ZELIRA THERAPEUTICS

2024 Annual Shareholders General Meeting

Investor Briefing
14 November 2024

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Overview of Zelira 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 commercialisation.

Premium Product

Manufacturing Partner-EU GMP Certified.

Fast Tracking Commercialisation

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

FY24 Milestones

2023

17 Aug 23
First close of HOPE®-SPV funding US$3.25 million commitment, enabling the initiation of HOPE® clinical trial

17 Aug 23
Receipt of US$1,069,000 first tranche of funding

31 Oct 23
Zelira makes positive progress with the development work to change Zenivol® format to a capsule formulation powered by ZYRAYDI™ technology

31 Oct 23
Zelira vetting for a potential manufacturer for Zenivol® capsule

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. Total funds received by the HOPE® SPV to date of US$2,569,000

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

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Zelira's unique rapid commercialisation strategy

US FDA New Drug Approval (NDA) Program: HOPE® 1 for treatment of irritability in Phelan McDermid Syndrome (PMS) co-morbid with Autism Spectrum Disorder

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

IND will be opened with Ph 1 protocol

Can proceed to a Phase 3 pivotal trial as soon as Q2 2026

Aim for NDA submission as early as Q2 2027

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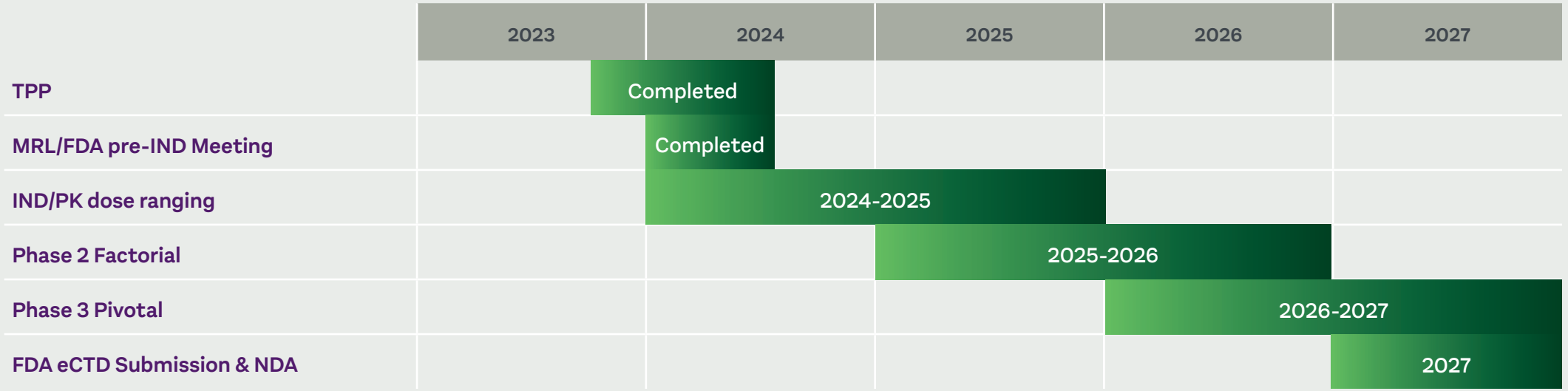
Development pathway for HOPE® 1 Phelan McDermid Syndrome (PMS) co-morbid with ASD program

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

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 Recognised As Safe) ingredients

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Successful and positive FDA Pre-IND meeting

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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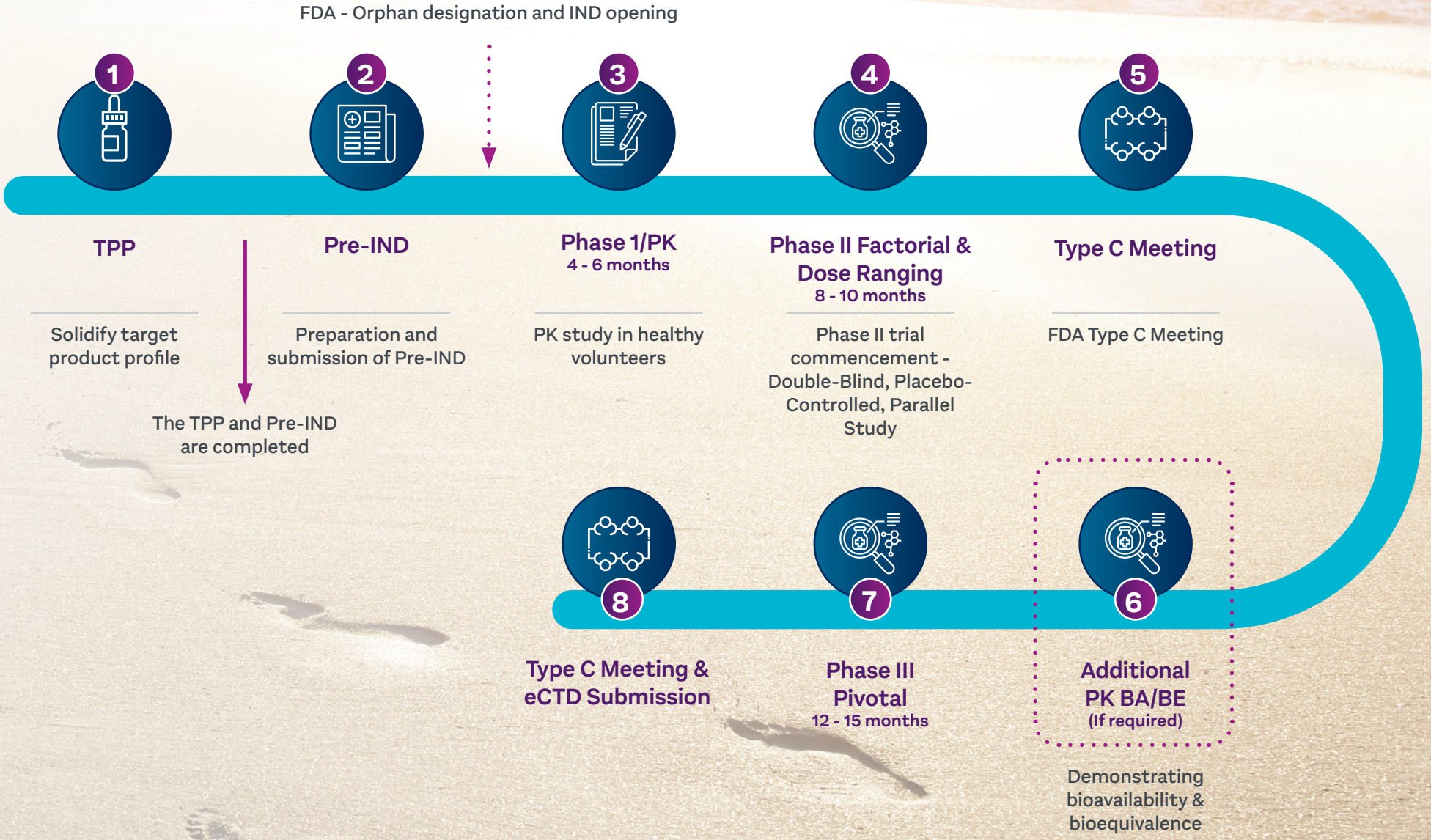
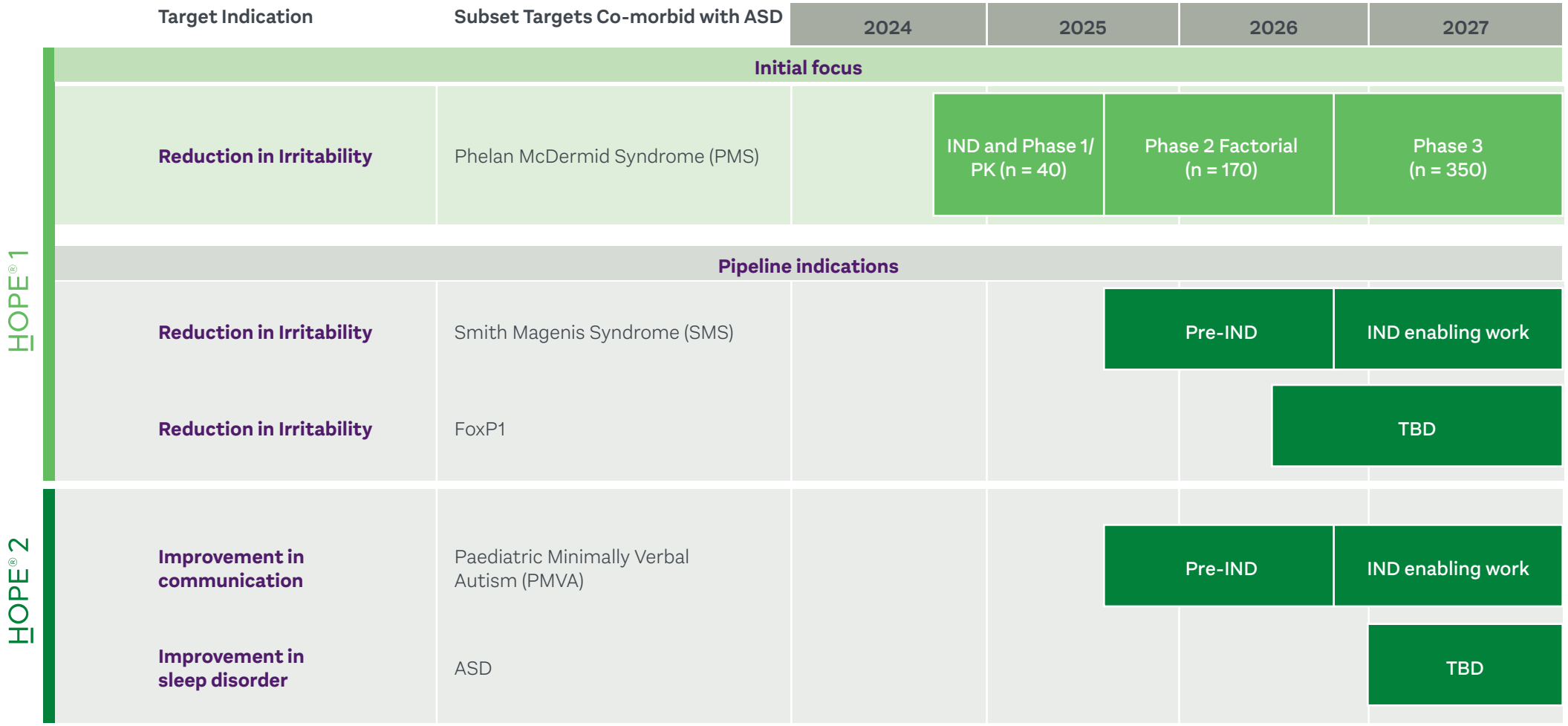
Full pathway to US-FDA in 36 months



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



Thank You

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