ASX ANNOUNCEMENT

30 July 2024

HOPE® SPV funding and trial process advanced; leading patents for HOPE® 1 and 2 secured

QUARTERLY ACTIVITIES REPORT FOR Q4 FY2024
ASX ANNOUNCEMENT

Key Highlights

Continued progress with HOPE® FDA trial process:

- Receipt of third tranche of SPV funding totalling US$681k from the 2011 Forman Trust
- Discussions advanced for final SPV funding tranche

A$919k R&D Tax Incentive refund received to further clinical development program

Development work for the transformation of Zenivol® into a capsule formulation remains on track to be completed late 2024 or early 2025:

- Continued to progress discussions with potential manufacturing partners for both Zenivol® and HOPE® 1

Post quarter-end achievements:

- Leading patents secured for HOPE® 1 and HOPE® 2 in Australia and the US
- Successful pre-Investigational New Drug (IND) meeting with FDA; Zelira poised to progress the HOPE® program toward IND submission
- US$1.4 million unsecured loan received on attractive terms from the Company's Chairman, Mr Osagie Imasogie

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) ("Zelira" or the "Company), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is pleased to provide its quarterly activities report and Appendix 4C for the three months ended 30 June 2024 (Q4 FY2024).

Commenting on the operational progress in Q4 FY2024, Global Managing Director & CEO, Dr Oludare Odumosu said:

Zelira was pleased to receive the third tranche of funding via the HOPE® SPV during the quarter, totalling US$681k from the 2011 Forman Trust which takes the Company's total funding under the SPV to US$2.569 million.

This funding is critical as we progress negotiations with the FDA and work towards our clinical trial programme for our proprietary and patent-protected HOPE® 1 product. The funds received to date have also allowed us to hold a successful pre-Investigational New Drug application meeting with the FDA in July. We are now poised to progress the HOPE® program toward IND submission, marking a significant step forward in the development of treatments for irritability associated with Autism Spectrum Disorder.

The direct SPV funding also enables us to utilise our own funds to undertake concurrent strategies such as the commercialisation of new assets, progressing our existing revenue generating assets and also further the research and development of our suite of products.

"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 and continue to progress discussions with potential manufacturing partners for both HOPE® 1 and Zenivol®.

Receipt of third tranche of HOPE® SPV funding totalling US$681k

In May, Zelira received the third tranche of funding totalling US$681k via its special purpose vehicle (SPV) with the SPV funds to be used for the conduct of FDA clinical trials for its proprietary and patent protected HOPE® 1 product.

The receipt of the third tranche of funding from the 2011 Forman Trust brings the total funds received via the SPV to US$2.569 million out of a total of US$3.25 million.

Zelira continues to manage the SPV as part of its business platform and the Company expects to have subsequent rounds of closings from continued fund-raising efforts to support the HOPE® 1 formal FDA clinical program.

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

Receipt of A$919k R&D Tax Incentive

During the quarter, Zelira received a A$919k 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.

Post quarter-end developments

Leading patents secured for HOPE® 1 and HOPE® 2

In July, Zelira announced a significant milestone in its effort in treating Autism Spectrum Disorder (ASD) by securing patents for HOPE® 1 and HOPE® 2 formulations from the Australian Government

Commission of Patents and the US Patent and Trademark Office (USPTO). Receiving these patents also strengthens the Company's ongoing drug development and clinical validation initiatives.

The Company expects additional patents to be granted for its HOPE® portfolio from the US Patent and Trademark Office (USPTO) later this calendar year.

Successful pre-IND meeting with the FDA

Following the submission of the Meeting Request Letter for a pre-Investigational New Drug (IND meeting with the FDA for HOPE® 1 during the quarter, Zelira held a successful meeting in July, marking a significant advancement in its HOPE® autism drug program.

Zelira received a positive and clear written response from the FDA to preliminary questions submitted ahead of the meeting. This response provided essential clarity on all matters presented, particularly in defining the indication for treatment of irritability associated with ASD.

The meeting was attended by key stakeholders, including the principals of iNGENu CRO, whose expertise significantly contributed to the productive dialogue. During the meeting, Zelira discussed the design of the IND-opening Phase 1 study in healthy volunteers. The FDA also provided guidance on the study design, aiming to evaluate the safety and pharmacokinetics of the proposed doses of ZEL-HOP1, ensuring a robust framework for further clinical development.

Following the positive feedback and productive meeting, Zelira is poised to progress the HOPE® program toward IND submission, marking a significant step forward in the development of treatments for irritability associated with ASD.

US$1.4 million received under unsecured loan facility

In July 2024, Zelira received US$1.4 million working capital loan funds pursuant to the Loan Note from the Company's Chairman, Mr Osagie Imasogie. The Loan Note is considered to be on terms favourable to the Company, particularly considering current market and economic conditions.

The funds will be used to support the advancement of the HOPE SPV clinical trial and general working capital purposes.

Subject to shareholder approval to be sought at the upcoming 2024 Annual General Meeting, the Loan Note will become a Convertible Loan Note with a US$0.40 conversion price. This represents more than a 100% premium to the closing price on 28 June 2024.

In the event that the Shareholders do not approve the conversion, Zelira shall pay a loan termination fee of 10% at the same time with the Loan Note repayment.

Operational activities

The performance in Q4 FY2024 reflects Zelira's continuous focus on its clinical validation strategy.

Financial snapshot

Cash receipts from customers of $23k (Q3 FY2024: $34k) were mainly driven by sales of HOPE® in Australia.

The Company's net cashflow used in operations for Q4 FY2024 was $553k. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $57k, up from $4k in Q3 FY2024 due to the purchases related to the manufacturing of HOPE®
- Research and development of $175k, down from $312k in Q3 FY2024 due to timing of R&D costs related to the HOPE® trial

- Advertising and marketing of $68k, up from $47k in Q3 FY2024
- Staff costs of $392k, consistent with $367k in Q3 FY2024
- Administrative and corporate costs of $715k, up from $404k in Q3 FY2024 due to timing of creditor payments
- 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 $185k Director Services and $74k to Non-Director Services.

As at 30 June 2024, the Company had a cash position of $586k.

Strategy and outlook

Clinical validation and product development remains core to Zelira's growth plans. Zelira is 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.
- 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 progressing discussions with potential manufacturing partners 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**