

## **Key Highlights**



## Non-Dilutive R&D Loan Facility

- The Facility is secured against the anticipated R&D Tax incentive rebate for FY25 and will be used for advancement of the HOPE® SPV clinical trial and general working capital.
- The Facility Limit is \$650,000, being less than 80% of the estimated R&D Tax Incentive for the financial year ending 30 June 2025. At the time of execution this estimate is based on calculations of eligible expenditure up to 30 April 2025.



## **Director Loans**

 Managing Director, Dr Oludare Odumosu and Non-Executive Director and Dr Donna Gentile O'Donnell will collectively provide a total of USD\$150,000 unsecured loan notes to the Company on attractive terms. **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 30 September 2025 (Q1 FY2026).



Commenting on the operational progress in Q1 FY2026, Global Managing Director & CEO, Dr Oludare Odumosu said:

Zelira is making exceptional strides toward a successful FDA program for the HOPE® clinical trial, reflecting another quarter of tangible and meaningful progress. With several key milestones approaching, we remain confident and excited about the transformative impact that lies ahead.

99

#### **HOPE® 1 SPV Update**

During the quarter Zelira continued to progress its HOPE® program's clinical development program by finalising Investigational New Drug (IND) submission which will set the stage to launch our Phase 1 trials. The IND development pathway for HOPE® 1 Phelan McDermid Syndrome (PMS) co-morbid with ASD program Phelan-McDermid Syndrome (PMS), an ultra-rare genetic condition caused by a deletion or change of chromosome 22 in the 22q13 region or disease causing (pathogenic) variant of the SHANK3 gene. Most affected individuals have moderate to profound intellectual disability and a very high prevalence of ASD. Upon allowance of the IND, Zelira will advance its accelerated regulatory pathway strategy utilizing existing pre-clinical, USDMF and CMC data sets already generated by Zelira through its Launch, Learn and Develop strategy and clinically-validated real-world patient data, using the FDA 505(b)(2) pathway.

The Company remains committed to bringing innovative and effective cannabinoid-based therapies to market, improving the quality of life for patients with ASD and their families.



#### **R&D Loan Facility**

Zelira entered into a loan agreement with RH Capital Finance Co., LLC (Rocking Horse Capital), enabling the Zelira to advance its research and development (R&D) initiatives and deploy additional capital to increase its R&D tax incentive claim for the financial year ended 30 June 2025 (FY25).

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

#### **Director Loans**

Managing Director, Dr Oludare Odumosu and Non-Executive Director and Dr Donna Gentile O'Donnell will collectively provide a total of USD\$150,000 unsecured loan notes to the Company on attractive terms.

Funds received will be used for general working capital purposes.

Subject to shareholder approval, the loan note will become convertible into shares at the higher of USD\$0.2585 and the 15-day VWAP prior Zelira electing to convert.

#### **Operational activities**

The performance in Q1 FY2026 reflects Zelira's continuous focus on its clinical validation strategy.

#### Financial snapshot

The Company's net cashflow used in operations for Q1 FY2026 was \$711k. Operational expenses mainly comprised:

 Research and development of \$145k, up from \$46k in Q4 FY2025 reflecting costs associated with the HOPE® 1trial preparations

- Advertising and marketing of \$10k, up from \$2k in Q4 FY2025 for due to timing of payments
- Staff costs of \$234k, up from \$191k in Q4 FY2025 due to timing of payments
- Administrative and corporate costs of \$262k, up from \$82k in Q4 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 \$155k Director Services.

As at 30 September 2025, the Company had a cash position of \$172k.

## 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

### Company

Dr Oludare Odumosu Managing Director & CEO

**\( \cdot\) +1 909 855 0675** 

#### **Australia**

Level 3, 101 St Georges Terrace Perth WA 6000, AUSTRALIA

+61 8 6558 0886
Fax: +61 8 6316 3337

<u>♠ enquiries@zeliratx.com</u>

www.zeliratx.com

ACN 103 782 378

#### **Investors**

Luke Maffei

Senior Manager - IR, Automic Group

**\( \cdot\)** +61 403 193 579

🖄 luke.maffei@automicgroup.com.au

#### USA

5110 Campus Drive, Suite 150 Plymouth Meeting, PA 19462 United States Of America

\$\text{+1 484 630 0650}

## Zelira Therapeutics Ltd (ASX:ZLD,

otcobe: Zeldaf) 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
<u> </u>

**ABN** Quarter ended ("current quarter")

27 103 782 378 30 SEPTEMBER 2025

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	2	2
1.2	Payments for		
	(a) research and development	(145)	(145)
	(b) product manufacturing and operating costs	(6)	(6)
	(c) advertising and marketing	(10)	(10)
	(d) leased assets	(12)	(12)
	(e) staff costs	(234)	(234)
	(f) administration and corporate costs	(262)	(262)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(44)	(44)
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	(712)	(712)

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

Page 1

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 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)	4	4
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	914	914
3.6	Repayment of borrowings	(39)	(39)
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	879	879

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7	7
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(712)	(712)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Page 2

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	879	879
4.5	Effect of movement in exchange rates on cash held	(3)	(3)
4.6	Cash and cash equivalents at end of period	172	172

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	163	(2)
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)	172	7

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	155
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 - \$101,000

Non-Executive Board Remuneration - \$3,000

## Non-Director Services

Accountancy fees - \$8,000

Company Secretarial services - \$4,000

Interest on Director loans - \$36,000

Other - \$3,000

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	2,905	2,905
7.2	Credit standby arrangements	-	
7.3	Other (please specify) Hope SPV convertible notes	-	-
7.4	Total financing facilities	2,905	2,905
7.5	Unused financing facilities available at qu	arter end	-

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:	<ol> <li>Mr. Osagie Imasogie</li> <li>Dr. Oludare Odumosu</li> <li>Dr. Donna Gentile O'Donnell</li> </ol>	RH Capital Finance Co., LLC	
Amount:	1) US\$1,400,000 2) US\$100,000 3) US\$50,000	A\$650,000	
Interest Rate:	<ol> <li>20.0% per annum paid monthly</li> <li>20.0% per annum paid monthly</li> <li>20.0% per annum paid monthly</li> </ol>	17% per annum	
Commencement date	<ol> <li>28 June 2024</li> <li>9 September 2025</li> <li>9 September 2025</li> </ol>	24 July 2025	
Maturity	<ol> <li>28 June 2026</li> <li>9 September 2026</li> <li>9 September 2025</li> </ol>	30 November 2025	

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(712)
8.2	Cash and cash equivalents at quarter end (item 4.6)	172
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)		0.2
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	-
	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:	

Does the entity expect that it will continue to have the current level of net operating 8.6.1 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 has lodged its income tax return and anticipated to receive the refund claim under the Federal Government Research and Development Tax Incentive Scheme in Q2 VY2026.
The Company has secured a \$1 million At-the-Market Facility (ATM) Agreement with Securities Vault Pty Ltd to support its growth objectives. The ATM facility provides Zelira with up to \$1 million of standby equity capital over the next 12 months enabling additional flexibility for the Company to conduct capital raising activities over time, closely aligning capital needs with operational activities.

Furthermore, the Company is substantially progressing 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.

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:	27 October 2025
Authorised	by:By the Board
	(Name of body or officer authorising release – see note 4

#### Notes

- 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.
- 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.