



ASX Release

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Tickers:

Australia (ASX): ZLD
USA (OTC): ZLDAF

Ordinary Shares:

755,341,934

Options:

46,000,000

1,500,000 (\$0.04 – 6/2/2020)

*4,500,000 (\$0.04 – 6/2/2020)

*40,000,000 (\$0.03125 – 17/11/2021)

* subject to vesting conditions

Insomnia Clinical Trial Update Patient Recruitment Completed

- Recruitment into Australia's first clinical study of medical cannabis to treat insomnia is now complete
- Next phase to commence shortly
- Study has been designed to the highest standards
- Working with one of Australia's leading sleep research centres
- State of the art technologies used for monitoring and data collection
- Zelda's formulations for the clinical trial manufactured by Eurofins Sinensis, a leading European GMP manufacturing pharmaceutical company

The Board of **Zelda Therapeutics Ltd** (ASX: ZLD, OTCQB: ZLDAF, **Zelda** or the **Company**) is very pleased to announce it has now completed patient recruitment into its pioneering insomnia trial.

The next phase of the study will commence shortly with patients undergoing baseline sleep measurements before commencing pharmaceutical dosing.

The clinical trial will be undertaken by the prestigious University of Western Australia (UWA) Centre for Sleep Science (CSS), which has state of the art research facilities and is directed by Professor Peter Eastwood, National Health and Medical Research Council Senior Research Fellow.

Zelda's clinical trial will target a sample population of people with characteristic symptoms of chronic insomnia, which include difficulty falling and staying asleep on a long-term basis. A randomised, placebo controlled, cross over study design will be used, where patients are selected at random to be treated with Zelda's medicinal cannabis formulation or a placebo formulation.

In addition to a series of baseline measurements conducted within the Centre for Sleep Science, patients will be supplied with wrist monitors to record sleep activity at home over a period of two weeks. State of the art data collection techniques will be employed in the trial providing high quality data sets generated in near real time.

The study will collect and analyse data to determine the effect of the Zelda formulation on the time of onset of sleep, sleep cycle duration and quality of sleep. In addition, subjective feedback from patients via standard questionnaires will be collected and analysed alongside the analytical data collected.

The medicinal cannabis formulation for the clinical trial is being manufactured to Good Manufacturing Practice (GMP) standards by a global leader in pharmaceutical manufacturing - Eurofins Sinensis, based in The Netherlands.

It is anticipated that preliminary results from this clinical trial will be available in late 2018. Should the trial be successful, it is the intention of the Company to rapidly pursue commercialisation activities for this formulation in markets that provide a rapid path to widespread patient access.

Zelda has established a number of relationships in key global markets and is well placed to rapidly move into the commercialisation phase of its business plan upon the successful conclusion of this trial.

Harry Karelis, Executive Chairman said *“This is a significant achievement for Zelda and has the potential to introduce a safe, effective and affordable treatment for patients. It is no small feat to be progressing a pioneering study of this nature using medicinal cannabis and is a testament to the quality of people involved that we have reached this point in such a rapid time-frame. Positive results will mean Zelda will rapidly focus on commercialisation activities in markets where we have existing knowledge, relationships and access to patients.”*

Professor Peter Eastwood, Director, Centre for Sleep Science said *“We are delighted that we have achieved this significant milestone and look forward to the next phase of the study. We have been very deliberate in designing a very robust study design to the highest standards which has the potential to be a pivotal trial in the field of insomnia research. Should the trial be successful we see significant potential to provide a safe and effective medicine to patients with insomnia but also potentially for other sleep disorders.”*

Tim Slate
Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics (“Zelda”) is an Australian-based bio-pharmaceutical company that is focused on developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company has a two-pronged strategy comprising:

- A human clinical trial programme focused on insomnia, autism and eczema with activities in Australia, Chile and the United States.
- A pre-clinical research programme examining the effect of cannabinoids in breast, brain and pancreatic 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 and Curtin University targeting pancreatic cancer.

About University of Western Australia (UWA) Centre for Sleep Science (CSS) (www.sleepcentre.science.uwa.edu.au)

Western Australia (WA) has been a leader in Australian sleep medicine research for many years and through UWA's Centre for Sleep Science is at the forefront of sleep research and sleep education. Research conducted at the CSS at UWA aims to identify the causes of, and investigate therapies for, poor sleep. The CSS boasts five bedrooms equipped with state-of-the-art sleep recording and analysis equipment for laboratory-based research sleep studies. The CSS also contains a range of training and seminar rooms and is the base for a number of national postgraduate sleep training courses offered through the University of Western Australia. Members of the CSS regularly publish their research in leading international medical and scientific journals and present their work at national and international scientific meetings.