

ZELIRA THERAPEUTICS

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



ASX: ZLD  
OTCQB:ZLDAF  
zeliratx.com



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**Zelira is a global biopharmaceutical company researching, developing, and marketing 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.



# Overview of Zelira<sup>®</sup> Therapeutics



## Global Markets Strategy

US, Australia, UK and EU footprint to rapidly access the largest, most profitable & fastest growing cannabis markets.



## Clinical Validation Focus

Leading pipeline of products in clinical development for insomnia, chronic pain and autism.



## Global Product Launch

Portfolio of branded, validated products launched globally.



## Revenue Generating

Multiple revenue streams from licensing payments, royalties and direct commercialization.



## Premium Product

Manufacturing Partner-EU GMP Certified.



## Fast Tracking Commercialization

Disruptive 'Launch, Learn, & Develop' model facilitates rapid commercialization.



## Rx & OTC Development and Commercialization strategies

Products developed from Cannabis are Rx, requiring a physician intervention.

Mid/long term revenue.

Products developed from hemp are OTC, as such direct to consumer.

Immediate to mid/long term revenue.



# 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% (see above) 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 .



## SIGNIFICANT EVENTS

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.

### **175:1 CAPITAL CONSOLIDATION**

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

# \$1.3 MILLION



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



# 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



5

Pharma  
**Rx**  
Pain  
GI

4

Clinical Trials  
**Rx**  
Insomnia  
Opioid Sparing  
Autism



## 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<sup>®</sup> for behaviours associated with Autism Spectrum Disorder

## Rx



## Autism Market

- Autism affects 1.8% children<sup>1</sup>
- Only 2 FDA approved drugs for Autism
- Existing medication has significant side-effects
- Global ASD market \$3.2B<sup>2</sup>

## Overview

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



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



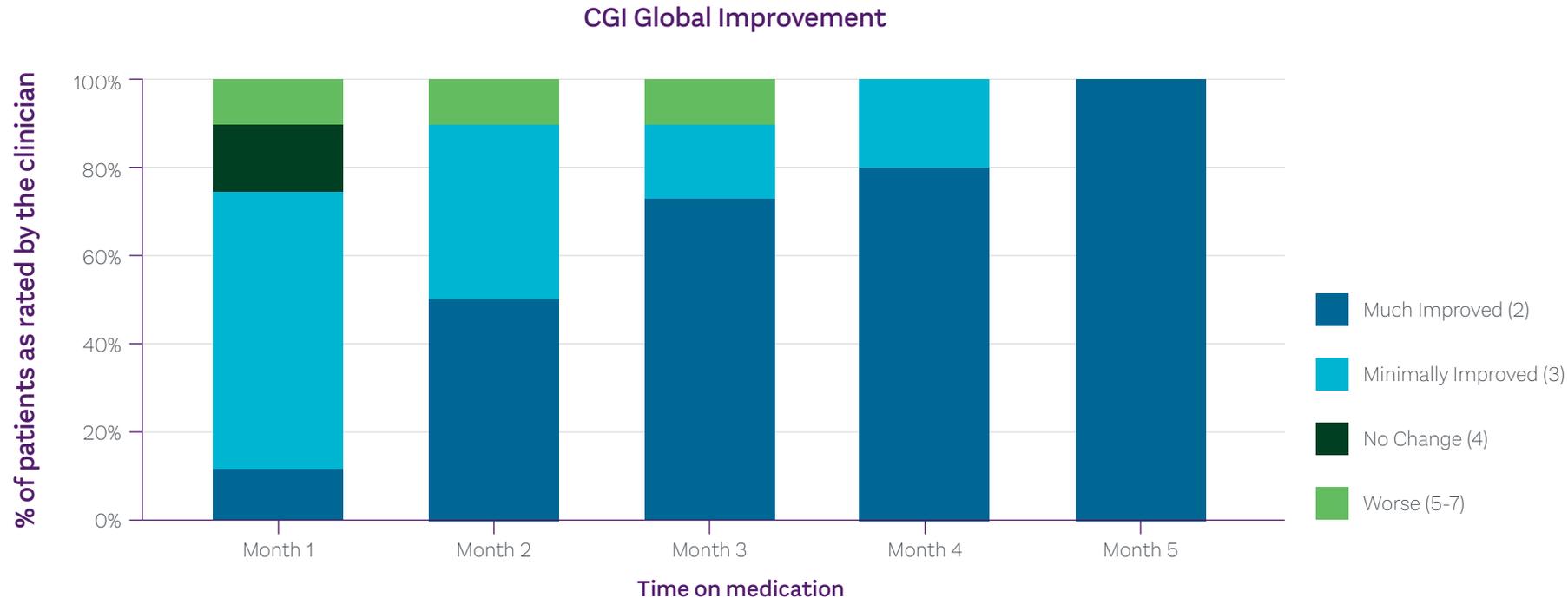
Launched and generating revenue in Australia, Washington, D.C., and Louisiana

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>



# Zelira sponsored – HOPE<sup>®</sup> longitudinal, real-world data study

Clinical Global Impression (CGI) Global Improvement and Efficacy scores of Emerald HOPE<sup>®</sup> 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 insomnia<sup>1</sup>
- US insomnia market: US\$4 billion by 2021<sup>2</sup>
- Current medications limited by side-effects

## 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



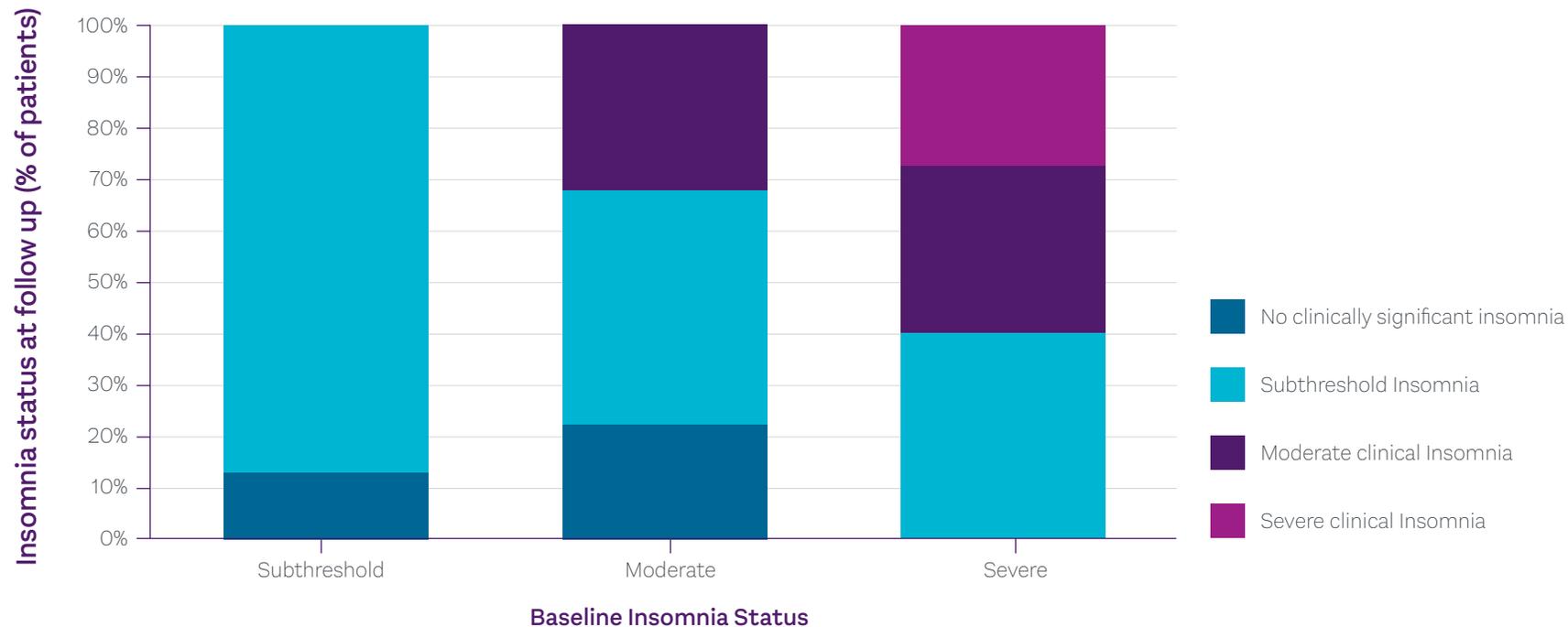
Launched and generating revenue in Australia

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



# 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](http://zeliraoralcare.com), [sprinjenecbd.com](http://sprinjenecbd.com), [amazon.com](http://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



# Oral Care – SprinJene CBD

Bursting with the unique benefits of 3 natural ingredients



## Hemp derived full spectrum CBD (*cannabis sativa*)

Our CBD-based toothpaste boosts your endocannabinoid system which helps fight inflammation and regulate internal systems to maintain a healthy balance.

## Black Seed Oil (*nigella sativa*)

Our patented formula is bursting with Black Seed Oil, which contains Thymoquinone, which has anti-inflammatory and antibacterial benefits for maintaining healthy gums for relieving dry mouth.

## Zinc

The FDA has recently approved the use of Zinc as a natural anti-gingivitis agent. It also enhances the effectiveness of the Black Seed Oil to provide its beneficial properties and delivers long lasting oral freshness.

Ingredients featured in CBD SprinJene Natural Toothpaste help...



Protect teeth from decay



Fight gingivitis



Control bacteria, plaque and tartar



Relieve dry mouth



Fresh breath



Remove surface stains



Reduce gum inflammation



# 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



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

#### SOLUTION



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 103 under prosecution across 9 different therapeutic areas

Therapeutic Area	Granted/Allowed	Under Prosecution/Examination
Cancer compositions	8	13
Skin compositions	4	8
Sleep compositions	8	27
Cancer prognosis	18	
Autism compositions		12
Pain compositions	1	16
PTSD/Anxiety composition	1	13
Opioid sparing compositions	1	13
Encapsulation	0	1
<b>Total</b>	<b>41</b>	<b>103</b>



# Corporate Snapshot

## Financials (as at 23 August 2022)

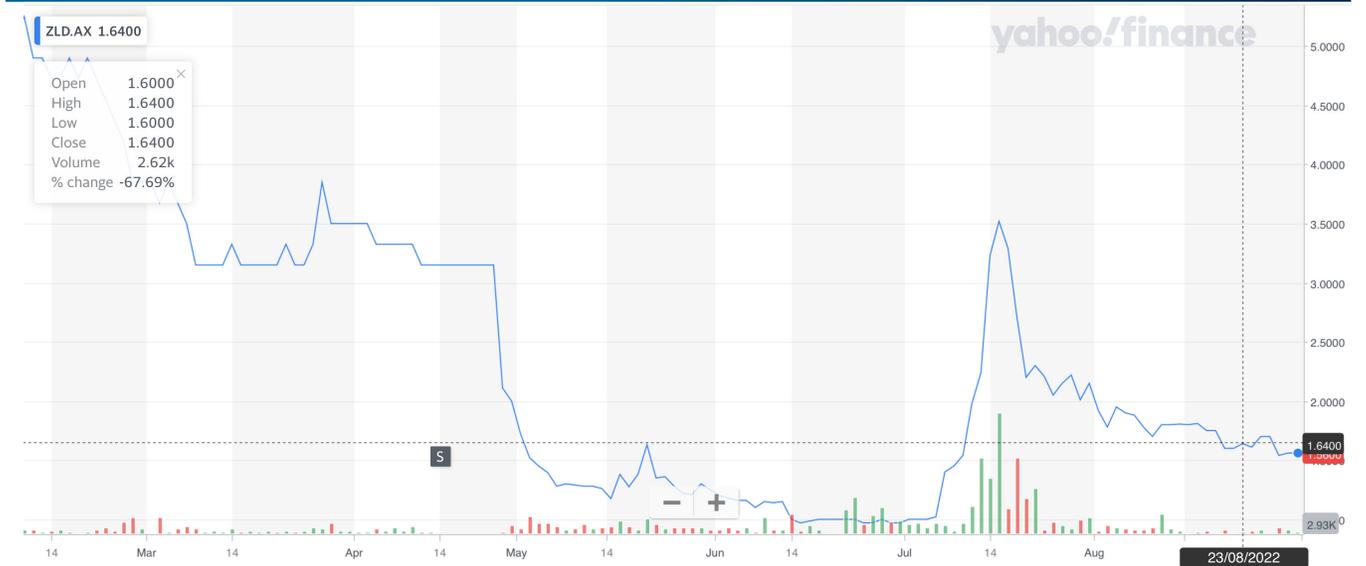
	AUD\$
Share Price	1.60
52w Range	0.97 - 9.97
Market Capitalisation	15M
Cash (at 31 March 2022)	2.7M

## Capital Structure (Fully Diluted<sup>2</sup>)

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 23 August 2022)



# 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 TerrAscend (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 TerrAscend.
- 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





# Thank You

Zelira Therapeutics

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