ASX Release

31 January 2020

- **Transformational quarter with shareholders overwhelmingly approving merger with US-based Ilera Therapeutics**
- **Merged company renamed Zelira Therapeutics**
- **Global launch strategy for HOPE® range of products, developed to address autism symptoms, and first licensing deal in the USA**
- **Distribution deal with Health House for Zelira-branded products in Australasia and the UK**
- **Zelira to supply products for NSW Government CARE clinical trial**
- **Updates for ongoing clinical trials for Insomnia, Opioid Sparing and Autism**

Zelira Therapeutics Ltd (**ASX: ZLD, OTCQB: ZLDAF**) is pleased to provide this operational update with its Appendix 4C for the three-months to 31 Dec 2019.

OPERATIONAL UPDATE

Successful merger with US-based Ilera Healthcare

In Oct 2019, Zelda announced its intention to merge with Ilera Healthcare, a privately held medicinal cannabis company based in the United States through an all-scrip transaction. At the Company's Annual General Meeting, held in November 2019, shareholders voted overwhelmingly to support the transaction and to rename the company Zelira Therapeutics.

Zelira Company Overview:

The successful completion of the merger represents a transformational opportunity for shareholders of both companies.

The merger has created a leading medicinal cannabis biotechnology company with a global footprint, an extensive development pipeline coupled with revenue generating products and access to global markets.

Zelira's strategic focus on the 'last mile to the patient' maximises investor returns while minimising capital requirements as it pivots towards revenues and, longer term, profitability.

Key Investment Highlights:

- *Proprietary-Branded Product Range:* Zelira has a portfolio of products, including HOPE® which has already launched in the US, and a pipeline of clinical candidates ready to launch globally starting first-half 2020
- *Access to Global Markets:* With operations in Australia and the US, Zelira has unique access to the world's largest (US), and fastest growing cannabis markets (Australia, Germany) and emerging sizable markets such as the United Kingdom.
- *Focus on Revenues:* Zelira is forecasting revenues in global markets from the first half of 2020. First US-licensing deal with upfronts and double-digit royalty already announced.
- *First Mover Advantage:* Zelira has an early mover advantage in development of clinically validated cannabis-derived medicines. Australia's regulatory framework enables Zelira to undertake clinical trials, which are currently illegal at the federal level in the US, providing a key point of differentiation amongst global cannabis companies.
- *Track Record of Generating Significant Investor Returns:* The Zelira Board offer unprecedented transactional and commercial experience across the entire cannabis market. The US-based members recently sold a vertically integrated cannabis business founded in 2017 in a transaction worth up to US$225m, which is recognised as one of the largest deals to be completed in the US in 2019.

Global 'Launch, Learn & Develop Strategy' for the HOPE® Range of Products.

HOPE® is a family of revenue generating medicinal cannabis formulations developed by Ilera Therapeutics and now owned by Zelira Therapeutics. HOPE® consists of two proprietary medicinal cannabis formulations developed as pharmaceutical-grade products to address symptoms of Autism Spectrum Disorder.

The HOPE® (HOPE® 1 & 2) products were launched by Ilera Healthcare in Pennsylvania in May 2019 with the support of *HOPE Grows for Autism*, a leading autism advocacy group based in Pennsylvania. Since launch, HOPE® has established itself as the top selling formulated medicinal cannabis product in Pennsylvania. Ilera Healthcare has been granted an exclusive royalty-free license to sell HOPE® in Pennsylvania while Zelira Therapeutics has retained global rights for HOPE®in all other markets.

Post-merger, Zelira has commenced the process of launching HOPE® into global markets, with the aim of generating revenues in the first half of 2020.

In December 2019, Zelira announced its maiden post-merger licensing transaction and inaugural revenues in the United States when it entered into an agreement with Advanced Biomedics to license HOPE® into Louisiana, a state with approximately 5 million residents. The agreement includes an upfront payment, that was paid in Q1 2020, and ongoing royalties on sales, which are expected to commence from mid-2020. Zelira expects to announce multiple licensing deals in 2020 as it continues to roll-out HOPE® in other US-states.

In ex-US markets, Zelira will leverage its existing network of suppliers and distributers to launch HOPE® by mid-2020, commencing with Australia. In November 2019, Zelira announced it had entered a distribution

agreement with Health-House International Ltd to distribute Zelira-branded products, including HOPE®, in Australasia and the United Kingdom. Health House is one of the largest independent distributors of medicinal cannabis products in Australia and was the first group licensed to import medicinal cannabis products into Australia. It has also established infrastructure within the United Kingdom to distribute highly regulated products such as medicinal cannabis.

Zelira has already established a strategic partnership with German-based HAPA pharm BV to supply pharmaceutical-grade medicinal cannabis formulations for its clinical trials.

Zelira's 'Launch, Learn and Develop' Strategy to Accelerate HOPE® Clinical Studies

Zelira's global launch strategy for HOPE® complements the company's long-term commitment to the development of medicinal cannabis medicines to improve treatment options for children with autism.

In addition to HOPE®, Zelira has undertaken pilot clinical studies in Chile to assess the efficacy of medicinal cannabis formulations in children diagnosed with autism. Zelira is currently funding one of the world's largest observational studies to assess the real-world use and impact of medicinal cannabis in children with Autism Spectrum Disorder. Real-world data collected from these clinical studies and from patients using HOPE® is being used to guide the design of an interventional trial aimed at assessing the efficacy of different cannabis formulations to treat autism.

This outcome highlights the power of Zelira's 'Launch, Learn and Develop' model to simultaneously generate revenues and data that informs the design of clinically validated products to best meet patient needs.

Zelira Therapeutics cannabis formulations to be supplied to the CARE NSW clinical trial for symptom control in cancer patients

Zelira was pleased to announce it has entered into an agreement with the National Health and Medical Research Council (NHMRC)-funded Australian Centre for Clinical Cannabinoid Research Excellence (ACRE), based at the University of Newcastle, to commercially supply a cannabis oil formulation, where prescribed, for participants in the Cannabinoids for Symptom Control in Advanced Cancer, An Open Label Prospective Clinical Trial in NSW (CARE NSW).

The CARE NSW Clinical Trial is seeking to enrol up to 600 advanced cancer patients who will be prescribed a product selected from a range of cannabis medicines for symptom management. Zelira is one of several suppliers selected to supply investigation product for the trial under a commercial contract.

Clinical Trial Updates

Insomnia Clinical Trial (Perth, Australia).

An estimated 70 million Americans have insomnia where the market for prescription and over-the-counter medications used to treat the condition generates over US$2 billion in annual revenue. Zelira is leading the development of clinically validated full spectrum cannabis medicines to access global markets for insomnia medications.

The Zelira insomnia trial was designed to evaluate 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 was used to treat 24 patients with Zelira'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.

During the quarter, Zelira was pleased to advise the trial was fully enrolled and the last patient had completed dosing by December 2019. No serious adverse events were reported. Zelira is on-track to provide interim results for the trial by late-February 2020.

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.

The Phase I trial has commenced recruitment with a number of patients having started and completed dosing. No serious adverse events have been reported to date. The trial is on-track to complete recruitment and patient dosing by Q12020. The company will provide an interim update in February.

Corporate

At the Company's Annual General Meeting, held in November 2019, shareholders voted overwhelmingly to support the transaction and to rename the company Zelira Therapeutics. The consideration paid to Ilera Therapeutics Shareholders for the acquisition of their respective Shares at Settlement was:

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,

issued pro rata between the Ilera Therapeutics shareholders.

Shareholders also approved the appointment of Osagie Imasogie (Chairman), Lisa Gray and Dr Oludare Odumosu from Ilera to the Zelira Board joining Harry Karelis (Deputy Chairman), Jason Peterson and Dr

Richard Hopkins. Directors Mara Gordon and Dr Stewart Washer stepped down from the Zelira Board following the merger.

Looking forward, Zelira remains on-track to report on its clinical trials for insomnia, autism and opioid reduction in the first quarter of 2020 and also to launch multiple products into global markets. See below for a summary of Zelira's upcoming milestones for the next quarter.

Next quarter operational activities/milestones:

- Insomnia phase II trial results (Feb 2020).
- Report on Opioid Sparing Trial and observational study for Autism
- Maiden revenues from US licensing deals for HOPE® (upfront fees plus royalties).
- Preparations for global launch of HOPE® and Insomnia (contingent on results) in Q2
- Submit Ethics application for Autism clinical trial

The Company closed the quarter with a cash position of $1.2 million. In November 2019, Zelira announced it had received a $982,000 cash refund under the Federal Government's Research and Development Tax Incentive Scheme.

Tim Slate

Company Secretary

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:

- **Human clinical trial programs** 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.

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; and St. Vincent's Hospital in Melbourne, Australia.

Zelira has also formed a strategic partnership with European medicinal cannabis group HAPA Pharm BV, to access HAPA Pharm's EU-GMP grade manufacturing capabilities and accessing its German distribution network providing a credible and rapid path to commercialization for successful clinically validated formulations.

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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