29 July 2022

Zelira delivers record year to date cash receipts and milestone achievements in clinical validation across multiple products

QUARTERLY ACTIVITIES REPORT FOR Q4 FY2022
ASX ANNOUNCEMENT

Q4 FY2022 Highlights

- Record 12-month year to date product and service related cash receipts of $1.549 million in FY22, up 148% on 12-month FY21 cash receipts of $0.624 million
  - Cash receipts for the 12 months include Rx sales, SpinjeneCBD toothpaste, RAF FIVE™, Development Advisory Services and non-refundable up front EDCDM technology licensing fee
  - Cash receipts in Q4 of $0.369 million, relatively stable across all quarters in FY22 (Q1: $0.362 million; Q2 $0.341 million; Q3 $0.478 million)
- Successfully launched ITURA™ Advance Relief Cream with Cardiovascular Solutions of Central Mississippi (CVSCM)
  - Zelira will receive royalties on commercialised ITURA™ sales in USA
- Announced results of HOPE® 1 longitudinal, real-world data trial in autism spectrum disorder supporting safe and effective use
- Completed enrolment of 20 patients in the diabetic nerve pain drug trial, representing the first of three arms in the multi arm head-to-head trial against Big Pharmaceutical company's multi-billion-dollar revenue drug
- Announced results of Zenivol® longitudinal, real-world data trial supporting the effectiveness in managing treatment of insomnia
- Post quarter-end, Zenivol® received formal approval from German regulatory authority BfArM, for commercialisation by Adjupharm GmbH. This is a major milestone in Zelira's expansion into Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest market, and advances the Company's global commercialisation strategy to grow its Pharmaceutical (Rx) portfolio

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 2022 (Q4 FY2022).

Commenting on the operational progress in Q4 FY2022, Global Managing Director & CEO, Dr Oludare Odumosu said:

"Zelira delivered a record 12 months operationally with product and service related cash receipts for the 12 month period of $1.549 million, a significant 148% increase on the prior 12 months in financial year 2021. This level of product and service related revenue is unique and demonstrative of our multiple shots on goal strategy. We continue to deliver revenue growth while continuing to focus on our core business, a clinical research cannabinoid based bio-tech firm. We are confident that the growth momentum will continue supported by our commitment to deliver on our product development, commercialisation, and licensing strategy.

During the June 2022 quarter, we successfully launched Zelira's ITURA™ Advance Relief Cream product through our partnership with CVSCM in the US. We are excited by this partnership, and via a licensing agreement, we will work closely together to further formulate proprietary novel therapeutic options for patients whose lives are heavily impacted by pain.

"Clinical validation of our products is critical as we expand into highly regulated markets. We were very excited to announce a number of significant clinical validation milestones over the past quarter. The results of the HOPE®1 longitudinal, real-world data trial in autism spectrum disorder, supported its safe and effective use. In addition, the results of the Zenivol ® longitudinal, real-world data trial supported the effectiveness and safety of Zenivol ® as a therapeutic option to manage insomnia symptoms. These results are essential in providing physicians and patients with proof of the safety, efficacy and dosing guidelines for our cannabinoid-based medicines.

"The completion of the enrolment of 20 patients in the diabetic nerve pain drug trial, representing arm one of the three arm trial, was another significant clinical validation milestone achieved over the June quarter. This trial is particularly monumental as it will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion dollar Big Pharmaceutical company drug. It is imperative that our cannabinoid-based medicines are clinically evaluated against the wider Pharmaceutical drug industry, not only to prove the safety and efficacy of cannabinoid based medicines, but also to support regulatory reform. We are very pleased by the rate of recruitment for arm one of this trial and look forward to what we hope will be a positive result at the end of this calendar year.

"The recent announcement regarding the formal regulatory approval of Zenivol® in Germany marked another major milestone for our business. Germany is one of the largest global markets for cannabinoid-based medicines, and also one of the highest quality global regulatory markets for pharmaceuticals. We look forward to working with our German Partner, Adjupharm, in launching Zenivol® in Germany and supporting patients and physicians in treating chronic insomnia in a safe and effective manner. With formal regulatory approval now received in Germany, we continue to progress activities to license Zenivol® into other global markets."

"The outlook for Zelira is very promising. Our 'multiple shots on goal' growth strategy of having a diversified product suite across multiple distribution channels is delivering. Having gained access to Germany and New Zealand via additional distribution agreements in the first half of FY22, launching multiple new products and making significant advancements on clinical validation across a number of key products, we are very well placed to continue our strong growth trajectory."

Record 12-month year to date product and service related cash receipts of $1.549 million in FY22, up 148% on 12-month FY21 cash receipts of $0.624 million

Zelira generated record 12-month product and service related cash receipts in FY22 of $1.549 million, 148% increase on the prior 12 months to June 2021.

Zelira generated relatively stable quarterly cash receipts over FY22, with Q4 cash receipts of $0.369 million. (FY22 - Q1: $0.362 million; Q2 $0.341 million; Q3 $0.478 million). Q4 cash receipts consisted of USD$250k (AUD$356k) 2nd instalment on the US$1 million EDCDM technology, Rx, SpinjeneCBD toothpaste and RAF FIVE™ sales and Development Advisory Services. Zelira will be assessing new opportunities for further commercialisation of the EDCDM technology and is focused on growing the new revenue generating product offering as part of the wider growth strategy.

Successful launch of ITURA™ Advance Relief Cream with Cardiovascular Solutions of Central Mississippi (CVSCM)

Zelira launched a new product ITURA™ through its partnership with CVSCM. ITURA™ is an Advanced Relief Cream formula using CBD and Hemp Spectra Technology that targets multi-symptoms such as numbness and tingling, muscle cramps, insensitivities and neuropathies including pain associated with Peripheral Artery Disease and diabetes.

The initial purchase order of 10,000 units has been manufactured and paid for by CVSCM. Under the licensing agreement (announced 20 July 2020), Zelira received an upfront payment on executing the license agreement and upon the completion of ITURA™ development, Zelira will receive ongoing royalties on the commercialisation of ITURA™. CVSCM has exclusive marketing rights to the USA market and Zelira retains rights for all other markets, ex-USA.

Results of HOPE®1 longitudinal, real-world data trial supports the safe and effective use in autism spectrum disorder (ASD)

Zelira published a white paper detailing the analysis of longitudinal, real-world data trial generated from patients using HOPE®1.

The results of the longitudinal, real-world data trial from 45 patients with ASD using HOPE®1 supports the safe and effective use of our product. The Clinical Global Impression (CGI) rating scale improved with duration of use. Results show that almost 70% of patients in the study cohort were rated by clinicians as having achieved at least 'moderate' therapeutic effect after 5 months on HOPE®1.

An effective dosing range was established for both paediatrics and adult ASD patients based on the results of the study. The data will be used to support the design of future interventional clinical trials with HOPE®1.

Completed enrolment of 20 patients in the diabetic nerve pain drug trial, representing the first of three arms in the multi arm head-to-head trial against Big Pharmaceutical company's multi-billion dollar revenue drug

Zelira completed the enrolment of the investigative drug arm of its Institutional Review Board (IRB) approved pain drug trial study.

This trial will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical drug. This is a very significant milestone for the trial, designed as a multi arm head-to-head comparison of 60 subjects with 20 subjects in each arm, powered to show statistical difference. A total of 20 patients in the investigative drug arm have been completely enrolled, with clinical trial results expected by the end of this calendar year.

Results of Zenivol® longitudinal, real-world data trial supports effectiveness in managing treatment of insomnia

Zelira published a white paper detailing the analysis of longitudinal, real-world data from 94 patients using Zenivol®. The results support Zenivol®'s effectiveness as a therapeutic option to manage chronic insomnia symptoms.

Zenivol® reduced the Insomnia Severity Index (ISI) scores from 19.5 (Moderate clinical insomnia) to 14.3 (Subthreshold insomnia) and 44% of patients on Zenivol® were reduced to Subthreshold insomnia levels and a further 22% achieved a rating of *No clinically significant insomnia.*

An effective dosing range was established based on the results of the study. The data will be used to support the design of future interventional clinical trials with Zenivol®.

Zenivol® achieves major milestone with formal regulatory approval received in Germany

Post quarter-end, Zenivol® received formal approval from the German regulatory authority BfArM (The Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte) via its German commercialisation partner Adjupharm GmbH (Adjupharm).

This approval is a necessary and major milestone for Zelira to enter Germany – one of the world's largest markets for cannabinoid-based medicines and Europe's largest market – via its 5-year exclusive distribution agreement with Adjupharm (announced in September 2021). This approval will expand the availability of Zenivol®, Zelira's clinically validated cannabinoid-based insomnia medication, beyond Australia for the first time.

German regulatory approval highlights Zelira's expertise in quality and pharmaceutical production and supports the Company's strategy of further validating the safety and efficacy of Zenivol® and Zelira's other clinically, real world data backed cannabinoid-based medicines.

Operational activities

The strong performance in Q4 FY2022 reflects Zelira's continuous focus on product development, commercialisation, and licensing strategy.

Financial snapshot

The Company's net cashflow used in operations for Q4 FY2022 was -$2.134 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $407k, down from $532k in Q3 FY2022
- Research and development of $251k, in line with $280k in Q3 FY2022
- Advertising and marketing of $304k, up on $244k in Q3 FY2022
- Staff costs of $0.515 million, down on $1.113 million in Q3 FY2022
- Administrative and corporate costs of $1.010 million, up on $905k in Q3 FY2022

Cash receipts of $0.369 million (Q3 FY2022: $0.478 million) were generated from USD$0.250 million (AUD$0.356 million) 2nd instalment of the EDCDM technology licensing fee, Rx sales, SpinjeneCBD toothpaste, RAF FIVE™ and Development Advisory Services.

The company's net cashflows from investing activities of -$1.5 million represents the working capital facility loan provided to Health House International Ltd under the proposed acquisition. As announced on 22 June 2022, the acquisition is no longer proceeding, and the working capital facility loan is being repaid and due in August 2022.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately $221k comprised Director Services of $179k and Non-Director Services including Accountancy Fees $21k and Company Secretarial Services of $21k

As at 30 June 2022, the Company had a cash position of $2.746 million.

Well positioned to continue growth trajectory

Zelira continues to deliver on its commercialisation plans, with revenues being generated from multiple products launched in Australia, US and UK, while expanding into new geographies including Germany and New Zealand. The clinical validation success in Q4 has continued, and will support cannabinoid therapeutics as safe and effective medicines.

Zelira is continuing to progress additional licensing discussions for HOPE™ and Zenivol® in the US, while looking to conclude ongoing negotiations to expand distribution of these products into other global markets.

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

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About Zelira www.zeliratx.com

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) Zelira is a leading global biopharmaceutical company developing, manufacturing and marketing clinically validated cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development positioned to enter global markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines in its prescription [Rx] business for the treatment of a variety of medical conditions including insomnia, autism and chronic non-cancer pain as well as offering over the counter [OTC] products.

Zelira Rx business generates revenue from two proprietary medications, HOPE™ and Zenivol®. The Company has two proprietary formulations under the HOPE™ brand that are generating revenue in Australia, New Zealand, Washington, D.C., Pennsylvania and Louisiana.

Zelira is also generating revenue in Australia from its proprietary and patented Zenivol® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia. Zelira will also be expanding commercialisation of Zenivol® into New Zealand and Germany via its German commercialisation partner Adjupharm GmbH following recent approval from German regulatory authority BfArM.

Zelira's OTC products in the oral and dermatology health care sectors are also generating revenue. Zelira, in partnership with SprinJeneCBD, launched a full line of oral care products, currently generating revenue in the US and UK. The SprinJeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, blackseed oil and zinc utilising proprietary and patented technology. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating Cannnabidiol (CBD).

Zelira has developed Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology that solves the problem of non-uniformity and separation of cannabinoid form power bed, opening new ways to develop pharmaceutical grade solid oral dosage forms such as capsules and tablets. Zelira will be assessing opportunities for commercialisation of this technology.

The Company conducts its work in partnership with world-leading researchers and organisations which since inception includes Curtain University in Perth, Australia; the Telethon Kids Institute in Perth, Australia; the University of Western Australia, in Perth, Australia; St Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.