ZELIRA THERAPEUTICS

2025 Annual General Meeting CEO Update

2025 FOCUS

Validating Zelira's Operational Scale

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FY Milestones and Achievements 2025

Clinical & R&D Advancements

- Publication of the IRB-approved observational study for proprietary formulation ZLT-L-007 in adults with diabetic neuropathy — demonstrating significant superiority to pregabalin (Lyrica®) in pain reduction, sleep and neuropathic symptoms.
- Progression of the HOPE® 1 program via the SPV structure (for autism spectrum disorder / Phelan–McDermid Syndrome) including full conversion of USD 3.25 m convertible notes into equity in the SPV.
- Transition of formulation technology: work to convert existing oil-based products (e.g., ZENIVOL®) to capsule format via the proprietary Zyraydi™ platform.

Capital & Funding Initiatives / Corporate Strengthening

- Secured an At-the-Market (ATM) equity facility of A$1 m (March 2025) to provide standby equity capital with minimal dilution.
- Received A$1.152 m R&D Tax Incentive refund (Feb 2025) and subsequently secured a non-dilutive R&D loan facility of A$650,000 (July 2025) against anticipated FY25 R&D rebate.
- Strengthened SPV capital structure via conversion of debt to equity and preparation for larger raise (target ~US$35 m funding of HOPE® SPV).
- Active cash-management steps taken including debt conversions and non-dilutive financing to preserve shareholder value.

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Zelira's Strategic Pillars - Clinical Validation First

1 Launch Learn Develop a "proof then scale" framework

Emphasising observational / head-to-head data (ZLT-L-007), SPV model for HOPE® to derisk and professionalise cannabinoid-drug development.

2 Portfolio Approach

Multiple shots on goal (HOPE®, ZLT-L-007, ZENIVOL®, OTC lines) to spread risk and maximise optionality.

3 Lifecycle Management

Current and pipeline Rx formulations converted to Zyraydi™ technology to enhance patient and doctor familiarity and in preparation for regulatory path

4 Capital Efficiency & Balance Sheet Discipline

Use of non-dilutive mechanisms, ATM facility, R&D loan, strong IP base, SPV structure to attract external capital.

5 Globalisation & Regulatory Pathways

Engaging the US FDA via SPV, preparing IND pathways, aligning with international therapeutic standards

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US FDA Clinical Trials

HOPE® 1 – Treatment of Irritability in PMS Co-morbid with Autism Spectrum Disorder (ASD)

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FDA clinical trials and registration for its HOPE® 1 drug candidate, targeting Autism Spectrum Disorder (ASD)

Proprietary platform of cannabinoid medicine

HOPE® 1 is a THC:CBD oral solid capsule

Large pipeline potential on the back of lead programs

Strong IP position

Drug candidates targeting cluster symptoms associated with Autism Spectrum Disorder (ASD)

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 late 2027/early 2028

Aim for NDA submission as early as 2029

Clinically validated, highly de-risked ASD treatment

Unique “Launch, Learn, Develop” model and approach to real-world data

Zelira has spent many years collecting real-world patient data to develop an optimised therapeutic and clinical plan for this population

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Full pathway to US- FDA in 36 months

FDA - Orphan designation and IND opening

1

TPP

Solidify target product profile

2

Pre-IND

Preparation and submission of Pre-IND

The TPP and Pre-IND are completed

3

Phase 1/PK
4 - 6 months

PK study in healthy volunteers

4

Phase II Factorial & Dose Ranging
8 - 10 months

Phase II trial commencement - Double-Blind, Placebo-Controlled, Parallel Study

5

Type C Meeting

FDA Type C Meeting

6

Additional PK BA/BE
(If required)

Demonstrating bioavailability & bioequivalence

7

Phase III Pivotal
12 - 15 months

8

Type C Meeting & eCTD Submission

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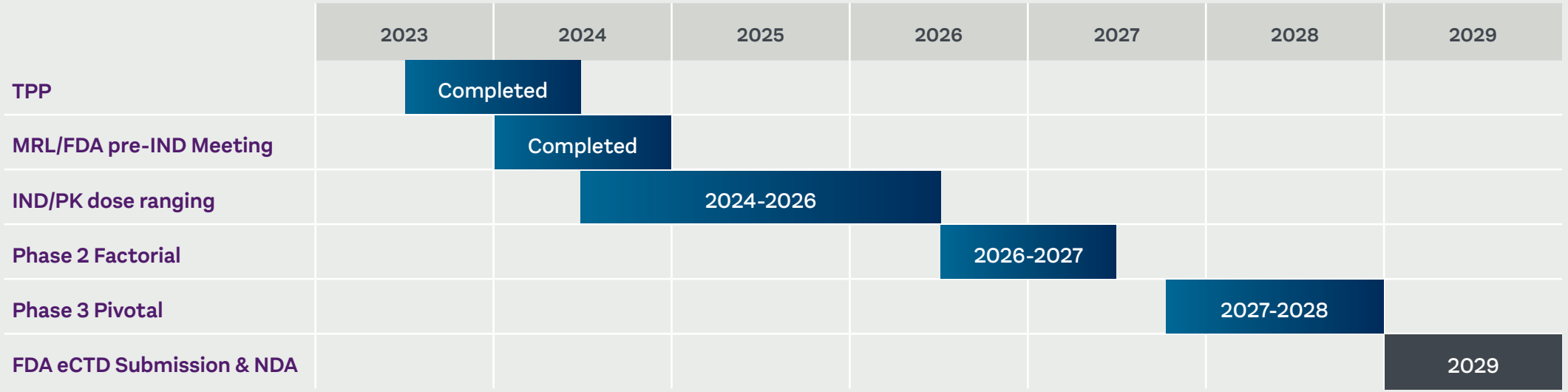
Development pathway for HOPE® 1 Phelan McDermid Syndrome (PMS) co-morbid with ASD program

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 utilising 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.

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

Prompt FDA response	U.S. FDA responded quickly to Zelira's Pre-IND meeting request, demonstrating the Agency's engagement in advancing the HOPE® 1 program
Positive feedback on study design	The FDA provided valuable guidance on the design of the IND-opening Phase 1 study, reinforcing the scientific rigor of Zelira's proposed clinical development plan
Support for target population	The FDA acknowledged the potential link between Phelan-McDermid Syndrome (PMS) and Autism Spectrum Disorder (ASD), supporting our rationale for targeting these populations in the clinical trials
Clear direction on bridging studies	The FDA accepted Zelira's justification for the low CBD dose in ZEL-HOP1 compared to Epidiolex® and provided clear guidance on the design of bridging studies, including the possibility of single-dose studies with Marinol®
Flexibility on study components	The FDA agreed that omitting the Single Ascending Dose (SAD) component from the Phase 1 study was reasonable, allowing us to streamline the study design
Guidance on dosing and ratios	The FDA provided insights on optimising the ratio of THC and CBD in ZEL-HOP1, which will help us fine-tune the formulation for maximum efficacy and safety
Confirmation on PK sampling	The FDA recommended longer pharmacokinetic (PK) sampling periods to adequately characterise the terminal elimination phase of CBD, aligning with the pharmacological profile of oral CBD products
Ethical considerations supported	The FDA supported Zelira's approach to limiting PK sampling when drug levels are no longer measurable, aligning with our ethical considerations in study design

Zelira has made significant progress in its HOPE® 1 program following a successful Pre-IND meeting with the FDA, setting the stage for the IND submission and the launch of Phase 1 clinical trials.

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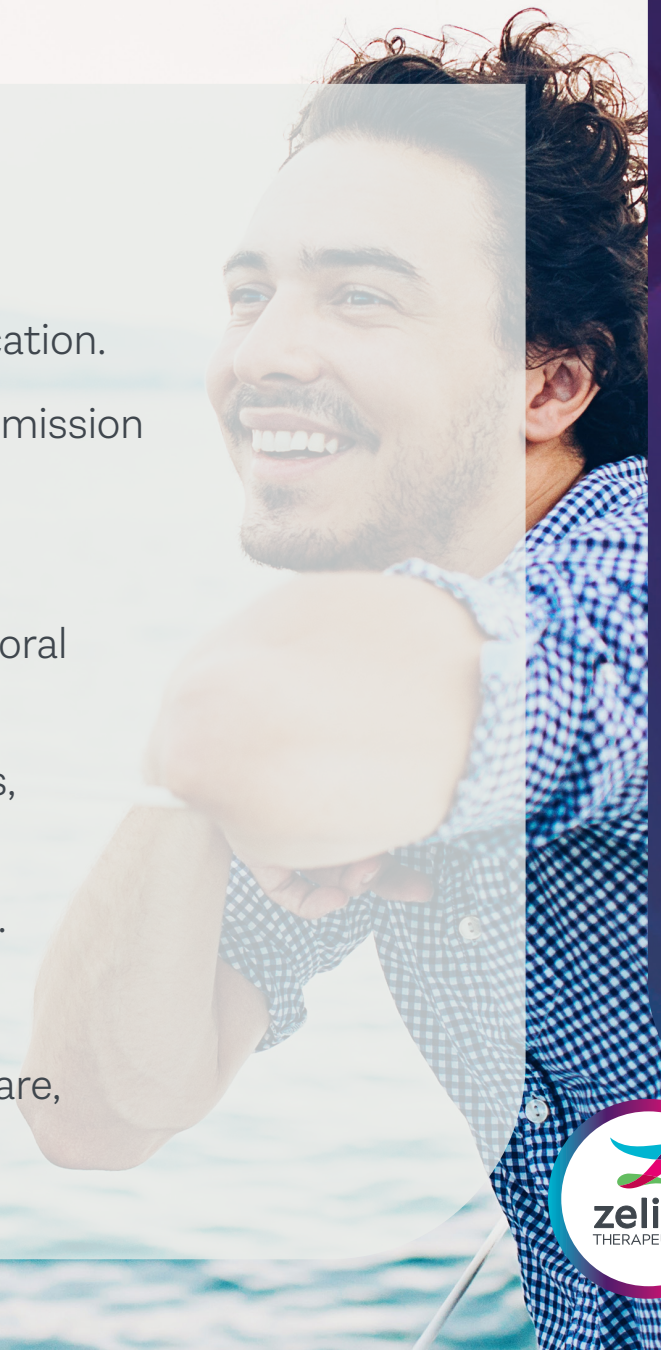
2026 Outlook & Key Priorities

- Accelerate IND-/FDA-clinical trial pathway for HOPE® 1 in ASD/PMS indication.
- Advance formulation transition of ZENIVOL® into capsule format and submission for regulatory approval in Zelira's commercial markets
- Initiate the advancement of ZLT-L-007 for Diabetic neuropathy
- Monetise the Zyraydi™ platform through partnerships/licensing for solid oral cannabinoid formulation
- Mitigation of clinical and regulatory execution risk (e.g., clinical trial delays, regulatory issues) via experienced CRO, SPV model, phased approach.
- Capital risk / dilution - non-dilutive funding, strong IP to attract partners.
- Commercial ramp - diversified product portfolio, incremental launches,
- Strong pipeline and market differentiation - clinical data vs standard of care, proprietary delivery tech, IP coverage.



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 commercialisation
- 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

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Thank You

Zelira Therapeutics
Phone (Australia) 1300 ZELIRA (1300 935 472)
Phone (USA) +1 484 630 0650
Email info@zeliratx.com
zeliratx.com