

December Quarterly Update

29 January 2021

- **HOPE™ Products launched in Australia following TGA approval**
- **Autism Observational Trial for HOPE™ products in partnership with Emyria**
- **New licensing deal in Washington DC expands HOPE™ distribution in USA**
- **CBD Toothpaste launched in USA in partnership with SprinJene®**
- **Zelira receives R&D rebate of \$1.38m**

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 31 December 2020.

The last quarter saw Zelira accelerate its transition to the ‘Launch, Learn and Develop’ model for rapid commercialisation. Key milestones included the successful launches of HOPE™ in Australia (complementing its recent launch of Zenivol™ for Insomnia) and an Observational Trial for HOPE™ targeting patients diagnosed with Autism, which will be one of the largest of its kind ever undertaken. Zelira also continued to expand its commercial activities in the United States of America (USA) with a new licensing deal announced for HOPE™ in Washington DC and the launch of a proprietary CBD toothpaste. These deals take to five the number of licensing agreements Zelira has entered into in the USA in the past 12 months.

With the successful launch of multiple proprietary products in Australia and the USA, Zelira will focus on two key priorities for 2021. First, Zelira will leverage the competitive advantages of its products to generate revenues in global markets. Second, it will continue to progress clinical development of selected programmes to unlock further value and better inform our marketing strategies. Zelira’s international footprint and exposure to international markets, means it is well-positioned to benefit from the rapidly expanding global medicinal cannabis sector.

HOPE™ Autism Products Launched in Australia as TGA Adds to Special Access Scheme

In late October 2020, Zelira announced that its proprietary cannabinoid medicines, HOPE 1™ and HOPE 2™, were available for prescription to patients in Australia through the Therapeutic Goods Administration's (TGA) Special Access Scheme and via Authorised Prescribers. Manufacturing of the first batch of both products was successfully completed by Tasmanian Alkaloids in November.

HOPE™ is part of Zelira's family of revenue generating medicinal cannabis formulations. The products consist of two pharmaceutical-grade proprietary formulations developed as pharmaceutical-grade products targeting Autism Spectrum Disorder (ASD) as a disease indication. The products are now working their ways through the TGA Special Access Scheme, via Authorized Prescribers into the market and patients.

Zelira Therapeutics Expands HOPE™ Distribution to Washington DC, USA

In December 2020 Zelira announced it has entered into a binding licensing agreement with Alternative Solutions LLC, a licensed grower, manufacturer and distributor of medical cannabis products in the District of Columbia (Washington DC) to manufacture and distribute Zelira's HOPE™ products. Under the terms of the licensing agreement, Zelira will receive licensing fees and ongoing royalties from HOPE™ product sales in Washington DC.

Washington DC has reciprocity with 32 other states in the USA with approved medical cannabis programs. This expands access to patients registered in all the 32 states as they can legally purchase medical cannabis products at an approved dispensary in Washington DC.

Zelira Partners with Emyria for Autism Observational Trial for HOPE™ Products

To support the Australian launch of HOPE™, in November 2020 Zelira partnered with Emyria to undertake an Observational Trial in patients diagnosed with Autism Spectrum Disorder (ASD) treated with the HOPE range of products.

The 150 patient Observational Trial will be one of the largest medicinal cannabis studies ever undertaken involving a specific range of products in patients diagnosed with ASD. The study design will facilitate strategic engagement with key stakeholders in the Autism community and streamline patient access via Emyria's national network of specialist medical clinics – Emerald Clinics.

Under the terms of the agreement, Emyria will provide Zelira with real-world longitudinal data collected from ASD patients prescribed a HOPE™ product. Data will include patient's efficacy and safety relating to co-morbidities, concomitant medications, dosing information and patient responses to HOPE™ treatment as measured using standard ASD clinical and behavioural endpoints.

Subsequent to the announcement, ethics approval was obtained which has cleared the path for recruitment to commence from January 2021. We are encouraged by the significant number of expressions of interest that have already been lodged suggestive that recruitment will progress rapidly.

Zelira Partners with SprinJene® to Launch CBD Toothpaste in United States

In December 2020 Zelira, was pleased to announce the launch of its proprietary CBD toothpaste in the USA in partnership with SprinJene®, a leader in natural oral care products.

The CBD toothpaste is a proprietary formulation developed by Zelira and SprinJene's® CEO and Founder Dr Sayed Ibrahim. The product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, including broad-spectrum CBD, that will be created and launched under the Zelira Oral Care subsidiary that has partnered with the SprinJene® brand as announced in September 2020 (www.zeliraoralcare.com).

The Zelira-SprinJene® CBD product will be distributed in the USA through SprinJene's® existing distribution channels including retail stores such as Bed Bath & Beyond, Central Market, Sprouts, Lassen's, Haggens, and VitaCos and e-commerce platforms such as Amazon. Discussions are ongoing to access SprinJene's® global distribution networks in France, Russia, UK, Singapore, Ukraine, China, Morocco, United Arab Emirates, Saudi Arabia and Sudan Shoprite.

Operational Activities

Zelira's commercialisation plans were focused on the launch and commercialisation 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 Over the Counter CBD Toothpaste that launched in the USA.

In relation to sales of our various medicinal cannabis products, these have commenced for both Zenivol™ in Australia and HOPE™ in Louisiana (USA) and Australia. In both cases, the clinical/patient data supporting the products is being marketed to physicians who have not previously or typically prescribed medicinal cannabis due to the lack of clinical evidence. This group represents the majority of doctors and hence captures a large addressable market. Feedback from doctors has confirmed there is a significant unmet need for safe and effective alternative to current treatments for chronic insomnia and autism.

Sales reported are in-line with forecasts for new product launches although they were also impacted by COVID and associated lockdowns. Increasing sales are forecast as we continue to build market awareness of our products and the improvement in market conditions expected as the COVID vaccine rolls-out internationally.

Financial Snapshot

The Company's net cashflow used in operations for the quarter was \$0.9 million. The Company's operational expenses mainly comprised of product manufacturing and operating costs (\$0.9 million), research and development (\$0.3 million), staff costs (\$0.5 million) and administrative and corporate costs (\$0.5 million).

Cash receipts included \$1.38 million from the R&D Tax Rebate.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately \$284,000 comprising of Director Services of \$270,000 and Non-Director Services – corporate advisory services of \$8,000 and storage services of \$6,000 were paid during the quarter.

The Company closed the quarter with a cash position of \$8.6 million.

Forward Looking Activities

Zelira's commercialisation plans are focused on generating revenues from the multiple products it has launched into the Australian and USA market and continuing to launch new product lines. Zelira will also progress additional licensing discussions for HOPE™ and Zenivol™ in the USA and look to conclude ongoing negotiations to expand distribution of these products into other global markets including Germany and the UK.

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 Louisiana and Australia. 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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