



ASX Release

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**ZELDA THERAPEUTICS LIMITED**  
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**Tickers:**

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

**Ordinary Shares:**  
755,341,934

**Options:**  
49,000,000

1,500,000 (\$0.04 – 6/2/2020)  
\*4,500,000 (\$0.04 – 6/2/2020)  
1,000,000 (\$0.125 – 22/8/2021)  
\*2,000,000 (\$0.125 – 22/8/2021)

40,000,000 (\$0.03125 – 17/11/2021)  
\* subject to vesting conditions

**ZELDA PARTNERS WITH ST VINCENT'S HOSPITAL  
ON OPIOID REDUCTION STUDY**

- **Zelda to expand clinical trial program to include opioid reduction study**
- **Working with world-class pain and addiction medicine researchers at prestigious St Vincent's Hospital Melbourne**
- **Study to investigate potential to use cannabinoids to reduce the use of opioids in patients on chronic, high dose regimen for pain management**
- **Clinical trial protocols being finalised with near term submission to human ethics committee**
- **Chronic pain and addiction management is a large market opportunity**

**Zelda Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF, Zelda):** has expanded its human clinical trial program in a clinical trial partnership with the prestigious St Vincent's Hospital in Melbourne to examine the potential to use certain cannabinoid medications in patients on chronic, high dose opioid pain management therapy.

Prescription opioids are used to treat chronic pain and these drugs can have serious side effects including physical dependence, which is a global crisis. Research shows a growing number of Australians receiving treatment for dependence on painkillers<sup>1</sup>. The rate of accidental deaths due to opioids has doubled for Australians aged 35 to 44 since 2007. More than two thirds of these deaths have been due to pharmaceutical opioids<sup>2</sup>

This joint clinical trial program is aimed at assisting patients who have become dependent on opioids for chronic pain management.

The clinical team will be led by Associate Professor Yvonne Bonomo, and includes Dr Jane Trinca, Professor David Castle and Dr Nigel Strauss. An initial pharmacokinetic study will inform a small scale 20 patient double-blinded, randomised, placebo-controlled study, with the potential to expand into a larger trial depending on results.

The clinical trial protocols are being finalised and are expected to soon be lodged with the human ethics committee for review. Subject to approvals, the trial would be expected to start in early 2019.

Medication for the trial will be sourced from HAPA Medical, Zelda's strategic partner for manufacture and supply of pharmaceutical-grade medicinal cannabis.

Should the trial results show benefits then Zelda expects to be able to supply these medicines to Australian patients via specialists registered under the Authorised Prescriber Scheme.

Managing Director of Zelda Dr Richard Hopkins said, *"Zelda is delighted to work with the team at St Vincent's, which continues our partnership activities with world class institutes across the globe. While similar studies have been conducted in other countries with promising results, we believe that local medical community participation in these studies will accelerate acceptance of the potential of cannabinoid-based medicines."*

**Tim Slate**

**Company Secretary**

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

Zelda Therapeutics Ltd 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 is undertaking;

- **Human clinical trials** focused on insomnia, autism and opioid reduction with activities in Australia and the USA.
- **Pre-clinical research** 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.

Zelda has partnered with HAPA Medical BV to manufacture GMP-grade cannabis formulations for clinical trials and to distribute Zelda products in Germany, one of the world's largest cannabis markets. Zelda is also collaborating with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to test the efficacy of cannabis-based formulations against human cancers in order to generate data packs acceptable to regulators and the pharmaceutical industry. Similar programmes are underway with the Australian Telethon Kids Institute, targeting paediatric brain cancer, and Curtin University, targeting pancreatic cancer and cognitive decline.

### **About St Vincent's Hospital Melbourne (<https://www.svhm.org.au/>)**

St Vincent's Hospital Melbourne is a recognised leader in the area of Addiction Medicine providing clinical services and contributing to research, education and training, and advocacy around alcohol and drugs. St Vincent's Health Australia is a tertiary public healthcare group providing a range of services, including acute medical and surgical services, emergency and critical care, aged care, diagnostics, rehabilitation, allied health, mental health, palliative care and residential care. The hospital works with a vast network of collaborative partners to deliver high quality treatment, teaching, education and research. St Vincent's has more than 5,000 staff and 880 beds in daily use across its services. St Vincent's Hospital Melbourne is at the forefront of innovative research and a premier site for medical research and clinical trials in Australia.

<sup>1</sup> *National Drug & Alcohol Research Centre, UNSW Sydney, "Changing the Face of opioid Dependency Australia, 2015:* <https://ndarc.med.unsw.edu.au/news/changing-face-opioid-dependence-australia>

<sup>2</sup> *Drug and Alcohol Research Connections," More Australians dying of accidental overdose of pharmaceutical opioids", 2017:* <http://connections.edu.au/news/more-australians-dying-accidental-overdose-pharmaceutical-opioids>