



30 July 2021

# Zelira accelerating commercialisation and growing products

## QUARTERLY ACTIVITIES REPORT FOR Q4 FY21 - ASX ANNOUNCEMENT

### Q4 FY2021 Highlights

#### Receipts from customers continuing to grow

-  38% growth (on Q3 FY2021) in cash receipts to a record \$311,000
-  Continues strong quarter-on-quarter growth with trend expected to continue
-  Growth reflects sales of SprinjeneCBD, and licensing and clinical trial management fee payments

#### Commercialisation accelerating

-  HOPE™ range of products available for sale to approved dispensaries in Washington DC
-  SprinjeneCBD toothpaste to launch in the United Kingdom (UK) through exclusive distribution agreement with Health House International
-  Licensing and management agreement with Levin Health to conduct chronic pain treatment clinical trial on retired athletes

#### Research underpinning new products

-  Publication of breakthrough research in peer-reviewed PLOS ONE journal describing new technology that improves delivery of cannabidiol (CBD) based drugs into the brains of mice by up to 40-times
-  Clinical trial results of Zenivol® published in the prestigious peer-reviewed journal SLEEP®
-  Zelira's observational clinical pain trial receives IRB/ethics approval in the USA



**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)**, a global leader in the development of clinically validated cannabinoid medicines, is pleased to provide this quarterly activities report alongside its Appendix 4C for the three months ended 30 June 2021 (Q4 FY21).



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**Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented:**

“Our company continues to grow revenues with its strongest quarterly cash receipts from customers reported since its inception and 38% growth on the previous quarter. This growth demonstrates our ability to ramp up commercialisation with a focus on generating revenue from both over the counter [OTC] products as well as our prescription [Rx] licensing and clinical trial programs. Zelira is well positioned to build on the momentum of the past six months and further accelerate our progress in 2021 as we launch new products and expand into new geographies”.

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**Receipts from customers continuing to grow**

The Company generated record cash receipts of \$311,000 in the June 2021 quarter, driven by a combination of growth in SprinjeneCBD sales, clinical trial management and product licensing fees from Levin.

Zelira generated record quarterly cash receipts (product sales and licensing payments) of \$311,000 in Q4 FY21, up 38% on Q3 FY21.

Cash receipts for HY2 FY21 of \$536,000 represented 5X growth on HY1 FY21. Growth was driven largely by the product sales of SprinjeneCBD oral care product in the USA and licensing and management fee receipts.

With a suite of new products planned for launch next quarter, Zelira is well positioned to generate further growth in revenue via its diversified Rx and OTC income streams across multiple territories.

**Commercialisation accelerating**

HOPE™ range of autism spectrum disorder products available for sale to approved dispensaries in Washington DC.

Since May 2021, Alternative Solutions LLC, a licensed grower, manufacturer, and distributor of medical cannabis products, has been distributing Zelira's HOPE™ range of products

in the District of Columbia (Washington DC). HOPE™ is initially available at the National Holistic Healing Center, a medical cannabis dispensary located near Dupont Circle, whose dedicated team assists patients in treating their symptoms through ailment-strain alignment. HOPE™ products will be available in all Washington DC dispensaries by the end of 2021.

Washington DC has reciprocity with 32 other States in the USA with approved medical cannabis programs. As such, the market for Zelira's HOPE™ range of products is far larger than just the population of the District of Columbia as all patients registered in the 32 reciprocal States can legally purchase Zelira's medical cannabis products at an approved dispensary in Washington DC.

**CBD toothpaste to launch in the United Kingdom (UK) via exclusive distribution agreement with Health House International.**

In June 2021, Zelira signed a five year exclusive distribution agreement with Health House International Limited (ASX:HHI) (Health House) in the United Kingdom (UK). The distribution agreement further expands the availability of Zelira's SprinjeneCBD toothpaste brand beyond the USA into the UK. The UK market provides significant growth opportunities for Zelira's clinically validated, hemp-derived oral care products.



Health House will purchase and exclusively distribute a minimum US\$250,000 of Zelira's CBD toothpaste over the first six months of the agreement, and a further US\$250,000 over the second six month period.

### **Levin Health Licensing and Management Agreement to conduct Chronic Pain Treatment Clinical Trial on retired athletes.**

In June 2021, Zelira licensed a proprietary cannabinoid formulation to privately-held Australian sports science company Levin Health Limited (Levin) for the purpose of undertaking a clinical trial to test the efficacy of the formulation in treating sports-related chronic pain experienced by retired professional and amateur athletes.

Studies show that retired athletes are more likely to suffer chronic pain and associated conditions such as depression and anxiety as a result of injuries and physical exertion over long periods of time. While clinical data is currently limited, medicinal cannabis may provide a safe and effective targeted treatment option for this large cohort. The clinical trial to be conducted by Levin will address this.

In addition to licensing the proprietary formulation to Levin, Zelira and Levin have entered into a Project Management Agreement, whereby Levin will pay for the trial and engage Zelira to project manage the clinical trial to be undertaken at La Trobe University's Sport and Exercise Medicine Research Centre in Victoria, Australia.

The licensing and project management agreements between Zelira and Levin utilise Zelira's leading intellectual property portfolio and expertise in clinical trial design for medicinal cannabis, including chronic pain, along with Levin's advisory team and network of retired professional athletes. This targeted approach provides an opportunity to build a leading international brand supported by clinical data that addresses a specific and widespread unmet global medical need.

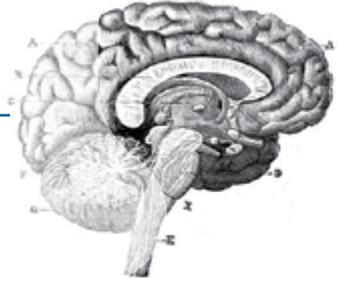
## **Research underpinning new products**



### **Breakthrough research demonstrates significant uptake of CBD into the brain**

In June 2021, Zelira announced that a Company-funded team of researchers at Curtin University (Australia) had developed a new technology that improves delivery of cannabidiol-based drugs into the brains of mice by up to 40-times. The technology has potential for cannabinoid-based therapies to treat neurological disorders such as Alzheimer's disease, multiple sclerosis, and traumatic brain injury.

The Curtin University research team created tiny capsules containing cannabinoids which, when taken orally, were absorbed by the body faster and penetrated the brain quicker in mice models with neurological diseases, than when delivered in liquid form. This research was published in the leading peer-reviewed open access scientific journal [PLOS ONE](#).



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### Clinical trial results of Zelira's Zenivol® published in the prestigious peer-reviewed journal SLEEP®

Also in June 2021, the trial results of the University of Western Australia's investigational team that undertook the double-blind, placebo controlled, cross-over trial of Zelira's ZTL-101 (on market as Zenivol®) in chronic insomnia patients were published in the peer-reviewed journal [SLEEP®](#).

SLEEP® is the benchmark international journal for all sleep-related conditions with a mission to publish innovative, high-impact research findings across the basic, translational, and clinical research spectrum. It is the official publication of the Sleep Research Society.



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### Zelira US observational clinical pain trial receives IRB approval

In July 2021, Zelira announced that it had obtained IRB/ethics approval for its 12-week Observational Clinical Study to evaluate the efficacy, safety and tolerability of its proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical company drug.

Zelira confirmed it had successfully navigated a unique regulatory path for this trial and looks forward to the results of the study, which are anticipated in the first half of CY2022. Zelira continues to lead the world in creating and validating proprietary products such as Zenivol®, with a focus on taking these drugs through regulatory registration.



## Operational activities

The Q4 FY2021 performance reflects Zelira's focus on the expansion of commercialisation activities and revenue generation, with the strongest cash receipts generated since the Company's inception. Zelira's commercialisation program is expected to lead to the launch of a suite of new cannabinoid-based products next quarter. These are expected to drive additional revenue growth for the Company as the product portfolio continues to expand.

## Financial snapshot

The Company's net cashflow used in operations for the quarter was \$1.5 million. Operational expenses mainly comprised product manufacturing and operating costs (\$0.3 million), research and development (\$0.2 million), staff costs (\$0.6 million) and administrative and corporate costs (\$0.6 million).

Cash receipts of \$311,000 were mainly generated from sales of SprinjeneCBD Toothpaste and licence and management payments.

## Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately \$0.27 million comprise Director Services of \$0.25 million and Non-Director Services – corporate advisory services of \$0.01 million and storage services of \$0.01 million – were paid during the quarter.

As at 30 June 2021, the Company had a cash position of \$4.97 million.



## Well positioned to drive further growth

Zelira's commercialisation plans are focused on generating revenues from the multiple products it has launched into the Australian and USA markets, and continuing to launch new product lines while expanding into new geographies.

Zelira is progressing additional licensing discussions for HOPE™ and Zenivol™ in the USA and is looking to conclude ongoing negotiations to expand distribution of these products into other global markets including Germany and the United Kingdom.

Zelira continues to focus on its clinical activities to develop and evaluate the efficacy, safety and tolerability of its proprietary formulations and products.

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



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**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)** is a leading global biopharmaceutical company manufacturing and marketing cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to access the world's largest and fastest growing markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines for the treatment of a variety of medical conditions in its Rx business, including insomnia, autism and chronic non-cancer pain.



The Company has two proprietary formulations under the HOPE™ brand that are generating revenues in Australia, Pennsylvania, Louisiana and Washington D.C. with other states in the US expected to follow. Zelira is also generating revenue in Australia from its proprietary and patented Zenivol™ - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol™ has successfully completed the first Phase 1b clinical trial for chronic insomnia where it was found to be a safe and effective treatment. This clinical trial is published in the prestigious journal 'Sleep'. In 2020, Zelira partnered with SprinJene® Natural to develop and commercialise natural and organic oral care products under the SprinjeneCBD brand, as part of Zelira's OTC business. The SprinjeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids and based on the proprietary and patented technology of Blackseed oil and Zinc.

The Company conducts its work in partnership with world-leading researchers and organizations which since inception includes 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.