31 October 2022

Zelira expands geographical footprint and progresses with diabetic nerve drug trial in Q1 FY23

QUARTERLY ACTIVITIES REPORT FOR Q1 FY2023
ASX ANNOUNCEMENT

Key Highlights

Expanded geographical footprint into highly regulated markets

- 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

Achieved further clinical validation milestone

- Completed successful enrolment of 40 out of 60 patients in the diabetic nerve pain drug trial, representing two-thirds enrolled in the multi arm head-to-head trial against big Pharmaceutical company's multi-billion dollar revenue drug
- Provided Diabetic Pain Drug Trial Summary Update (21.09.22)

Partial receipt of Health House loan

- Received repayment of $400k, a partial amount of the short-term $1.5 million loan provided by ZLD to Health House Limited (ASX: HHI) (Health House)
- Remaining loan to be repaid and due today

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, provides its quarterly activities report alongside its Appendix 4C for the three months ended 30 September 2022 (Q1 FY2023).

Commenting on the operational progress in Q1 FY2023, Global Managing Director & CEO, Dr Oludare Odumosu said:

"I am very pleased with our Q1 progress, and despite the slowdown in cash receipts, we achieved two very significant milestones that are core to our business' growth trajectory as a clinical research focused cannabinoid based bio-tech firm.

The first milestone was the formal regulatory approval of ZENIVOL® received in Germany from German regulatory authority BfArM. Germany is one of the largest global markets for cannabinoid-based medicines, and one of the highest quality global regulatory markets for pharmaceuticals.

The second milestone was the successful enrolment of 40 patients in the diabetic nerve pain drug trial, representing two-thirds enrolled. We are very pleased by the rate of recruitment. The clinical validation of this trial, where we clinically evaluate our cannabinoid-based medicines against the wider Pharmaceutical drug industry, is imperative not only to prove the safety and efficacy of cannabinoid based medicines, but also to support regulatory reform. We are looking forward to what we hope will be a positive result at the end of this calendar year."

Expanded geographical footprint into highly regulated markets

In July 2022, 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.

Achieved further clinical validation milestone

Zelira progressed the enrolment of the Institutional Review Board (IRB) approved diabetic nerve pain drug trial study, announcing two thirds (40 subjects) of patients successfully enrolled.

The trial will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical drug. Progressing the enrolment to two-thirds is a 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.

Zelira announced a summary update of the diabetic nerve pain drug trial which provides details on trial endpoints, method and progress status.

Quarterly cash receipts from customers

Zelira generated quarterly cash receipts of $0.078 million over Q1 FY2023, capturing Australian sales of HOPE® 1 and ZENIVOL® and consulting payments.

The quarterly cash receipts of $0.078 million in Q1 FY2023, represents 80.4% decline on previous quarter (Q4 FY2022: $0.369 million) reflecting no cash receipts being received from newly developed Zyradi technology as reflected in prior quarter and slightly softened demand in the OTC products, driven by broader economic conditions impacting the wider consumer marketplace.

The newly developed Zyradi technology has strong commercialisation potential and Zelira focused on securing additional licensing agreements as a key priority. As a bio-tech clinical research-based company, Zelira is uniquely positioned to generate significant revenue intermittently from its Zyraydi brand, which will support the continued focus on the research portion of Zelira's business.

Operational activities

The performance in Q1 FY2023 reflects Zelira's continuous focus on clinical validation and commercialisation strategy.

Financial snapshot

Cash receipts of $0.078 million (Q4 FY2022: $0.369 million) were generated from Australian sales of HOPE® 1 and ZENIVOL® and consulting payments.

The company's net cashflows from investing activities of $400k represents the partial repayment of the working capital facility loan provided to Health House under the proposed acquisition that is no longer proceeding (announced 22 June 2022). As announced on 8 September 2022, the remainder of the working capital facility loan is being repaid and due 31 October 2022. The Company's net cashflow used in operations for Q1 FY2023 was -$1.97 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $345k, down from $407k in Q4 FY2022
- Research and development of $215k, down from $251k in Q4 FY2022
- Advertising and marketing of $235k, down from $304k in Q4 FY2022
- Staff costs of $580k, in line with $515k in Q4 FY2022
- Administrative and corporate costs of $624k, down from $1.010 million in Q4 FY2022

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $197k comprised Director Services of $165k and Non-Director Services including Accountancy Fees $21k and Company Secretarial Services of $11k.

As at 30 June 2022, the Company had a cash position of $1.214 million.

Continue on growth trajectory

Zelira continues to deliver on its multiple shots on goal strategey, with clinical validation a critical success factor to enable cannabinoid-based medicines to extend into highly regulated markets, such as Germany.

The progress made over Q1 FY23 on the diabetic nerve pain drug trial is of high importance in terms of clinical validation. It is imperative that 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.

Zelira is also 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 in the research, development and commercialisation of 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's 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, 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 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. 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 under the brand name Zyraydi, that solves the problem of non-uniformity and separation of cannabinoid from powder 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.

For further information, please visit: **zeliratx.com**