Appendix 4D

1. Company Details

Name of Entity

	Zelira Therapeutics Limited	
ABN	Half year ended ("current period")	Half year ended ("previous period")
27 103 782 378	31 December 2022	31 December 2021

2. Results for announcement to the market

				AUD\$
2.1 Revenues from ordinary activ	ities	Down	89% to	76,949
2.2 Profit / (loss) from ordinary a	ctivities after tax			
attributable to members - 31 Dec	ember 2021: loss of	Up	35% to	(3,664,787)
(\$5,613,420)				
2.3 Net profit / (loss) for the period	od attributable to	Up	35% to	(3,664,787)
members - 31 December 2021: lo	oss of (\$5,613,420)	·		.,,,,
2.4 Dividends	Amount per sec	urity	Franked amoun	t per security
Interim dividend declared	N/A		N/A	4
2.5 Record date for determining of	entitlements to the divi	dend	N/A	A

2.6 Brief explanation of any of the figures in 2.1 to 2.4 above necessary to enable figures to be understood

During the financial period Zelira achieved the following milestones

- received formal approval from the German regulatory authority BfArM for Zenivol®,
- completed enrolment (60 subjects) of the IRB approved diabetic nerve pain drug trial study, evaluating the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical drug,
- further developed its Zyraydi technology, which has strong commercialisation potential and focused on securing additional licensing agreements.
- varied and settled the Health House International Ltd \$1,500,000 working capital facility loan agreement, resulting in Zelira receiving repayment of \$950,000 cash and \$800,000 in Creso Pharma Limited shares.

The decrease in revenue is mainly due to softened demand in the OTC products, driven by broader economic conditions impacting the wider consumer marketplace.

The performance for the period reflects the continuous focus on clinical validation strategy.

3. Net tangible assets per security	31 December 2022	31 December 2021
Net tangible asset backing per ordinary security	0.078	0.006
4. Details of entities over which control has been gaine	d or lost	
4.1. Control gained over entities		
N/A		

4.2. Control lost over entities

N/A

5. Dividends

Individual dividends per security

	Date dividend is payable	Amount per security	Franked amount per security at 30% tax	Amount per security of foreign source dividend
Interim dividend:				
Current year	N/A	N/A	N/A	N/A
Previous year	N/A	N/A	N/A	N/A

6. Dividend reinvestment plans

The dividend or distribution plans shown below are in operation.

N/A	
The last date(s) for receipt of election notices for	N/A
the dividend or distribution plans.	IV/A

7. Details of associates and joint entities

N/A			

8. Foreign entities

N/A		

9. If the accounts are subject to audit dispute or qualification, details are described below.

N/A			
Sign here:	J. D. Bin	Date:	28 February 2023

Managing Director

Print Name: Oludare Odumosu





2023 HALF-YEAR FINANCIAL REPORT

31 DECEMBER 2022

Zelira Therapeutics Limited
ABN 27 103 782 378



Contents





Your directors submit the financial report of the Group for the half-year ended 31 December 2022. In order to comply with the provisions of the *Corporations Act 2001*, the directors report as follows:

Directors

The names of directors who held office during or since the end of the half-year and until the date of this report are noted below. Directors were in office for the entire period unless otherwise stated.

Osagie Imasogie	Chairman	
Oludare Odumosu	Managing Director	
Lisa Gray	Non-Executive Director	
Tim Slate	Non-Executive Director	
Greg Blake	Executive Director	Appointed 20 February 2023

Business performance

Expanded geographical footprint into highly regulated markets

In July 2022, Zenivol® received formal approval from the German regulatory authority BfArM (The Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte) via its German commercialisation partner Adjupharm GmbH (Adjupharm). This approval was a necessary and major milestone for Zelira to enter Germany – one of the world's largest markets for cannabinoid-based medicines and Europe's largest market – via its 5-year exclusive distribution agreement with Adjupharm.

Completed enrolment for diabetic nerve pain drug trial

Zelira progressed to the complete enrolment of the IRB approved diabetic nerve pain drug trial study, announcing all (60 subjects) patients successfully enrolled. The trial will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical drug. The trial is designed and approved as an observational multi-arm head-to-head study and powered to show statistical difference with 60 subjects (20 subjects in each arm).

The trial also extends to validate the safety and efficacious use of Zelira's protected, proprietary technology Zyraydi™, which was used to formulate the investigational drug.

Zenivol ® Capsule Formulation Powered by Zyraydi™ Technology

In January 2023, Zelira announced it will be discontinuing Zenivol® in its current oil-based formulation whilst it completes the development work to reintroduce Zenivol® in a capsule formulation, a format common to the wider pharmaceutical industry. This important transition is anticipated to be completed late 2023 or early 2024.

Corporate

On 8 September 2022, Zelira announced that it had agreed with Health House Limited ("Health House") to extend the date for repayment of its short-term loan provided in February 2022 to 31 October 2022. Following agreement, Zelira received an initial payment of \$400,000.

On 21 November 2022, Zelira announced a variation to the loan agreement as follows:

- Creso Pharma Limited("Creso", ASX:CPH) on behalf of Health House to make an immediate payment of \$550,000; and
- Subject to shareholder approval on or prior to 31 December 2022, Creso agrees to issue Zelira that number of Creso shares equal to \$800,000 divided by the closing price of Creso's ordinary shares as traded on the ASX the day prior to the Shareholder Meeting.

Zelira received \$550,000 on 21 November 2022.

After balance date events

On 10 January 2023, Zelira announced that it had released Health House of any obligation under the loan agreement following receipt of 40,000,000 Creso shares from Creso at an issue price of \$0.02 being equal to \$800,000.

On 30 January 2023, Zelira received a \$1,141,000 cash refund under the Federal Government's Research and Development Tax Incentive Scheme.

On 15 February 2023, Zelira announced the establishment of the HOPE® 1 special purpose vehicle (SPV) to facilitate investment to fund HOPE® 1 US FDA clinical trials. Zelira will retain 55% equity ownership of the SPV, contribute its HOPE® 1 product, IP and real-world data and manage the SPV as part of its business platform.

Cash investors will contribute circa US\$35 million to fund the SPV and US FDA trials for HOPE® 1 in exchange for a maximum cumulative equity interest of 45% of the SPV. US based Cantheon Capital LLC, has agreed to provide cornerstone funding for the SPV of US\$8.6m. SW4 Advisors Limited (SW4 Partners) has been mandated to raise the remaining circa US\$26 million required for the SPV.

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.

On 20 February 2023, Greg Blake was promoted from VP - Global Head of Commercial and Partnering to Executive Director. Mr Blake has been employed by Zelira since 2020, Greg brings extensive commercial and operational leadership experience in the pharmaceutical and biotech sectors both within Australia and internationally. Greg has led the strategic development and commercialisation of a number of products across a range of therapeutic categories.

Review of operations

During the period ended 31 December 2022, Zelira Therapeutics Limited ("Zelira" or "the Group") reported a net loss after tax attributable to the members of Zelira Therapeutics Limited of \$3,664,787 (31 December 2021: \$5,613,420).

About the business

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 non-cancer pain as well as offering over the counter [OTC] products.

Zelira's Rx business generates revenue from two proprietary medications, HOPE® and Zenivol®. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., and Louisiana.

Zelira is also generating revenue in Australia from its proprietary and patented Zenivol® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia. 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.

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. The SprinJeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, blackseed oil and zinc utilising proprietary and patented technology. Zelira also launched in 2021 the RAF FIVETM brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannabidiol (CBD).

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. The Company conducts its work in partnership with world-leading researchers and organisations which since inception includes Curtain University in Perth, Australia; the Telethon Kids Institute in Perth, Australia; the University of Western Australia, in Perth, Australia; St Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

Material Business Risks

(a) Risk of adverse publicity

The clinical trials being undertaken by Zelira involve the use of controlled substances and their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, its products. These pressures could also limit or restrict the introduction and marketing of its products. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by the Company's products.

The nature of Zelira's business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, its reputation may be harmed.

(b) Risks associated with clinical trials

Clinical trials are expensive, time consuming and difficult to design and implement. Even if the results of the Company's clinical trials are favourable, the clinical trials for a number of the Company's product candidates are expected to continue for several years and may take significantly longer to complete. In addition, regulatory authorities, including state and local, may suspend, delay or terminate the clinical trials at any time, or suspend or terminate the registrations and quota allotments the Company requires in order to procure and handle controlled substances, for various reasons, including:

- (i) lack of effectiveness of any product candidate during clinical trials;
- (ii) discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- (iii) slower than expected rates of subject recruitment and enrolment rates in clinical trials;
- (iv) difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- (v) delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- (vi) inadequacy of or changes in the Company's manufacturing process or product formulation;
- (vii) delays in obtaining regulatory authorisation to commence a trial, including "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency before or after a trial is commenced;
- (viii) changes in applicable regulatory policies and regulations;
- (ix) delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- (x) delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- (xi) unfavourable results from ongoing pre-clinical studies and clinical trials;

- (xii) failure of the Company's contract research organisations (CROs), or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- (xiii) failure by the Company, its employees, CROs or their employees to comply with all applicable regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;
- (xiv) scheduling conflicts with participating clinicians and clinical institutions; or
- (xv) failure to design appropriate clinical trial protocols; or regulatory concerns with cannabinoid products generally and the potential for abuse.

Any of the above could have a material adverse effect on the Company's business, results of operations and financial conditions.

In addition, even if the Company views the results of a clinical trial to be positive, the Food and Drug Administration or other regulatory authorities may disagree with the Company's interpretation of the data.

(c) Risk of adverse events or other safety risks

If any of Zelira's products, prior to or after any approval for commercial sale, cause serious or unexpected side effects, or are associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including:

- (i) regulatory authorities may interrupt, delay or halt clinical trials or sale of those products;
- (ii) regulatory authorities may withdraw their approval, or require more onerous labelling statements for any product that is approved;
- (iii) Zelira could be sued and held liable for harm caused to patients; or
- (iv) Zelira's reputation may suffer.

Zelira may voluntarily suspend or terminate its clinical trials or sale of products if at any time it believes that they present an unacceptable risk to participants or if preliminary data demonstrate that its products or product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialised.

(d) Loss of key relationships

The medicinal cannabis industry is undergoing rapid growth and substantial change, which has resulted in increasing consolidation and formation of strategic relationships. Zelira expects this consolidation and strategic partnering to continue. Acquisitions or other consolidating transactions could harm Zelira in a number of ways, including:

- (i) Zelira could lose strategic relationships if third parties with whom it has arrangements (including the Complutense University Madrid in Spain and Curtin University, Telethon Kids Institute and CannPal Pty Ltd in Australia) are acquired by or enter into relationships with a competitor (which could cause Zelira to lose access to distribution, content, technology and other resources);
- (ii) the relationship between Zelira and such third parties may deteriorate and cause an adverse effect on its business; and
- (iii) Zelira's current competitors could become stronger, or new competitors could form, from consolidations.

Any of these events could put Zelira at a competitive disadvantage, which could cause Zelira to lose research facilities or access to technology. Consolidation could also force Zelira to expend greater resources to meet new or additional competitive threats, which could also harm Zelira's results.

(e) Protection of proprietary technology

Zelira's success will depend, in part, on its ability to obtain patents, protect its trade secrets and operate without infringing on the proprietary rights of others. Zelira relies upon a combination of patents, trade secret protection (i.e., know how), and confidentiality agreements to protect the intellectual property.

If Zelira fails to adequately protect its intellectual property, it may face competition from companies who attempt to create a generic product to compete with its proposed products. Zelira may also face competition from companies who develop a substantially similar product to one of its products or proposed products.

Many companies have encountered significant problems in protecting and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for Zelira to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce intellectual property rights in foreign jurisdictions could result in substantial cost and divert Zelira's efforts and attention from other aspects of its business.

Patents

The strengths of patents in the pharmaceutical field involve complex legal and scientific questions and can be uncertain. Where appropriate, Zelira will seek patent protection for certain aspects of its products and technology. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so Zelira's policy is to patent commercially potential technology in jurisdictions with significant commercial opportunities. However, patent protection may not be available for some of the products or technology to be developed.

If Zelira must spend significant time and money protecting or enforcing its patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, Zelira's business, results of operations and financial condition may be harmed. Zelira may not develop additional proprietary products that are patentable.

Furthermore, others may independently develop similar products, may duplicate Zelira's products, or may design around Zelira's patent rights. In addition, issued patents may be declared invalid.

Trade secrets

Trade secrets are difficult to protect. Zelira relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect its trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorised disclosure of confidential information. In addition, others may independently discover Zelira's trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of Zelira's proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect Zelira's intellectual property, could enable competitors to develop generic products or use Zelira's proprietary information to develop other products that compete with Zelira's products or cause additional, material adverse effects upon Zelira's business, results of operations and financial condition.

Cash flow

The Group's cash at bank was \$133,790 at 31 December 2022 (31 December 2021: \$7,611,244).

Auditor's Independence Declaration

Section 307C of the *Corporations Act 2001* requires our auditors, HLB Mann Judd, to provide the directors of the Company with an Independence Declaration in relation to the review of the half-year financial report. This Independence Declaration is set out on page 10 and forms part of this directors' report for the half-year ended 31 December 2022.

This report is signed in accordance with a resolution of the Board of Directors made pursuant to section 306(3) of the *Corporations Act 2001*.

Oludare Odumosu

Managing Director

28 February 2023



AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the consolidated financial report of Zelira Therapeutics Limited for the half-year ended 31 December 2022, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- the auditor independence requirements of the Corporations Act 2001 in relation to the review;
 and
- b) any applicable code of professional conduct in relation to the review.

Perth, Western Australia 28 February 2023

L Di Giallonardo Partner

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Condensed Consolidated Statement of Comprehensive Income

	Notes	31 December 2022 (\$)	31 December 2021 (\$)
Continuing operations			
Revenue	3	76,949	727,699
Cost of sales		(122,368)	(634,275)
Gross (loss/)/profit		(45,419)	93,424
Finance income		72	1
Compliance and regulatory expenses		(164,098)	(138,255)
Consultants and professional fees		(1,704,755)	(1,241,115)
Administration expenses		(225,262)	(198,875)
Director and employee expenses		(1,409,567)	(1,426,895)
Research and development		(548,436)	(763,403)
Commercialisation expenses		(32,276)	(428,357)
Share-based payments	11	(303,365)	(859,128)
Changes in fair value of financial assets at fair value through profit or loss		-	(66,783)
Reversal of expected credit loss	5	1,500,000	-
Depreciation and amortisation		(274,474)	(322,721)
Impairment of inventory		(251,618)	-
Bad debts expense		(39,633)	-
Finance costs		(32,150)	(27,391)
Other expenses		(133,806)	(233,922)
Loss before income tax expense		(3,664,787)	(5,613,420)
Income tax expense		-	-
Net loss for the period		(3,664,787)	(5,613,420)
Loss attributable to minority interests		(387,419)	(346,967)
Loss attributable to members of the parent entity		(3,277,368)	(5,266,453)
		(3,664,787)	(5,613,420)
Other comprehensive income			
Exchange difference on translating foreign operations	_	(111,177)	(437,677)
Other comprehensive loss for the period, net of tax		(111,177)	(437,677)
Total comprehensive loss for the period	=	(3,775,964)	(6,051,097)
Loss attributable to minority interests		(387,419)	(346,967)
Loss attributable to members of the parent entity	_	(3,388,545)	(5,704,130)
	_	(3,775,964)	(6,051,097)
Basic loss per share (cents per share)	10	(38.27)	(80.60)
Diluted loss per share (cents per share)	10	(38.27)	(80.60)

 $\label{thm:company} \textit{The accompanying notes form part of these financial statements.}$

Condensed Consolidated Statement of Financial Position

Assets Current Assets 133,790 2,746,409 Cash and cash equivalents 133,790 2,746,409 Trade and other receivables 233,460 372,590 Inventories 4 1,708,595 1,957,147 Loan receivable 5 550,000 Total Current Assets 2,625,845 5,076,146 Non-Current Assets 6 390,186 398,967 Other financial assets 6 390,186 398,967 Other financial assets 7 31,635,602 31,713,603 Intangible assets 7 31,635,602 31,713,603 Total Non-Current Assets 32,382,130 32,625,345 Total Assets 35,007,975 37,701,491 Liabilities Current Liabilities
Cash and cash equivalents 133,790 2,746,409 Trade and other receivables 233,460 372,590 Inventories 4 1,708,595 1,957,147 Loan receivable 5 550,000 - Total Current Assets 2,625,845 5,076,146 Non-Current Assets 8 390,186 398,967 Other financial assets 42,693 64,110 Property, plant and equipment 313,649 448,665 Intangible assets 7 31,635,602 31,713,603 Total Non-Current Assets 32,382,130 32,625,345 Total Assets 35,007,975 37,701,491 Liabilities
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Non-Current Assets Right-of-use assets 6 390,186 398,967 Other financial assets 42,693 64,110 Property, plant and equipment 313,649 448,665 Intangible assets 7 31,635,602 31,713,603 Total Non-Current Assets 32,382,130 32,625,345 Total Assets 35,007,975 37,701,491 Liabilities
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Intangible assets 7 31,635,602 31,713,603 Total Non-Current Assets 32,382,130 32,625,345 Total Assets 35,007,975 37,701,491 Liabilities
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Total Assets 35,007,975 37,701,491 Liabilities
Liabilities
Current Liabilities
Trade and other payables 2,127,461 1,510,045
Lease liabilities 8 133,288 116,709
Total Current Liabilities 2,260,749 1,626,754
Non-Current Liabilities
Lease liabilities 8 360,902 384,199
Total Non-Current Liabilities 360,902 384,199
Total Liabilities 2,621,651 2,010,953
Net Assets 32,386,324 35,690,538
Equity
Issued capital 9 43,745,957 43,745,957
Reserves 30,880,280 30,651,454
Accumulated losses (42,471,626) (39,194,258)
Parent entity interest 32,154,611 35,203,153
Minority interest 231,713 487,385
Total Equity 32,386,324 35,690,538

Condensed Consolidated Statement of Changes in Equity

	Issued Capital (\$)	Accumulated Losses (\$)	Foreign Currency Reserve (\$)	Performance Rights Reserve (\$)	Share-Based Payments Reserve (\$)	Contribution Reserve (\$)	Total (\$)	Minority interest (\$)	Total Equity (\$)
Balance at 1 July 2021	36,651,436	(27,248,955)	(162,693)	26,608,570	1,981,281	1	37,829,639	1	37,829,639
Loss for the period	I	(5,266,453)	1	ı	ı	1	(5,266,453)	(346,967)	(5,613,420)
Other comprehensive income	1	1	(437,677)	1	,	,	(437,677)	1	(437,677)
Total comprehensive loss for the period	I	(5,266,453)	(437,677)	1	ı	1	(5,704,130)	(346,967)	(6,051,097)
Transaction with minority interest	ı	1	1	1	ı	1,696,752	1,696,752	1,026,384	2,723,136
Shares issued during the period	4,794,521	1	1	ı	1	ı	4,794,521	1	4,794,521
Issue of performance rights to Directors	1	1	1	707,424	1	1	707,424	1	707,424
Share-based payments	ı	1	1	1	151,704	ı	151,704	1	151,704
Share options exercised	343,750	1	1	-	1	ı	343,750	1	343,750
Balance at 31 December 2021	41,789,707	(32,515,408))	(600,370)	27,315,994	2,132,985	1,696,752	39,819,660	679,417	40,499,077
Balance at 1 July 2022	43,745,957	(39,194,258)	(482,190)	27,112,223	2,213,080	1,808,341	35,203,153	487,385	35,690,538
Loss for the period	1	(3,277,368)	1	1	1	1	(3,277,368)	(387,419)	(3,664,787)
Other comprehensive income	ı	1	(111,177)	ı	1	ı	(111,177)	ı	(111,177)
Total comprehensive loss for the period	I	(3,277,368)	(111,177)	ı	I	ı	(3,388,545)	(387,419)	(3,775,964)
Transaction with minority interest	ı	1	1	,	ı	36,638	36,638	131,747	168,385
Share-based payments	1	1	1	260,599	42,766	1	303,365	ı	303,365
Balance at 31 December 2022	43,745,957	(42,471,626)	(593,367)	27,372,822	2,255,846	1,844,979	32,154,611	231,713	32,386,324

Condensed Consolidated Statement of Cash Flows

	Notes (\$)	31 December 2022 (\$)	31 December 2021 (\$)
		Inflows/(Out	flows)
Cash flows from operating activities			
Receipts from customers		122,626	702,461
Payments to suppliers and employees		(3,331,159)	(4,711,807)
Payments for research		(385,531)	(605,494)
Interest received		3	2
Interest paid		(10,530)	(10,482)
Net cash (used in) operating activities		(3,604,591)	(4,625,320)
Cash flows from investing activities			
Repayment of third party loan	5	950,000	
Net cash from investing activities	_	950,000	
Cash flows from financing activities			
Proceeds from issue of shares		_	4,794,521
Proceeds from issue of shares - subsidiary		_	1,961,323
Proceeds from issue of options		-	343,750
Net cash from financing activities	_	_	7,099,594
	_		.,000,00
Net (decrease)/ increase in cash held		(2,654,591)	2,474,274
Effect of exchange rate fluctuations on cash held		41,972	165,854
Cash and cash equivalents at the beginning of the period	_	2,746,409	4,971,116
Cash and cash equivalents at the end of the period		133,790	7,611,244



 $\label{thm:companying} \textit{The accompanying notes form part of these financial statements.}$

1. Statement of Significant Accounting Policies

Statement of compliance

These half-year financial statements are general purpose financial statements prepared in accordance with the requirements of the *Corporations Act 2001*, applicable accounting standards including AASB 134 'Interim Financial Reporting', Accounting Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board ('AASB'). Compliance with AASB 134 ensures compliance with IAS 34 'Interim Financial Reporting'.

This condensed half-year financial report does not include full disclosures of the type normally included in an annual financial report. Therefore, it cannot be expected to provide as full an understanding of the financial performance, financial position and cash flows of the Group as in the full financial report. It is recommended that this financial report be read in conjunction with the annual financial report for the year ended 30 June 2022 and any public announcements made by Zelira Therapeutics Limited during the half-year in accordance with continuous disclosure requirements arising under the *Corporations Act 2001* and the ASX Listing Rules.

The accounting policies adopted and methods of computation are consistent with those of the previous financial year and corresponding half-year reporting period. The interim financial statements were authorised for issue on 28 February 2023.

Basis of preparation

The half-year report has been prepared on a historical cost basis except for the revaluation of certain financial instruments to fair value. Cost is based on the fair value of the consideration given in exchange for assets. The Company is domiciled in Australia and all amounts are presented in Australian dollars, unless otherwise noted. For the purpose of preparing the interim report, the half-year has been treated as a discrete reporting period.

Going Concern

The Company incurred a loss of \$3,664,787 for the period ended 31 December 2022 and a net cash outflow from operating activities amounting to \$3,604,591.

The ability of the entity to continue as a going concern is dependent on Zelira continuing to grow revenues for both current and new products and/or securing additional funding through capital raising activities or via loan funds to continue its operational and marketing activities. Should these initiatives be unsuccessful, there is a material uncertainty that may cast significant doubt as to the ability of the Group to continue as a going concern.

The directors have reviewed the Group's financial position and are of the opinion that the use of the going concern basis of accounting is appropriate as they believe the Group will be able to generate sufficient revenue or secure funds to meet its commitments.

There are a number of inherent uncertainties relating to the Group's future plans including but not limited to:

- whether the Group is able to generate sufficient revenue from HOPE 1[™] and HOPE 2[™], its Oral Care range of products, or its RAF FIVE[™] range of products;
- whether the Group is able to generate sufficient revenue from licensing its Zyraydi[™] technology;
- whether the Group is able to successfully capitalise on its distribution agreements in both German and New Zealand;
- whether the Company can generate additional cash from the sale of its 40,000,000 Creso shares;
- whether the Company will be able to raise equity in this current market; and
- whether the Group would be able to secure any other sources of funding.

Significant accounting judgments and key estimates

The preparation of half-year financial reports requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expense. Actual results may differ from these estimates.

In preparing this half-year report, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the financial report for the year ended 30 June 2022.

1. Statement of Significant Accounting Policies (continued)

Adoption of new and revised Accounting Standards

The Group has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

2. Segment Reporting

Identification of reportable operating segments

The Group is organised into two operating segments based on geographic location of operations: Australia and United States of America. These operating segments are based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('CODM')) in assessing performance and in determining the allocation of resources.

The CODM reviews EBITDA (earnings before interest, tax, depreciation and amortisation). The accounting policies adopted for internal reporting to the CODM are consistent

with those adopted in the financial statements. The information reported to the CODM is on a monthly basis.

Intersegment receivables, payables and loans

Intersegment loans are initially recognised at the consideration received. Intersegment loans receivable and loans payable that earn or incur non-market interest are not adjusted to fair value based on market interest rates. Intersegment loans are eliminated on consolidation.

Operating segment information

The following tables present revenue and profit/loss information and certain asset and liability information regarding business segments for the half years ended 31 December 2022 and 31 December 2021.

2. Segment Reporting continued

Segment Reporting 31 December 2022			
	Australia (\$)	USA (\$)	Total (\$)
Segment revenues	65,368	11,581	76,949
Segment loss before income tax expense	(790,530)	(2,874,257)	(3,664,787)
Segment assets	32,913,540	2,094,435	35,007,975
Segment liabilities	(667,468)	(1,954,183)	(2,621,651)

Segment Reporting 31 December 2021			
Segment revenues	28,920	698,779	727,699
Segment loss before income tax expense	(3,413,946)	(2,199,474)	(5,613,420)
Segment assets	33,437,944	8,412,920	41,850,864
Segment liabilities	(244,976)	(1,106,811)	(1,351,787)

3. Revenue

	Six months to 31 December 2022 (\$)	Six months to 31 December 2021 (\$)
Sale of goods	76,949	727,699
_	76,949	727,699
Disaggregation of revenue The disaggregation of revenue from the sale of goods is as follows:		
Sale of Zenivol® and HOPE® – Australia	65,368	28,920
Sale of Oralcare products – US	3,950	627,881
Other sales – US	7,631	70,898
	76,949	727,699

4. Inventories

	31 December 2022 (\$)	30 June 2022 (\$)
Raw materials	624,326	646,774
Work in progress	571,292	550,515
Finished goods	512,977	759,858
	1,708,595	1,957,147

5. Loan Receivable

	Six months to 31 December 2022 (\$)	Year to 30 June 2022 (\$)
Opening balance	-	-
Loan to Health House International Limited	-	1,510,000
Provision for expected credit loss	-	(1,510,000)
Repayment of loan	(950,000)	-
Reversal of expected credit loss	1,500,000	<u>-</u>
Closing Balance	550,000	-

On 24 February 2022, the Company announced the proposed acquisition of Health House International Ltd ('Health House'). To assist Health House with its short-term working capital requirements, the Company agreed to provide a \$1.5 million short-term loan facility to Health House. On 22 June 2022, the Company announced the termination of the Scheme Implementation Deed with Health House.

On 29 July 2022 Health House announced they have signed a non-binding term sheet with Creso Pharma Limited ('Creso') for Creso to acquire Health House ('Term Sheet').

Following a review of the Health House cash position as at 30 June 2022 and the non-binding nature of the Term Sheet, the Company determined it appropriate to recognise a provision for doubtful debts in relation to the present value of the loan and accrued interest until the proposed acquisition was more certain.

On 8 September 2022, Zelira announced that it had agreed with Health House to extend the date for repayment of its short-term loan provided in February 2022 to 31 October 2022. Following agreement, Zelira received an initial payment of \$400,000.

On 21 November 2022, Zelira announced a variation to the loan agreement as follows:

- · Creso Pharma Limited("Creso") on behalf of Health House to make an immediate payment of \$550,000; and
- Subject to shareholder approval on or prior to 31 December 2022, Creso agrees to issue Zelira that number of Creso shares equal to \$800,000 divided by the closing price of Creso's ordinary shares as traded on the ASX the day prior to the Shareholder Meeting.

Zelira received \$550,000 on 21 November 2022.

As disclosed in Note 15, On 10 January 2023, Zelira announced that it had released Health House of any obligation under the loan agreement following receipt of 40,000,000 Creso shares from Creso at an issue price of \$0.02 being equal to \$800,000.

6. Right-of-use Assets

Carrying value – Premises		
	31 December 2022 (\$)	30 June 2022 (\$)
Cost	734,374	649,157
Accumulated depreciation	(344,188)	(250,190)
Carrying value as at 31 December 2022	390,186	398,967

Reconciliation - Premises		
	31 December 2022 (\$)	30 June 2022 (\$)
Opening balance	398,967	478,996
Additions	43,865	-
Foreign currency differences	7,014	34,948
Depreciation expense	(59,660)	(114,977)
Closing balance	390,186	398,967

7. Intangible Assets

Reconcilliation				
	Trademarks (\$)	Favourable leases (\$)	Goodwill (\$)	Total (\$)
Six months to 31 December 2022				
Opening balance	873,842	92,678	30,747,083	31,713,603
Amortisation expense	(58,868)	(19,133)	-	(78,001)
Closing balance	814,974	73,545	30,747,083	31,635,602
Year to 30 June 2022				
Opening balance	1,109,314	169,206	30,747,083	32,025,603
Amortisation expense	(235,472)	(76,528)	-	(312,000)
Closing balance	873,842	92,678	30,747,083	31,713,603

Impairment test for goodwill

Goodwill acquired through the acquisition of Ilera Therapeutics has been allocated to a single cash generating unit (CGU) – the USA – for impairment testing.

The Directors assessed the carrying value of goodwill at balance date and are of the opinion that the intangible assets associated with the US business continue to have value. The recoverable amount of the goodwill has been determined by a value-in-use calculation using the discounted cash flow method, based on a five-year projection period.

Key assumptions are those to which the recoverable amount of a CGU is most sensitive. The following key assumptions were used in the discounted cash flow model for the US CGU:

- 29% pre-tax discount rate
- 5% increase in year 5 projected revenue growth rate
- · No significant changes in working capital

Based on the above, the Directors believe the recoverable amount of the goodwill associated with the US CGU exceeds the carrying amount

8. Lease Liabilities

Carrying value		
	31 December 2022 (\$)	30 June 2022 (\$)
Current liabilities	133,288	116,709
Non-current liabilities	360,902	384,199
	494,190	500,908

Reconciliation - Premises		
	Six months to 31 December 2022 (\$)	Year to 30 June 2022 (\$)
Opening balance	500,908	551,081
Additions	43,865	-
Interest	17,397	36,194
Principal repayments	(76,665)	(129,142)
Foreign currency differences	8,685	42,775
Closing balance as at 31 December 2022	494,190	500,908

Underlying assets serve as a security for the related lease liabilities. A maturity analysis of future minimum lease payments is presented below:

		Lease payn	nents due	
31 December 2022	< 1 year (\$)	1 – 2 years (\$)	2 - 5 years (\$)	Total (\$)
Lease payments	164,080	166,560	219,997	550,637
Interest	(28,847)	(19,585)	(8,015)	(56,447)
Net present value	135,233	146,975	211,982	494,190

9. Issued Capital

Ordinary shares				
			31 December 2022 (\$)	30 June 2022 (\$)
Issued and fully paid			43,745,957	43,745,957
	Six months to 31 December 2022 (No.)	Year to 30 June 2022 (No.)	Six months to 31 December 2022 (\$)	Year to 30 June 2022 (\$)
Movements in ordinary shares on issue				
At start of period	9,577,116	1,190,322,966	43,745,957	36,651,436
Shares issued from exercise of options	-	11,000,000	-	343,750
Shares issued to sophisticated investors	-	79,908,676	-	4,794,521
Conversion of performance rights	-	393,870,322	-	1,956,250
Share consolidation (175:1)	-	(1,665,524,848)	-	-
At end of period	9,577,116	9,577,116	43,745,957	43,745,957

10. Loss Per Share

	31 December 2022 (\$)	30 June 2022 (\$)
(a) (Loss) used in the calculation of basic and dilutive loss per share	(3,664,787)	(5,613,420)
Basic loss per Share Basic loss per Share	Number of Shares	Number of Shares (Restated)
(b) Weighted average number of ordinary shares outstanding during the year used in the calculation of basic loss per share	9,577,116	6,964,147
Basic (loss) per share (cents per share)	(38.27)	(80.60)
Diluted loss per Share	Number of Shares	Number of Shares (Restated)
(c) Weighted average number of ordinary shares outstanding during the year used in the calculation of diluted loss per share	9,577,116	6,964,147
Diluted (loss) per share (cents per share)	(38.27)	(80.60)

The number of ordinary shares used in the calculated of Diluted Loss per Share is the same as the number used in the calculation of Basic Loss per Share in the period ending 31 December 2022 and the prior period ended 31 December 2021, as options and performance rights are not considered dilutive as a loss was incurred in both periods.

11. Share-Based Payments

Unlisted Options (as at Balance date)

Set out below are the summaries of options granted as share based payments during the current period and previous periods:

	Number	Grant date	Expiry date	Exercise price (\$)	Fair value at grant date	Vesting date
1	28,572	11 August 2020	11 August 2023	\$17.50	\$0.0195	11 August 2020
2	28,572	11 August 2020	11 August 2023	\$26.25	\$0.0156	2 December 2020
3	28,572	11 August 2020	11 August 2023	\$35.00	\$0.0130	2 December 2020
4	28,572	11 August 2020	11 August 2023	\$49.00	\$0.0102	2 December 2021 subject to vesting conditions
5	28,572	11 August 2020	11 August 2023	\$52.50	\$0.0096	2 December 2021 subject to vesting conditions
6	22,858	11 September 2020	11 September 2023	\$17.50	\$0.0151	9 November 2020
7	22,858	11 September 2020	11 September 2023	\$26.25	\$0.0114	9 November 2021 subject to vesting conditions
8	22,858	11 September 2020	11 September 2023	\$35.00	\$0.0090	9 November 2021 subject to vesting conditions
9	22,858	11 September 2020	11 September 2023	\$49.00	\$0.0066	9 November 2022 subject to vesting conditions
10	22,858	11 September 2020	11 September 2023	\$52.50	\$0.0062	9 November 2022 subject to vesting conditions
11	22,858	20 January 2021	20 January 2024	\$17.50	\$0.0356	20 January 2021
12	22,858	20 January 2021	20 January 2024	\$26.25	\$0.0291	3 March 2021
13	22,858	20 January 2021	20 January 2024	\$35.00	\$0.0246	3 March 2021
14	22,858	20 January 2021	20 January 2024	\$49.00	\$0.0195	3 March 2022
15	22,858	20 January 2021	20 January 2024	\$52.50	\$0.0186	3 March 2022
16	17,715	22 October 2021	22 October 2025	\$17.50	\$0.0070	22 October 2022
17	17,715	22 October 2021	22 October 2025	\$26.25	\$0.0046	22 October 2023
18	17,715	22 October 2021	22 October 2025	\$35.00	\$0.0033	22 October 2023
19	17,715	22 October 2021	22 October 2025	\$49.00	\$0.0021	22 October 2024
20	17,715	22 October 2021	22 October 2025	\$52.50	\$0.0019	22 October 2024
21	11,429	22 October 2021	22 October 2025	\$17.50	\$0.0070	22 October 2022
22	31,431	22 October 2021	22 October 2025	\$26.25	\$0.0046	22 October 2022
23	42,860	22 October 2021	22 October 2025	\$43.75	\$0.0024	22 October 2023
24	42,860	22 October 2021	22 October 2025	\$52.50	\$0.0019	22 October 2024

11. Share-Based Payments continued

The fair value of the equity-settled options granted is estimated as at the date of grant using the Black and Scholes model taking into account the terms and conditions upon which they were granted.

	Expected volatility (%)	Risk-free interest rate (%)	Expected life of options (years)	Exercise price (cents)	Grant date share price (cents)
1	86	0.26	3	\$17.50	6.2
2	86	0.26	3	\$26.25	6.2
3	86	0.26	3	\$35.00	6.2
4	86	0.26	3	\$49.00	6.2
5	86	0.26	3	\$52.50	6.2
6	80	0.26	3	\$17.50	5.7
7	80	0.26	3	\$26.25	5.7
8	80	0.26	3	\$35.00	5.7
9	80	0.26	3	\$49.00	5.7
10	80	0.26	3	\$52.50	5.7
11	83	0.1	3	\$17.50	9.7
12	83	0.1	3	\$26.25	9.7
13	83	0.1	3	\$35.00	9.7
14	83	0.1	3	\$49.00	9.7
15	83	0.1	3	\$52.50	9.7
16	61	0.1	4	\$17.50	4.2
17	61	0.1	4	\$26.25	4.2
18	61	0.1	4	\$35.00	4.2
19	61	0.1	4	\$49.00	4.2
20	61	0.1	4	\$52.50	4.2
21	61	0.1	4	\$17.50	4.2
22	61	0.1	4	\$26.25	4.2
23	61	0.1	4	\$43.75	4.2
24	61	0.1	4	\$52.50	4.2

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome. No other features of options granted were incorporated into the measurement of fair value.

12 Financial Instruments

Fair value measurement

Financial assets and financial liabilities measured at fair value in the statement of financial position are grouped into three levels of a fair value hierarchy.

The three levels are defined based on the observability of significant inputs to the measurement, as follows:

- · Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and
- · Level 3: unobservable inputs for the asset or liability.

The Group has a number of financial instruments which are not measured at fair value in the statement of financial position. The Directors consider that the carrying amounts of current receivables, loan receivable, other financial assets and current payables are considered to be a reasonable approximation of their fair values.

13 Contingent Liabilities

There has been no change in contingent liabilities since the last annual reporting date.

14 Related Party Transactions

There are no related party transactions requiring disclosure since the last annual reporting date.

15 Events Subsequent to Reporting Date

On 10 January 2023, Zelira announced that it had released Health House International Limited of any obligation under the loan agreement following receipt of 40,000,000 Creso shares from Creso at an issue price of \$0.02 being equal to \$800,000.

On 30 January 2023, Zelira received a \$1,141,000 cash refund under the Federal Government's Research and Development Tax Incentive Scheme.

On 15 February 2023, Zelira announced the establishment of the Hope®1 special purpose vehicle (SPV) to facilitate investment to fund Hope®1 US FDA clinical trials. Zelira will retain 55% equity ownership of the SPV, contribute its HOPE® 1 product, IP and real-world data and manage the SPV as part of its business platform.

Cash investors will contribute circa US\$35 million to fund the SPV and US FDA trials for HOPE® 1 in exchange for a maximum cumulative equity interest of 45% of the SPV. US based Cantheon Capital LLC, has agreed to provide cornerstone funding for the SPV of US\$8.6m. SW4 Advisors Limited (SW4 Partners) has been mandated to raise the remaining circa US\$26 million required for the SPV.

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.

On 20 February 2023, Greg Blake was promoted from VP - Global Head of Commercial and Partnering to Executive Director. Mr Blake has been employed by Zelira since 2020, Greg brings extensive commercial and operational leadership experience in the pharmaceutical and biotech sectors both within Australia and internationally. Greg has led the strategic development and commercialisation of a number of products across a range of therapeutic categories.

DIRECTORS' DECLARATION

In the opinion of the directors of Zelira Therapeutics Limited ('the Company'):

- 1. The attached financial statements and notes thereto are in accordance with the Corporations Act 2001 including:
 - a. complying with Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements; and
 - b. giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half-year then ended; and
- 2. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is signed in accordance with a resolution of the Board of Directors made pursuant to s303(5) of the *Corporations Act 2001.*

Oludare Odumosu

Managing Director

28 February 2023



INDEPENDENT AUDITOR'S REVIEW REPORT

To the members of Zelira Therapeutics Limited

Report on the Condensed Half-Year Financial Report

Conclusion

We have reviewed the accompanying half-year financial report of Zelira Therapeutics Limited ("the company") which comprises the condensed consolidated statement of financial position as at 31 December 2022, the condensed consolidated statement of comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration, for the Group comprising the company and the entities it controlled at the half-year end or from time to time during the half-year.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Zelira Therapeutics Limited does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity. Our responsibilities are further described in the Auditor's responsibilities for the review of the financial report section of our report. We are independent of the company in accordance with the auditor independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (including Independence Standards) (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Material uncertainty related to going concern

We draw attention to Note 1 in the financial report, which indicates that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

Responsibility of the directors for the financial report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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HLB Mann Judd (WA Partnership) ABN 22 193 232 714

Level 4, 130 Stirling Street, Perth WA 6000 / PO Box 8124 Perth BC WA 6849 T: +61 (0)8 9227 7500 E: mailbox@hlbwa.com.au Liability limited by a scheme approved under Professional Standards Legislation.

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Auditor's responsibility for the review of the financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

HLB Mann Judd Chartered Accountants

HLB Mann Judd

Perth, Western Australia 28 February 2023

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Diallounds.

Partner

Corporate Directory

CHAIRMAN

Osagie Imasogie

MANAGING DIRECTOR

Oludare Odumosu

NON-EXECUTIVE DIRECTORS

Tim Slate

Lisa Gray

EXECUTIVE DIRECTOR

Greg Blake

COMPANY SECRETARY

Tim Slate

Principal & Registered Office

Level 3, 101 St George's Terrace Perth WA 6000

Telephone: (08) 6558 0886 Facsimile: (08) 6316 3337

Auditors

HLB Mann Judd (WA Partnership)

Level 4, 130 Stirling Street Perth WA 6000

Share Register

Perth WA 6000

Computershare Investor Services Pty Ltd

Level 2, Reserve Bank Building 45 St George's Terrace

Telephone: (08) 08 9323 2000 Facsimile: (08) 9323 2033

Securities Exchange Listing

Australian Securities Exchange (Home Exchange: Perth, Western Australia)

Code: ZLD

USA

OTCQB

Code: ZLDAF





Zelira Therapeutics Level 3, 101 St Georges Terrace, Perth WA 6000 Phone +61 8 6558 0886

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