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ASX Release

September Quarterly Update

30 October 2020

- **HOPE™ 1 & 2 launched in Louisiana, USA**
- **Zenivol™ manufactured and available to Australian patients. Launch supported by Real-world Data Agreement with Emyria**
- **Oral Health Care Subsidiary formed to develop hemp-derived oral care cannabinoid products**
- **Licensing agreement with USA-based Cardiovascular Solutions of Central Mississippi (CVSCM) to develop and commercialise products targeting Peripheral Arterial Disease (PAD)**
- **Primary and secondary endpoints for safety and efficacy achieved in Phase 1 Dose Escalation Study in Chronic Pain patients**
- **Oversubscribed Capital Raise and Strategic Placement to Thorney Investment Group**

Zelira Therapeutics Ltd (**ASX:ZLD, OTCQB:ZLDAF**), a global leader in the development of clinically validated cannabinoid-derived medicines, is pleased to provide this operational update along with its Appendix 4C for the three months to 30 October 2020.

The last quarter saw Zelira achieve a number of key commercial and clinical milestones that marked its successful transition to the 'Launch, Learn and Develop' model for rapid commercialisation. Milestones included the successful launch of HOPE™ in Louisiana, Zenivol™ in Australia, the formation of an Oral-Healthcare subsidiary and a successful outcome to a Phase 1 clinical trial in chronic pain patients. Zelira also continued to leverage its strong intellectual property portfolio by entering into a new licensing agreement with Cardiovascular Solutions of Central Mississippi (**CVSCM**), which provided access to upfront revenues and downstream royalties. This was the third licensing agreement Zelira has entered into in the United States of America (USA).

With multiple products now entering global markets Zelira is on-track to complete its transition to a revenue generating company.

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Update on Global Launch of Zenivol™ and HOPE™ products

HOPE™ launched in Louisiana

In August 2020, Zelira was pleased to launch HOPE™ 1 & 2 in the state of Louisiana, USA. The launch was undertaken by Zelira's licensee Advanced Biomedics. Under the terms of the licensing agreement, as announced in December 2019, Zelira received an up-front payment and will receive revenue from ongoing royalties from HOPE™ sales in Louisiana.

HOPE™ was previously launched in Pennsylvania (PA) in May 2019 under Ilera Healthcare, which holds the license for that state. Zelira is aiming to repeat the success of HOPE™ in PA where it has established itself as one of the top selling medicinal cannabis products.

Zenivol™ Launched in Australia as the world's most clinically validated cannabinoid-based treatment for chronic insomnia

Following the successful clinical trial, Zelira announced in September 2020 that Zenivol™, its proprietary cannabinoid medicine, was approved by the Therapeutics Goods Administration (TGA) for prescription to patients in Australia via its Special Access Scheme.

Approximately 10% of the Australian population suffers from chronic insomnia with 1 in 5 of these patients failing all existing medications. This equates to 2% of the Australian population and represents a large addressable market. Zenivol™ will be targeting the unmet need for chronic insomnia patients who fail existing medications and are looking for clinically validated alternatives.

Zenivol™ recently successfully completed a world-first twenty-three patient randomised, double-blind, cross-over designed Phase 2A clinical trial in patients suffering from chronic insomnia. The results confirmed that Zenivol™ is a safe and effective therapy for chronic insomnia.

Zelira Signs Real-World Data Agreement for Insomnia Drug Zenivol™ with Emyria

In September 2020, Zelira entered into an agreement with Emyria Ltd (formerly Emerald Clinics), a leader in the collection and translation of real-world patient data, to collect data from patients treated with Zenivol™ in Emyria's network of specialist medical clinics.

Real-world data collected from patients will complement the existing clinical data-pack for Zenivol™ and be used to inform further clinical development and, evaluation of the path to product registration.

Zelira and Cardiovascular Solutions of Central Mississippi (CVSCM) entered into a binding agreement to develop and commercialise products targeting Peripheral Arterial Disease (PAD)

In July 2020, Zelira entered into a binding product development agreement with USA-based CVSCM to develop products that target symptoms associated with PAD.

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PAD is the leading cause of non-traumatic amputations. For the 30 million Americans who suffer from diabetes, 1 out of 3 over the age of 50 will develop PAD. The products to be developed by Zelira under this agreement will be based on CBD and other cannabinoids derived from hemp which can facilitate a faster path to market. These products will provide novel and proprietary therapeutic options with potentially improved efficacy and better tolerability to target a significant unmet medical need.

Under the Agreement, CVSCM paid to Zelira a six-figure upfront fee and will pay double-digit royalties on the commercialized products that result from the Agreement. CVSCM has exclusive marketing rights to the USA market and Zelira retains rights for all other markets, ex-USA.

Subsidiary Formed to Launch Hemp-Derived Cannabinoid-based Oral-Care products in the USA

In September 2020, Zelira formed an Oral Health subsidiary to commercialise scientifically formulated, hemp-derived cannabinoid-based oral-care products.

Zelira's first oral-care product will be a cannabinoid-containing proprietary toothpaste formulation developed by Sprinjene® CEO and Founder Dr. Sayed Ibrahim. This will be Zelira's first Over-the-Counter (OTC) product line that will complement the Company's existing therapeutic portfolio. Commercialisation activities are expected to begin in Q4 2020 with distribution across retail and other channels across the USA.

Phase 1 Dose Escalation Study in Chronic Pain Patients on Long-Term Opioid Treatment Meets Primary and Secondary Endpoints

In July 2020, Zelira received the final clinical report for its Phase 1 dose escalation trial in chronic pain patients on long-term high-dose opioid treatment. Zelira was pleased to report the trial successfully met its primary and secondary endpoints for safety and efficacy.

The nine patient Phase 1 dose-escalation trial was designed to assess the safety of Zelira's cannabis formulation (ZTL-103) in chronic pain patients already on long-term high-dose opioid treatment. Prescription opioids for treating chronic pain are linked to serious side effects including physical dependence, which is an acknowledged growing global crisis.

In terms of next steps, these trial results are informing the design of the trial we will be undertaking with Levin Growing targeting retired athletes with chronic pain. The data will also accelerate plans to expand Zelira's portfolio of chronic pain products, supported by clinical trial data.

Operational Activities

Zelira is also pleased to confirm that after an exhaustive and competitive selection process, Greg Blake was appointed as the Director of Commercialisation. Greg brings more than 12 years of commercial experience in senior leadership roles across sales, marketing and general management within the pharmaceutical, biotechnology and medical diagnostics arenas in Europe and Australia.

To support its Go-to-Market efforts in Australia, Zelira also engaged a leading specialist healthcare provider offering outsourced sales and marketing solutions.

Capital Raising and Strategic Placement

In August 2020, Zelira successfully completed an oversubscribed AUS$8.75 million placement (before costs) via the issue of circa 175,000,000 fully-paid ordinary shares at an issue price of A$0.05 a share to Australian and USA-based sophisticated and institutional investors (Placement). The Placement was managed by Morgans Corporate Ltd. and received firm bids exceeding twice that of the Placement.

In September 2020, Zelira completed a subsequent placement of A$2 million to the Thorney Investment Group (Thorney Placement) which increased their holding to a substantial investor with a 5.2% stake in the Company.

Under the Thorney Placement the Company issued 37,037,000 new shares at an issue price of A$0.054 per share. The price represented a discount of 11.8% of the 15-day volume weighted average price. Subject to shareholder approval at Zelira's Annual General Meeting in November, the Company will issue Thorney a one-for-one free attaching unquoted option, exercisable at A$0.07 and expiring two years from the date of issue.

Financial Snapshot

The Company's net cashflow used in operations for the quarter was $2.3 million. The Company's operational expenses mainly comprised of research and development ($1.1 million), staff costs ($0.5 million) and administrative and corporate costs ($0.7 million).

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately $246,000 comprising of Director Services of $224,000 and Non-Director Services – corporate advisory services of $16,000 and storage services of $6,000 were paid during the quarter.

The Company closed the quarter with a cash position of $9.6 million

Forward Looking Activities

Zelira's commercialisation plans are focused on the launch of multiple products into global markets in the second half of 2020. These include the Zenivol™ and HOPE™ range of products in the US and Australia, and a new OTC product line that will launch in the US during the next quarter. Zelira is also continuing to progress discussions with third parties aimed at licensing its products, including HOPE™ and Zenivol™, in the USA.

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This announcement has been approved and authorised for release by the board of Zelira Therapeutics Limited.

Richard Hopkins

Managing Director ex-USA

About Zelira Therapeutics (www.zeliratx.com)

Zelira Therapeutics Ltd is a leading global therapeutic medical 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 and human clinical trial programs focused on insomnia, autism and opioid reduction in patients with chronic non-cancer pain.

The Company has developed two proprietary formulations (HOPE™) targeting Autism Spectrum Disorder already launched and generating revenues in Pennsylvania and Louisianna, Zelira has also launched Zenivol in Australia as the worlds leading clinically validated proprietary formulation for treatment of chronic insomnia.

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

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