ASX ANNOUNCEMENT

29 April 2024

Further progress with HOPE® SPV and trial process

QUARTERLY ACTIVITIES REPORT FOR Q3 FY2024

Key Highlights

- Continued progress with HOPE® FDA trial process for our HOPE® Autism Spectrum Disorder program:
  - Discussions advanced for final SPV funding tranche
  - Receipt of second tranche of SPV funding totalling US$819,000 from the 2011 Forman Trust
  - Meeting Request Letter submitted to the FDA in April
- Finalised and lodged R&D Tax Incentive refund documentation
  - A$919,000 R&D Tax Incentive refund received subsequent to the end of the quarter.
- Development work for the transformation of Zenivol® into a capsule formulation remains 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), 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 2024 (Q3 FY2024).

Commenting on the operational progress in Q3 FY2024, Global Managing Director & CEO, Dr Oludare Odumosu said:

Zelira made significant progress both in terms of the funding and the FDA trial process for our HOPE® Autism Spectrum Disorder program in Q3 FY2024. During the quarter, we progressed discussions for the final tranche of the HOPE® SPV funding following the receipt of the second US$819,000 tranche of funding from the 2011 Forman Trust.

The SPV funding is vital as we progress negotiations with the FDA and further the research and development of our products. It enables us to support commercialisation of new assets while we continue to progress our existing revenue generating assets. The funds received to date have allowed us to complete the Target Product Profile (TPP) assessment, which is a key initial step for FDA approval, and to progress our FDA meeting request documentation with our CRO.

We also remain on track to complete the transformation of Zenivol® to a capsule formulation by late 2024 or early 2025, powered by Zyraydi™ technology. We continue to explore a manufacturing partner for both HOPE® 1 and Zenivol®. We look forward to updating our shareholders on further developments

Progress towards final tranche of SPV funding received to conduct FDA clinical trials

During the quarter, Zelira progressed discussions towards securing its final tranche of funding under its special purpose vehicle (SPV) to conduct FDA clinical trials for Zelira's proprietary and patent-protected HOPE® 1.

This follows the receipt of the second tranche of US$819,000 of the total US$3.25 million SPV funding in January 2024. The receipt of the second tranche of funding from the 2011 Forman Trust brings to total funds received via the SPV to US$1.888 million.

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

FDA meeting request documentation progresses with MRL submitted in April

Zelira also continued to progress the FDA meeting request documentation with its Contract Research Organisation, iNGENU CRO.

Post the end of the quarter (April 2024), Zelira submitted its Meeting Request Letter to the FDA.

Receipt of A$919,000 R&D Tax Incentive

During the quarter, Zelira prepared and lodged the required documentation under the Australian Federal Government's R&D Tax Incentive Scheme

Subsequent to the end of the quarter, in April, Zelira received a A$919,000 R&D Tax Inventive scheme refund under the Australian Federal Government's R&D Tax Incentive Scheme.

Funds received will be used for working capital purposes to progress Zelira's clinical development programs and business operations.

Appointment of Hall Chadwick as new auditor

In January, Zelira appointed Hall Chadwick WA Audit Pty Ltd as its new auditor following the receipt of approval from the Australian Securities and Investments Commission.

Hall Chadwick replaces HLB Mann Judd (WA Partnership) as the Company's auditor.

Operational activities

The performance in Q3 FY2024 reflects Zelira's continuous focus on its clinical validation strategy.

Financial snapshot

Cash receipts of $34k (Q2 FY2024: $121k) were mainly driven by sales of HOPE® in Australia.

The Company's net cashflow used in operations for Q3 FY2024 was $1.183 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $4k, down from $26k in Q2 FY2024 reflects Zelira's focus on the transition towards research and development of our products to Zyraydi™ format.
- Research and development of $312k, down from $318k in Q2 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 $47k, down from $49k in Q2 FY2024
- Staff costs of $367k, up from $254k in Q2 FY2024
- Administrative and corporate costs of $404k, up from $366k in Q2 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 comprised of $198k Director Services and $32k to Non-Director Services.

As at 31 March 2024, the Company had a cash position of $118k.

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 is progressing 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 manufacturing 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**