ASX ANNOUNCEMENT

27 April 2023

Zelira secures additional funding to accelerate clinical validation progress in Q3 FY2023

QUARTERLY ACTIVITIES REPORT FOR Q3 FY2023
ASX ANNOUNCEMENT

Key Highlights

- Established special purpose vehicle (SPV) for HOPE® 1 to support discrete investment to fund FDA clinical trials
  - Secured US$8.6 million cornerstone funding from Cantheon Capital LLC, an experienced US-based global investor in pharmaceutical and biotech companies engaged in clinical trials that have near-term catalysts
  - Appointed iNGENū CRO Pty Ltd (iNGENū), a specialist cannabinoid Contract Research Organisation (CRO) with FDA experience, as CRO for the HOPE® 1 US FDA clinical trials
- Raised A$1.77 million via a placement to US-based investors
  - Provides additional working capital for the company
- Received A$1.14 million cash refund under the Australian Federal Government's R&D Tax Incentive Scheme
- Received A$800,000 worth of shares in Creso Pharma Limited (bringing total repayments to $1.75 million) finalising the full settlement of $1.5 million Health House working capital loan
- Appointed Greg Blake as Executive Director

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 this quarterly activities report alongside its Appendix 4C for the three months ended 31 March 2023 (Q3 FY2023).

Commenting on the operational progress over Q3 FY2023, Global Managing Director & CEO, Dr Oludare Odumosu said:

"I am very pleased with the progress achieved over the third quarter as we continue to make significant strides forward in clinical validation. This quarter we have made strategic capital management and partnership decisions that position us very well for the next phase of clinical trials.

In terms of clinical validation, we have progressed HOPE® 1 to the third and final stage of our Launch, Learn and Develop strategy for validation and commercialisation. We enter the final 'Develop' stage with a high level of confidence having successfully executed on the Launch and Learning phases, providing a significant amount of real-world data supporting positive safety and efficacy results.

As part of the final 'Develop' stage for HOPE® 1, it is critical for our proprietary product to advance through formal clinical trials and seek FDA approval. In order to meet the capital investment needed to support this final stage, we made the strategic decision to enable investment directly into the product via a SPV for HOPE® 1. On establishing the SPV, we secured US$8.6 million in cornerstone funding from Cantheon, an experienced global investor in pharmaceutical and biotech companies engaged in clinical trials. We also appointed iNGENu as our Contract Research Organisation, to lead the clinical validation and regulatory registration process.

In addition, we have successfully raised an additional A$1.77 million via a placement, which was well supported by our existing shareholders and new US-based investors. It is validating to know that our shareholders are supportive and share in the confidence of our 'multiple shots on goal' strategy. The additional funds raised will support working capital and help create meaningful long-term value for our shareholders."

zelira® THERAPEUTICS

Established special purpose vehicle (SPV) for HOPE® 1 to facilitate investment to fund FDA clinical trials and secured US$8.6 million cornerstone funding

Zelira is contributing to the SPV its HOPE® 1 product, IP and real-world data for 55% equity ownership of the SPV. Zelira will manage the SPV to advance HOPE® 1 through formal clinical trials and seek FDA approval as part of its business platform.

Cash investors will contribute a total of circa US$35 million to fund the SPV and US FDA trials for HOPE® 1 in exchange for a cumulative equity interest of 45% in the SPV.

Cantheon Capital LLC (Cantheon), a global investor focused on the promotion of clinical trial assets with near term catalysts, has provided cornerstone funding of US$8.6 million to the SPV. Cantheon's investment represents approximately 25% of the total US$35 million US FDA trial cost to be raised for the SPV. Zelira has executed a mandate with SW4 Advisors Limited (SW4 Partners) to raise the remaining circa US$26 million required.

The SPV has appointed iNGENū CRO Pty Ltd (iNGENū), a specialist cannabinoid Contract Research Organisation (CRO) and FDA experienced, as its CRO to lead the clinical validation and regulatory registration of the study product with the US FDA.

A$1.77 million raised from US-based investors via a placement

Zelira raised A$1.77 million from US based investors via a placement of 1,770,039 Zelira fully paid ordinary shares at A$1.00 per share.

The funds raised will be used to provide additional working capital.

$1.14 million received under the Australian Federal Government R&D Tax Incentive Scheme

Under the Australian Federal Government's R&D Tax Incentive Scheme, Zelira received a $1,141,000 cash refund. The R&D Tax Incentive Scheme is an Australian Government program under which companies receive cash refunds for eligible expenditure on research and development.

The funds will be used for working capital purposes to accelerate Zelira's clinical development programs and support business operations.

Corporate

Receipt of Creso Shares and Settlement of Health House loan

Following the receipt of 40,000,000 Creso Pharma Limited (ASX:CPH) (Creso) Shares being equal to $800,000 (issue price of $0.02), full settlement of the $1,500,000 Health House working capital loan has been received.

Total repayments equate to $1,750,000 consisting of:

- $400,000 cash received on 8 September 2022;
- $550,000 cash received 21 November 2022; and
- $800,000 Creso Shares received on 10 January 2023.

Director appointment

On 20 February 2023, Greg Blake was appointed an Executive Director of the Board, and continues in his executive role as VP - Global Head of Commercial and Partnering.

Operational activities

The performance in Q3 FY2023 reflects Zelira's continuous focus on clinical validation strategy.

Financial snapshot

Cash receipts of $0.077 million (Q2 FY2023: $0.045 million) were generated from Australian Rx portfolio sales.

The Company's net cashflow used in operations for Q3 FY2023 was $1.156 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $30k, in line with $35k in Q2 FY2023
- Research and development of $258k, up from $171k in Q2 FY2023
- Advertising and marketing of $278k, up from $214k in Q2 FY2023
- Staff costs of $614k, slightly up on $514k in Q2 FY2023
- Administrative and corporate costs of $1,122k, up on $665k in Q2 FY2023 mainly consisting of additional legal cost for the company's growing IP portfolio and cost deferment
- Variations in costs reflect timing of payments.

The Company's net cashflows from investing activities of $666k represents the receipt of 40,000,000 Creso shares, following the last instalment of the repayment of the full settlement of the $1.5 million Health House working capital loan.

The Company's net cashflows from financing activities of $1.77 million represents the proceeds from the placement of 1,770,039 Zelira fully paid ordinary shares at A$1 per share.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $263k comprised Director Services of $231k and Non-Director Services including Accountancy Fees of $21k and Company Secretarial Services of $11k.

As at 31 March 2023, the Company had a cash position of $1,417k.

Strategy and outlook

Commenting on Zelira's operational strategy and growth outlook, Dr Odumosu said

"The outlook for Zelira is very encouraging. We are progressing on the delivery of our 'multiple-shots on goal' strategy, clinically validating multiple cannabinoid-based products, across different therapeutic purposes and across multiple geographies. We will continue to accelerate both current and pipeline products via Zelira's ongoing clinical and product development programs.

The results of the IRB approved drug trial are expected in Q2 CY 2023. The results of the trial are of great significance, as for the first time, we are evaluating our cannabinoid-based medicine against an established pharmaceutical frontline therapy for diabetic nerve pain. The study presents multiple prospects for positive readouts and generating one or more positive results could be transformational for our Company.

We will continue to progress the important development work on ZENIVOL® to transition the format from an oil-based formulation to a powder capsule utilising our Zyraydi™ technology. As part of our progress to clinically validate the therapeutic potential of our cannabinoid-based medicine, we recognise the importance that our therapies need to replicate the capsule form that is commonly utilised in the wider pharmaceutical industry. Not only does it provide a more convenient and familiar pharmaceutical dosage form for patients and prescribers, but also provides us with additional IP protection for our already patented formulations.

Having recently established the HOPE® 1 SPV, we have formalised our binding term sheet with Cantheon via a signed agreement and working closely with SW4 to raise the remaining circa US$26 million required for the SPV."

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

For further information please contact

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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 cannabidiol (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 Curtin 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**

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