ZELIRA THERAPEUTICS

2023 Annual Shareholders General Meeting

Investor Briefing 15 November 2023

ASX: ZLD
OTCQB:ZLDAF
zeliratx.com

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Highlights

2022

13 Jul 22
ZENIVOL® achieves major milestone with formal regulatory approval received in Germany

8 Sep 22
$400K partial repayment of loan received from Health House

15 Sep 22
Zelira completes two thirds of enrolment for IRB-approved diabetic nerve pain trial

21 Nov 22
$550K partial repayment of loan received from Health House

21 Nov 22
Zelira completes enrolment for diabetic nerve pain trial

2023

10 Jan 23
Full repayment of $1.75M in cash and shares received from Health House/Creso

30 Jan 23
Zelira receives $1.14M cash from R&D tax incentive

15 Feb 23
Zelira secures commitment for US $8.6M cornerstone funding into SPV for HOPE® 1 FDA clinical trials

20 Feb 23
Greg Blake joins Zelira Board as Executive Director

15 Mar 23
Zelira raises $1.77M from US-based investors

19 May 23
Zelira secures additional commitment for US $3.25M investment into HOPE® SPV

30 May 23
Zelira's diabetic nerve pain drug outperforms multi-billion dollar Lyrica® in clinical trial

31 May 23
Dr Donna Gentile O'Donnell joins Zelira Board as Non-Executive Director

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Achievements- Q.1 FY24:
First close of SPV funding leads to stronger cash position

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

Stronger closing cash position of $1.03 million (as at 30 September 2023), following receipt of the first close (US$1.07 million) with subsequent closes expected throughout the year

Total committed investment in HOPE® SPV to date is $11.85 million

Positive progress on development work to change Zenivol® format to a capsule powered by Zyraydi™ technology. Zelira vetting potential manufacturers for HOPE® and Zenivol®

Positive Readout of topline results from Diabetic Nerve trial

Zelira's Diabetic Nerve Pain Drug Outperforms Big Pharma drug; successful clinical trial against multi-billion-dollar Lyrica®

Demonstrated Safety, Tolerability, and Improved Efficacy

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

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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

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HOPE®- Real World Evidence

Autism patients report improvement in symptoms and quality of life with Zelira Therapeutics' HOPE®

Video of Australian patient and family taking HOPE®

Launch & Learn

HOPE® Grows For Autism video showing a before and after experience on cannabinoid medication

Autism Spectrum Disorder patients demonstrate improvements in Clinical Global Impression (CGI) whilst on HOPE®

A natural history study of medical cannabis consumption in paediatric autism in the United States

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

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

Key Highlights Of The Announcement Progressing HOPE® 1 into US FDA Clinical Trials

MAJOR 2023 MILESTONE

HOPE® special purpose vehicle (SPV) established to facilitate investment to fund HOPE® 1 US FDA clinical trials

US-based Cantheon Capital LLC, global investor focused on clinical trial assets with near term catalysts, commits cornerstone US $8.6M to support HOPE® 1 US FDA clinical trials

Zelira to raise up to an additional circa US $26M in SPV to fund HOPE® 1 US FDA trials for total gross proceeds of circa US $35M, and retain a 55% interest in the HOPE® SPV

Specialist cannabinoid CRO and FDA experienced iNGENū appointed as CRO for the HOPE® 1 US FDA trials

Execution of definitive agreements for HOPE® SPV totalling US $3.25M to advance HOPE® 1 through FDA. Receipt of first tranche US $1.07M.

iNGENU

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ZELIRA'S PORTFOLIO OF CLINICALLY VALIDATED ASSETS

						
PRODUCT	**Autism** HOPE®	**Insomnia** ZENIVOL®	**Oral Care** SprinJene CBD	**Dermatology** RAF FIVE™	**Neuropathy** ITURA™	**Platform Technology** ZYRADI™ (EDCDM) & Novel Encapsulation
DATE OF LAUNCH	**2020**	**2020**	**2021**	**2021**	**2021**	**2022**
CURRENT MARKETS	US AUS	AUS GERMANY	US UK	US	US	US

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

US AUS GERMANY UK

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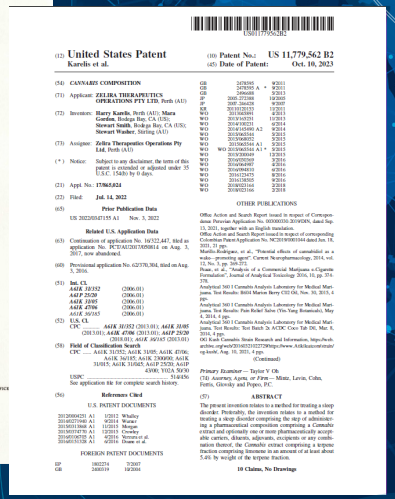
Zelira Patent Portfolio

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

Patent Family	Accepted, Granted, Certified or Validated as at 1 Nov 2022	Accepted, Granted, Certified or Validated as at 1 Nov 2023
Autism 1	1	2
Autism 2	0	1
Breast Cancer Prognosis	17	17
Cancer	11	13
Encapsulation Technology	0	0
Opioid Sparing	1	1
Pain 1	1	2
Pain 2	1	1
PTSD/Anxiety	1	1
Skin 1	4	4
Skin 2	0	1
Sleep 1	5	8
Sleep 2	5	7
TOTAL	**47**	**58**



58
patents granted

US Patent Office granted the HOPE® patent in April 2023

9
Therapeutic areas

26
Countries

100+
patents awaiting approval

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Advancing Product Development

Positive progress with the development work to change Zenivol® format to a capsule formulation powered by Zyraydi™ technology.

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Advancing Clinical Validation of Key Patent Protected Products

FDA clinical trials will be an important next step for two key patent protected products:

- HOPE®1: Via the establishment of the HOPE® SPV, Zelira has successfully gained the resources to start the FDA clinical trials for HOPE® 1, a patent protected autism treatment. Zelira has commenced the FDA trial process with appointed CRO iNGENU, currently focused on the completion of the Target Product Profile, a key initial step in the FDA clinical trial process
- Diabetic Nerve Drug Treatment ZLT-L-007: Following the receipt of the positive top-line results from the IRB approved diabetic drug trial, demonstrating ZLT-L-007 outperformed Pharma drug Lyrica®, Zelira is evaluating the further progression of ZLT-L-007 into formal FDA clinical trials.

Corporate Snapshot

Financials (as at 7 November 2023)	AUD$
Share Price	$0.99
52 week range	$0.90 -$ 3.05
Market Capitalisation	$11.2M
Cash (at 30 Sept 2023)	$1.0M

Capital Structure (Fully Diluted[2])

Structure		Major Shareholders	
Director Holdings	5.00%	Ilera Investors	31.70%
Top 20	52.70%	Malik Majeed	10.0%
Employee Options	2.25M	Quincy Street Capital	4.0%

Share Price (Market Data as at 7 November 2023)

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 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.

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.

Thank You

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