ZELIRA THERAPEUTICS

Zelira secures US $8.6M cornerstone funding for HOPE® 1 US FDA clinical trials for Autism Spectrum Disorder (ASD)

Investor Briefing February 2023

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ZELIRA'S UNIQUE RAPID COMMERCIALISATION STRATEGY – KEY TO SUCCESS

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

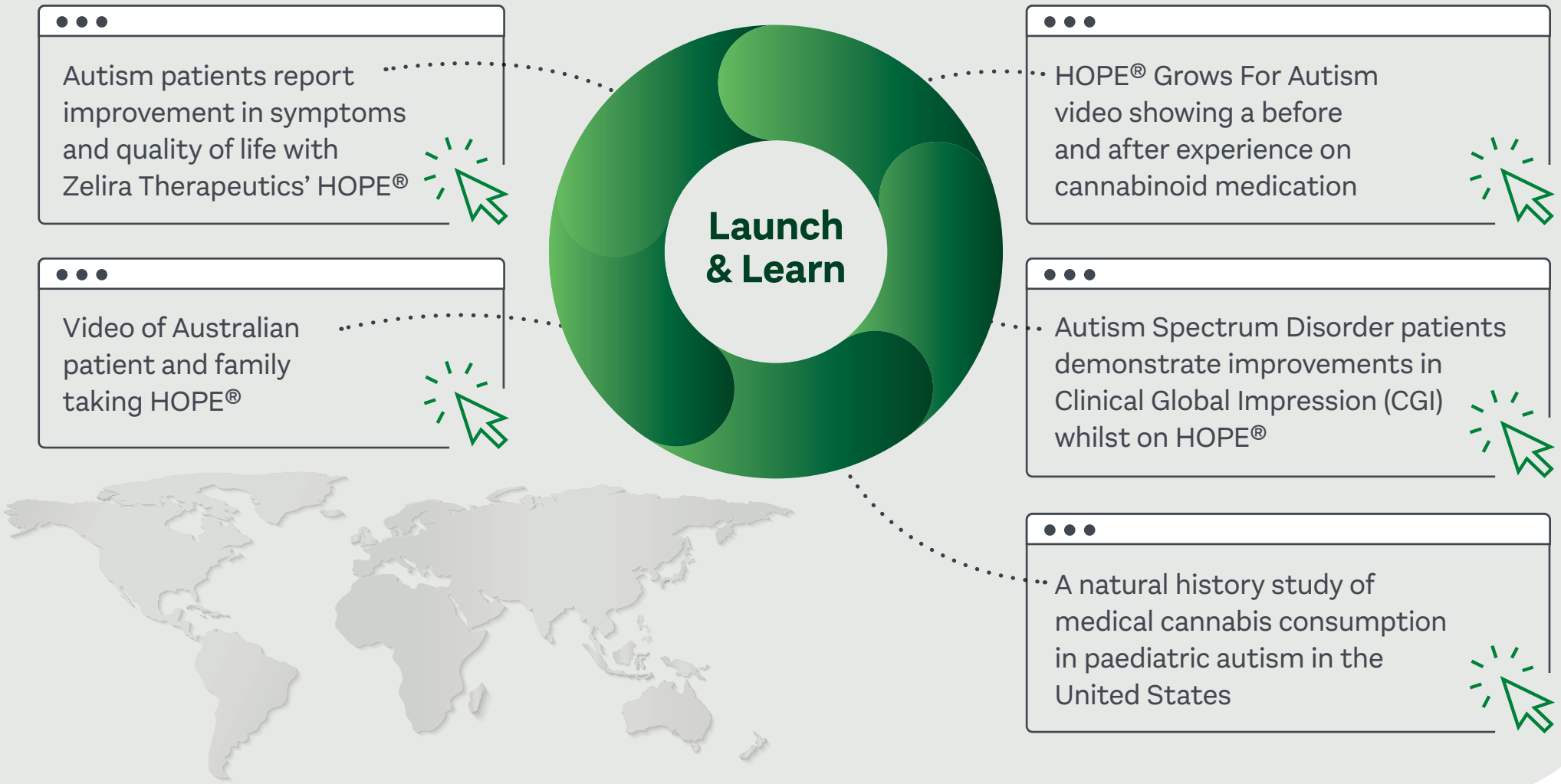
Develop

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

Background on Autism Spectrum Disorder (ASD)

Prevalence	• About 1 in 44 children have been identified with autism spectrum disorder (ASD) according to estimates from CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network • The CDC estimates that 5,437,988 (2.21%) adults in the United States have ASD • This prevalence estimate rose 57% (95% CI 27%–95%) from 2002 to 2006 - the increment in ASD cases has arisen from increased awareness, education and environmental factors
Total Addressable Market (TAM)	• The Autism Spectrum Disorders (ASD) Market Is Projected To Reach US $4.53B By 2026 (PR Newswire, 2021)
Existing Therapies	• Based on drug therapy, the global market is segmented into antipsychotic drugs, SSRIs/antidepressants, stimulants, sleep medications, and others • Drugs such as Aripiprazole®, Risperidone®, and Melatonin® are FDA approved drugs that aid in the treatment of ASD. Bumetanide® and Balovaptan® are drugs that are under clinical trial and investigation to evaluate their safety and efficacy for the treatment of ASD. (Coherent Market Insights, 2021)
Opportunity	• An increase in the prevalence of autism spectrum disorder (ASD) is positively impacting the growth of the market globally, which has led to increasing demand for clinical research for effective treatments

HOPE® - Real World Evidence

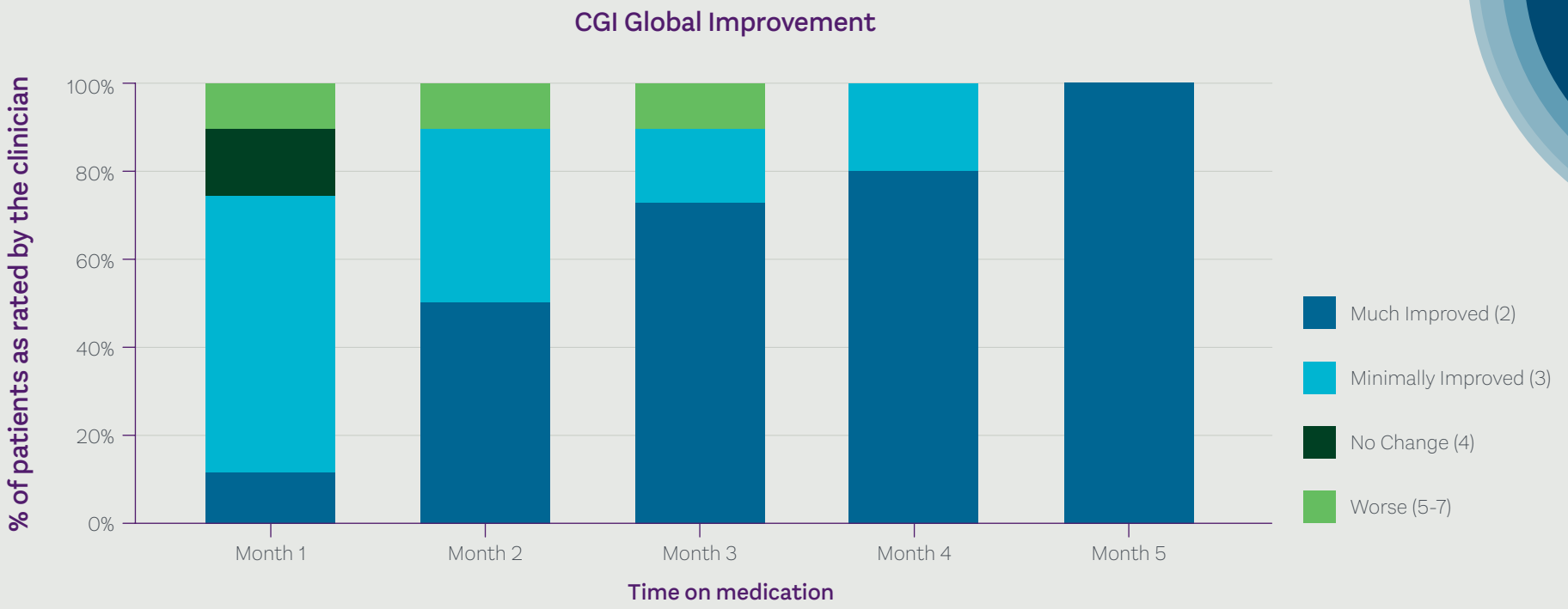


Zelira sponsored – HOPE® 1 Longitudinal, Real-world Data Study

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

HOPE® 1 For US FDA Clinical Trials

HOPE® launched in Pennsylvania in 2020 and subsequently in Washington DC, Louisiana and Australia under the TGA Special Access Program

Over 9 Million doses of HOPE® dispensed in Pennsylvania over the past three (3) years without any negative safety signal

All sales in the US are out of pocket payments by parents that buy HOPE® to administer to their children with ASD, on a consistent, repeated, monthly basis

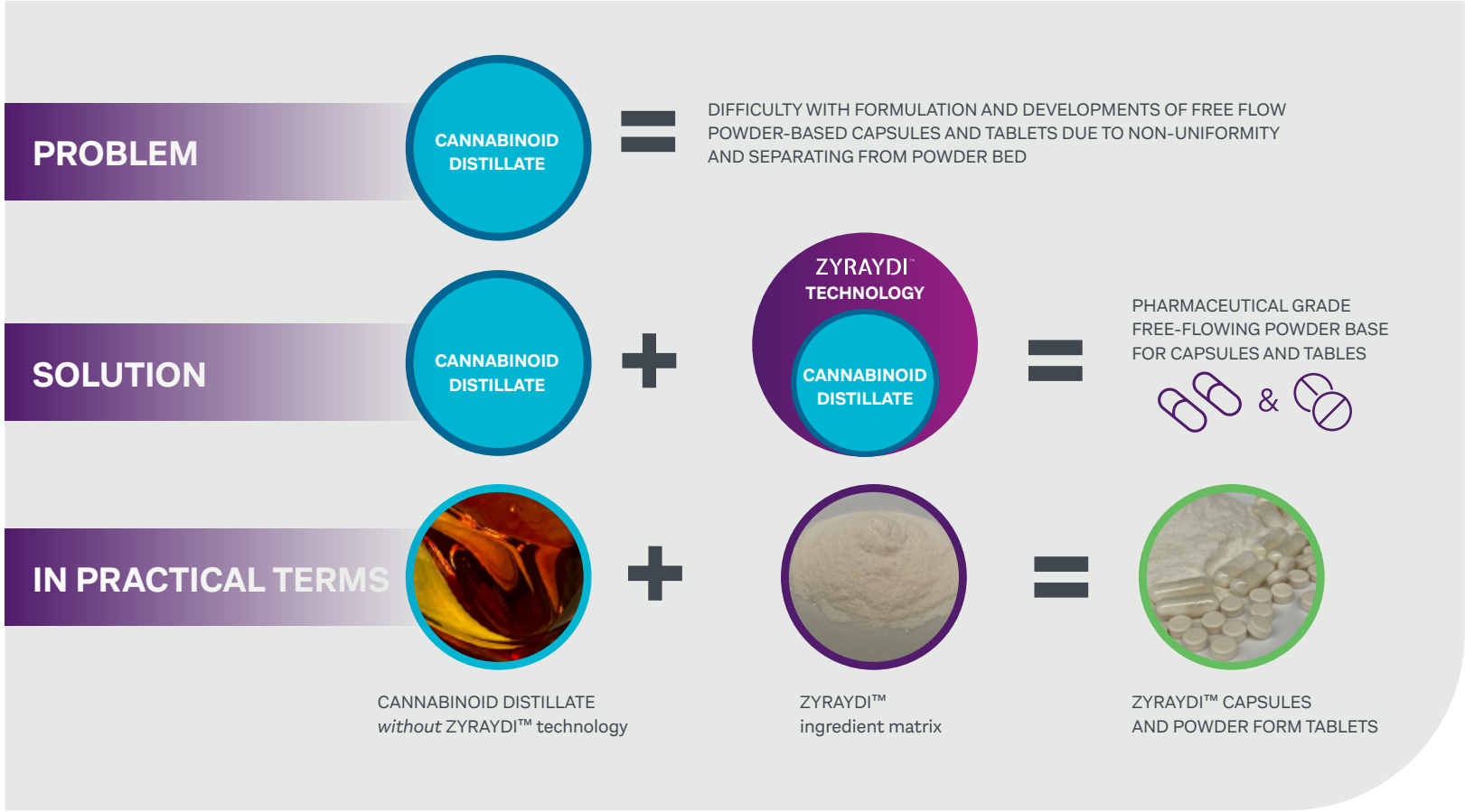
Proprietary HOPE® 1 product currently on the market as a tincture, reformulated into a free-flowing powder and pharmaceutical grade capsule using Zelira's proprietary, patent protected Zyraydi™ technology

ZYRAYDI™

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.



Pathway to US FDA NDA

1

TPP

Solidify Target Product Profile

2

Pre-IND & ODD

Application Preparation and submission of Pre-IND & ODD Application to FDA

3

IND Opening

Successful opening of IND

4

Phase II POC

Proof-of-Concept Phase II Trial Commencement

5

Type C Meeting

FDA Type C Meeting post-Ph II POC

6

Phase I

Commencement of subsequent Phase I study

7

PK BA/BE

Demonstrating Bioavailability & Bioequivalence

8

Phase II Factorial & Dose Ranging

9

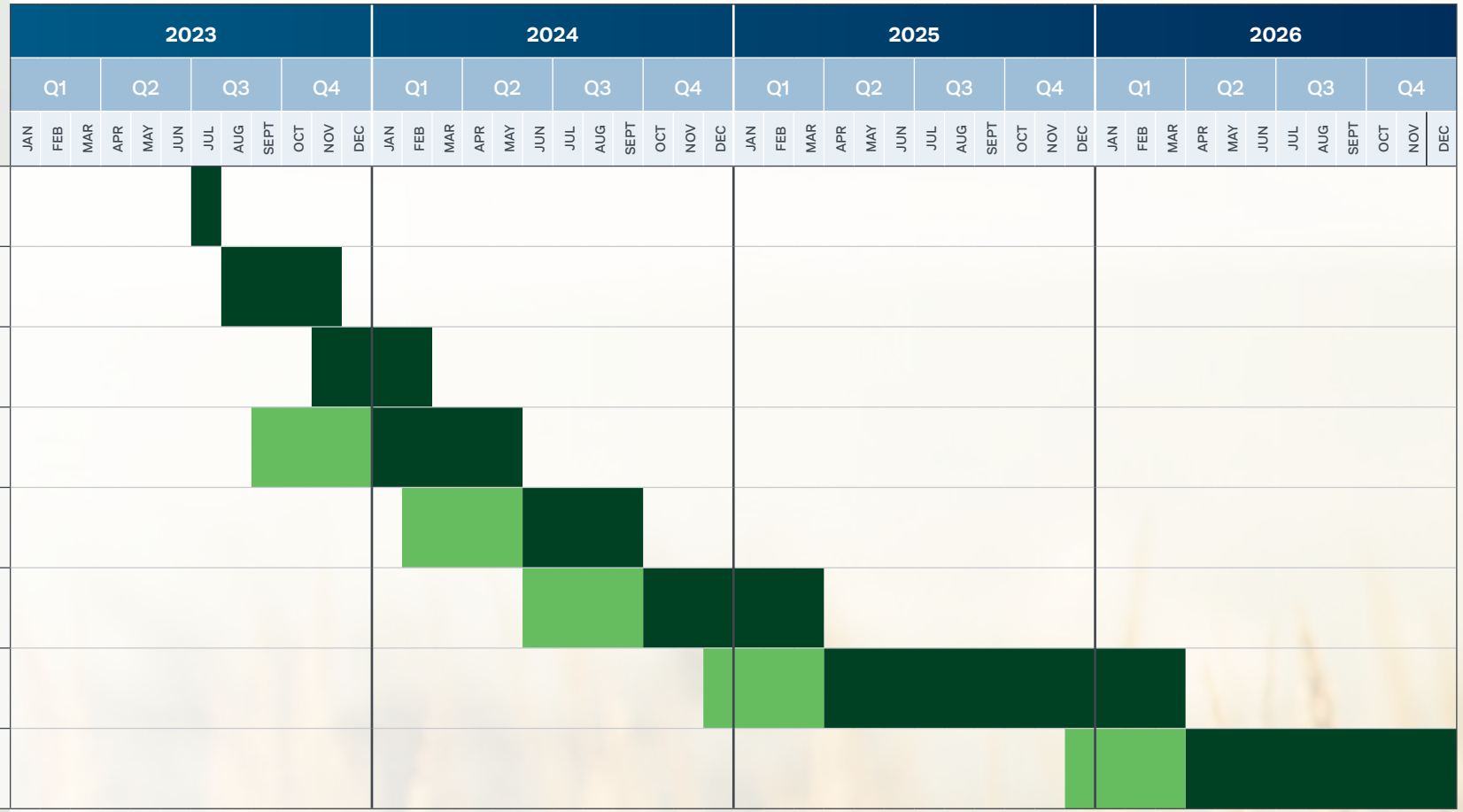
Phase III Pivotal

10

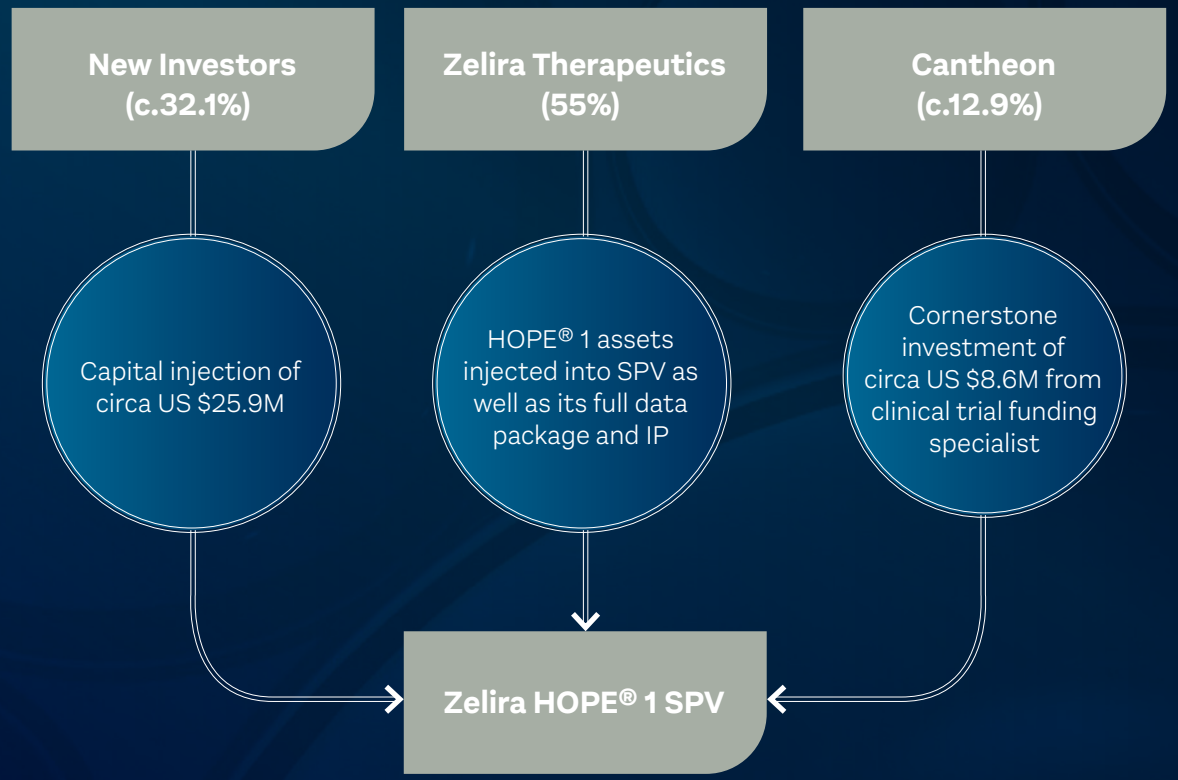
Type C Meeting & eCTD Submission

Summary of Strategy and Timeline

	Duration
TPP	2 weeks
PRE-IND	16 weeks / 4 Mos.
IND	16 weeks / 4 Mos.
PHASE 2 POC	6 months
PK / Dose Ranging	4 months
PHASE 2 FACTORIAL	6 months
Phase III Pivotal	(12-18 months)
FDA, eCTD Submission & NDA	(12-18 months)



SPV Structure



- Binding term sheet from Cantheon Capital LLC (Cantheon) to provide an initial US $8.6M cornerstone funding for Zelira to conduct FDA Phase 2 and Phase 3 clinical trials for Zelira's proprietary and patented protected HOPE® 1 product (Term Sheet), via a special purpose vehicle (SPV).
- Zelira will contribute to the SPV its HOPE® 1 product, IP and real-world data for 55% equity ownership of the SPV. Cash investors will contribute up to a total of circa US $35M to fund the SVP and US FDA trials for HOPE® 1 in exchange for a maximum cumulative equity interest of 45% of the SVP.
- Zelira will manage the SVP as part of its business platform.
- Cantheon's Term Sheet represents approximately 25% of the total US $35M US FDA trial cost to be raised for the SVP.
- Cantheon's Term Sheet, representing US $8,639,400, is structured as a convertible note that can be converted into a maximum of 12.93% of the SPV's common stock. Cantheon's investment values the HOPE® 1 SPV at US $66.5M

iNGENū

- Globally focused Contract Research Organization working exclusively in the cannabinoid and psychedelic space.
- Zelira HOPE® 1 SPV has appointed iNGENū CRO Pty Ltd (iNGENū) as its Contract Research Organisation (CRO) to lead the clinical validation and regulatory registration of the study product with the US FDA through the submission of an Investigative New Drug (IND) application.
- In addition, iNGENū will partner with the SPV to drive the execution of required clinical trials and pivotal studies for approval and licenses required for commercialisation.
- iNGENū and its US based affiliate, Benuvia, hold Schedule 1 licenses and the DEA and FDA licenses required to conduct the HOPE® 1 trials in Australia and the United States
- iNGENū and its US based affiliate, Benuvia, have a US based manufacturing facility that is fully licensed to provide both clinical trial material and commercial material for HOPE® 1

iNGENU

zelira® THERAPEUTICS

ZELIRA'S PORTFOLIO OF CLINICALLY VALIDATED ASSETS

	Autism	Insomnia	Oral Care	Dermatology	Neuropathy	Targeted Pain	Platform Technology
PRODUCT	HOPE®	ZENIVOL®	SprinJene CBD	RAF FIVE™	ITURA™		ZYRADI™ (EDCDM) & Novel Encapsulation
DATE OF LAUNCH	2020	2020	2021	2021	2021	2021 *IRB approved observational clinical study. Completion expected 2023'*	2022
CURRENT MARKETS	US, AUS	AUS, GERMANY	US, UK	US	US	US	US

Via Business Development focused on licensing and distribution we are taking these assets to the world

US AUS GERMANY UK

Zelira Patent Portfolio

A significant distinction of the Zelira strategy is our investment in patent protection

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

Thank You

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