ASX Release

Zelira March Quarter Operational Update

30 April 2020

- **Insomnia trial successfully meets clinical endpoints**
- **Opioid sparing trial completes recruitment and dosing**
- **Autism observational study completes recruitment**
- **Collaboration progressing with The Parkinson's Foundation**
- **Capital Raise & Revenues**

Zelira Therapeutics Ltd (**ASX: ZLD, OTCQB: ZLDAF**) is pleased to provide this operational update with its Appendix 4C for the three-months to 31 March 2020.

OPERATIONAL UPDATE

Insomnia Clinical Trial (Perth, Australia).

The Zelira insomnia study represents the most rigorous clinical trial ever undertaken to evaluate the safety and efficacy of a cannabinoid medicine 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 was used to treat 23 patients with Zelira's proprietary insomnia formulation and a placebo formulation delivered sublingually.

During the quarter, Zelira was pleased to release interim results confirming the trial had met its primary endpoints for efficacy and safety.

ZLT-101 therapy was well tolerated, with no serious adverse events reported. All adverse events were classified as mild and had either resolved (97.5%) overnight or soon after waking each day or were resolving at the end of the trial.

In terms of efficacy, results confirmed ZLT-101 therapy achieved the primary endpoint of a statistically significant improvement in Insomnia Severity Index scores, a gold-standard measure of insomnia severity, in patients diagnosed with chronic insomnia compared to placebo.

During the quarter, the company also initiated a complementary pharmacokinetic (PK) sub-study in the same patient cohort. The data generated from this study will provide important insights into the absorption of ZTL-101 following oral delivery. Following ethics approval, the study was initiated in

February and completed by March 2020. Data from the PK sub-study and the final report for ZTL-101 will form the most comprehensive clinical data-pack for the use of medicinal cannabis to treat chronic insomnia.

Subsequent to the end of quarter, Zelira released the final clinical report that confirmed the trial met all its primary and secondary endpoints for safety and efficacy.

Opioid Reduction Study (Melbourne, Australia)

In collaboration with St Vincent's Hospital in Melbourne, Zelira is undertaking a study to assess the safety and effectiveness of medicinal cannabis to reduce opioid dependence. 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 early July 2019, Zelira 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 trail.

During the quarter, Emerald Clinics were engaged as a second site. The trial reached full enrolment with all patients subsequently completing dosing by early April 2020. No serious adverse events have been reported to date. The company is on-track to provide a final report in Q2 2020.

Autism Observational Study (Philadelphia, PA, USA)

In July 2018, Zelira announced that recruitment had commenced for an observational autism study in collaboration with Children's Hospital of Philadelphia (CHOP). This trial aims to better understand the efficacy of medicinal cannabis treatment in patients diagnosed with autism.

The study closed recruitment in January 2020 having enrolled 119 participants, making it one of the largest observational studies of cannabis usage in children diagnosed with autism. A comprehensive statistical analysis of the data is ongoing and is being used to prepare a number of manuscripts, detailing key efficacy and safety outcomes, including the impact of medicinal cannabis on clinical pharmacological and behavioral data related to autism. Results from the observational trial are expected to be published in peer-reviewed journals over the coming months.

Autism Clinical Trial (Australia)

Information gained following the launch of HOPE^{TM} into Pennsylvania and insights learned from the Observational Trial with CHOP has helped inform the design of a Phase I/2a medicinal cannabis interventional clinical trial for children and adolescents with autism. The double-blinded, randomised-controlled, crossover trial was submitted to an Australian National Health and Medical Research Council (NH&MRC) certified Human Research Ethics Committee for review during the quarter.

Collaboration with the US Parkinson's Foundation

In January 2020 Zelira announced it had entered into a collaboration with the Parkinson's Foundation, the US's leading community for people living with Parkinson's disease (PD), to gather insights from people with PD about their understanding of and use of medical cannabis and hemp-derived therapies.

As part of this collaboration, Zelira and Parkinson's Foundation:

- Conducted a survey among people with Parkinson's to understand why and how they are using medical cannabis and hemp-derived CBD products currently;
- Reviewed results from over 1000 respondents with expected announcement in the coming months;
- Consult on the results as they relate to a future clinical trial on the safety and efficacy of medical cannabis use by people with Parkinson's disease.

Separately, Zelira will use survey insights in the future development of clinically validated medical cannabis for people with Parkinson's disease. Zelira is aiming to launch its first product for Parkinson's disease in the second half of 2020.

Corporate

Capital Raise and Maiden Revenues

In February 2020 Zelira announced it has successfully completed a placement to raise $4,642,759 (before costs). The Placement increased the Company's cash position to approximately $5,788,500 million before costs. The company also received its maiden revenues from Advanced Biomedics for its first licensing deal for HOPE™ in the United States (US), which was announced in December 2019. Advanced Biomedics has commenced plans to launch HOPE later in 2020.

The funds will be used to accelerate Zelira's plans to launch multiple products into global markets in the second half of 2020 and to advance its clinical programs including its Insomnia and Opioid Sparing trials. Finally, Zelira is progressing discussions with third parties aimed at licensing its products in the US and to secure agreements to distribute clinically validated Zelira products in emerging global medicinal cannabis markets including Australia, Germany and the United Kingdom.

The Company closed the quarter with a cash position of $4.02 million.

Tim Slate

Company Secretary

This announcement has been authorised by the Board.

About Zelira Therapeutics (www.zeliratx.com)

Zelira Therapeutics Ltd is a leading global therapeutic medicinal cannabis company with access to the world's largest and fastest growing cannabis markets. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to enter global markets from 2020. The company is focused on developing branded cannabis products for the treatment of a variety of medical conditions.

The Company is undertaking product development programs targeting specific conditions (e.g. HOPE™) and human clinical trial programs focused on insomnia, autism and opioid reduction with activities in Australia and the USA.

The Company conducts this work in partnership with world-leading researchers and organizations 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.

The Company has developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has laboratory 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.

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