31 January 2024

HOPE® SPV continues its progress towards further development

QUARTERLY ACTIVITIES REPORT FOR Q2 FY2024
ASX ANNOUNCEMENT

Key Highlights

- Progress made regarding the HOPE® SPV FDA trial process for our HOPE® Autism Spectrum Disorder program.
  - Progress reflected by receipt of second tranche of US$819,000 funding from 2011 Forman Trust subsequent to end of quarter
- Development work for the transformation of Zenivol® into a capsule formulation is on track to be completed late 2024 or early 2025.
  - Continued vetting of manufacturing partners for both Zenivol® and HOPE® 1

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), aglobal 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 December 2023 (Q2 FY2024).

Commenting on the operational progress in Q2 FY2024, Global Managing Director & CEO, Dr Oludare Odumosu said:

This quarter, I am pleased with the progress we have made regarding our FDA trial process for our HOPE® Autism Spectrum Disorder program. Reflective of the progress made, subsequent to the end the quarter we received further funding to continue to progress our HOPE® Autism Spectrum Disorder program. In January 2024, Zelira received the second tranche funding of US$819,000 from the 2011 Forman Trust for the HOPE® SPV. This brings the total amount of funding for the HOPE® SPV to date to US$1,888,000.

The funds have enabled us to complete the Target Product Profile (TPP) assessment, which is a key initial step, and we now have our focus on the FDA meeting request documentation with our CRO INGENU.

We are working with various potential investors and further investment is expected throughout the year. The funding is vital as we continue to research and develop our products, enabling us to support commercialisation of new assets while we continue to progress our existing, revenue generating assets. We look forward to updating our shareholders in the future with further developments.

We also remain on track to complete the transformation of Zenivol® to a capsule formulation by late 2024 or early 2025, powered by ZyraydiTM technology. We continue to explore a manufacturing partner for both HOPE® 1 and Zenivol®

Second close of HOPE® SPV funding US$819,000 to conduct FDA clinical trials

During the quarter, Zelira completed the Target Product Profile (TPP) assessment, which is a key initial step, and we are now focused on compiling the FDA meeting request documentation with our CRO iNGENU.

In January 2024, Zelira received the second tranche $US819,000 of the US$3.25 million funding to conduct FDA clinical trials for Zelira's proprietary and patent-protected HOPE® 1 via a special purpose vehicle (SPV), bringing the total amount of funding for the HOPE® SPV to date to US$1,888,000.

HOPE® 1 SPV was first established in February 2023 to facilitate investment to fund HOPE® 1 US FDA clinical trials.

Operational activities

The performance in Q2 FY2024 reflects Zelira's continuous focus on clinical validation strategy.

Financial snapshot

Cash receipts of $0.121 million (Q1 FY2024: $0.330 million) were mainly driven by sales in our OTC product lines with Zelira Oral Care.

The Company's net cashflow used in operations for Q2 FY2024 was $0.952 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $26k, down from $101k in Q1 FY2024 reflects Zelira's focus on the transition of our products to Zyradi format
- Research and development of $318k, up from $136k in Q1 FY2024 reflects work completing the Target Product Profile (TPP) assessment, which is a key initial step, and we are now focused on compiling the FDA meeting request documentation with our CRO iNGENU.
- Advertising and marketing of $49k, down from $62k in Q1 FY2024
- Staff costs of $254k, down from $190k in Q4 FY2023
- Administrative and corporate costs of $366k, up from $267k in Q1 FY2024
- Variations in costs reflect the timing of payments.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $64k comprised Director Services and $21k to Non-Director Services.

As at 31 December 2023, the Company had a cash position of $65k.

Zelira continues to make significant progress towards execution of the definitive agreements with respect to the HOPE® SPV. With the second tranche of the US$819,000 of the $3.25 million of funding, 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, and has completed the Target Product Profile, and now moving towards FDA meeting request documentation.
- 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 manufacture partner for both HOPE® 1 and Zenivol®.

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 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**