

ZELIRA THERAPEUTICS

A Global Biopharmaceutical Company Developing and Commercialising Clinically Validated Cannabinoid-Based Medicines

AGM 17 NOVEMBER 2022

ASX: ZLD
OTCQB:ZLDAF
zeliratx.com



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Global Board of Directors



Osagie Imasogie
Chairman

- Over 30 years in the field of law, finance, business management, healthcare and the pharmaceutical industry.
- Founder and VP for Glaxo Smith Kline ("GSK") Ventures.
- Co-founder and the Senior Managing Partner of PIPV Capital, a Private Equity Firm focused on the Life Sciences vertical.
- Chairman and Founder of Ilera Healthcare, Ilera Therapeutics, iCeutica Inc., Churchill Pharma, Ception Therapeutics Inc. and Trigenesis Therapeutics Inc.



USA



Dr. Oludare Odumosu
Global CEO

- Post-clinical development of Iroko Pharmaceutical's Zorvolex® Tivorbex® and Vivlodex® through FDA approvals and successful US market commercialization.
- Founding COO of Ilera Healthcare. Ilera Healthcare was acquired by TerraAscend (TER.CN) for \$225M Mid 2019. Founding CSO/EVP of Ilera Therapeutics.



GLOBAL



Lisa Gray
Director

- Served as COO for Glaxo Smithkline ("GSK") Ventures.
- Was Co-Founder and Vice Chair of Ilera Healthcare, and lead on the sale of this business to TerraAscend.
- Vice Chair for Advanced Biomedics Holdings.
- Served as Vice Chair for Ilera Therapeutics.
- Co-Founder and Managing Partner of PIPV Capital.



USA



Tim Slate
Non-Executive Director

- Founder, Director of accounting, secretarial and advisory firm Catalyst Corporate
- Appointed Company Secretary on 16 December 2016
- Over 15 years of experience in the ASX, accounting and secretarial advisory sector.



AUS



VOTING


How to Vote


When the poll is open, select the vote icon at the top of the screen


To vote, select either For, Against or Abstain


You will see a vote confirmation

To change or cancel your vote “click here to change your vote” at any time until the poll is closed


Broadcast


Vote


Q&A



Documents

Items of business

2A Re-elect Mr Sam Sample as a Director

FOR	AGAINST	ABSTAIN
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2B Re-elect Mrs Jane Citizen as a Director



We have received your vote for
[Click here to change your vote](#)




QUESTIONS


How to ask a Question


To ask a written question select the Q & A icon


Select the topic your question relates to from the drop-down list

Type your question in the text box and press the send button


Broadcast


Vote


Q&A


Documents

Your question(s)

You may enter a question using the field below

Select Topic ▼

Questions are limited to 2,000 characters

0 Character(s)

Send

To ask a verbal question follow the instructions below the broadcast window.



Chairman's Address



CEO & Managing Director's Address



Zelira is a global biopharmaceutical company researching, developing, and commercialising clinically validated cannabinoid-based medicines.

It offers investors exposure to a rapidly emerging global industry at a very attractive valuation, with multiple shots on goal - to create significant value.



Milestones achieved in 2021



Levin health licensing and management agreement signed to conduct chronic pain treatment clinical trial on retired athletes

3 Jun



Breakthrough research at Curtin University (Australia) demonstrates significant uptake of CBD into the brain

18 Jun



Zelira® US Observational Clinical Pain Trial receives IRB approval

12 Jul



Zelira® raises US\$5 million from Quincy Street Capital LLC, a US-based family office fund

20 Oct



Zelira® partners with Health House International via exclusive distribution agreement to launch CBD toothpaste in the United Kingdom

15 Jun



Clinical trial results of Zelira's Zenivol® published in prestigious peer-reviewed journal SLEEP

21 Jun



Zelira® Launches RAF FIVE™ Acne Treatment products through its dermatology focussed subsidiary

23 Sept



Zelira® Develops EDCDM technology for making free flow powder from cannabinoid distillate and signs new licensing deal

3 Nov



Milestones achieved YTD in 2022



Zelira®, in partnership with CVSCM launched ITURA™ Advance Relief Cream

9 May



Progressed arm one (enrolment of 20 patients) of a three-arm diabetic nerve pain drug trial, a head-to-head trial against a Big Pharmaceutical company's multi-billion dollar revenue drug

30 May



Zenivol® receives formal BfArM approval in Germany

13 Jul



HOPE®1 results of longitudinal, real-world data (RWD) study in autism support safe and effective use

17 May



Zenivol® results of longitudinal, RWD support its effectiveness in managing the treatment of insomnia

8 Jun



Total revenue in FY22 was up 132% to \$1.5 million (FY21: \$0.7 million)



Zelira expands into Germany with ZENIVOL®



- In July 2022 Zenivol® received formal approval from German regulatory authority BfArM, for commercialisation by Adjupharm GmbH
- Formal approval of Zenivol® is a major milestone in Zelira's expansion into Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest market
- Advances the Company's global commercialisation strategy to grow its Pharmaceutical (Rx) portfolio
- Expands the availability of Zenivol® beyond Australia for the first time
- Reinforces the pharmaceutical quality of Zelira's Australian production capabilities, including the safety and efficacy of Zelira's clinically validated cannabinoid-based medicines .



FUNDRAISING

At a Group level, fundraising values Zelira® at

A\$122.8M

*US\$5 million raised from
US-based family office fund,
Quincy Street Capital LLC*

US\$3.5M A\$4.79M

*US\$3.5 million (A\$4.79 million) via a placement of
Zelira® fully paid ordinary shares*

US\$1.5M A\$2.05M

*via an equity investment in Ilera Derm LLC (Zelira
Dermatology) for a 3% shareholding in that company,
valuing Zelira Dermatology at US\$50 million.*



Australian operations remain a core and important part of the Company with world class clinical trials to continue to be conducted in Australia and managed by Australian-based employees.



February 2021, Zelira® announced management changes designed to strengthen the Company's focus on global markets, and in particular the US.



Milestones of US based product sales exceeded US \$1 million thereby satisfying the Class A Performance rights held by Zelira directors and the original Ilera Therapeutics shareholders who have received 393,870,322 shares.



\$1.3 MILLION

January 2022, Zelira® received \$1.3M cash refund under the Australian Federal Government's R&D Tax Incentive Scheme

175:1 CAPITAL CONSOLIDATION

*In April 2022, Zelira completed a consolidation
of its issued securities on a 175:1 basis*



REVENUE STREAMS



1

Launch & Learn **Rx**

Autism
Aged disorders
Insomnia

2

Oral Health **OTC**

Toothpaste
Additional Products, 2022 Launch



3

Dermatology **OTC**

Five acne treating
products launched 2021



4

Clinical Trials **Rx**

Insomnia
Opioid Sparing
Autism



5

Pharma **Rx**

Pain
GI



RAPID COMMERCIALISATION STRATEGY



Launch

- Generate proprietary formulations
- Launch products in global markets
- Rapid path to revenues
- Low Capex model



Learn

- Collect real-world patient data
- Refine product to meet patient needs
- Real-time response to market



Develop

- Patient data informs and de-risks design of clinical trial
- 43% costs reimbursable via Australian R&D rebate program
- Supports path to registration



PIPELINE



HOPE[®] for behaviours associated with Autism Spectrum Disorder Rx



Autism Market

- Autism affects 1.8% children¹
- Only 2 FDA approved drugs for Autism
- Existing medication has significant side-effects
- Global ASD market \$3.2B²

1. Center for Disease Control and Prevention. Autism Spectrum Disorder: Data & Statistics. Accessed December 14, 2017 (<https://www.cdc.gov/ncbddd/autism/data.html>) 2. <https://www.medgadget.com/2019/12/autism-spectrum-disorder-therapeutics-market-size-growth-analysis-insights-and-forecast-2019-2026.html>

Overview

Two published, longitudinal real world data studies demonstrated improvements in autism related behaviours and quality of life for patient and carers with HOPE[®]



US Revenues: Licensed in Louisiana and Washington DC (Deal Structure: Upfronts + double digit royalty).



Manufacturing agreement for Australia: Extractas Biosciences



Distribution agreement for Australia: Health House



Distribution agreement for NZ: NUBU Pharmaceuticals

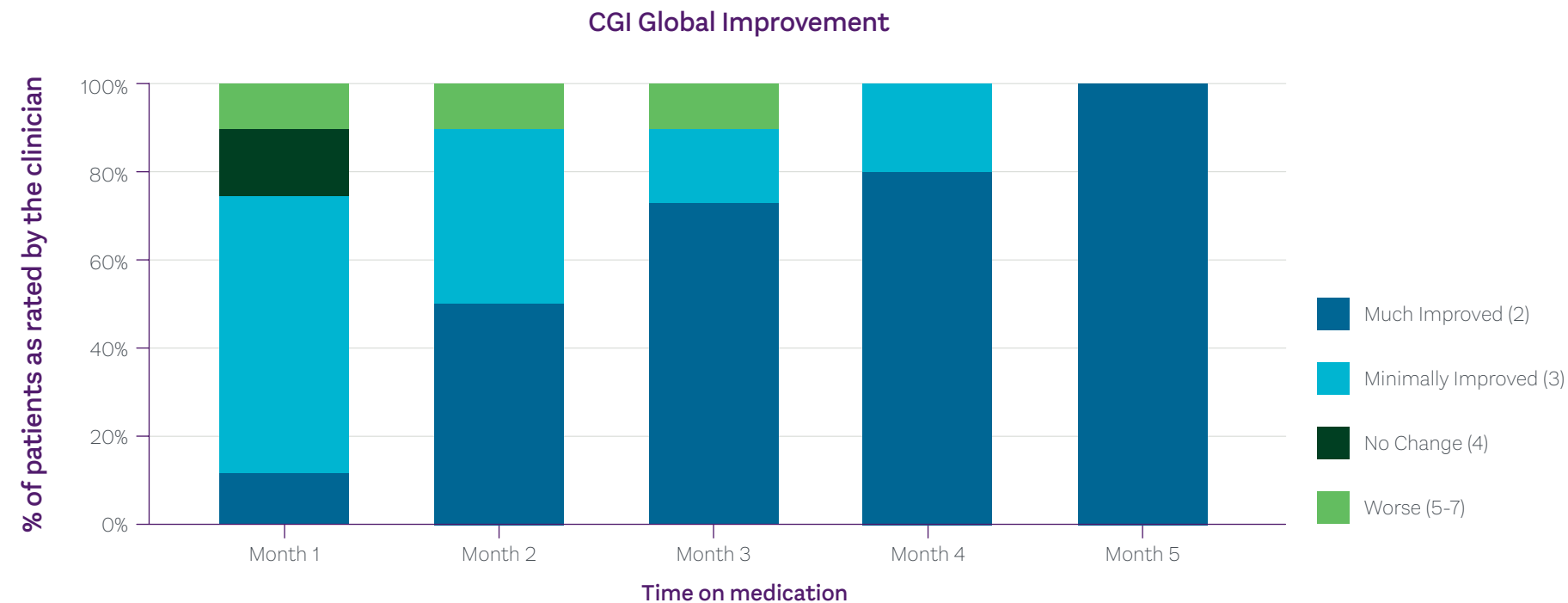


Launched and generating revenue in Australia, Washington, D.C., and Louisiana



Zelira sponsored – HOPE[®] longitudinal, real-world data study

Clinical Global Impression (CGI) Global Improvement and Efficacy scores of Emerald HOPE[®] patients



Improvements in CGI Global were observed with generally increasing improvements the longer the patient was on treatment

OBJECTIVE: Investigate the effect of HOPE 1 on behavioural symptoms in people with ASD, ENDPOINTS: Improvement in CGI scores (Clinician and Caregiver) , PATIENTS: N = 45
PATIENT AGE: Mean age of patients was 14.1 years of age; the youngest patient was 5.1 years
DURATION: Mean time on treatment was 4.8 months; maximum treatment time to-date was 8.9 months



Zenivol® for chronic, unresolved insomnia Rx



Insomnia Market

- 30% of adults report symptoms of insomnia¹
- US insomnia market: US\$4 billion by 2021²
- Current medications limited by side-effects

¹ Roth, T. (2007). Insomnia: definition, prevalence, etiology, and consequences. Journal of Clinical Sleep Medicine, 3(5 Suppl), S7–10., 2. <https://www.marketsandmarkets.com/Market-Reports/us-insomnia-market-55727597.html>

Overview

- World's first clinically validated cannabinoid drug for chronic insomnia
- Phase 1B/2A clinical trial confirmed Zenivol® safe, efficacious and improved quality of life
- Significant reduction in insomnia symptoms
- Clinical trial results published in peer reviewed journal of *Sleep*®



Approved by BfArM for German market



Manufacturing agreement for Australia: Extractas Biosciences



Distribution agreement for Australia: Health House



Distribution agreement for Germany: Adjupharm GmbH



Distribution agreement for NZ: NUBU Pharmaceuticals

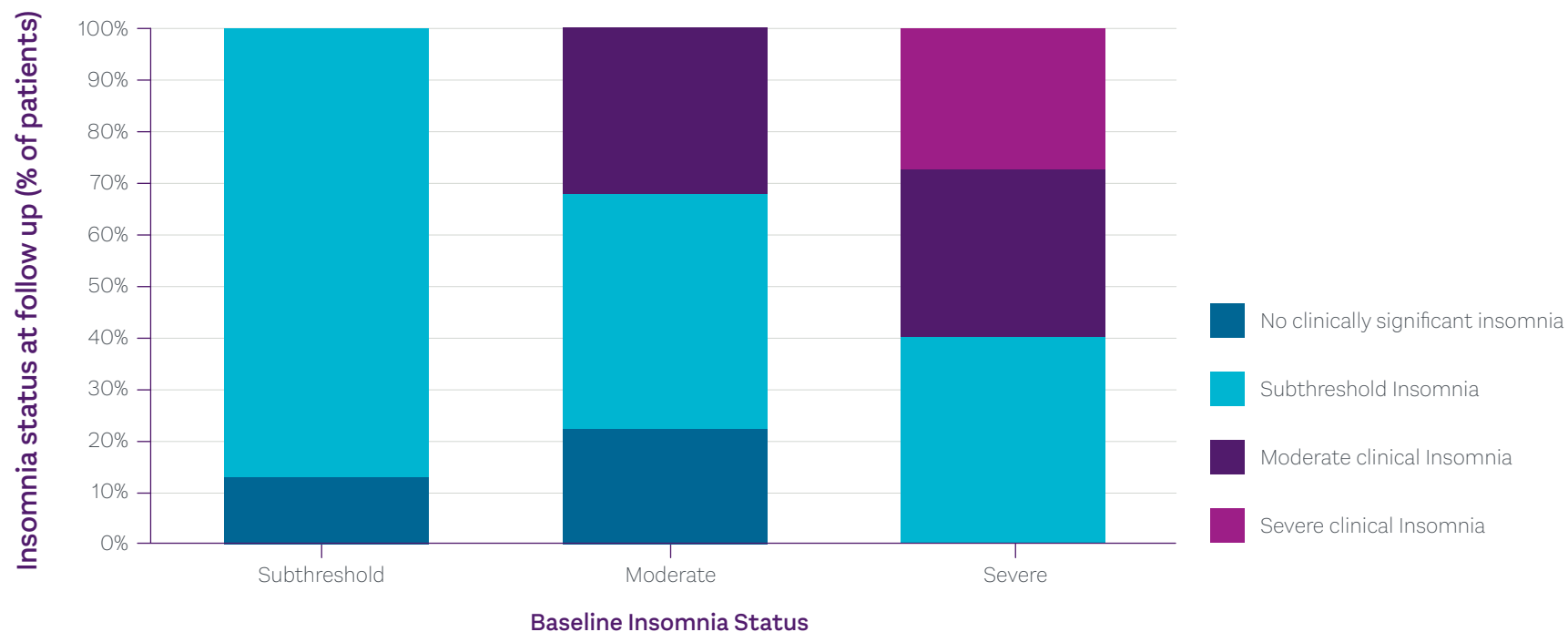


Launched and generating revenue in Australia



Zelira sponsored – ZENIVOL® longitudinal, real-world data study

Change in Insomnia status whilst on ZENIVOL®, as measured by the Insomnia Severity Index (ISI)



Overall, patients taking ZENIVOL® improved from a baseline ISI score of 19.5 (Moderate clinical insomnia) to 14.3 (Subthreshold insomnia levels) ($p < 0.001$).

OBJECTIVE: Investigate the effect of Zenivol in improving sleep in people with chronic insomnia, ENDPOINTS: Improvement in ISI scores (Insomnia Severity Index), PATIENTS: N = 94
PATIENT AGE: The mean age of active patients was 56 years of age with the oldest patient being 77 years of age DURATION: Maximum time to-date that a patient had taken ZENIVOL® was 10.8 months (or 329 days). The mean time on treatment for active ZENIVOL® patients was 4.3 months



Oral Care – SprinJene CBD OTC



Overview

- Full line of CBD oral care products



Toothpaste was launched in Q1 2021 and generating revenue with strong growth potential



Available for purchase on zeliraoralcare.com, sprinjenecbd.com, amazon.com and wholesale distribution channels in the US



Expanded to the UK Market through exclusive distribution agreement with Health House International



Additional Products to be launched in 2022



RAF FIVE™ - Differentiated dermatology OTC

Dr. Karyn Grossman in the News



- Renowned board-certified cosmetic dermatologist
- Trained at Harvard Medical School
- Successfully launched products with clinical and commercial success
- Key opinion leader in all fields of esthetics
- Popular celebrity following
- In-demand resource for high-value media outlets



Overview

- Science-backed Platform Technology
- Focus on significant unmet needs in Dermatology
- Innovative Branding and Market-ready products
- World Class Inventors and Formulators

Zylorma™, a proprietary, patent pending, acne fighting complex with CBD, Salicylic acid and additional compounds to fight bacteria and clogged pores associated with acne, balance sebum production to help eliminate & prevent break-outs

RAF FIVE™ is inspired by a true story. It all started from a fateful bus ride in 1964, when Raphael Mechoulam brought 5 kilo of Lebanese hashish he received from the Israeli Police to his laboratory at the Weizmann Institute in Rehovot. With that material he was able to isolate and identify the psychoactive component in Cannabis, Tetrahydrocannabinol (THC), that had eluded scientists for decades.





RAF FIVE™ Product Range



WASH AWAY GEL CLEANSER
ACNE TREATMENT



SPOT ON ACNE TREATMENT



KICK OFF HYDRATING LOTION BROAD
SPECTRUM SPF 30 SUNSCREEN



AFTER HOURS MOISTURIZING
LOTION ACNE TREATMENT



CLEAR THE WAY
ACNE TREATMENT PADS



Enhanced Distillate Capture and Dissolution Matrix (EDCDM)

Distillate into capsules and tablets, made easy

We have solved two key issues holding back wider acceptance of cannabinoid medicinal products – the difficulty in formulating solid oral dosage drugs with distillate and the low rate of dissolution in the body from capsules and tablets.

PROBLEM

CANNABINOID
DISTILLATE



DIFFICULTY WITH FORMULATION AND DEVELOPMENTS OF FREE FLOW POWDER-BASED CAPSULES AND TABLETS DUE TO NON-UNIFORMITY AND SEPARATING FROM POWDER BED

SOLUTION

CANNABINOID
DISTILLATE



ZYRAYDI™
TECHNOLOGY

CANNABINOID
DISTILLATE



PHARMACEUTICAL GRADE
FREE-FLOWING POWDER BASE
FOR CAPSULES AND TABLETS



IN PRACTICAL TERMS



CANNABINOID DISTILLATE
without ZYRAYDI™ technology



ZYRAYDI™
ingredient matrix



ZYRAYDI™ CAPSULES
AND TABLETS

Zelira Patent Portfolio

Going into 2022-23 Zelira's patent portfolio has been granted or under consideration in 26 countries spanning across the globe. There are 41 patents granted and 100 under prosecution across 9 different therapeutic areas

Therapeutic Area	Granted/Allowed	Under Prosecution/Examination
Cancer compositions	10	12
Skin compositions	3	8
Sleep compositions	7	27
Cancer prognosis	18	-
Autism compositions	-	12
Pain compositions	1	16
PTSD/Anxiety composition	1	11
Opioid sparing compositions	1	13
Encapsulation	0	1
Total	41	100



Corporate Snapshot

Financials (as at 11 November 2022)

	AUD\$
Share Price	1.04
52w Range	0.97 - 7.54
Market Capitalisation	10M
Cash (at 30 Sept 2022)	1.2M

Capital Structure (Fully Diluted²)

Structure		Major Shareholders	
Directors Holdings:	14.6%	Ilera Investors	35.2%
Top 20 Shareholders:	62.2%	Jason Peterson	4.2%
Employee Options:	1.1M	Quincy Street Capital	3.5%

If all performance rights are converted and options exercised

Share Price (Market Data as at 11 November 2022)



Formal Business



AGM RESOLUTIONS

Resolution 1

Adoption of Remuneration Report

To consider and, if thought fit, to pass, with or without amendment, the following as an **non-binding resolution**:

That, for the purposes of section 250R(2) of the Corporations Act and for all other purposes, approval is given for the adoption of the Remuneration Report as contained in the Company's annual financial report for the financial year ended 30 June 2022.

FOR	AGAINST	PROXY DISCRETION	ABSTAIN
781,832	41,669	9,899	396,261



AGM RESOLUTIONS

Resolution 2

Election of Director – Tim Slate

To consider and, if thought fit, to pass, with or without amendment, the following as an **ordinary resolution**:

That, for the purpose of clause 12.7 of the Constitution, ASX Listing Rule 14.4 and for all other purposes, Mr Tim Slate, a Director who was appointed to fill a casual vacancy on 31 January 2022, retires and, being eligible, is elected as a Director as described in the Explanatory Statement.

FOR	AGAINST	PROXY DISCRETION	ABSTAIN
1,976,400	19,768	10,759	5,565



Resolution 3

Approval Of 10% Placement Capacity

To consider and, if thought fit, to pass, with or without amendment, the following as an **special resolution**:

That, for the purposes of Listing Rule 7.1A and for all other purposes, approval is given for the Company to issue up to that number of Equity Securities equal to 10% of the issued capital of the Company at the time of issue, calculated in accordance with the formula prescribed in ASX Listing Rule 7.1A.2 and otherwise on the terms and conditions set out in the Explanatory Statement

FOR	AGAINST	PROXY DISCRETION	ABSTAIN
1,566,091	428,562	11,257	6,582



Resolution 4

Adoption of Incentive Plan

To consider and, if thought fit, to pass, with or without amendment, the following as an ordinary resolution:

That, for the purposes of ASX Listing Rule 7.2 (Exception 13(b)) and for all other purposes, approval is given for the Company to adopt an employee incentive scheme titled “Zelira Therapeutics Employee Option Plan” and for the issue of up to a maximum number of 478,855 securities under that Plan, on the terms and conditions set out in the Explanatory Statement.

FOR	AGAINST	PROXY DISCRETION	ABSTAIN
778,992	432,406	10,759	7,504



AGM RESOLUTIONS

Resolution 5

Replacement of Constitution

To consider and, if thought fit, to pass, with or without amendment, the following as an **special resolution**:

That, for the purposes of section 136(2) of the Corporations Act and for all other purposes, approval is given for the Company to repeal its existing Constitution and adopt a new constitution in its place in the form as signed by the chairman of the Meeting for identification purposes.

FOR	AGAINST	PROXY DISCRETION	ABSTAIN
1,571,693	416,918	10,399	13,482



Thank You

Zelira Therapeutics

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