ZELIRA THERAPEUTICS

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

ASX: ZLD
OTCQB:ZLDAF
zeliratx.com

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Zelira is a global biopharmaceutical company researching, developing, and commercialising 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.

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.

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 to mid/long term revenue.

Milestones achieved in 2021

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

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

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

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

12 Jul — Zelira® US Observational Clinical Pain Trial receives IRB approval

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

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

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

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Milestones achieved YTD in 2022

9 May

Zelira®, in partnership with CVSCM launched ITURA™ Advance Relief Cream

17 May

HOPE®1 results of longitudinal, real-world data (RWD) study in autism support safe and effective use

30 May

Progressed arm one (enrolment of 20 patients) of a three-arm diabetic nerve pain drug trial, a head-to-head trial against a Big Pharmaceutical company's multi-billion dollar revenue drug

8 Jun

Zenivol® results of longitudinal, RWD support its effectiveness in managing the treatment of insomnia

13 Jul

Zenivol® receives formal BfArM approval in Germany

Total revenue in FY22 was up 132% to $1.5 million (FY21: $0.7 million)

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Zelira expands into Germany with ZENIVOL®

- In July 2022 Zenivol® received formal approval from German regulatory authority BfArM, for commercialisation by Adjupharm GmbH
- Formal approval of Zenivol® is a major milestone in Zelira's expansion into Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest market
- Advances the Company's global commercialisation strategy to grow its Pharmaceutical (Rx) portfolio
- Expands the availability of Zenivol® beyond Australia for the first time
- Reinforces the pharmaceutical quality of Zelira's Australian production capabilities, including the safety and efficacy of Zelira's clinically validated cannabinoid-based medicines .

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.

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.

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

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.

$

$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

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REVENUE STREAMS

1

Launch & Learn
Rx

Autism

Aged disorders

Insomnia

2

Oral Health
OTC

Toothpaste

Additional Products, 2022 Launch

3

Dermatology
OTC

Five acne treating products launched 2021

4

Clinical Trials
Rx

Insomnia

Opioid Sparing

Autism

5

Pharma
Rx

Pain

GI

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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

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PIPELINE

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

US AUS GERMANY UK

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HOPE® for behaviours associated with Autism Spectrum Disorder

Rx

Autism Market

- Autism affects 1.8% children[1]
- Only 2 FDA approved drugs for Autism
- Existing medication has significant side-effects
- Global ASD market $3.2B[2]

Overview

Two published, longitudinal real world data studies demonstrated improvements in autism related behaviours and quality of life for patient and carers with HOPE®

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

Manufacturing agreement for Australia: Extractas Biosciences

Distribution agreement for Australia: Health House

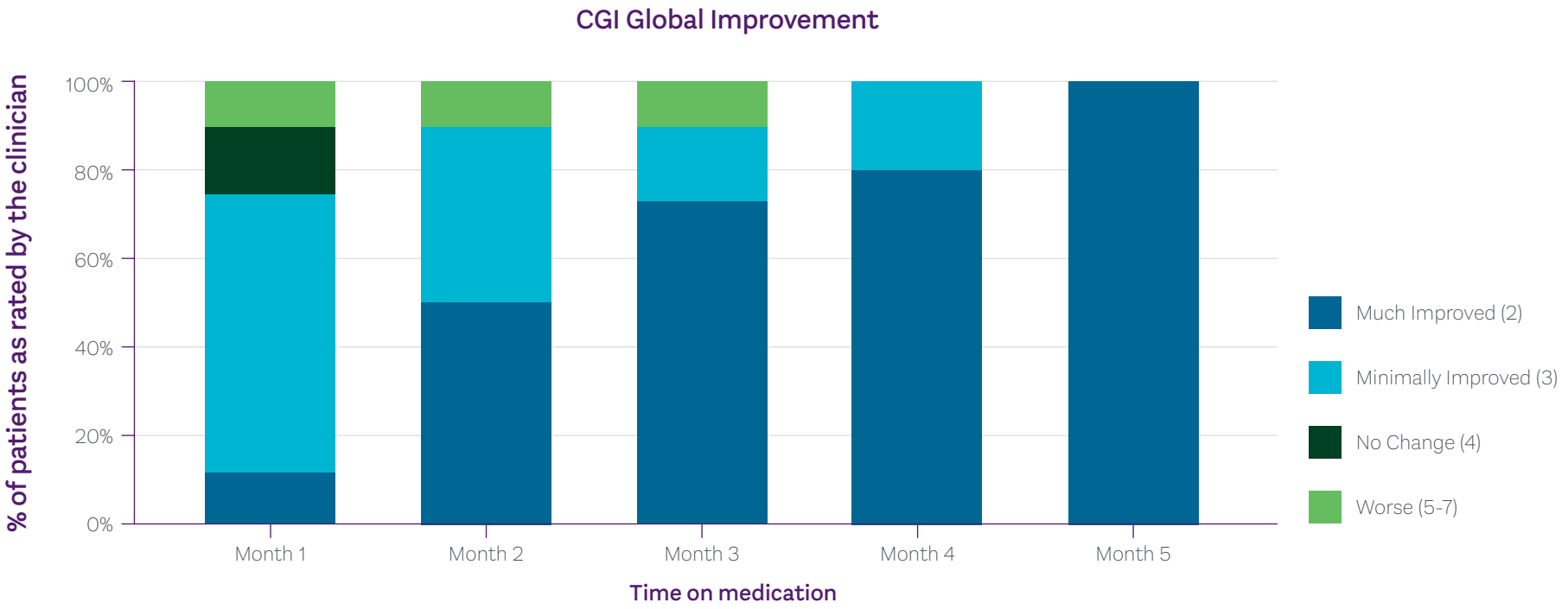
Distribution agreement for NZ: NUBU Pharmaceuticals

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

1. Centerfor Disease Controland 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

Zelira sponsored – HOPE® 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

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Zenivol® for chronic, unresolved insomnia Rx

Insomnia Market

- 30% of adults report symptoms of insomnia[1]
- US insomnia market: US$4 billion by 2021[2]
- 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®***

Approved by BfArM for German market

Manufacturing agreement for Australia: Extractas Biosciences

Distribution agreement for Australia: Health House

Distribution agreement for Germany: Adjupharm GmbH

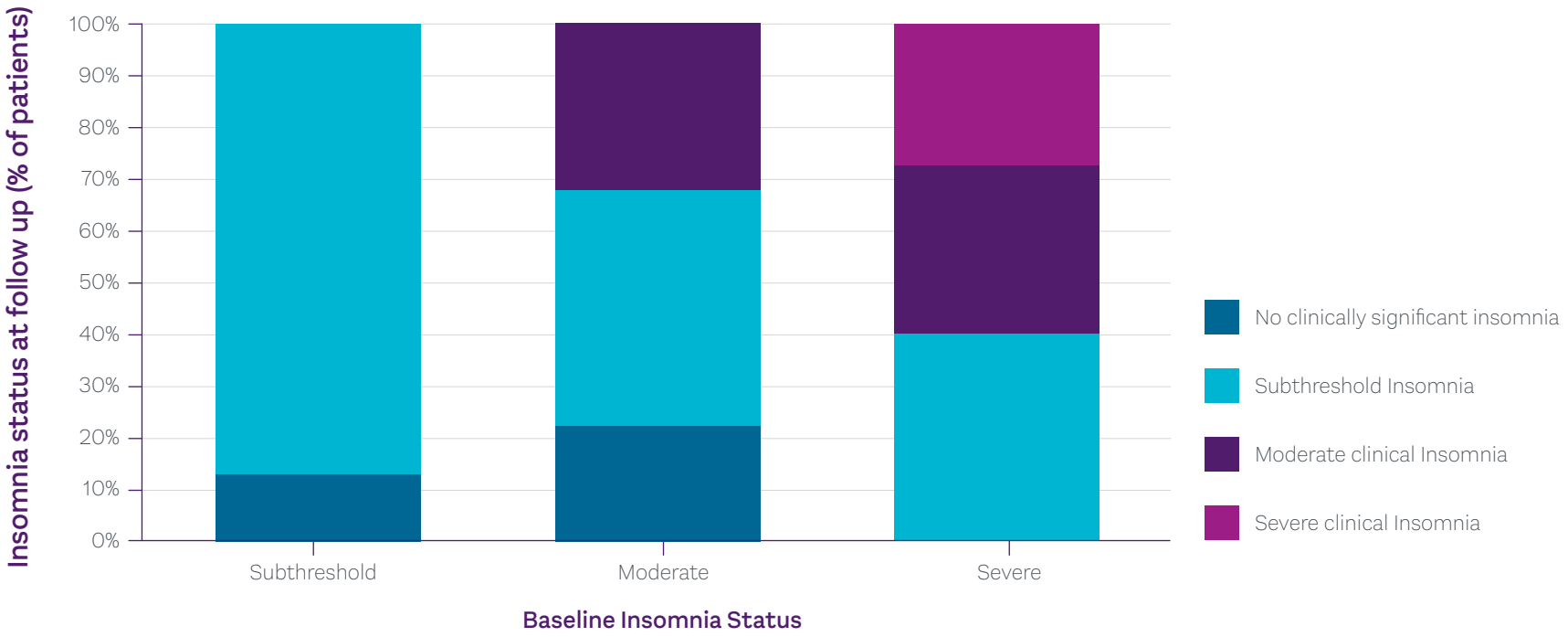
Distribution agreement for NZ: NUBU Pharmaceuticals

Launched and generating revenue in Australia

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

Zelira sponsored – ZENIVOL® longitudinal, real-world data study

Change in Insomnia status whilst on ZENIVOL®, as measured by the Insomnia Severity Index (ISI)



Overall, patients taking ZENIVOL® improved from a baseline ISI score of 19.5 (Moderate clinical insomnia) to 14.3 (Subthreshold insomnia levels) (p<0.001).

OBJECTIVE: Investigate the effect of Zenivol in improving sleep in people with chronic insomnia, ENDPOINTS: Improvement in ISI scores (Insomnia Severity Index) , PATIENTS: N = 94
PATIENT AGE: The mean age of active patients was 56 years of age with the oldest patient being 77 years of age DURATION: Maximum time to-date that a patient had taken ZENIVOL® was 10.8 months (or 329 days). The mean time on treatment for active ZENIVOL® patients was 4.3 months

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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

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Oral Care – SprinJene CBD

Bursting with the unique benefits of 3 natural ingredients

Hemp derived full spectrum CBD (*cannabis sativa*)

Our CBD-based toothpaste boosts your endocannabinoid system which helps fight inflammation and regulate internal systems to maintain a healthy balance.

+

Black Seed Oil (*nigella sativa*)

Our patented formula is bursting with Black Seed Oil, which contains Thymoquinone, which has anti-inflammatory and antibacterial benefits for maintaining healthy gums for relieving dry mouth.

+

Zinc

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.

Ingredients featured in CBD SprinJene Natural Toothpaste help...

- Protect teeth from decay
- Fight gingivitis
- Control bacteria, plaque and tartar
- Relieve dry mouth
- Fresh breath
- Remove surface stains
- Reduce gum inflammation

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RAF FIVE™ - 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
- Innovative Branding and Market–ready products
- World Class Inventors and Formulators

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

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.

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RAF FIVE™ Product Range

WASH AWAY GEL CLEANSER
ACNE TREATMENT

SPOT ON ACNE TREATMENT

KICK OFF HYDRATING LOTION BROAD SPECTRUM SPF 30 SUNSCREEN

AFTER HOURS MOISTURIZING
LOTION ACNE TREATMENT

CLEAR THE WAY
ACNE TREATMENT PADS

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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.

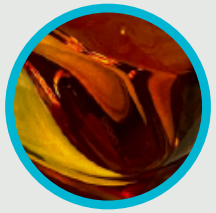
PROBLEM

CANNABINOID DISTILLATE = DIFFICULTY WITH FORMULATION AND DEVELOPMENTS OF FREE FLOW POWDER-BASED CAPSULES AND TABLETS DUE TO NON-UNIFORMITY AND SEPARATING FROM POWDER BED

SOLUTION

CANNABINOID DISTILLATE + ZYRAYDI™ TECHNOLOGY (CANNABINOID DISTILLATE) = PHARMACEUTICAL GRADE FREE-FLOWING POWDER BASE FOR CAPSULES AND TABLES

IN PRACTICAL TERMS



CANNABINOID DISTILLATE *without* ZYRAYDI™ technology

+

ZYRAYDI™ ingredient matrix

=

ZYRAYDI™ CAPSULES AND TABLETS

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Zelira Patent Portfolio

Going into 2022-23 Zelira's patent portfolio has been granted or under consideration in 26 countries spanning across the globe. There are 41 patents granted and 100 under prosecution across 9 different therapeutic areas

Therapeutic Area	Granted/Allowed	Under Prosecution/Examination
Cancer compositions	10	12
Skin compositions	3	8
Sleep compositions	7	27
Cancer prognosis	18	-
Autism compositions	-	12
Pain compositions	1	16
PTSD/Anxiety composition	1	11
Opioid sparing compositions	1	13
Encapsulation	0	1
Total	**41**	**100**

Corporate Snapshot

Financials (as at 11 November 2022)	AUD$
Share Price	1.04
52w Range	0.97 - 7.54
Market Capitalisation	10M
Cash (at 30 Sept 2022)	1.2M

Capital Structure (Fully Diluted[2])			
Structure		**Major Shareholders**	
Directors Holdings:	**14.6%**	Ilera Investors	**35.2%**
Top 20 Shareholders:	**62.2%**	Jason Peterson	**4.2%**
Employee Options:	**1.1M**	Quincy Street Capital	**3.5%**

If all performance rights are converted and options exercised

Share Price (Market Data as at 11 November 2022)

Global Board of Directors

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.

USA

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.

GLOBAL

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.

USA

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

Thank You

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