

ZELIRA THERAPEUTICS

A Global Biopharmaceutical
Company Developing and
Marketing Clinically Validated
Cannabinoid-Based Medicines



ASX: ZLD
OTCQB:ZLDAF
zeliratx.com

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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.



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.



Rx & OTC Development and Commercialization 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.



Revenue Generating

Multiple revenue streams from licensing payments, royalties and direct commercialization.



Premium Product

Manufacturing Partner-EU GMP Certified.



Fast Tracking Commercialization

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



2020

Milestones achieved in 2020



14 July 2020

Zelira® reports Phase 1 dose escalation study in chronic pain patients on long-term opioid treatment meets primary and secondary endpoints



22 July 2020

Zelira® and Cardiovascular Solutions of Central Mississippi (CVSCM) enter into binding agreement to develop and commercialize products targeting Peripheral Arterial Disease (PAD)



20 Aug 2020

HOPE® 1 and HOPE® 2 launched in Louisiana, USA



16 Sept 2020

Zenivol® launched in Australia as the world's most clinically validated cannabinoid-based treatment for chronic insomnia



30 Sept 2020

Zelira® signs real world data agreement for insomnia drug Zenivol® with Emyria



27 Oct 2020

HOPE® 1 and HOPE® 2 launched in Australia as TGA adds to Special Access Scheme



9 Nov 2020

Zelira® partners with Emyria for Autism Observational Trial for HOPE® products



2 Dec 2020

Zelira® partners with SprinJene to launch CBD toothpaste in USA



14 Dec 2020

HOPE® 1 and HOPE® 2 expands distribution with launch in Washington DC, USA



2021

Milestones achieved in 2021



3 June 2021

Levin health licensing and management agreement signed to conduct chronic pain treatment clinical trial on retired athletes



21 June 2021

Clinical trial results of Zelira's Zenivol® published in prestigious peer-reviewed journal SLEEP



20 October 2021

Zelira® raises US\$5 million from Quincy Street Capital LLC, a US-based family office fund



15 June 2021

Zelira® partners with Health House International via exclusive distribution agreement to launch CBD toothpaste in the United Kingdom



12 July 2021

Zelira® US Observational Clinical Pain Trial receives IRB approval



3 November 2021

Zelira® Develops EDCDM technology for making free flow powder from cannabinoid distillate and signs new licensing deal



18 June 2021

Breakthrough research at Curtin University (Australia) demonstrates significant uptake of CBD into the brain



23 September 2021

Zelira® Launches RAF FIVE™ Acne Treatment products through its dermatology focussed subsidiary

Maiden revenues achieved totalling \$663,316 driven by growth in SprinjeneCBD sales, Rx sales, product development agreement, clinical trial management and product licensing fees from Levin Health.



SIGNIFICANT EVENTS

At a Group level, fundraising values Zelira® at

A\$122.8M

US\$5 million raised from US-based family office fund, Quincy Street Capital LLC

US\$3.5M A\$4.79M

US\$3.5 million (A\$4.79 million) via a placement of Zelira® fully paid ordinary shares

US\$1.5M A\$2.05M

via an equity investment in Ilera Derm LLC (Zelira Dermatology) for a 3% shareholding in that company, valuing Zelira Dermatology at US\$50 million.



September 2020, Zelira® completed a placement of A\$2 million to the Thorney Investment Group (Thorney Placement) which increased their holding to a substantial investor with a 5.2% stake in the Company at the time of investment.



Australian operations remain a core and important part of the Company with world class clinical trials to continue to be conducted in Australia and managed by Australian-based employees.



Milestones of US based product sales exceeded US \$1 million thereby satisfying the Class A Performance rights held by Zelira directors and the original Ilera Therapeutics shareholders who have received 393,870,322 shares.



February 2021, Zelira® announced management changes designed to strengthen the Company's focus on global markets, and in particular the US.

\$8.75 MILLION

In August 2020, Zelira® successfully completed an oversubscribed AUS\$8.75 million placement (before costs) to Australian and USA-based sophisticated and institutional investors (Placement). The Placement was managed by Morgans Corporate Ltd. and received firm bids exceeding twice that of the Placement.

\$1.3 MILLION

January 2022, Zelira® received \$1.3M cash refund under the Australian Federal Government's R&D Tax Incentive Scheme

175:1 CAPITAL CONSOLIDATION

In April 2022, Zelira completed a consolidation of its issued securities on a 175:1 basis



REVENUE STREAMS



Revenue Stream 1

Launch & Learn
Rx

Autism
Aged disorders
Insomnia

Revenue Stream 2

Oral Health
OTC

Toothpaste
Additional Products, 2022 Launch



Revenue Stream 3

Dermatology
OTC

Five acne treating
products launched 2021

Revenue Stream 4

Clinical Trials
Rx

Insomnia
Opioid Sparing
Autism



Revenue Stream 5

Pharma
Rx
Pain
GI
Insomnia



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
- 43% costs reimbursable via Australian R&D rebate program
- Supports path to registration



PIPELINE

Product	Status	Current Markets	Next Steps
Autism HOPE®	Launched 2020	 USA  AUS	 GERMANY  UK  NZ
Insomnia Zenivol®	Launched 2020	 AUS	 USA  GERMANY  UK  NZ
Oral Care SprinJene CBD	Launched 2021	 USA  UK	 ADDITIONAL PRODUCTS
Dermatology RAF FIVE™	Launched 2021	 USA	
Targeted Pain	IRB approved observational clinical study Launched 2021	 USA	
Aged Disorder	Launches 2022	 USA	



HOPE[®] for Behaviours associated with Autism Spectrum Disorder Rx



Autism Market

- Autism affects 1.8% children¹
- Only 2 FDA approved drugs for Autism
- Existing medication has significant side-effects
- Global ASD market \$3.2B²

Overview

- HOPE[®] developed with and for the Autism community
- Published Real life data report-HOPE[®] improves autism-related behaviours and quality of life for survey participants



US Revenues: Licensed in Louisiana and Washington DC (Deal Structure: Upfronts + double digit royalty).



Manufacturing agreement for Australia: Extractas Biosciences (formerly Tasmanian Alkaloids)



Distribution agreement for Australia: Health House



Distribution agreement for NZ: NUBU Pharmaceuticals



Launched and generating revenue in Australia, Washington, D.C., and Louisiana

1. Center for Disease Control and Prevention. Autism Spectrum Disorder: Data & Statistics. Accessed December 14, 2017 (<https://www.cdc.gov/ncbddd/autism/data.html>) 2. <https://www.medgadget.com/2019/12/autism-spectrum-disorder-therapeutics-market-size-growth-analysis-insights-and-forecast-2019-2026.html>



Zenivol® for chronic, unresolved insomnia Rx



Insomnia Market

- 30% of adults report symptoms of insomnia¹
- US insomnia market: US\$4 billion by 2021²
- Current medications limited by side-effects

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
- Significant reduction in insomnia symptoms
- Clinical trial results published in peer reviewed journal of *Sleep*®



Manufacturing agreement for Australia: Extractas Biosciences (formerly Tasmanian Alkaloids)



Distribution agreement for Australia: Health House



Distribution agreement for Germany: Adjupharm GmbH



Distribution agreement for NZ: NUBU Pharmaceuticals



Launched and generating revenue in Australia

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



Oral Care – Sprinjene CBD OTC



Overview

- Full line of CBD oral care products



Toothpaste was launched in Q1 2021 and generating revenue with strong growth potential



Available for purchase on zeliraoralcare.com, sprinjenecbd.com, amazon.com and wholesale distribution channels in the US



Expanded to the UK Market through exclusive distribution agreement with Health House International



Additional Products to be launched in 2022

1. Center for Disease Control and Prevention. Autism Spectrum Disorder: Data & Statistics. Accessed December 14, 2017 (<https://www.cdc.gov/ncbddd/autism/data.html>) 2. <https://www.medgadget.com/2019/12/autism-spectrum-disorder-therapeutics-market-size-growth-analysis-insights-and-forecast-2019-2026.html>



Oral Care – Sprinjene CBD

Bursting with the unique benefits of 3 natural ingredients



Hemp derived full spectrum CBD (*cannabis sativa*) – Enhancing your body’s endocannabinoid function

Our CBD-based toothpaste boosts your endocannabinoid system, a network of receptors in our bodies that helps us fight inflammation and regulate internal systems in order to maintain a healthy balance.



Black Seed Oil (*nigella sativa*) – Maintaining healthy gums and relief for dry mouth

Our patented formula is bursting with Black Seed Oil, which contains Thymoquinone. Thymoquinone has been documented for its anti-inflammatory benefits, its anti-bacterial properties for maintaining healthy gums, and for lubrication of oral surfaces in relieving dry mouth.



Zinc – A powerful natural antibacterial agent

The FDA has recently approved the use of Zinc as a natural anti-gingivitis agent. It also enhances the effectiveness of the Black Seed Oil to provide its beneficial properties and delivers long lasting oral freshness.



Oral Care – Sprinjene CBD

<p>Ingredients featured in CBD SprinJene Natural Toothpaste help...</p>	 <p><i>Protect teeth from decay</i></p>	 <p><i>Fight gingivitis</i></p>	 <p><i>Control bacteria, plaque, and tartar</i></p>
 <p><i>Relieve dry mouth</i></p>	 <p><i>Freshen breath</i></p>	 <p><i>Remove surface stains</i></p>	 <p><i>Reduce gum inflammation</i></p>



Differentiated dermatology OTC

Dr. Karyn Grossman in the News



- Renowned board-certified cosmetic dermatologist
- Trained at Harvard Medical School
- Successfully launched products with clinical and commercial success
- Key opinion leader in all fields of esthetics
- Popular celebrity following
- In-demand resource for high-value media outlets

Overview

- Science-backed Platform Technology
- Focus on significant unmet needs in Dermatology

Zylorma™, a proprietary, patent pending, acne fighting complex with CBD, Salicylic acid and additional compounds to fight bacteria and clogged pores associated with acne, balance sebum production to help eliminate & prevent break-outs

Experienced team with pharmaceutical and dermatological drug and cosmetic product development expertise and track record with understanding of drug physiology, mechanism of action and cannabinoids science

- Innovative Branding and Market-ready products
- World Class Inventors and Formulators

Leveraging Zylorma™ proprietary complex technology to create safe, efficacious and consumer validated treatments for dermatological conditions

RAF FIVE™ is inspired by a true story. It all started from a fateful bus ride in 1964, when Raphael Mechoulam brought 5 kilo of Lebanese hashish he received from the Israeli Police to his laboratory at the Weizmann Institute in Rehovot. With that material he was able to isolate and identify the psychoactive component in Cannabis, Tetrahydrocannabinol (THC), that had eluded scientists for decades.



Soft launch of five products in Q4 2021



RAF FIVE™ Product Range

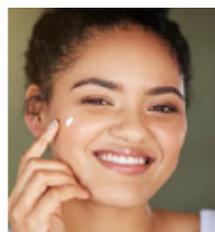




**WASH AWAY GEL CLEANSER
ACNE TREATMENT**



**AFTER HOURS MOISTURIZING
LOTION ACNE TREATMENT**



WASH UP ACNE CLEANSER



**CLEAR THE WAY
ACNE TREATMENT PADS**



**KICK OFF HYDRATING LOTION
BROAD SPECTRUM SPF
30 SUNSCREEN**



Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology

Zelira has successfully developed and demonstrated enhanced dissolution of cannabinoids using its enhanced distillate capture and dissolution matrix (EDCDM)

- Breakthrough technology developed by Zelira.
- EDCDM captures distillate in a unique and proprietary matrix.
- EDCDM will allow cannabis manufacturers to formulate and develop free flow solid oral dosage forms based from cannabinoid distillate.
- This technology will lead to the development of capsules and tablets filled with free-flowing powder base.
- EDCDM has the potential to significantly expand the prescriber and patient base for cannabinoid-based medicines.

3 year licensing deal with DRCN includes

- US\$1M upfront, non-refundable licence fee, US\$250k received Jan 2022
- DRCN can develop up to 3 products using EDCM technology
- Zelira to receive 20% royalty on net sales



Enhanced Distillate Capture and Dissolution Matrix (EDCDM)



DIFFICULTY WITH FORMULATION
AND DEVELOPMENTS OF FREE FLOW
CAPSULES AND TABLETS DUE TO NON
UNIFORMITY AND SEPARATING
FROM POWDER BED



FREE FLOW CAPSULES
AND TABLETS



CANNABINOÏD DISTILLATE
WITHOUT EDCDM
TECHNOLOGY

CANNABINOÏD DISTILLATE
WITH EDCDM
TECHNOLOGY

CAPSULE

This novel matrix absorbs the distillate into a nano porous silicate particle where the distillate is effectively trapped in the structure of the silicate rendering the powder bed dry.

As a result, this prevents the distillate from separating from the powder bed during encapsulation and under the compression forces utilised in tableting thus opening new ways to develop pharmaceutical grade, cannabinoid-based medicines in solid oral dosage forms such as capsules and tablets.



Zelira Patent Portfolio

Zelira's patent portfolio has been granted or under consideration in 26 countries spanning across the globe. There are 41 patents granted and 103 under prosecution across 9 different therapeutic areas

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



Financial Media Coverage

1 Zenivol® clinical trial results published in the prestigious peer-reviewed journal SLEEP®  [↗](#)

2 Clinical Pain Trial with Retired Professional Athletes  [↗](#)

3 Breakthrough Research Demonstrates Significant Uptake of CBD Into the Brain  [↗](#)

4 Zelira® to launch CBD toothpaste in the United Kingdom UK) via exclusive distribution agreement with Health House International  [↗](#)

5 Entered Agreement with Cardiovascular Solutions of Central Mississippi for Product Development  [↗](#)

6 Results from Phase 1 Dose Escalation Trial in Chronic Pain Patients  [↗](#)



7 Moved Global Headquarters to Pennsylvania to Optimize U.S. Cannabis Market Exposure

PHILADELPHIA
BUSINESS JOURNAL 

8 Zelira® enters Germany, Europe's largest medicinal cannabis market, via an exclusive distribution agreement with Adjupharm GmbH

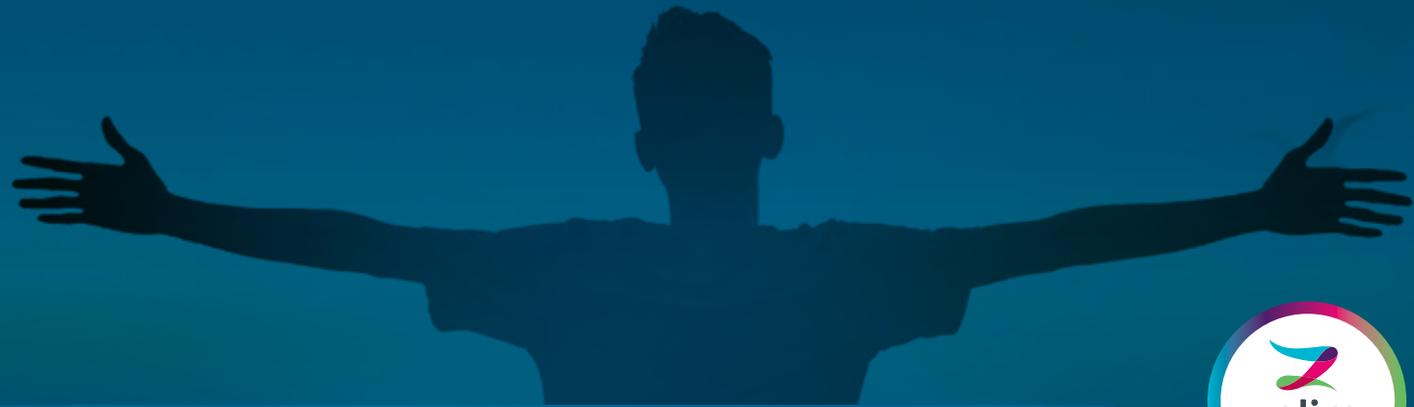
 proactive 

9 Zelira® Launches RAF FIVE™ Acne Treatment products through its dermatology focused subsidiary

The Market Herald 

10 Zelira® Develops EDCDM technology for making free flow powder from cannabinoid distillate and signs new licensing deal

 proactive 



Health House International Ltd Acquisition Transaction Structure

Key highlights:

- On 24th of February 2022 Zelira announced that it entered into a binding term sheet with Health House, under which it is proposed that Zelira will acquire 100% of the shares in Health House by way of a scheme of arrangement (“Scheme”)
- On 19 April 2022, Zelira signed a Scheme Implementation Deed with Health House
- The Scheme is subject to Health House’s shareholders and Court approval in accordance with the requirements of Part 5.1 of the Corporations Act 2001
- Under the Scheme, Zelira will issue shares to Health House giving Health House a 19.45% interest in the expanded Zelira
- Prior to the Transaction, Zelira provided Health House with a A\$1.5mm loan facility to assist with working capital requirements



Zelira Therapeutics Founder & Chairman Osagie Imasogie said:

“The proposed acquisition of Health House will provide Zelira with control of direct access to highly regulated European and other markets for its products. In addition, the successful conclusion of this transaction will improve the margin to Zelira from products that will be directly sold in the markets in which Health House is currently active. This transaction will also provide Zelira with direct access to GMP manufacturing facilities in Europe that will further improve margins for our products and provide stronger control of our product life cycle.

In addition, this transaction will provide Zelira with control of direct access to high quality international standard clinical trial capabilities for our proprietary cannabinoid-based products. This will materially improve the speed at which these products can obtain clinical validation while improving the cost of such clinical trials. We look forward to welcoming Health House shareholders as important members of our mutually enhanced Zelira”



Zelira Therapeutics Global Managing Director & CEO Oldare Odumosu said:

“The proposed acquisition of Health House will maximise Zelira’s unique capability to develop new clinically validated products that can be marketed and distributed on a global basis.

Post merger it is anticipated, Zelira’s revenue profile will be accelerated, margins will increase from the sale of Zelira’s products in markets that Health House is currently active, and cashflow breakeven will be brought forward.”



Health House International Ltd Acquisition Combined Value Proposition



Accelerated revenues
and accelerates the
product pipeline

Direct access to GMP
manufacturing facilities
in Europe

Access to European,
US and Australian
opportunities and
expansion

Control of direct access
to highly regulated
European and other
markets for its products

Improved margins for
markets Health House
are active in

Access to Kalapa,
a doctor / patient
consultancy driving
education

Increases ability to
create new products
to distribute and
manufacture on a global
basis

Increased scale
allowing for access to
a larger, wider pool of
institutional capital

Additional cashflow,
giving the combined
group greater access to
leverage

**Additional and
diversified** monthly
revenue streams from
HHI's operations

An established, low
cost distribution
network

Multi product
distribution access



Corporate Snapshot

Financials (as at 29 April 2022)

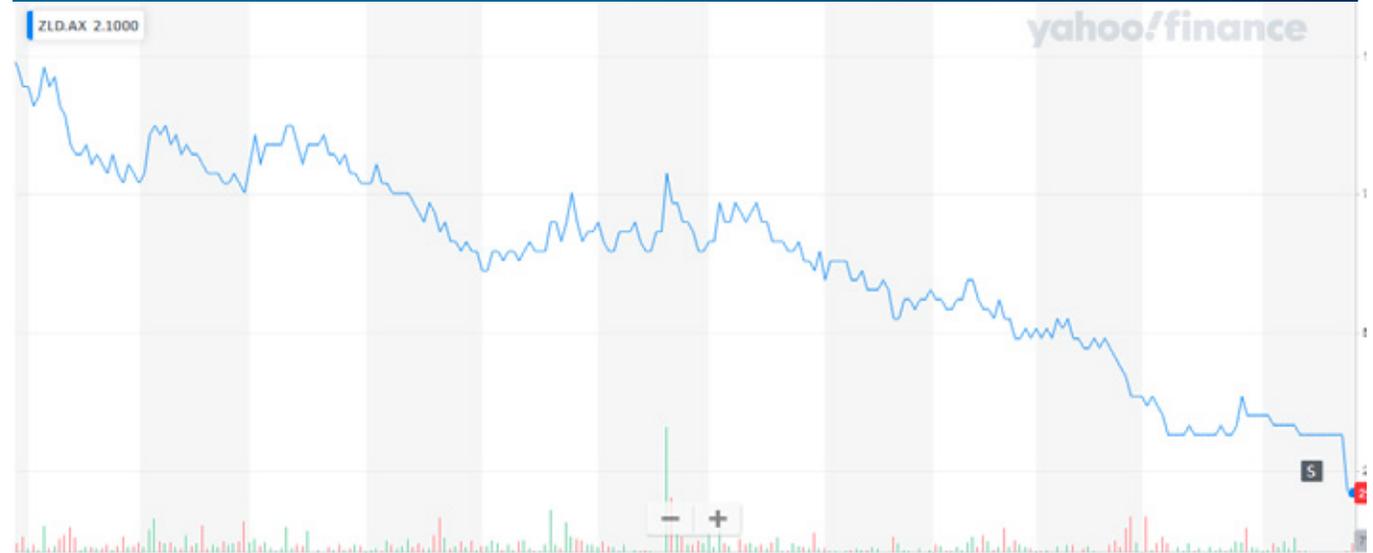
	AUD\$
Share Price	2.10
52w Range	2.10 - 9.97
Market Capitalisation	20M
Cash (at 31 March 2022)	4.6M

Capital Structure (Fully Diluted²)

Structure		Major Shareholders	
Directors Holdings:	17.00%	Ilera Investors	35.2%
Top 20 Shareholders:	62.20%	Jason Peterson	4.2%
Employee Options:	1M	Harry Karelis	3.0%
		Quincy Street Capital	3.5%

If all performance rights are converted and options exercised

Share Price (Market Data as at 29 April 2022)



Global Board of Directors

GLOBAL



Dr. Oludare Odumosu **CEO & Managing Director**

- 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 \$225 Mid 2019. Founding CSO/EVP of Ilera Therapeutics.

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.



Lisa Gray **Director**

- Served as COO for Glaxo Smithkline ("GSK") Ventures.
- Was Co-Founder and Vice Chair of Ilera Healthcare, and lead on the sale of this business to TerrAscend.
- Vice Chair for Advanced Biomedics Holdings.
- Served as Vice Chair for Ilera Therapeutics.
- Co-Founder and Managing Partner of PIPV Capital.

AUSTRALIA



Harry Karelis **Vice Chairman**

- Founding Director/Shareholder of numerous ASX-listed companies including in the global medicinal cannabis sector.
- +25 years corporate/finance experience, specialising in med-tech private equity investing.
- Principal of investment firm Gemelli Group.



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.



Thank You

Zelira Therapeutics

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