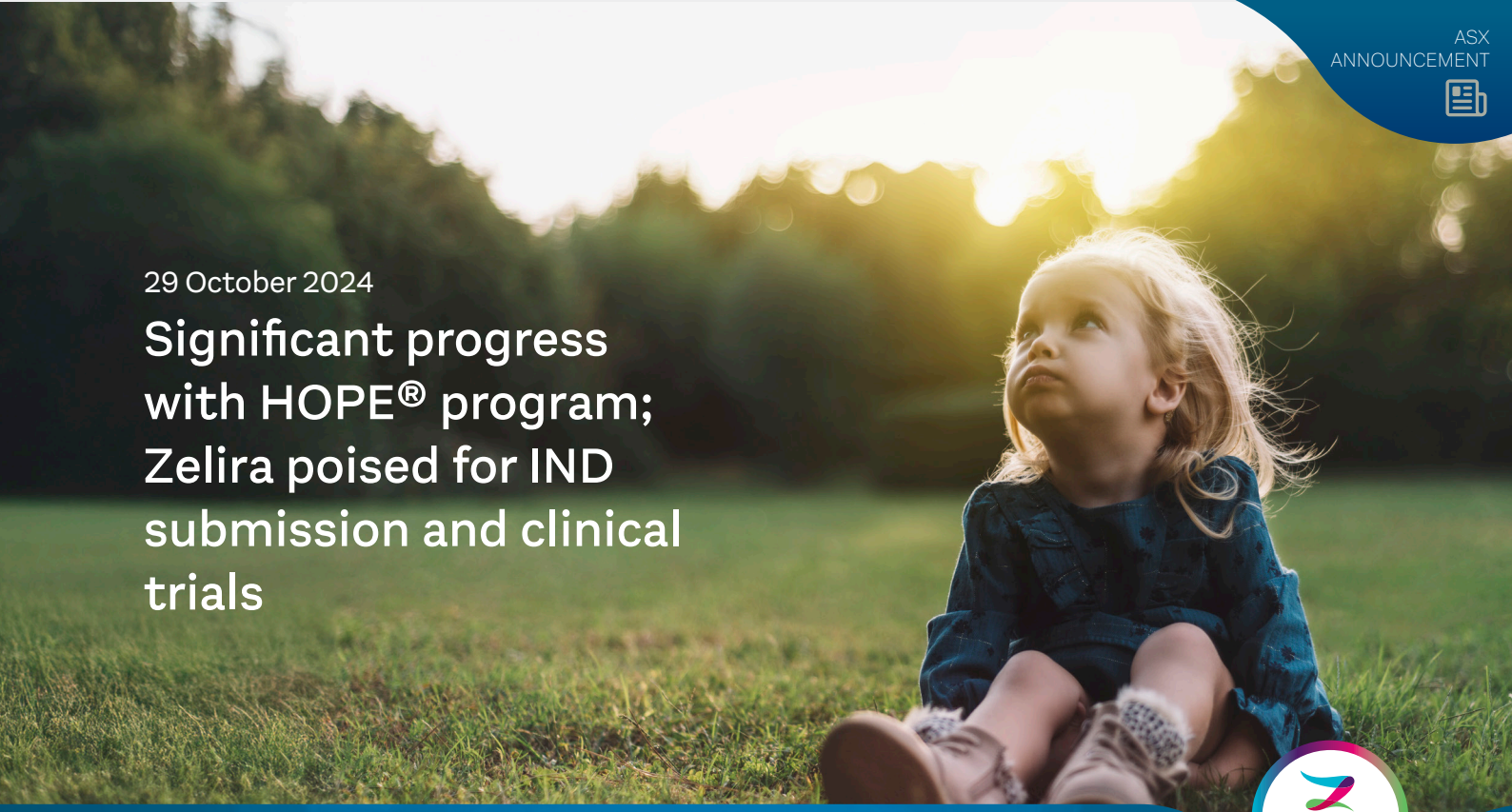
ASX ANNOUNCEMENT



29 October 2024

Significant progress with HOPE® program; Zelira poised for IND submission and clinical trials

QUARTERLY ACTIVITIES REPORT FOR Q1 FY2025
ASX ANNOUNCEMENT

Key Highlights

- Continued progress with HOPE® FDA trial process:
  - Successful pre-Investigational New Drug (IND) meeting with FDA; Zelira poised to progress the HOPE® program toward IND submission and Phase 1 clinical trials
  - Leading patents secured for HOPE® 1 and HOPE® 2 in Australia and the US
- US$1.4 million received under unsecured loan facility
- 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), 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 September 2024 (Q1 FY2025).

Commenting on the operational progress in Q1 FY2025, Global Managing Director & CEO, Dr Oludare Odumosu said:

Zelira made significant progress with the HOPE® program during the quarter with positive feedback and clear direction received from the US Food and Drug Administration (FDA) in their formal minutes following a successful pre-Investigational New Drug (IND) submission meeting on July 10.

The meeting minutes confirm the clarity Zelira has gained regarding the next steps in its clinical development program and represent a significant milestone towards IND submission and the launch of Phase 1 clinical trials for the HOPE® program.

This also marks a significant step forward in the development of treatments for irritability in Phelan McDermid Syndrome (PMS) comorbid with Autism Spectrum Disorder (ASD) and ensures a solid foundation for progressing the HOPE® program.

We also remain on track to complete the transformation of Zenivol® to Zelira's proprietary Zyraydi™ capsule formulation by late 2024 or early 2025. Significant progress has been made in securing a manufacturing partnership for production of both HOPE® 1 and Zenivol®.

Positive feedback from pre-IND meeting with the FDA for HOPE® program

In August, Zelira received positive feedback and clear direction from the US FDA in their official minutes for the Pre-IND meeting held on 10 July 2024 for its HOPE® autism drug program.

Prior to the Pre-IND meeting, Zelira had already received clear and positive written responses from the FDA to its preliminary questions, which provided essential clarity and reinforced the FDA's support for the direction the Company is taking with its HOPE® program.

The meeting focused on the design of the IND-opening Phase 1 study in healthy volunteers, particularly on defining Zelira's target indication and patient population. The FDA offered valuable guidance on the study design, emphasising the importance of evaluating the safety and pharmacokinetic profile of the proposed doses of ZEL-HOP1.

As a result of these discussions, Zelira has clearly defined the study's target population and endpoints, specifically focusing on treating irritability in PMS comorbid with ASD.

The meeting minutes received confirm the clarity Zelira has gained regarding the next steps in its clinical development and represent a significant milestone towards the IND submission and the commencement of clinical trials, further advancing the HOPE® program.

This also marks a significant step forward in the development of treatments for irritability associated with ASD and ensures a solid foundation for further clinical development.

Leading patents secured for HOPE® 1 and HOPE® 2

In July, Zelira achieved a significant milestone in its effort in treating ASD by securing patents for HOPE® 1 and HOPE® 2 formulations from the IP Australia 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 USPTO later this calendar year.

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 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, the date of the Note.

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 Q1 FY2025 reflects Zelira's continuous focus on its clinical validation strategy.

Financial snapshot

Cash receipts from customers of $15k (Q4 FY2024: $23k) were mainly driven by sales of HOPE® in Australia.

The Company's net cashflow used in operations for Q1 FY2025 was $1,555k. Operational expenses mainly comprised:

- Research and development of $219k, up from $175k in Q4 FY2024 reflects our clinical trial spend for the HOPE® trial
- Advertising and marketing of $40k, down from $68k in Q4 FY2024
- Staff costs of $500k, up from $392k in Q4 FY2024 due to timing of payments
- Administrative and corporate costs of $625k, down from $715k in Q4 FY2024 due to timing of payments
- Variations in costs reflect the timing of payments

The Company's net cashflows from investing activities of $71k represents sale of Melodiol Global Health Ltd (ASX:ME1) (formally Creso Pharma Ltd) shares during the quarter.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties comprised of $189k Director Services, $23k to Non-Director Services and $70k interest under the unsecured loan facility.

As at 30 September 2024, the Company had a cash position of $1,073k.

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.

At the same time, 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. The Company is also progressing activities to license the drug into other global markets.

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 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 commercialization 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**