



ASX Release

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**ZELDA THERAPEUTICS LIMITED**  
ACN 103 782 378

Level 26  
140 St Georges Terrace,  
Perth Western Australia 6000  
Tel: +61 8 6558 0886  
Fax: +61 8 6316 3337  
E: enquiries@zeldatherapeutics.com  
W: www.zeldatherapeutics.com

#### **Contacts**

Dr Richard Hopkins  
Managing Director  
+61 405 656 868  
rhopkins@zeldatherapeutics.com

Monsoon Communications  
Rudi Michelson  
+61 3 9620 3333  
rudym@monsoon.com

#### **Directors**

Dr Richard Hopkins  
Mr Harry Karelis  
Dr Stewart Washer  
Ms Mara Gordon  
Mr Jason Peterson

#### **Tickers:**

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

#### **Ordinary Shares:**

755,341,934

#### **Options:**

85,700,000

## MARCH 2019 QUARTERLY REPORT

- **Insomnia, opioid reduction and autism clinical trials update**
- **Conditional ethics approval for opioid reduction trial**
- **Zelda partners Ilera HealthCare to access US medicinal cannabis market**
- **Dr Ethan Russo appointed to Medical Advisory Team**
- **Prognostic cancer patent granted**

The Board of **Zelda Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF)** is pleased to provide this operational update with its Appendix 4C for the three-months to 31 March 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 Sep., 2018. A second batch of GMP-grade cannabis formulation has since been ordered to complete the trial. The ethics committee overseeing the trial has requested a short delay to ensure the new product meets the required specifications for stability. As confirmation of product stability will be needed for subsequent regulatory approval, we have committed to this step. The trial is expected to recommence by mid-May.

The trial remains on-track to complete patient dosing by the end of Q3 2019. Preliminary results will be reported around this time with final results in 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. 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 study of its kind globally to test the efficacy of a full-spectrum cannabis extract in such patients.

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.

Zelda is pleased to report the protocol for the pharmacokinetic study was recently granted conditional ethics approval. Pending final approval, the trial is on-track to commence in Q2 2019, with preliminary results expected by late Q3 2019 and final results in 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 clinical pharmacological data, making it the first significant study of its kind.

As of the end of March 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, we expect recruitment rates will continue to improve.

Preliminary results are expected to be reported by mid-2019.

### **SUDA Pharmaceuticals Collaboration**

In December 2018 Zelda announced a feasibility and option agreement with oro-mucosal drug delivery company SUDA Pharmaceuticals Ltd (ASX: SUD). SUDA will apply its proprietary OroMist® oro-mucosal spray technology to deliver Zelda's pharmaceutical-grade cannabis formulations.

The agreement also includes a 24-month option that provides Zelda with the exclusive right to extend the agreement and to enter into an exclusive global development and licensing agreement for oral spray formulations containing medicinal cannabis developed by SUDA.

Over the past three months SUDA has obtained all the relevant licenses to import, store and develop cannabis formulations under GMP conditions. Together with Zelda, SUDA has also undertaken a review of the intellectual property landscape to help inform our development strategy. High concentration cannabis product has been ordered from HAPA Medical BV, our strategic supplier of GMP-grade cannabinoid oils, and formulation trials are expected to commence in coming months.

### **Zelda Partners with Ilera HealthCare to Access US Medicinal Cannabis Market**

Zelda was delighted to announce a binding Heads of Agreement (HoA) with US-based medicinal cannabis company Ilera Healthcare, LLC to explore a broad range of commercialisation opportunities.

Ilera is a vertically integrated medicinal cannabis company with operations based in Pennsylvania and Louisiana. Ilera was founded as a science-driven company by executives with extensive experience in the life science capital markets, corporate management and pharmaceutical industries. The chairman Mr Osagie Imasogie has held senior positions in companies such as GlaxoSmithKline, Endo Pharmaceuticals and DuPont Merck, while Vice Chair Ms Lisa Gray has worked with SmithKline Beecham Pharmaceuticals and GlaxoSmithKline Pharmaceuticals. The founding CEO Gregory Rochlin is a successful entrepreneur and has also served on the boards of medical centres and hospitals.

Under the terms of the binding HoA, Zelda and Ilera will explore a range of collaborative and commercialisation opportunities including:

- co-development of potential full spectrum, uniquely formulated products supported by pharmacokinetic and clinical studies;

- licensing of clinically validated products; and
- data-sharing and generation of joint intellectual property.

As a vertically integrated company, Ilera's strength in cultivation, extraction/formulation and distribution are complemented by Zelda's expertise in clinical validation, product differentiation and downstream value-adding. Given the current barriers to undertaking clinical trials using medicinal cannabis at the Federal level in the US, Zelda can help fast-track clinical validation of Ilera products in jurisdictions such as Australia while Zelda potentially gains access to a significant North American market for its products.

This partnership reinforces the global breadth of Zelda's relationships and reaffirms its focus on commercialising its clinically validated formulations. When considered alongside the recent manufacturing and distribution agreement with HAPA Medical in Germany, these partnerships provide access to over 110,000 registered medicinal cannabis patients globally, which is approximately 30 times larger than the current Australian market.

### **Engagement of ICCI/Dr Ethan Russo**

In February 2019 Zelda announced it had engaged Dr Ethan Russo, a leading global authority on medicinal cannabis, and the International Cannabis and Cannabinoids Institute (ICCI) to advise on its clinical programs.

Dr Russo is a US-trained, board-certified paediatric and adult neurologist, psychopharmacology researcher, former Senior Medical Advisor to GW Pharmaceuticals, and Medical Director of PHYTECS. He served as study physician to GW Pharmaceuticals for numerous Phase I-III clinical trials of Sativex<sup>®</sup>, and early stage investigations of Epidiolex<sup>®</sup>.

Zelda is working closely with Dr Russo and the ICCI to accelerate its clinical programs and also to develop strategies for future clinical trials and formulations.

### **Zelda Awarded Australian Patent for Novel Cancer Prognostic Marker**

In March 2019 Zelda was granted an Australian patent for a novel method to predict disease-free survival in breast cancer patients.

The patent (AU2017346940A) entitled "*Prognostic method and kits useful in said method*" details a method for detecting levels of expression of a novel receptor complex containing HER2 and CB2. HER2 is a well-recognised marker of aggressive breast cancer while CB2 is a key receptor in the endocannabinoid system. Together they form a novel receptor complex that represents a prognostic marker for HER2 positive breast cancer.

This work was recently published in the prestigious peer-reviewed *Proceedings of the National Academy of Sciences* and supports Zelda's strategy of building a world-class intellectual property portfolio for the development of cannabis-based products. Further news is expected as this patent family progresses through the international examination phase.

### **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 later in 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.

On 19 February 2019 Zelda issued 25,000,000 unlisted options to key executives with various exercise prices from \$0.10 to \$0.30 expiring on 19 February 2022 and subject to vesting conditions.

The Company closed the quarter with a cash position of \$3.24 million. Subsequent to the end of the quarter, Zelda Therapeutics Ltd lodged its income tax return for the 2017/18 financial year and a refund relating to the research and development incentive tax rebate amounting to approximately \$769,000 is expected in the coming weeks.

For the next quarter, the Company is forecasting expenditure of approximately \$0.85m. This reflects prudent management of its costs notwithstanding the company's expanding clinical trial activities and intellectual property portfolio. The Company remains fully funded for all of its upcoming clinical milestones.

**Tim Slate**

### **Company Secretary**

#### **About Zelda Therapeutics ([www.zeldatherapeutics.com](http://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 programme** focused on insomnia, autism and opioid reduction with activities in Australia and the USA.
- A **pre-clinical research programme** 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 formed strategic partnerships with European medicinal cannabis group 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 Louisiana. Together these partnerships provide access to over 110,000 registered medicinal cannabis patients globally for clinically validated Zelda products.