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## **SLEEP DISORDER CLINICAL TRIALS UPDATE**

### **HIGHLIGHTS**

- Identified trial sites in multiple target locations, including the USA and Australia
- Discussions with Clinical Research Organisations (CROs) underway and relevant submissions for ethics approvals in progress
- Trials to assess the clinical efficacy of Zelda's formulation to treat insomnia
- Substantial anecdotal evidence of compounds' effectiveness exists for sleep disorders
- Trials to clinically validate effectiveness and drive broader use of medical cannabis to treat sleep disorders, with trial data expected in late 2017
- Insomnia affects ~35% of the global population and the global sleep aids market alone is expected to be worth US\$80.8 billion by 2020

**Zelda Therapeutics Ltd (ASX: ZLD, "Zelda" or the Company)** is pleased to announce its strategy to target the significant sleep disorder market is progressing and the Company has identified trial sites in multiple target locations, including the USA and Australia.

The Company is also progressing discussions with potential partner Clinical Research Organisations (CROs) in local markets and submissions for the necessary approvals from the relevant ethics committees in each location are now in progress.

The Company anticipates receiving approvals early next year with the trials able to commence shortly thereafter in 2017.

The trials will assess the efficacy of Zelda's medical cannabis-based formulation for treating sleep disorders. Zelda will be leveraging the significant amount of anecdotal evidence and data for the compounds' effectiveness in treating sleep disorders accessed through its exclusive agreement with *Aunt Zelda's*.

The sleep disorder market provides a significant opportunity for Zelda. Insomnia is estimated to impact approximately 35% of the global population and is considered to be a prime factor for chronic disability in the workforce. The global sleep aids market was valued at US\$58.1 billion in 2014 and is expected to expand to reach US\$80.8 billion by 2020, according to the research firm *Persistence Market Research*. Sleep aids are drugs and medical devices that help a person to fall asleep.

Due to the safety data already in place for medicinal cannabis extracts, Zelda is able to progress directly to human clinical trials, rapidly accelerating the time to commercialisation.

Upon achieving positive results in the trial, the Company will pursue the necessary approvals in key geographic markets to register the product and make it available for sale to consumers as an effective sleep aid.

The Company anticipates commencing its first trial in the first half of 2017, following the relevant approvals and recruitment of patients with results expected thereafter.

Executive Chairman Harry Karelis stated:

*“The sleep disorder market represents a significant opportunity for medical cannabis treatments. We believe that consumers are looking for safe, effective, affordable alternatives to current prescription medication. Our exclusive access to Aunt Zelda’s patient data has provided us with the ability to trial a formula that already has existing evidence and data to demonstrate its efficacy in this particular disorder. The purpose of these trials is to establish robust, clinical evidence and to create a comprehensive data pack that can be used to progress later stage trials and/or seek product registrations in certain markets and generate product sales in the medium term.”*

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### **About Zelda Therapeutics ([www.zeldatherapeutics.com](http://www.zeldatherapeutics.com))**

Zelda Therapeutics (“Zelda”) is an Australian-based bio-pharmaceutical company that has secured exclusive, global access to an extensive set of human data related to medicinal cannabis based formulations and treatment protocols. This human data has been generated over several years by a California-based group (*Aunt Zelda’s*) that has a very high profile within the USA and a growing international profile based upon its deep knowledge of the scientific rationale for certain cannabis-based formulations and protocols to treat a variety of medical conditions.

Zelda has been granted a worldwide, exclusive and perpetual licence to this data, related systems, formulations and treatment protocols. Zelda will use this information to design a series of human clinical trials that have a high probability of success given the existing patient data and experiences it has access to.

In addition, Zelda is building a pre-clinical research portfolio targeting cancer. It has partnered with the world’s leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry. A similar programme is in place with the Australian Telethon Kids Institute targeting paediatric brain cancer.