



ASX Release

13 April 2018

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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

US Autism Observational Study Receives IRB Approval

- Institutional Review Board (IRB) approval received
- Autism observational trial in USA now clear to proceed at Children’s Hospital of Philadelphia
- Study will monitor paediatric patients already being treated with medicinal cannabis formulations
- Seeks to better understand the efficacy of these treatments and identify appropriate components, dosage and effectiveness
- Preliminary results expected within six months
- Lays groundwork for a possible future clinical trial to generate high quality, robust data to validate extensive anecdotal patient data

The Board of **Zelda Therapeutics Ltd (ASX: ZLD, US OTC: ZLDAF, Zelda or the Company)** is pleased to announce that its previously announced autism project, to be conducted at the USA-based Children’s Hospital of Philadelphia (CHOP) has received Institutional Review Board (IRB) approval.

This is the equivalent to Human Research Ethics Approval in Australia and essentially allows the planned study to commence within the parameters of the approved trial protocols.

This research will seek to better understand the efficacy of treatment in existing patients and will work closely with patient advocacy groups and licensed growers.

This study will utilise CHOP’s extensive research infrastructure and is designed to capture a number of key efficacy and safety measures including bioanalytical studies.

This initial study will lay the groundwork for a possible future clinical trial to generate high quality, robust and acceptable data to validate the extensive positive anecdotal data amongst patient populations.

The ultimate goal is to identify cannabinoid-based compounds that may demonstrate efficacy in the treatment of paediatric autism.

Harry Karelis, Executive Chairman said *“We are very excited to be formally commencing this study in the US working alongside CHOP. The high calibre of CHOP researchers and clinicians coupled with access to extensive infrastructure positions this study to be one of the first formal, robust studies of its type conducted to date. Positive results will allow Zelda to potentially expand into a formal clinical trial to study the efficacy of standardised, high quality medicines. This study is being conducted in parallel with our pending clinical trial in Chile leveraging the observational data generated in 2017.”*

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.