31 October 2023

Secured first close in Q1 FY24 of the US$3.25 million investment in HOPE® SPV enabling formal FDA trial to begin

QUARTERLY ACTIVITIES REPORT FOR Q1 FY2024
ASX ANNOUNCEMENT

Key Highlights

- First close of HOPE-SPV funding US$3.25 million commitment, enabling the initiation of HOPE® clinical trial
- Stronger closing cash position of $1.03 million (as at 30 September 2023), following receipt of the first close (US$1.07 million) with subsequent closes expected throughout the year
  - Total secured commitment in HOPE® SPV to date is $11.85 million
- Positive progress with the development work to change Zenivol® format to a capsule formulation powered by Zyraydi™ technology. Zelira is currently vetting for a potential manufacturer
  - Potential manufacturer applicable to both HOPE® and Zenivol®

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 30 September 2023 (Q1 FY2024).

Commenting on the operational progress in Q1 FY2024, Global Managing Director & CEO, Dr Oludare Odumosu said:

This quarter, we are excited to have received the first close of the US$3.25 million investment made by the Forman Family Foundation and Mr. Malik Majeed as co-partners into the HOPE® SPV. The receipt of these funds has enabled us to commence the FDA trial process with our CRO iNGENU for the HOPE Autism Spectrum Disorder program. We are currently focused on the completion of the Target Product Profile (TPP) which is a key initial step in the FDA clinical trial process.

Subsequent rounds of closings of the total secured commitments of US$11.85 million are expected throughout the year.

The FDA trials for HOPE®1 represents the third and final stage of our Launch, Learn, Develop strategy for validation and commercialisation. Having obtained real-world data showing positive safety and efficacy results from the Launch and Learning phases, we enter stage three with a high degree of confidence. We are very focused on executing the FDA trials and look forward to updating our shareholders as the trial progresses.

We have also made positive progress on the important development work to transform Zenivol®'s format to a capsule formulation. We are currently undertaking a vetting process to choose a manufacturing partner, which will be relevant for both HOPE®1 and Zenivol®, with the aim of achieving standardisation and efficiencies. The Zenivol® transition process is on time and anticipated to be completed mid to late 2024.

First close of HOPE® SPV funding US$3.25 million commitment, enabling the initiation of HOPE® FDA clinical trial

In August 2023, Zelira executed definitive agreements with the 2011 Forman Trust and Mr Malik Majeed, to close a first tranche of US$1,069,000 out of the US$3.25 million funding for Zelira to initiate HOPE® FDA clinical trials.

Zelira first established HOPE® 1 SPV in February 2023 to facilitate investment to fund HOPE® 1 US FDA clinical trials. On the establishment of the SPV, Zelira secured US$8.6 million cornerstone commitment from Cantheon Capital LLC (Cantheon), a global investor focused on the promotion of clinical trial assets with near-term catalysts.

In May 2023, Zelira secured the additional US$3.25 million investment from Forman Family Foundation and Mr Malik Majeed in HOPE® 1 SPV, bringing the total committed to US$11.85 million, representing approximately 34% of the total US$35 million to be raised.

Zelira will continue to raise up to an additional US$23 million to complete.

Operational activities

The performance in Q1 FY2024 reflects Zelira's continuous focus on clinical validation strategy.

Financial snapshot

Cash receipts of $0.02 million (Q4 FY2023: 0.17 million) consisted of sales in our OTC product lines with Sprinjene CBD and RAF FIVE™.

The Company's net cashflow used in operations for Q1 FY2024 was $0.78 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $101k, up from $17k in Q4 FY2023 reflects the progress made with manufacturing HOPE®1 and diabetic studies in collaboration with Curtin University.
- Research and development of $136k, in line with $113k in Q4 FY2023, reflects preparation work for the FDA clinical trials for HOPE®.
- Advertising and marketing of $62k, down on $286k in Q4 FY2023.
- Staff costs of $190k, down from $509k in Q4 FY2023. Zelira continues to efficiently manage staff costs, this variance is driven by timing of payments.
- Administrative and corporate costs of $267k, down from $514k in Q4 FY2023
- To preserve capital for Zelira's core growth objective of clinically validating and developing proprietary formulations, Zelira has actively managed costs accordingly, reducing spend where possible in the short term.

The Company's net cashflows from financing activities of $1.66 million represents the close of the first tranche of US$1,069,000 out of the US$3.25 million funding for Zelira to initiate HOPE® FDA clinical trials.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $61k comprised Director Services.

As at 30 September 2023, the Company had a cash position of $1.03 million.

Zelira continues to make significant progress towards execution of the definitive agreements with respect to the HOPE® SPV. Post completing the first close this quarter of the $3.25 million investment, subsequent rounds of closings of the total secured investment of US$11.85 million are expected throughout the year.

Strategy and outlook

Clinical validation and product development remains core to Zelira's growth plans. Zelira will be focused on its clinical activities to develop and evaluate the efficacy, safety and tolerability of its proprietary formulations and products.

FDA clinical trials will be an important next step for two key patent protected products:

- HOPE®1: Via the establishment of the HOPE®1 SPV, Zelira has successfully gained the resources to start the FDA clinical trials for HOPE® 1, a patent protected autism treatment. Zelira has commenced the FDA trial process with appointed CRO iNGENU, currently focused on the completion of the Target Product Profile, a key initial step in the FDA clinical trial process.
- Diabetic Nerve Drug Treatment ZLT-L-007: Following the receipt of the positive top-line results from the IRB approved diabetic drug trial, demonstrating ZLT-L-007 outperformed Pharma drug Lyrica®, Zelira is evaluating the further progression of ZLT-L-007 into formal FDA clinical trials.

Zelira is also vetting for a manufacturing partner for both HOPE®1 and Zenivol®.

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) 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 noncancer pain as well as offering over the counter [OTC] products.

Zelira has established a special purpose vehicle (SPV) to conduct FDA Phase 1, Phase 2 and Phase 3 clinical trials for Zelira's proprietary and patent protected HOPE® 1. Zelira has contributed to the SPV its HOPE® 1 product, IP and real-world data for 55% equity ownership of the SPV. 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% of the SPV. Zelira will manage the SPV as part of its business platform. The SPV has appointed iNGENū CRO Pty Ltd (iNGENū) as its Contract Research Organisation (CRO) to lead the clinical validation and regulatory registration of the study product with the US FDA through the submission of an Investigative New Drug (IND) application.

In May 2023, Zelira completed an IRB approved strategically designed multi-arm, head-to-head study targeting diabetic nerve pain. The clinical trial included a comprehensive comparison against the widely recognised and highly successful multi-billion dollar revenue generating drug Lyrica® (Pregabalin). With the findings underscoring the exceptional efficacy of our treatments in managing pain, with ZLT-L-007 demonstrating the most substantial reduction in pain severity, particularly at the 60-day and 90-day follow-up periods. 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.

Zelira's Rx business generates revenue from its proprietary medication, HOPE. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana. Zelira will also be expanding commercialisation of ZENIVOL® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia 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. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannabidiol (CBD).

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