ASX Release

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

Ordinary Shares:
755,341,934

Options:
60,700,000

December 2018 Quarterly Report and Board Transition

- **Opioid Reduction Clinical Trial with St Vincent's Hospital**
- **Insomnia trial update**
- **Observational Autism trial update**
- **Partnership with SUDA Pharmaceuticals to develop novel oral mucosal spray to deliver cannabis medicines**
- **Harry Karelis transitions to Non-Executive Chairman role**

The Board of **Zelda Therapeutics Ltd** (**ASX: ZLD**, **Zelda** or the **Company**) is pleased to provide an operational update to accompany its Appendix 4C for the three-month period to 31 December 2018.

OPERATIONAL PROGRESS

Opioid Reduction Trial with St Vincent's Hospital

Zelda was pleased to announce a new 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.

This joint clinical trial program is aimed at assisting patients who have become dependent on opioids for chronic pain management. 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 remains on-track for submission to the human ethics committee during Q1 2019. The trial is expected to commence immediately following approval from the committee.

Prescription opioids are used to treat chronic pain and these drugs can have serious side effects including physical dependence, which is an acknowledged growing global crisis. Research shows a growing number of Australians receiving treatment for dependence on painkillers. 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[1].

Insomnia Trial

In September 2018, Zelda was pleased to announce the first patient received medication in its pioneering insomnia trial. A number of patients have now completed the programme with no reports of significant adverse events.

The clinical trial is targeting patients with characteristic symptoms of chronic insomnia, which include difficulty falling and staying asleep on a long-term basis. A randomised, placebo controlled, cross over study design will be used to treat 24 patients with Zelda's medicinal cannabis formulation and a placebo formulation delivered sublingually. The medicine to be used in the trial has been manufactured to pharmaceutical grade GMP standards by a European-based speciality manufacturer.

It is anticipated that preliminary results from this clinical trial will be available by mid-2019. Should the trial be successful, it is the intention to rapidly commercialise this formulation as a clinically validated cannabis medication for treatment of insomnia.

Autism Observational Trial

In September 2018, Zelda announced that recruitment had commenced for its observational autism study, which is being conducted in collaboration with the Children's Hospital of Philadelphia, a leading children's hospitals in the US. 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 December 2018, a total of 32 patients had been enrolled with a target sample size of >100 patients. A number of eligible patients had also agreed to participate in a pharmacological study using a novel micro-sampling technique.

Recruitment rates are accelerating with preliminary results expected in the first half of 2019.

SUDA Pharmaceuticals Collaboration

In December 2018, Zelda announced it had entered into a feasibility and option agreement with oro-mucosal drug delivery company SUDA Pharmaceuticals Ltd (ASX: SUD) ("SUDA").

Under the 12-month workplan, SUDA will apply its proprietary OroMist® oro-mucosal spray technology to deliver Zelda's pharmaceutical-grade cannabis formulations.

The 24-month option 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.

Transition of Chair to Non-executive Role

Mr Harry Karelis will transition to a Non-Executive Chairman role effective from 31 January 2019.

Mr Karelis commented "*This move marks a key step in Zelda's strategic plan to position the company for success as it enters into the clinical trial and commercialisation phases of its development. With the recent appointment of Dr Richard Hopkins as Managing Director, along with key additions to our Medical Advisory Board and operational team, the time is right for me to step-back from the executive role, as we intended.*

In my ongoing role as Chair, I will continue to work with my colleagues on the Zelda Board and the executive team to ensure we deliver on our key milestones. With a number of clinical trials underway and our path to commercialisation well advanced, this promises to be a transformational year for the company."

New Website

The company has commenced a project to upgrade its website to a more modern platform and to better reflect recent progress with the company's corporate and clinical development strategies. The company is expecting to launch the new website on 6 February 2019.

CORPORATE

Zelda has continued to progress its core clinical and pre-clinical activities and has also establish the foundations to rapidly commercialise its medicinal cannabis products in the event the clinical programmes are successful.

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

As Zelda continues to grow and expand its activities, it remains focused on generating shareholder value through identifying and securing new intellectual property and pursuing a rapid commercialisation strategy for its medicinal cannabis products.

The Company closed the quarter with a cash position of $4.41 million. For the next quarter, the Company is forecasting expenditure of approximately $1.4m, including approximately $980k on R&D. The increase in R&D expenditure reflects an expansion to the company's clinical trial activities, as per recent announcements, and additional costs associated with management of its growing intellectual property portfolio.

Tim Slate

Company Secretary

About Zelda Therapeutics (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:

- 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. It has partnered with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct 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 and cognitive decline.

The Company has also formed a strategic partnership with European medicinal cannabis group HAPA Medical BV, to access HAPA'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.