

Zelira: June Quarterly Update

30 July 2020

- **Australian launch of Zenivol™ (insomnia) and HOPE™ (autism) products on-track for Q3 2020**
- **Phase 2A Chronic Insomnia Clinical Trial successfully achieves endpoints for safety and efficacy**
- **Agreement with Tasmanian Alkaloids to manufacture and supply Zenivol™ and HOPE™ range of products in the Asia-Pacific region**
- **Levin partnership to jointly undertake a clinical trial to develop a chronic pain treatment targeting retired athletes**

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 with its Appendix 4C for the three months to 30 June 2020.

Update on Australian Launch of Insomnia and HOPE products

Zelira is pleased to report it is on-track to launch its Zenivol™ and HOPE™ range of products into the Australian market by the end of Q3 2020. Zelira has entered into the necessary manufacturing and distribution agreements (see below), has finalised branding and packaging details and has engaged one of Australia's leading healthcare agencies who specialise in outsourced sales solutions to support the company's Australian launch of all three products.

This phase marks a major milestone for Zelira as it accelerates its transition from a purely research-based organisation to become a revenue generating company.

Zenivol™ – targeting symptoms associated with Chronic Insomnia: In April 2020, Zelira achieved a world-first when it reported a successful outcome to its Phase 2A trial, which showed that its proprietary cannabinoid-derived drug (Zenivol™) is an effective and safe treatment for people suffering Chronic Insomnia (see below). This outcome paves the way to launch Zenivol™ into global markets as the world's most clinically validated cannabinoid-derived medicine for the treatment of chronic insomnia

HOPE™ – targeting symptoms associated with Autism: The pharmaceutical grade product line HOPE™ was developed to address patient symptoms associated with Autism Spectrum Disorder. The HOPE™ franchise has received support from organisations such as HOPE Grows for Autism, a leading autism advocacy group base in Pennsylvania (USA). HOPE™ was successfully launched in Pennsylvania in May 2019 under Ilera Healthcare which holds the license for that state. Since entering the market, HOPE has shown strong revenue growth establishing itself as a top selling cannabinoid-derived formulation product line in Pennsylvania. In December 2020, Zelira announced HOPE™ has been licensed into Louisiana in a deal which attracted an upfront licensing fee, in addition to royalties on sales.



Insomnia Clinical Trial

In April 2020, Zelira announced the final report from its world-first Phase 2A clinical trial for chronic insomnia. The company was pleased to confirm the study met its primary and secondary endpoints for safety and efficacy.

Treatment with Zenivol™ was shown to lead to significantly improve key insomnia symptoms. Treated patients showed 26% improvement in their Insomnia Severity Index (ISI) scores – a current standard for measuring effectiveness of insomnia treatments – while patients on the highest dose achieved a 36% improvement in symptoms.

Analysis of secondary endpoints showed treated patients slept significantly longer, went to sleep faster and went back to sleep sooner after waking. Patients also reported significant improvement in quality of life measures including feeling rested after sleep, feeling less stressed, less fatigued and improved overall functioning.

Manufacturing agreement with Tasmanian Alkaloids

In May 2020, Zelira announced it had entered into an agreement with Tasmanian Alkaloids (TasAlk) to supply Zenivol™ and HOPE™ in the Asia Pacific (APAC) region. TasAlk is a global leader in the extraction and purification of high-value plant-derived products for the pharmaceutical industry and has added cannabinoid-derived medicinal products and services to its portfolio.

Under the agreement, TasAlk will have exclusive rights to manufacture and supply Zelira's Insomnia and HOPE™ formulations initially in the APAC region for three years. In Australia, all products will be supplied to patients under the Australia Government TGA Special Access Scheme (SAS).

New partnership for a chronic pain study in retired athletes

In June, Zelira announced it had entered into a non-binding Heads of Agreement with Melbourne-based medical cannabis company Levin Growing Pty Ltd (since re-named Levin Health Ltd) to develop a novel cannabinoid-based treatment for sports-related chronic pain experienced by retired professional and amateur athletes.

Levin will fund the trial while Zelira will be responsible for designing and co-ordinating the study. Zelira will hold marketing rights for North and South America with Levin retaining rights to all other world markets. Profits will be shared equally between both companies. The trial is expected to commence in 2021 following negotiation of a definitive agreement and finalisation of clinical trial protocols and necessary ethics approvals.

Corporate Activities

Zelira's commercialisation plans are focused on the launch of up to five different products into global markets in the second half of 2020. These include the Zenivol™ and HOPE™ range of products in Australia, an aged care formulation, which is expected to launch at the end of the year in the US and a new Over the Counter (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 US.

Subsequent to the end of this reporting period, Zelira announced its third licensing deal within seven months, when it disclosed a new partnership to develop products targeting symptoms associated with Peripheral Arterial Disease. Consistent with previous licensing agreement in the US, the deal attracted an upfront licensing fee and royalty on net sales.

Financial Snapshot

The Company's net cashflow used in operations for the quarter was \$2.059 million. The Company's operational expenses mainly comprised of research and development (\$1.1 million), staff costs (\$0.46 million) and administrative and corporate costs (\$0.4 million).

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately \$244,000 comprising of Director Services of \$226,000 and Non-Director Services – corporate advisory services of \$12,000 and storage services of \$6,000 were paid during the quarter.

The Company closed the quarter with a cash position of \$1.67 million

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 (e.g. HOPE™) and human clinical trial programs focused on insomnia, autism and opioid reduction in patients with chronic non-cancer pain.

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.

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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