ASX ANNOUNCEMENT

30 January 2025

Zelira progresses HOPE® SPV FDA trial process with fourth US$681,000 funding tranche secured

QUARTERLY ACTIVITIES REPORT FOR Q2 FY2025
ASX ANNOUNCEMENT

Key Highlights

- Progress with the HOPE® SPV FDA trial process for the HOPE® Autism Spectrum Disorder program:
  - HOPE® SPV secures US$681,000 Fourth Funding Tranche to Drive FDA Program Milestones
- Ongoing evaluation of manufacturing partners for both HOPE® 1 and Zenivol®
- Development work for the transformation of Zenivol® into a capsule formulation is on track to be completed in early 2025

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development and commercialisation of clinically validated cannabinoid-based medicines, is pleased to provide its quarterly activities report and Appendix 4C for the three months ended 31 December 2024 (Q2 FY2025)

Commenting on the operational progress in Q2 FY2025, Global Managing Director & CEO, Dr Oludare Odumosu said:

We continued to advance our efforts for the HOPE® 1 program over the quarter, which culminated in the receipt the fourth tranche of US$681,000 of the US$3.25 million funding to conduct FDA clinical trials for our proprietary and patent protected HOPE® 1 product in January.

Although we have demonstrated improvements in Clinical Global Impression (CGI) in patients with Autism Spectrum Disorder (ASD) with HOPE® 1 under a special access scheme, our FDA Phase 1 study will mark a meaningful step forward in the development of treatments for irritability in Phelan McDermid Syndrome (PMS) comorbid with ASD. It will also ensure a solid foundation for progressing the HOPE® program.

At the same time, we continue to evaluate manufacturing partners for both HOPE® 1 and Zenivol®. We also remain on track to complete the transformation of Zenivol® to Zelira's proprietary Zyraydi™ capsule formulation by early 2025.

HOPE® SPV Secures US$681,000 Fourth Funding Tranche to Drive FDA Program Milestones

In January, Zelira received the fourth tranche of US$681,000 of the US$3.25 million funding for it to conduct FDA clinical trials for its proprietary and patent protected HOPE® 1 product.

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

The funding follows clear and constructive feedback from the U.S. Food and Drug Administration (FDA) during the pre-IND meeting held on 10 July 2024. The FDA's official minutes confirmed support for the program and outlined key guidance for the design of the IND-opening Phase 1 study in healthy volunteers.

The discussions with the FDA helped Zelira define the study's target population and endpoints, focusing on treating irritability in patients with PMS comorbid with ASD. This represents an important step toward submitting the IND application and initiating clinical trials. The FDA's feedback highlights the potential of the HOPE® program to address significant unmet medical needs in patients with ASD and PMS.

Zelira expects to have subsequent rounds of closings from its continuing fund-raising efforts to support the HOPE® 1 formal FDA clinical program.

This funding, managed through the SPV, follows the company's earlier ASX announcement dated 17 August 2023. Zelira continues to manage the SPV as part of its business platform.

Operational activities

The performance in Q2 FY2025 reflects Zelira's continuous focus on its clinical validation strategy.

Financial snapshot

The Company's net cashflow used in operations for Q2 FY2025 was $1.077k. Operational expenses mainly comprised:

- Research and development of $292k, up from $219k in Q1 FY2025 reflects the clinical trial spend for the HOPE trial
- Advertising and marketing of $32k, down from $40k in Q1 FY2025
- Staff costs of $315k, down from $500k in Q1 FY2025 due to timing of payments
- Administrative and corporate costs of $278k, down from $625k in Q1 FY2025 due to timing of 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 $216k Director Services, $7k to Non-Director Services and $70k interest under the unsecured loan facility.

As at 31 December 2024, the Company had a cash position of $38k.

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.

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

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Zelira Therapeutics Limited	
ABN	**Quarter ended ("current quarter")**
27 103 782 378	31 DECEMBER 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	4	18
1.2	Payments for		
	(a) research and development	(292)	(511)
	(b) product manufacturing and operating costs	(1)	(5)
	(c) advertising and marketing	(32)	(72)
	(d) leased assets	(79)	(177)
	(e) staff costs	(315)	(816)
	(f) administration and corporate costs	(278)	(903)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(84)	(165)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,077)**	**(2,631)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	2,098
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**2,098**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,073	586
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,077)	(2,631)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	2,098
4.5	Effect of movement in exchange rates on cash held	42	(15)
4.6	**Cash and cash equivalents at end of period**	**38**	**38**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	29	1,064
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	9	9
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**38**	**1,073**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	216
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Director Services

Executive Board Remuneration – $116,000

Non-Executive Board Remuneration - $7,000

Non-Director Services

Accountancy fees - $15,000

Company Secretarial Services - $8,000

Interest on loan $70,000

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	2,098	2,098
7.2	Credit standby arrangements	-	
7.3	Other (please specify) Hope SPV convertible notes	5,228	4,132
7.4	**Total financing facilities**	7,326	6,230

7.5	**Unused financing facilities available at quarter end**	1,096

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Loan facilities

Lender:	Mr Osagie Imasogie
Amount:	US$1,400,000
Interest Rate:	20.0% per annum paid monthly
Commencement date	28 June 2024
Maturity	28 June 2026

Hope SPV convertible notes

Issuer:	Zelira-Hope1, LLC - Special Purpose Vehicle
Securities:	Convertible note
Amount:	$3,250,000
Interest Rate:	10.0% paid in cash annually in arrears
Note Term:	12 months each

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,077)
8.2	Cash and cash equivalents at quarter end (item 4.6)	38
8.3	Unused finance facilities available at quarter end (item 7.5)	1,096
8.4	Total available funding (item 8.2 + item 8.3)	1,134

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.05

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Yes.

8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?
Answer:	The Company is continuing to progress it funding efforts its HOPE SPV to close the remaining the balance of the circa US$32 million capital raise to fund HOPE® 1 trials in the USA. Zelira expects to have subsequent rounds of closings this quarter from its continuing fund-raising efforts to support the HOPE® 1 formal FDA clinical program. The SPV funding includes working capital for the Company to enable it to continue its operations and to meet its business objectives. Furthermore, the Company is in the process of finalising its refund claim under the Federal Government Research and Development Tax Incentive Scheme.
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
Answer:	Yes, refer above.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: .....30 January 2025……

Authorised by: .....By the Board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.