- Brings together a team with relevant and complementary skill-sets, experiences and networks
- > Global sentiment is changing with an increasing number of jurisdictions legislating in favour of the use of cannabis for medical purposes
- Numerous clinical trials and significant anecdotal evidence demonstrates medical benefits in a range of conditions - anti-convulsion, neuroprotectant, antiinflammatory, anti-nausea, glaucoma, pain management & cancer
- Zelda is leveraging its close relationship with established medical cannabis player, Aunt Zelda's, in California where the Founders of Zelda have invested
- Aunt Zelda's has a significant database of patient records indicating solid anecdotal evidence for treating a variety of ailments using protocols and formulations developed by Aunt Zelda's over several years
- Zelda seeks to fund clinical trials aimed at validating this anecdotal evidence in controlled conditions initially aiming for topical treatment for wound healing, eczema, post-burn itch, acne and certain cancers
- > Success in these trials should result in significant value creation
- Gleneagle Gold Ltd announced on 9th December a scrip acquisition of Zelda subject to shareholder approval

Cannabis 101

- > Cannabis is a flowering plant containing at least 85 types of cannabinoids with evidence suggesting it has been used for medicinal purposes since antiquity
- Cannabinoids are the chemical compounds secreted by cannabis flowers and include tetrahydrocannabinol (THC) and cannabidiol (CBD)
- When cannabis is consumed, cannabinoids bind to receptor sites in the brain and body mimicking naturally occurring compounds in the body known as endocannabinoids
- ➤ Different cannabinoids have different effects depending on which receptors they bind to. For example, THC binds to CB1 and CB2 receptors in the brain and other body sites, whereas CBD has a low affinity for these receptors but conceivably stronger affinity for other as-yet-unknown receptors. Different types of medical effects can be achieved through targeting different receptors using differing quantities of cannabinoids (eg. THC vs CBD)
- ➤ This concept is the cornerstone of cannabis as a medicine so much so that these cannabinoids have been synthesized for legal prescription use including *Marinol* (appetite stimulant), *Nabilone* (pain) as well as naturally-derived *Sativex* (MS spasticity). While these synthetic forms are effective, research shows that herbal cannabis contains a far wider variety of therapeutic compounds
- ➤ Cannabis products and strains have been developed to deliver larger doses of different cannabinoids and different varieties grow best in certain environments. Knowledge of these key factors is an important piece of the puzzle in ensuring consistent medicinal profiles.

Cannabinoids



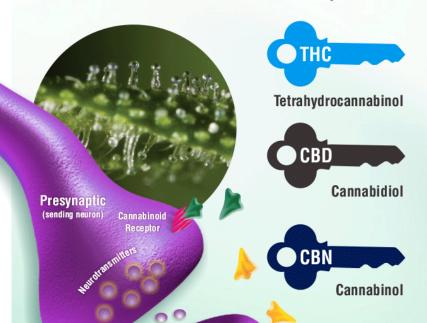
Human Endocannabinoid System

The Human Endocannabinoid System

CBD, CBN and THC fit like a lock and key into existing human receptors. These receptors are part of the endocannabinoid system which impact physiological processes affecting pain modulation, memory, and appetite plus anti-inflammatory effects and other immune system responses. The endocannabinoid system comprises two types of receptors, CB1 and CB2, which serve distinct functions in human health and well-being.

CB1 receptors are primarily found in the brain and central nervous system, and to a lesser extent in other tissues.

Receptors are found on cell surfaces

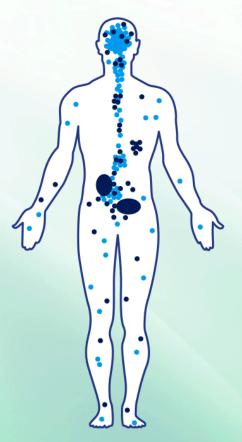


CB1

CBD does not directly "fit"
CB1 or CB2 receptors but
has powerful indirect
effects still being studied.

CB2

CB2 receptors are mostly in the perepheral organs especially cells associated with the immune system.

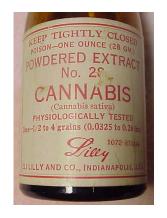


source: www.fhe-human-solution.org

Medical Uses

- Medical cannabis comprises preparations from extracted cannabinoids and the vapourised, dried flower
- ➤ It is widely accepted that medical cannabis can be effective in providing relief from a range of ailments including:
 - > Spasticity in Multiple Sclerosis
 - Chemotherapy-induced nausea, vomiting and anorexia
 - Chronic neuropathic pain
 - Wasting Syndrome
 - Assists in treating symptoms of HIV/AIDS
 - ➢ Glaucoma
 - > Epilepsy/Seizures
 - Certain cancers
- ➤ Whilst synthetic versions of THC and CBD exist, the biochemical effect does not seem to be as pronounced as the naturally occurring compounds most likely due to interactions amongst the other cannabinoids and terpenes present in the natural extract



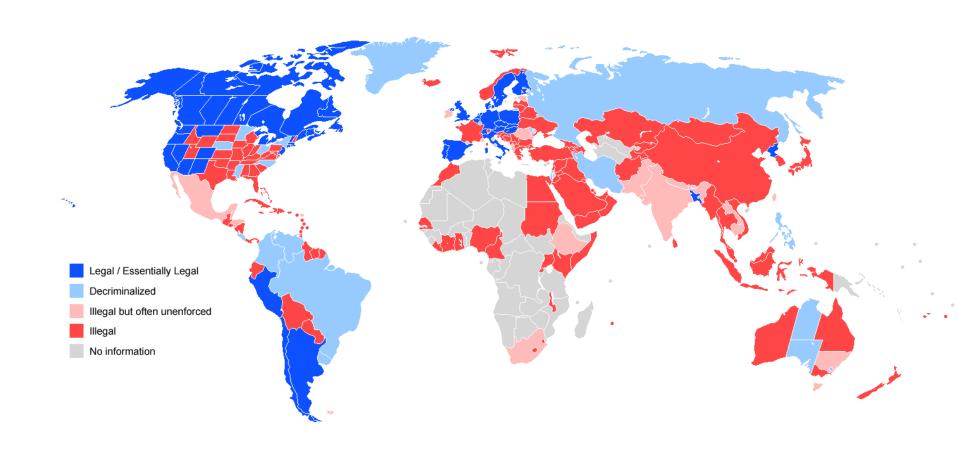




Regulatory Environment

- ➤ **USA** cannabis for medical use has been legalised in 24 states with legislation pending in a further 10 states. Remains illegal at the Federal level.
- > Canada medical use legalised and regulated since 1999
- ➤ **United Kingdom** illegal (however a medical cannabis product "Sativex" is being produced there by GW Pharmaceuticals and distributed globally)
- > Australia currently under review, decriminalised in SA, ACT, NT
- Austria cannabis cultivation approved for scientific and medical use
- > **Belgium** trials initiated to determine medical effectiveness
- Czech Republic medical use legalised and regulated
- France approved for medical usage
- > Israel approved for medical usage
- Italy approved for medical usage
- Netherlands approved for medical usage
- North Korea fully legal and not regulated
- > **Spain** legal to grow and consume on private property
- Uruguay legal to grow and consume on private property

Legal Status for Medical Use



Source: Wikipedia

Board of Directors



Harry Karelis - Founder & Executive Chairman

Harry is the founder of Titan Capital Partners - a privately held investment group involved in a range of projects. He graduated from The University of Western Australia with Bachelors and Honours in Science majoring in Biochemistry and Microbiology as well as a Masters in Business Administration. He is a Fellow of the Financial Services Institute of Australia, a Fellow of the Australian Institute of Company Directors and has qualified as a Chartered Financial Analyst (CFA) from the CFA Institute in the United States. He has in excess of 23 years diversified experience in the financial services sector including fundamental analysis, funds management and private equity investing and has acted as a Director on several public and private companies in Australia, Singapore and the United Kingdom. Harry resides in Australia.



Mara Gordon - Founder & Director

Mara Gordon specializes in the development of cannabis extract treatment protocols for seriously ill patients in California. She is the co-founder of Aunt Zelda's and Zelda Therapeutics and sits on the advisory board of Washington-based New Frontier - a group specialising in collecting and analysing data for the cannabis industry as well as #illegallyhealed - a leading social media platform for patients. Prior to that, she worked as a process engineer for over a decade, helping large companies create intelligent software and this experience has enabled her to take a detailed and scientific approach to medical cannabis. She has presented at several CME-accredited medical conferences, along with inaugural medical cannabis conferences in Australia and Costa Rica as well as other events throughout the United States and enjoys a high profile in the media. The documentary "Weed the People" due for release in 2016 follows Mara and several of her patients over the course of their treatment. She graduated from the University of North Texas with a Bachelor of Arts (Political Science). Mara resides in California.



Jason Peterson - Founder & Director

Jason is a Director, major shareholder and Head of Corporate of boutique stock broking and corporate advisory firm, CPS Capital. He has more than 19 years of experience in the financial advisory sector, which he obtained by working in both local and international stockbroking companies such as Patersons, Tolhurst, and Merrill Lynch. He specialises in corporate structuring, capital raisings, corporate and strategic advice to small and medium size companies and reverse takeovers. He holds a Bachelor of Commerce degree from Curtin University and a Graduate Diploma of Finance from FINSIA (Financial Services Institute of Australia)/SDIA (Securities & Derivatives Institute of Australia). Jason resides in Australia.

Board of Directors



Dr Stewart Washer - Founder & Director

Stewart has 20 years of CEO and Board experience in medical technology, biotech and agrifood companies. He is currently Chairman of ASX-listed Orthocell Ltd (culturing tendon cells to repair damaged tendons) and Cynata Therapeutics Ltd (developing stem cell therapies) and Chairman of privately-held Minomic International Ltd (accurate non-invasive test for prostate cancer). Stewart has held several past senior executive roles including CEO of Celentis and managed the commercialisation of intellectual property from AgResearch in New Zealand with 650 Scientists and \$130m revenues. He was also a founder of a NZ\$120m New Zealand based life science fund and Venture Partner with the Swiss based Inventages Nestlé Fund. Stewart resides in Australia.



Scott Walters - Advisor to the Board

Scott has more than 20 years experience in the capital markets and has most recently focused on the Canadian medical cannabis industry where he is well known as an advisor and entrepreneur. He is a founding shareholder of the Toronto-based Canabo Medical Clinic which is a specialist medical cannabis referral clinic. He is currently a senior executive with Jacob Securities Inc. specialising in servicing the Canadian medical cannabis industry. He has a Bachelor of Economics from The University of Western Ontario. Scott resides in Canada.

Scientific Advisory Board



Professor Manuel Guzmán

Professor Guzmán is the Full Professor of Biochemistry and Molecular Biology at Madrid's Complutense University. His PhD and postdoctoral research focused on the study of the regulation of liver and brain lipid metabolism. During the last twenty years he has been mostly involved in the study of how cannabinoids act in the body, with special emphasis on the molecular mechanisms of that action and on understanding how cannabinoids control cell generation and death. This work has allowed characterizing new effects and signalling pathways evoked by cannabinoids, as well as putting forward new physiopathological implications derived from them. Dr. Guzmán has published 136 articles and 7 patents and supervised 15 PhD thesis. He has been Secretary of the SEBBM (2006-2010) and founder and secretary of the Spanish Society for Cannabinoids Research (SEIC) where he is the current President. He is also an Academic Member of The Royal National Academy of Pharmacy (Spain) as well as a member of the Board of Directors of the International Association for Cannabinoid Medicines (IACM). Professor Guzmán resides in Spain.



Associate Professor Dr Christina Sánchez

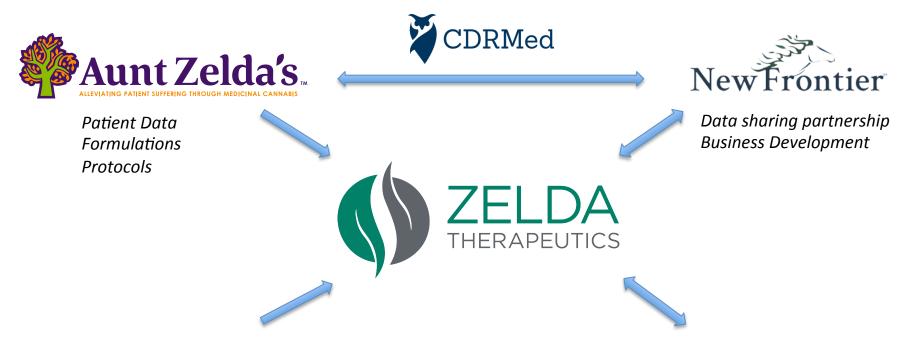
Dr Sánchez is an Assistant Professor at Complutense University, Madrid Spain. Her PhD and postdoctoral training were focused on lipid signaling, including that of cannabinoids in an oncology setting. The goal of her current research is to understand and exploit cannabinoids as potential antitumoral agents in breast cancer. More recently, she has also focused her attention on new cannabinoid receptors and their possible involvement in cannabinoid antitumoral action in breast cancer and other type of tumors. She has been Secretary of the Spanish Cannabinoid Research Society (2011-2015) and is one of the founders and Secretary of the Spanish Observatory on Medicinal Cannabis. Dr Sánchez resides in Spain.



Doctor Donald Abrams

Dr. Donald Abrams is a cancer and integrative medicine specialist at the UCSF Osher Center for Integrative Medicine at Mount Zion. He provides integrative medicine consultations for cancer patients and has completed research in complementary and alternative therapies including medical use of cannabis and traditional Chinese medicine herbal therapies. In addition to his role at the Osher Center, he is chief of Hematology and Oncology at San Francisco General Hospital. He has been at the forefront medicinal cannabis research having conducted clinical trials of inhaled cannabis funded by both the US National Institutes of Health and the University of California Center for Medicinal Cannabis Research. He is a co-editor of the National Cancer Institute's Physician Data Query Complementary and Alternative Medicine (NCI PDQ CAM) website posting on cannabinoids and cancer. Doctor Abrams resides in California.

Partnerships/Alliances





Supply of clinical trial material (subject to legislation being passed in Australia)



Partnership 2

Partnership 3

Research and clinical trial partnerships

- Complutense University Madrid
- Others pending



- The Aunt Zelda's group (www.azcannaoil.com) is based in California (Bay Area) supplying customised medical extracts to registered patients
- Founded by Mr Stewart Smith & Ms Mara Gordon who has a very high profile in the sector in the USA/World and is a keynote speaker at many of the world's medical cannabis conferences
 - LINKS: https://youtu.be/UWNo6W1ZNDk
- Have extensive patient data over past five years treating a range of ailments with a range of formulations and protocols
- Zelda Therapeutics has entered into an agreement providing for:
 - Exclusive data access for the planning and design of clinical trials in any therapeutic indication
 - Payments linked to clinical milestones payable by Zelda Therapeutics to Aunt Zelda's
 - Net Sales and Sub-License Royalty payable on any revenue generated by Zelda Therapeutics from formulations derived from Aunt Zelda's intellectual property



- AusCann is positioned as Australia's leading medicinal cannabis company
- It has developed extensive relationships through many levels of Federal and State governments
- Awaiting Federal legislation to be passed before being able to commence growing operations
- Several global partnerships in place provides access to proprietary medical cannabis strains and access to global markets
- Seeking an R&D licence to manufacture product for local clinical trials
- AusCann has exclusive rights to Aunt Zelda's formulations, protocols, systems and brandings in the Australian and New Zealand markets
- Agreement with AusCann to supply clinical trial material for Australian-based trial sites subject to appropriate legislation and licences being granted



- New Frontier (<u>www.frontierfinancials.com</u>) is based in Washington, USA and is at the forefront of collecting data of specific interest to the cannabis industry
- ➤ It has developed proprietary software to analyse millions of data points to generate usable information "big data" for cannabis
- It is positioned as the premier source of industry data and intelligence
- Aunt Zelda's has a joint-venture in place with New Frontier whereby de-identified clinical data will be provided and a global rollout of a SaaS based system (CDRMed™) to dispensaries and clinics generating recurring income streams
- This New Frontier JV will provide Zelda with access to industry data of interest including corporate groups that are potential licensees/partners and so is a very good business development resource
- Recently profiled in Forbes Magazine:

http://www.forbes.com/sites/alexkonrad/2015/11/09/legal-cannabis-gets-a-data-boost-from-arcview-new-frontier/

Corporate Strategy

- Very few public listed companies in the world provide investors with leveraged exposure to not only legislative change (opening up global markets) but also to new classes of medicines (ie. cannabinoids)
- ➤ The biggest company working on the above strategy is UK-based *GW Pharmaceuticals plc* who have one approved product (*Sativex*) which is an oral spray for treating spasticity in multiple sclerosis patients and enjoys a market capitalisation of US\$1.8 billion
- Zelda believes that the validation of anecdotal patient data in a controlled, clinical trial setting has the potential to create significant value for investors
- > The focus on a series of relatively low cost, short duration, high value clinical trials ensures that investors have multiple opportunities for value creation
- Will adopt a biotech/pharma mindset from inception and ensure protocols, intellectual property and clinical trials are all conducted as per world's best practice to ensure the data is in a form expected by future partners
- Zelda will adopt a traditional licensing model for key markets and partner with larger firms keen to enter the cannabinoid medicine space
- Solid clinical data would open up merger and acquisition opportunities leveraging Zelda's early mover advantage

Biotech Deal Values

- Zelda offers investors exposure to a clinical stage company leveraging existing human data
- Missing link is data in the form expected by regulators and partners.....as well as intellectual property
- Our core strategy is centred on generating industry standard data and then executing industry standard partnering deals
- Data below shows average deal values for different stage of development

Announced Deal Size of 2012-15 Alliances with >\$50m in payments

Stage	Sample size	Median Deal Value* (US\$m)
Discovery/Lead	93	292
Preclinical	91	252
Phase 1	45	382
Phase 2	64	361
Phase 3	34	260

^{*} Payments include Up-Front, Equity, Development/Regulatory Milestones & Sales Milestones SOURCE: BioSci Advisors

ASX Comparables

Comparable valuations of Phase 2 stage companies listed on the Australian Stock Exchange (ASX) demonstrates upside value creation potential for Zelda investors.

Company	Stage of development	Market Capitalisation* (A\$)
Sirtex Medical	On market	1851
pSivida	On market	147
Clinuvel	On market	124
Acrux	On market	95
Pharmaxis	On market	73
Orthocell	On market	55
Mesoblast	Phase 3	1066
Starpharma	Phase 3	251
Bionomics	Phase 2	199
Neuren	Phase 2	138
Viralytics	Phase 2	109
Prana Biotechnology	Phase 2	69
Oncosil Medical	Phase 2	52
Benitec Biopharma	Phase 2	51
Immuron	Phase 2	34
Innate Immunotherapeutics	Phase 2	32
Paradigm Biopharma	Phase 2	26
Antisense Therapeutics	Phase 2	15
Invion	Phase 2	12
Imugene	Phase 2	9
Circadian Technologies	Phase 1	29

AVERAGE PHASE 2 MARKET CAPITALISATION	A\$62.2 MILLION
MEDIAN PHASE 2 MARKET CAPITALISATION	A\$42.5 MILLION

* As at 30/9/2015

Pre-Clinical Research

- The company will allocate funding for pre-clinical research mainly in the areas of cancer and acute wound studies
- ➤ Cancer: Working with Professor Manuel Guzman and Dr Cristina Sanchez at Complutense University (Madrid, Spain) to conduct mechanism of action and other studies in glioblastoma and breast cancer
 - US National Cancer Institute summarising medical cannabis in cancer:
 http://www.cancer.gov/about-cancer/treatment/cam/patient/cannabis-pdq/#link/ 13
- Acute Wounds: In discussions with one of Australia's leading clinicians to conduct mechanism of action studies in acute wound models both from a healing and pain management perspective
- > This pre-clinical research ensures the company has a pipeline of therapeutic compounds and generates data packs consistent with that expected by the pharmaceutical and biotechnology industry
- May result in traditional licensing agreements with specialist companies seeking novel drug targets and molecules

Clinical Trial Focus

- The company will focus on trials that are:
 - Based upon positive anecdotal evidence generated by Aunt Zelda's
 - Relatively short duration
 - Relatively low cost
 - Clear end points
- Initially focused on skin-based conditions
 - Wound healing chronic sores (eg. bed sores)
 - Eczema
 - Post-Burn Itch (pruritus) chronic condition experienced by burns patients
- Will also conduct observation trials on adult and paediatric glioblastoma cancer patients comprising both retrospective (on existing patient data) and prospective (future) patients
 - Short term aim to publish results of this analysis in a respected peerreviewed journal before deciding on further steps

Indicative Clinical Timeline

26 27 MONTH 10 11 12 13 14 15 16 17 18 19 20 21 23 **OBSERVATIONAL TRIALS PLANNING DATA ANALYSIS RESULTS** Paediatric Glioblastoma **PLANNING DATA ANALYSIS RESULTS** Adult Glioblastoma PRE-CLINICAL RESEARCH **PLANNING** RESEARCH UNDERWAY **DATA ANALYSIS RESULTS** Breast Cancer **PLANNING** RESEARCH UNDERWAY DATA ANALYSIS RESULTS **Acute Wound Healing CLINICAL TRIALS PLANNING APPROVALS TRIAL UNDERWAY DATA ANALYSIS RESULTS** Post-Burn Itch **DATA ANALYSIS RESULTS PLANNING APPROVALS TRIAL UNDERWAY** Eczema

APPROVALS

TRIAL UNDERWAY

PLANNING

Chronic Wound Healing

RESULTS

DATA ANALYSIS

GW Pharmaceuticals



- Founded in 1998 and listed on NASDAQ and AIM (UK)
- Focused on developing a portfolio of cannabinoid-based medicines
- Only one approved product:
 - Sativex: Oral mucosal spray for treatment of spasticity symptoms in mild multiplesclerosis
- Orphan Drug and Investigative New Drug (IND) classification for:
 - Epidiolex: Childhood epilepsy therapy

Revenues for 9 months to 30 June 2015: US\$36.0m

Loss for 9 months to 30 June 2015: US\$50.8m

Cash at 30 June 2015: US\$398.9m

Market Capitalisation: US\$1.8 billion

> Zelda Therapeutics will adopt the same strategy to clinically validate the efficacy of cannabis-based medicines

Gleneagle Gold Transaction

- ASX-listed Gleneagle Gold Ltd (ASX:GLN) announced on 9th December the all-scrip acquisition of Zelda through the issuance of 1.6 billion shares for 100% of the issued capital of Zelda
- Values Zelda at A\$8 million comparing very favourably to the median valuation for other similar stage life-science companies listed on ASX
- Still subject to shareholder approval and other ASX conditions to achieve a relisting
- > Shareholder meeting expected to be held in Jan/Feb 2016 with full re-compliance and listing achieved in March/April 2016
- For full details on the Transaction, please refer to the announcement dated 9 December 2015 which can be found on Gleneagle Gold Limited's ASX platform at www.asx.com.au

Summary

- Zelda Therapeutics has been formed to focus on conducting specific clinical trials using cannabis-based medicines
- These trials will leverage the extensive anecdotal patient history developed by its California-based partner Aunt Zelda's
- Access to this anecdotal data helps accelerate the normal clinical trial development pathway and provides potential to commence Phase II pivotal trials in the short term
- Success in these trials should result in significant value creation for shareholders with GW Pharmaceuticals an excellent proxy in regards to what can be achieved
- Founders of Zelda have extensive biotech/pharma & capital markets experiences and networks
- Significantly de-risked and a strong foundation for success