



ASX Release

31 October 2019

- **Partnership with Emerald Clinics**
- **Insomnia, opioid reduction and autism clinical trials update**
- **Proposed merger with US-based Ilera Healthcare**

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

OPERATIONAL UPDATE

Partnership with Emerald Clinics

In July 2019, Zelda announced it had entered into a strategic partnership with Australia-based healthcare technology and services company Emerald Clinics Ltd (**Emerald**), which owns and operates an Australian network of dedicated medicinal cannabis clinics.

Under the terms of the agreement Emerald will provide access to de-identified real-world longitudinal data collected from patients prescribed cannabis medicines for treatment of pain and/or insomnia. Data will include details regarding cannabis formulations and dosages prescribed to patients, their responses to treatment and the impact on usage of non-cannabis medicines such as opioids.

This information will inform Zelda's ongoing clinical trial strategy, which is focussed on developing new cannabis-based treatments to reduce opioid usage in patients with chronic pain as well as patients with insomnia and autism.

The agreement also includes an option for Zelda to access real-world data collected from patients prescribed Zelda-branded cannabis products, which the company is aiming to bring to market in 2020. A further option is for Zelda to engage Emerald to assist with the design and patient recruitment for future clinical trials.

Insomnia Clinical Trial (Perth, Australia)

Recruitment for the insomnia trial continued to progress during the quarter, the trial was initiated in September 2018 and is expecting to be fully recruited by early November 2019.

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 remains on-track for all participants to have completed the study by late-Q4 2019.

Opioid Reduction Study (Melbourne, Australia)

In early July, Zelda commenced recruiting for a Phase I pharmacokinetic trial to 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 is expecting to complete patient recruitment and to report by Q4 2019.

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 outcome from this trial will inform the design of a subsequent Phase II double-blinded, randomised, placebo-controlled study which is expected to commence in 2020.

Autism Observational Study (Philadelphia, USA)

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

In August 2019, Zelda released results from a preliminary statistical analysis of the data. Results showed that treatments with a range of cannabis medicines were associated with improvements in several key behavioural markers that are prominent in children diagnosed with autism. This highlights the potential for medicinal cannabis to improve outcomes for autistic children.

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 September 2019, a total of 116 patients had been enrolled. A final target of 150 patients is expected to be achieved by early 2020.

To our knowledge, this was also the first study to report differences in autism severity based on responses to medicinal cannabis treatments. The ability to stratify patients according to various

clinical criteria could help us better predict whether patients will be more likely to benefit from medicinal cannabis treatments.

Outcomes from the Observation Study are helping inform the design a Phase I study to assess the use of cannabis to treat Autism, which Zelda is aiming to announce in Q4, 2019.

Zelda Sponsored Symposium on Cannabis Medicines and Autism.

Results from the CHOP Observational Study were subsequently presented at the recent Zelda-sponsored symposium on Medical Cannabis and Autism, which was held in Philadelphia in early October. The event included presentations from key global opinion leaders on the use of cannabis to treat autism, including Dr Dustin Sulak and Dr Bonni Goldstein. The event also brought together leading physicians, pharmacists, and researchers as well as parents using medicinal cannabis to treat their child's ASD symptoms.

The positive feedback and media generated from the Symposium has raised the profile and reputation of Zelda in the US as a science-driven medicinal cannabis company.

Corporate

Subsequent to the end of the quarter, on 9 October, Zelda announced plans to merge with Ilera Therapeutics (**Ilera**), a privately held medicinal cannabis and cannabinoid science company based in the United States, which will be renamed Zelira Therapeutics Limited (**Zelira**).

The merger will create a leading global therapeutic medicinal cannabis company with access to the world's largest and fastest growing cannabis markets. The merger will bring together a world-class portfolio of revenue generating medicines and products undergoing clinical development that are expected to enter the market from 2020.

Subject to approval from Zelda shareholders, and all conditions of sale being met, Zelda is proposing to acquire 100% of Ilera Therapeutics through an all-scrip transaction. The consideration to be paid to Ilera Therapeutics Shareholders for the acquisition of their respective Shares at Settlement is:

- a) 113,601,290 fully paid ordinary shares in the Company (Consideration Shares); and
 - b) 362,620,322 Class A Performance Rights; and
 - c) 362,620,322 Class B Performance Rights,
- to be issued pro rata between the Ilera Therapeutics shareholders (together the Consideration).

Furthermore, it is proposed that Zelira Therapeutics board will be made up by Osagie Imasogie (Chairman), Lisa Gray and Dr Oludare Odumosu from Ilera and with Harry Karelis (Deputy Chairman), Jason Peterson and Dr Richard Hopkins remaining from Zelda. Current Zelda Directors, Mara Gordon and Dr Stewart Washer will step-down from the Board once the merger has been approved. Mara Gordon will join Zelira's Advisory Board.

Shareholder approval for the transaction will be sought at the companies upcoming Annual General Meeting, which is scheduled for 28th of November at 10AM in the offices of Blackwell Legal (Level 26, 140 St Georges Tce, Perth, WA).

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 \$1.8 million. Subsequent to quarter end, Zelda lodged its income tax return for the 2018/19 financial year which included a refund relating to the research and development incentive tax rebate amounting to approximately \$982,000 which is expected to be received in early November.

Tim Slate
Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics Ltd is an Australian-based bio-pharmaceutical company developing proprietary cannabinoid formulations to treat 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.
- **Preclinical research** to examine the effect of cannabinoids in breast, brain and pancreatic cancer and also 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 strategic partnerships with HAPA Medical BV, to access their EU-GMP grade manufacturing capabilities and their German distribution networks and Ilera Healthcare, a vertically integrated cannabis company with operations in Philadelphia, and Aunt Zelda's, with operations based in California. Together these partnerships provide access to over four million registered medicinal cannabis patients globally for clinically validated Zelda products.

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About Ilera Therapeutics LLC

Ilera Therapeutics LLC is a US-based company established by a team of experienced executives in the global bio-pharmaceutical sector. The Company is based in Pennsylvania and engaged in the development and formulation of proprietary, branded cannabis products and cannabinoids science focused on targeted medical and other indications.

The Team developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has lab capabilities to develop formulations in Pennsylvania and Louisiana with ability to conduct clinical trials and is establishing a national footprint across the US for the licensing of its products. The company also has a partnership with Ethicann for the development of a proprietary product, CAN-001, which is being developed for the treatment of chemotherapy-induced nausea and vomiting (CINV), which occurs in approximately 80% of the new 23.6 million cases of cancer annually worldwide. The global market for treating CINV with THC is estimated by Ethicann at USD \$2.66 billion.

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