



ASX Release

31 July 2019

- **Insomnia, opioid reduction and autism clinical trials update**
- **Ethics approval for opioid reduction trial**
- **Received R&D Tax Rebate of \$769,000**

Zelda Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF) is pleased to provide this operational update with its Appendix 4C for the three-months to 30 June 2019.

OPERATIONAL UPDATE

Insomnia Clinical Trial (Perth, Australia)

The insomnia trial is evaluating the safety and efficacy of a cannabinoid extract containing THC and CBD in patients with symptoms of clinically diagnosed chronic insomnia. This trial is the first in the world to have a primary endpoint assessing the impact of a full-spectrum cannabis extract on sleep.

A randomised, double-blinded, placebo controlled, cross over study design will be used to treat 24 patients with Zelda's proprietary insomnia formulation and a placebo formulation delivered sublingually. The medicine for the trial has been manufactured to pharmaceutical grade GMP standards by a Europe-based speciality manufacturer.

The trial was initiated in September 2018 and, after a short delay to validate the stability of a second batch of the formulation, is actively recruiting

The trial remains on-track to report final results by late-Q4 2019.

Opioid Reduction Study (Melbourne, Australia)

Prescription opioids treating chronic pain are linked to serious side effects including physical dependence, which is an acknowledged growing global crisis. In the United States alone, an estimated 49,000 people died from opioid overdose in 2017.

In collaboration with St Vincent's Hospital in Melbourne, Zelda is undertaking an opioid reduction study. St Vincent's ranks in the world's top 100 hospitals and is recognised for its leading clinical expertise in chronic pain and addiction.

The aim is to assess the effectiveness of medicinal cannabis to reduce opioid dependence in patients with chronic non-cancer pain. As with insomnia, this is the first randomised controlled clinically trial of its kind to use a full-spectrum cannabis formulation. Longer term, a positive outcome to this trial will inform the design of future trials aimed at determining whether medicinal cannabis can substitute for a broader range of traditional medications.

The plan is to undertake an initial pharmacokinetic study to inform a subsequent small scale 20 patient double-blinded, randomised, placebo-controlled study; with the potential to expand into a larger trial depending on results.

In early July, Zelda was pleased to announce the Opioid Reduction Trial has been formally approved by the St Vincent's Hospital Ethics and Governance Committees.

The Phase I trial will evaluate the safety and tolerability of whole plant extract following single and repeated doses in nine patients with chronic non-cancer pain on long-term opioid analgesia. Secondary outcomes include pharmacokinetics and the effects on pain, mood, sleep and opioid use over the duration of the trial.

The Phase I trial will commence immediately with final results expected by Q4 2019.

Autism Observational Trial (Philadelphia, USA)

In September 2018, Zelda announced that recruitment had commenced for its observational autism study, which is being conducted in collaboration with Children's Hospital of Philadelphia. This trial is seeking to better understand the efficacy of medicinal cannabis treatment in patients diagnosed with autism.

The study combines a number of key efficacy and safety measures, including the impact of medicinal cannabis on clinical pharmacological and behavioural data, making it the first significant study of its kind.

As of the end of June 2019, a total of 72 patients had been enrolled, which represents significant progress towards the target sample size of between 100-200 patients. The increase in cohort size has seen a related increase in the number of patients eligible to participate in a pharmacological study using a novel micro-sampling technique. With expressions of interest in the study now extending to states outside of Pennsylvania, recruitment rates have been steady increasing.

The data is currently being subjected to rigorous statistical analysis with preliminary results expected to be reported by early Q3 2019.

R&D Tax Refund

In May 2019, Zelda confirmed it had received a \$769,000 cash refund under the Federal Government's Research and Development Tax Incentive Scheme.

Corporate

Zelda has continued to progress its core clinical and pre-clinical programs and has also prepared strategies to rapidly commercialise its medicinal cannabis products pending success in its clinical programs.

Looking forward, Zelda remains on-track to report on the outcome from its clinical trials for insomnia, autism and opioid reduction in the second half of 2019. The Company is also continuing to assess opportunities to expand its clinical programs where they align with its strategic objectives. Finally, Zelda is progressing discussions with third parties aiming to secure agreements to globally distribute clinically-validated Zelda products.

The Company closed the quarter with a cash position of \$3.1 million.

The Company also expects to lodge its R&D application for the 2018/19 FY, and is expecting to receive a refund in Q4 that reflects Zelda's increase in eligible R&D expenditure during 2018/19 FY. The Company remains fully funded for all of its upcoming clinical milestones.

Tim Slate

Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics Ltd is an Australian-based bio-pharmaceutical company developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company is undertaking:

- A **human clinical trial program** focused on insomnia, autism and opioid reduction with activities in Australia and the USA.
- A **pre-clinical research program** examining the effect of cannabinoids in breast, brain and pancreatic cancer as well as research examining the potential for cannabinoids to treat diabetes-associated cognitive decline.

The company conducts this work in partnership with world-leading researchers and organisations including Complutense University in Madrid, Spain; Curtin University in Perth, Western Australia; the Telethon Kids Institute in Perth; the University of Western Australia, in Perth; St. Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

Zelda has also formed a strategic partnership with European medicinal cannabis group HAPA Pharm BV, to access HAPA Pharm's EU-GMP grade manufacturing capabilities and accessing its German distribution network providing a credible and rapid path to commercialisation for successful clinically validated formulations.

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