31 January 2023

Zelira makes positive progress with diabetic nerve drug trial in Q2 FY2023

QUARTERLY ACTIVITIES REPORT FOR Q2 FY2023
ASX ANNOUNCEMENT

Q2 FY2023 Highlights

Completed enrolment for diabetic nerve pain drug trial

- In November, Zelira completed the enrolment of the Institutional Review Board (IRB) approved drug trial that has been designed as a multi-arm head-to-head against a major Big Pharmaceutical company's multi-billion dollar revenue drug, using Zelira's proprietary, patent protected product
- Trial read out expected in Q1 CY2023

Partial cash receipt received for the repayment of Health House loan and variation of repayment via Creso shares

- Zelira agreed with Health House Limited (ASX:HHI) (Health House) and Creso Pharma Limited (ASX:CPH) (Creso) for repayment of the $1,500,000 working capital facility loan provided to Health House as follows:
  - Partial cash receipt of $400,000 from HHI (received 8 September 2022)
  - Partial cash receipt of $550,000 from Creso, on behalf of Health House (received 21 November); and
  - Post quarter end, Zelira confirmed receipt of $800,000 of Creso shares bringing total repayments to $1,750,000 resulting in full settlement of $1,500,000 working capital facility loan

ZENIVOL® Capsule Formulation Powered by Zyraydi™ Technology

- Zelira will be discontinuing ZENIVOL® in its current oil-based formulation whilst it completes the development work to reintroduce ZENIVOL® in a capsule formulation using Zelira's proprietary Zyraydi™ technology

Post quarter end, on the 30 January 2023, Zelira received $1,141,000 cash refund under the Australian Federal Government's R&D Tax Incentive Scheme

- Funds will be used for working capital purposes to accelerate Zelira's clinical development programs and business operations

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is pleased to provide its quarterly activities report alongside its Appendix 4C for the three months ended 31 December 2022 (Q2 FY2023).

Commenting on the operational progress in Q2 FY2023, Global Managing Director & CEO, Dr Oludare Odumosu said:

"The successful completion of the full enrolment in the IRB approved diabetic nerve pain drug trial is a significant milestone for our company. Within this trial, we are clinically evaluating our cannabinoid-based medicine against an established pharmaceutical frontline therapy for diabetic nerve pain.

Clinical validation is core to our value creation strategy and this study presents multiple prospects for positive readouts on study endpoints. Generating one or more positive results from this trial could be pivotal and transformative for our company. Additionally, positive results from this trial support the advancement of generating scientifically rigorous and clinically validated data for our patent protected, proprietary cannabinoid-based drugs. This trial also provides real potential for creating a safer, more efficacious medicine for patients living with diabetic nerve pain."

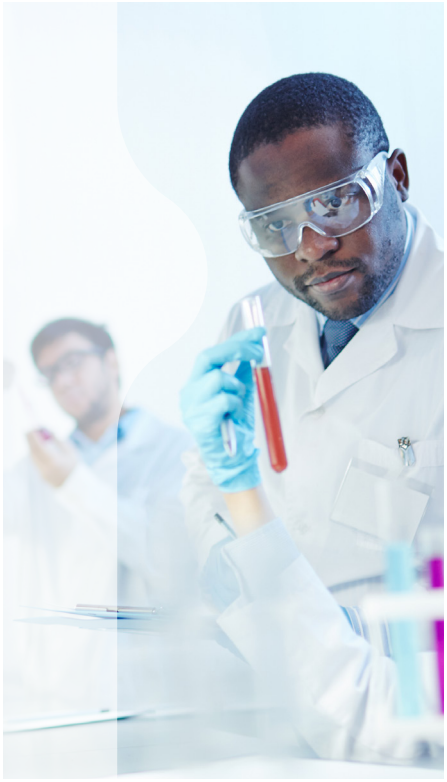
Completed enrolment for diabetic nerve pain drug trial

Zelira progressed to the complete enrolment of the IRB approved diabetic nerve pain drug trial study, announcing all (60 subjects) 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. The trial is designed and approved as an observational multi-arm head-to-head study and powered to show statistical difference with 60 subjects (20 subjects in each arm).

The trial also extends to validate the safe and efficacious use of Zelira's protected, proprietary technology Zyradi™, which was used to formulate the investigational drug.

Zelira expects top line trial results readout to be Q1 CY2023.



Partial cash receipt received for the repayment of Health House loan and variation of repayment via Creso shares

Zelira agreed with Health House and Creso for the repayment of the previous $1,500,000 working capital facility loan that Zelira provided to Health House as follows:

- Partial cash receipt of $400,000 from Health House (received 8 September 2022)
- Partial cash receipt of $550,000 from Creso, on behalf of Health House (received on 21 November 2022); and
- Post quarter end, announced on 10 January 2023 and following shareholder approval, Creso Pharma Limited (ASX:CPH) has issued to Zelira 40,000,000 Creso shares equal to $800,000 at an issue price of $0.02

Following receipt of the Creso shares, total repayments received equates to $1,750,000 and releases Health House of any obligation under the Zelira $1,500,000 working capital facility loan agreement.

ZENIVOL® Capsule Formulation Powered by Zyraydi™ Technology

Zelira will be discontinuing ZENIVOL® in its current oil-based formulation whilst it completes the development work to reintroduce ZENIVOL® in a capsule formulation, a format common to the wider pharmaceutical industry. This important transition is anticipated to be completed late 2023 or early 2024.

During the transition, the current form of medication will cease to be available via prescription and patients will be unable to access the current oil-based formulation of ZENIVOL® medication.

Zelira recommend patients who are already taking ZENIVOL® consult their prescribing doctors to consider suitable alternative sleep medication.

The medicine itself is not changing, ZENIVOL® is simply moving to a more convenient capsule formulation and therefore it is not anticipated there will be any change to the therapeutic response for patients.

Post quarter end, on the 30 January 2023, Zelira received a cash refund under the Australian Federal Government's R&D Tax Incentive Scheme

On the 30 January 2023, post the December quarter end, Zelira received a $1,141,000 cash refund under the Federal Government's Research and Development Tax Incentive Scheme. The R&D Tax Incentive Scheme is an Australian Government program under which companies receive cash refunds for 43.5% of eligible expenditure on research and development.

The funds will be used for working capital to accelerate Zelira's ongoing clinical and product development programs across current and pipeline products as well as the business operations necessary to achieve this.

Quarterly cash receipts from customers

Zelira generated quarterly cash receipts of $0.045 million over Q2 FY2023, capturing Australian sales of HOPE® 1 and ZENIVOL® and OTC product sales.

The quarterly cash receipts of $0.045 million in Q2 FY2023, represents 42.3% decrease on previous quarter (Q1 FY2022: $0.078 million) due to softened demand in the OTC products, driven by broader economic conditions impacting the wider consumer marketplace.

The Q2 FY2023 cash receipts, represented 86.8% decrease on pcp (Q2 FY22: $0.341 million) reflecting the softening demand for the OTC products.

Operational activities

The performance in Q2 FY2023 reflects Zelira's continuous focus on clinical validation strategy.

Financial snapshot

Cash receipts of $0.045 million (Q1 FY2023: $0.078 million) were generated from Australian sales of HOPE® 1 and ZENIVOL® and OTC product sales.

The Company's net cashflow used in operations for Q2 FY2023 was -$1.634 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $35k, down from $345k in Q1 FY2023, reflecting current transition of switching ZENIVOL® to capsule formulation

- Research and development of $171k, down from $215k in Q1 FY2023
- Advertising and marketing of $214k, slightly down from $235k in Q1 FY2023
- Staff costs of $514k, down on $580k in Q1 FY2023
- Administrative and corporate costs of $665k, slightly up on $624k in Q1 FY2023

The company's net cashflows from investing activities of $550k represents the partial repayments of the working capital facility loan provided to Health House under the proposed acquisition that is no longer proceeding (announced 22 June 2022). During the quarter, partial repayment has been made by Creso $550k (received 21st November) on behalf of Health House.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $160k comprised Director Services of $128k and Non-Director Services including Accountancy Fees $21k and Company Secretarial Services of $11k.

As at 31 December 2022, the Company had a cash position of $0.135 million.

Subsequent to the end of the quarter the Company received 40,000,000 Creso Pharmaceutical Shares (ASX:CPH) as part of the Health House facility loan agreement settlement, which the Company will utilise the sale of these Shares to provide additional funding.

In addition, on 30 January 2023, the Company received $1,141,000 refund under the Federal Government's Research and Development Tax Incentive Scheme.

Continue on growth trajectory

As a bio-tech clinical research-based company, we remain committed to continuing to focus on the research portion of our business. We continue to accelerate Zelira's ongoing clinical and product development programs across current and pipeline products. The progress made over Q2 FY2023 on the diabetic nerve pain drug trial is of high importance in terms of clinical validation. Results of this trial expected in the short term, scheduled for Q1 of CY2023.

We continue to explore opportunities to further commercialise our products in market and in particular, securing additional licensing agreements for our Zyradi™ technology that has significant commercialisation potential. We are currently in the process of utilising our Zyradi™ technology to transition the format of our ZENIVOL® medication from an oil-based formulation to a capsule, a capability that is unique to Zyradi™ technology for cannabinoid-based medicines, and a format that is widely utilised in the wider pharmaceutical industry.

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**