ZELIRA THERAPEUTICS

Investor Deck
April 2025

ASX: ZLD
OTCQB:ZLDAF
zeliratx.com

Zelira is a global biopharmaceutical company 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.

Zelira's unique 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

Supports path to registration

Zelira's portfolio of products: multiple shots on goal

	Autism	Insomnia	Neuropathy	Diabetic Nerve Pain	Oral Care	Dermatology
PRODUCT	HOPE® 1	ZENIVOL®	iTURA™	ZLT-L-007	SprinJene	RAV FIVE™
CLINICAL EVIDENCE/ PIPELINE	De-risked lead candidate: Significantly improved CGI and Efficacy Score in ASD patients in RWD study Phase 2 PoC trial upon IND opening	World's first clinically validated cannabinoid drug for chronic insomnia Phase 1B/2A clinical trial confirmed safety, efficacy and improved quality of life	Consumers have reported significant reductions in pain and itching and effective relief from muscle tension, numbness and tingling, aching and cramps and burning	Outperformed multi-billion-dollar Lyrica® in IRB-approved study Evaluate further progression to formal FDA clinical trials	Helps to protect teeth from decay, fight gingivitis, gum inflammation and plaque and tartar	Proprietary acne fighting complex that helps with bacteria and sebum production

Zelira's patented ZYRAYDI™ technology is a novel encapsulation system designed to enhance the disolution, stability and delivery of active ingredients in its oral dosage products.

HOPE® 1: A proven and de-risked lead candidate

About HOPE®1

Launched in US in 2020 and then Australia under the TGA Special Access Program

HOPE® 1 is a THC:CBD oral solid Capsule

Reformulated into a dry-powder pharmaceutical-grade capsule using Zelira's proprietary, patent-protected ZYRAYDI™ technology

Clinically validated, highly de-risked ASD treatment

Over 11 Million doses of HOPE® 1 dispensed in Pennsylvania over the past five years without any negative safety signal.

The HOPE® SPV gives Zelira the resources to start clinical trials – funds raised to date of US$3,250,000

Successful Pre-IND meeting with the FDA sets the stage for IND submission and the launch of Phase 1 clinical trials.

Near-term development milestones

Initial focus - Phelan McDermid Syndrome (PMS) co-morbid with ASD per pre-IND meeting held Q2 2024

Multiple targets within the ASD indication

Progressed company in a capital-efficient manner

Phase 2 PoC trial to start immediately upon IND opening

Can proceed to Phase 3 pivotal trials as soon as Q4 2026

Aim for NDA submission as early as Q2 2027

The formal FDA trials for HOPE® 1 represents the third and final stage of the Launch, Learn, Develop strategy for validation and commercialisation

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ASD is highly prevalent with ineffective current therapies that carry significant risks

Prevalence

About **1 in 44** children identified with Autism Spectrum Disorder (ASD)[1]

CDC estimates **5,437,988 (2.21%)** adults in the United States have ASD

Prevalence estimate rose **57%** from 2002 to 2006 – due to increased awareness, education and environmental factors

Existing Therapies have Significant Risks

Current treatments are antipsychotic drugs, SSRIs/antidepressants, stimulants and sleep medications.

Risks of these therapies are significant and include increased fracture risk; weight gain/ increased appetite; increased anxiety and fatigue; sedation/somnolence. They also carry warnings of: potential for cognitive impairment, motor skills impairment, cerebrovascular events, GI Disturbances/Dysphagia/Emesis

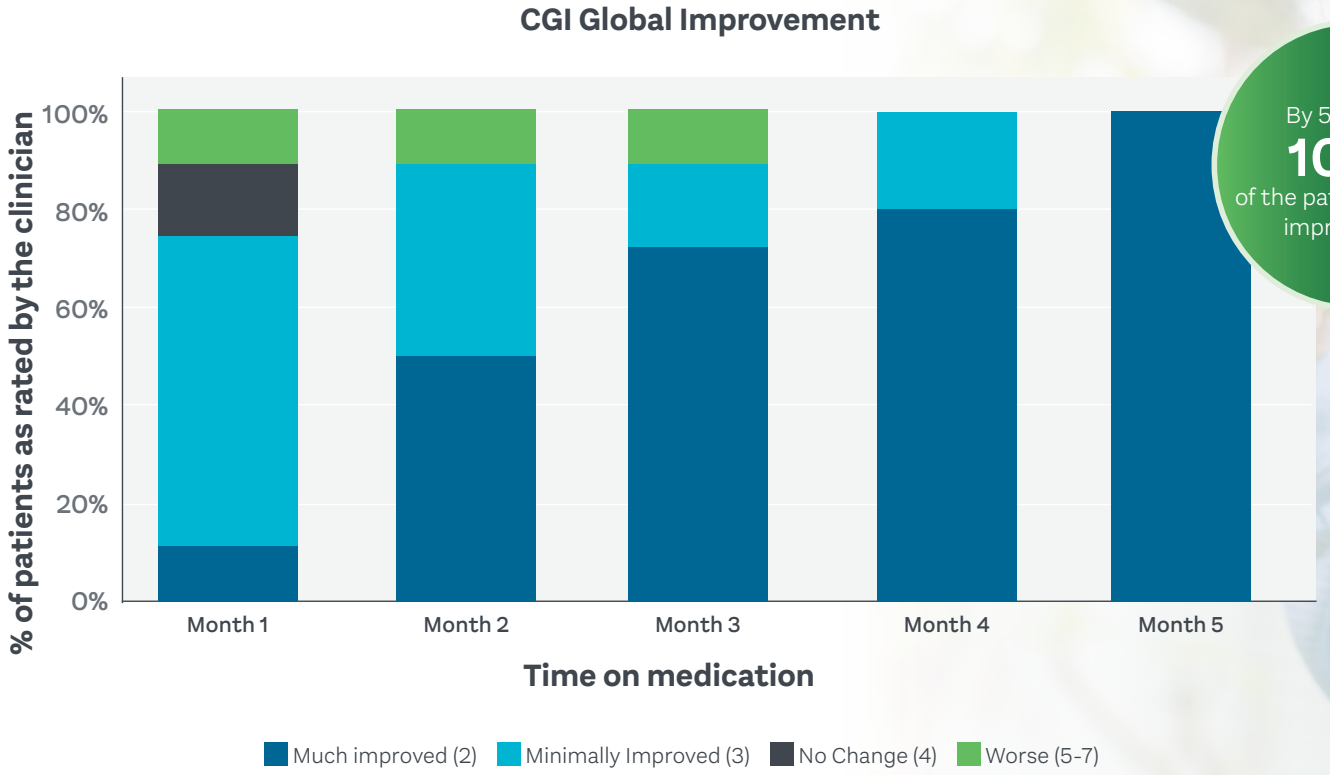
Significant Market Opportunity

Increased prevalence of ASD is positively impacting **growth of the global market**,which has led to increasing demand for clinical research for effective treatments

The ASD market is projected to reach **US $4.53B by 2026** (PR Newswire, 2021)

Reference: 1. *According to estimates from CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network*

Real world evidence – HOPE® 1 improved Clinical Global Impression (CGI) and Efficacy Score in ASD patients



By 5 months, **100%** of the patients showed improvement

After 1 month, 56% showed minimal improvement

After 3 months, 50% showed moderate improvement

After 4 months, 60% showed marked improvement

By 5 months, 100% of patients showed improvement

- HOPE® 1 tincture launched under the TGA's Special Access Scheme B in Australia
- Administered sublingually, optimal dosage not yet established at the start of the study
- This study focused on real-world patient data to assess the product's impact on CGI scores.

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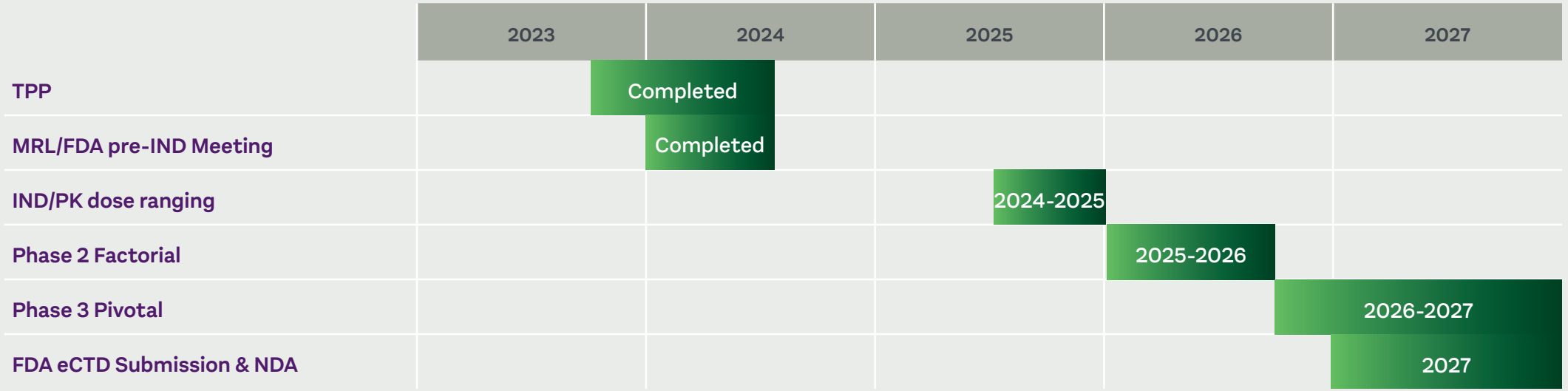
Development pathway for HOPE® 1 Phelan McDermid Syndrome (PMS) co-morbid with ASD program

Phelan-McDermid Syndrome (PMS)

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.

Regulatory Pathway

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.



Pre-IND meeting held in June 2024; feedback was to proceed in Autism Spectrum Disorder (ASD) subset indication, irritability associated with PMS patients

HOPE® 1 and HOPE® 2 development pathway for indications within Autism Spectrum Disorder (ASD) subset

	Target Indication	Subset Targets Co-morbid with ASD	2025	2026	2027
HOPE® 1	**Initial focus with fund raise**				
	Reduction in Irritability	Phelan McDermid Syndrome (PMS)	IND and Phase 1/ PK (n = 40)	Phase 2 Factorial (n = 170)	Phase 3 (n = 350)
	Pipeline indications				
	Reduction in Irritability	Smith Magenis Syndrome (SMS)	Pre-IND		IND enabling work
	Reduction in Irritability	FoxP1			TBD
HOPE® 2	**Improvement in communication**	Pediatric Minimally Verbal Autism (PMVA)	Pre-IND		IND enabling work
	Improvement in sleep disorder	ASD			TBD

Outlook

- Commencement of Phase 1 clinical trials for HOPE® 1
- Development work for the transformation of Zenivol® into a capsule formulation is on track to be completed in mid-late 2025
- Evaluating the further progression of ZLT-L-007 into formal FDA clinical trials

Investment highlights

De-risked, proven lead candidate

HOPE® 1 already proven to be effective in treating Autism Spectrum Disorder (ASD); successful pre-IND meeting with FDA.

Multiple shots on goal

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

DeriskedRx & OTC Development and Commercialisation 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-Mid/ Long term revenue.

Fast Tracking Commercialization

Disruptive ‘Launch, Learn, & Develop’ model facilitates rapid commercialisation.

Premium Product

Manufacturing Partner-EU GMP Certified.

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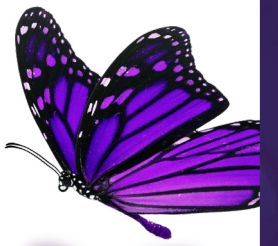

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Thank You

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Appendix

1H FY25 Milestones

2024

8 Jan 24
Zelira's HOPE® SPV receives US$819,000 second tranche of funding

15 Apr 24
Zelira receives $919,000 R&D Tax Incentive Scheme refund

29 Apr 24
Zelira submits Meeting Request Letter for Pre-IND meeting to the FDA

23 May 24
Zelira's HOPE® SPV receives US$681,000 third tranche of funding

11 Jul 24
Zelira advances HOPE® Program with positive pre-IND meeting with the FDA

16 Jul 24
Zelira secures leading patents for HOPE® 1 and HOPE® 2 formulations targeting Autism Spectrum Disorder

22 Aug 24
Zelira receives positive feedback from Pre-IND Meeting with FDA, Advancing HOPE® Autism Program

2025

28 Jan 25
Zelira's HOPE® receives US$681,000 fourth tranche of funding

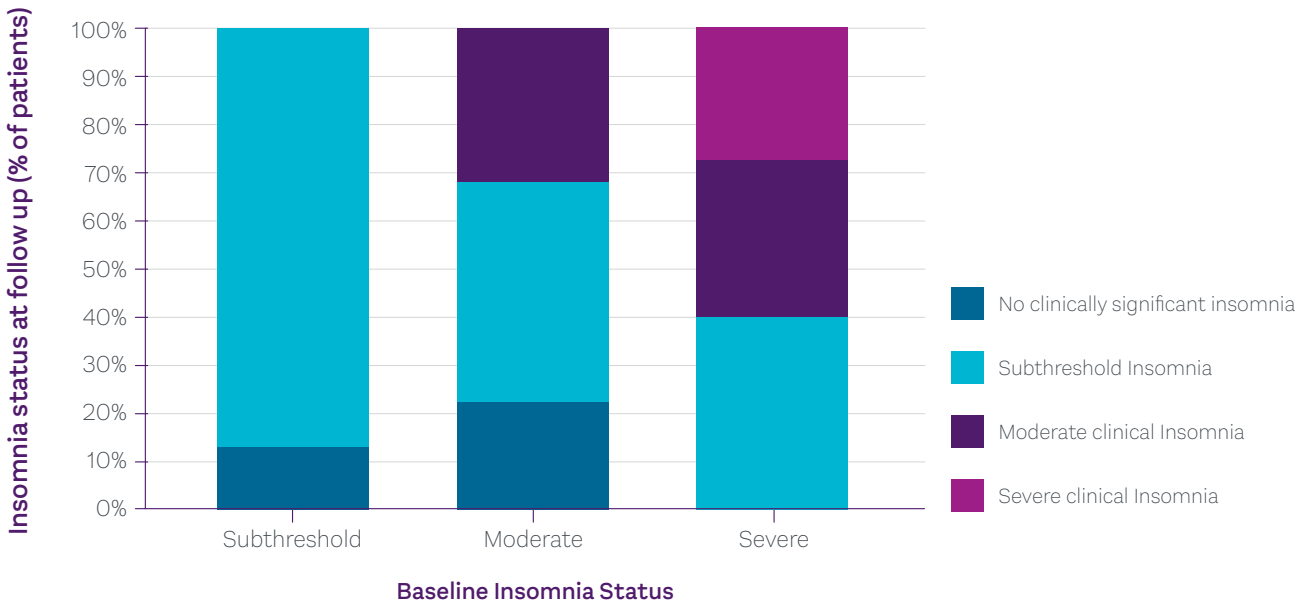
18 Feb 25
Zelira receives $1,153,000 R&D Tax Incentive refund. Total funds received by the HOPE® SPV to date of US$3,250,000

ZENIVOL® for chronic, unresolved insomnia

Insomnia Market

- 30% of adults report symptoms of insomnia[1]
- US insomnia market: US $4B by 2021[2]
- Current medications limited by side-effects

Taking ZENIVOL® improved from a baseline ISI score of 19.5 (Moderate) to 14.3 (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

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
- Clinical trial results published in peer reviewed journal of ***Sleep®***

Approved by BfArM for German market

Manufacturing agreement for Australia: Extractas Biosciences

Distribution agreements: Australia (Health House), Germany (Adjupharm), NZ (NUBU)

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

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Zelira's Diabetic Nerve Pain Drug (ZLT-L-007) Outperforms Big Pharma drug; successful clinical trial against multi-billion-dollar Lyrica® Demonstrated Safety, Tolerability, and Improved Efficacy

Objective of the study

- Comparing Zelira's patent protected, proprietary ZLT-L-007 with Lyrica® with regards to the reduction of diabetic nerve pain
- IRB-approved observational multi-arm head-to-head study powered to show statistical significance

Topline Results

- ZLT-L-007 materially outperformed Lyrica® in reducing NRS pain scores
- Significant decrease in symptom severity observed
- ZLT-L-007 met the primary endpoint with no Serious Adverse Events (SAE)
- ZLT-L-007 significant decreases in Visual Analog Scale (VAS) and Short form McGill scores- met secondary endpoints

Market Potential

- ZLT-L-007 demonstrated improved efficacy, enhanced safety and tolerability profile for diabetic nerve pain, a market in which Lyrica® is an established leader with peak year sales of approximately US$5B*

Next steps - Evaluate further progression of ZLT- L-007 in formal FDA clinical trials as part of Zelira's Launch, Learn & Develop strategy

References:
*-Grand View Research. (2021). Diabetic Neuropathy Market Size, Share & Trends Analysis Report By Disorder (Peripheral, Autonomic, Proximal, Focal), By Treatment (Drug, Radiotherapy, Physiotherapy), By Region, And Segment Forecasts, 2021 - 2028. Retrieved from https://www.grandviewresearch.com/industry-analysis/diabetic-neuropathy-market

ZYRAYDI™ (Enhanced Cannabinoid Capture and Dissolution Matrix)

- Breakthrough technology developed by Zelira
- Solves the problem of developing solid oral dosage forms from cannabinoid distillate
- Zelira's unique, proprietary matrix prevents cannabinoid separation from the powder providing a free flow powder base for tablets and capsules
- This technology allows development of standardised pharmaceutical grade, cannabinoid-based medicines in solid oral dosage
- A move from extracts (oils) to capsules and tablets enhances patient and HCP familiarity and increased acceptance of cannabinoid-based medicines

The ZYRAYDI™ matrix contains pharmaceutical grade excipients that are on the FDA-approved list of GRAS (Generally Recognized As Safe) ingredients

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Global Board of Directors

USA

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.

GLOBAL

Dr. Oludare Odumosu
Global CEO

- Post-clinical development of Iroko Pharmaceutical's Zorvolex® Tivorbex® and Vivlodex® through FDA approvals and successful US and global market commercialization
- Lead Scientist and Inventor of Patent Protected HOPE ® Drugs targeting treatment of Autism Spectrum Disorder (ASD) symptoms
- Founding Chief Scientific Officer CSO/EVP of Ilera Therapeutics
- Founding COO of Ilera Healthcare. Ilera Healthcare was acquired by TerrAscend (TER.CN) for $225M Mid 2019

USA

Dr Donna Gentile O'Donnell
Non-Executive Director

- Senior VP of the 'Innovation Pillar' at Thomas Jefferson University Health
- While President of Franklin Health Trust, led the merger of US $50M of assets into Drexel University College of Medicine
- Served as Deputy Health Commissioner for policy and planning for the City of Philadelphia
- Named Philadelphia Business Journal Woman of Distinction and elected to Fellow at Philadelphia College of Physicians
- Appointed by the Governor, serves on the Commonwealth Universal Research Enhancement (CURE) Board, and she has served on the boards of many non-profits and advisory councils

AUS

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

Greg Blake
Executive Director

- 20 years commercial and operational leadership in the pharmaceutical and biotech sectors in Australia and internationally
- As GM Rhythm Biosciences led pre-launch and commercialisation planning globally
- As Marketing Lead (Europe) Mundipharma International led 26 European countries pre-launch and launch phases for a novel pain medication
- Held leadership roles at large multinationals (J&J amd CSL) and publicly-listed biotech start-ups