ASX ANNOUNCEMENT

15 February 2023

# Zelira secures US$8.6 million cornerstone funding for HOPE® 1 US FDA clinical trials

## CANTHEON CAPITAL LLC TO INVEST IN HOPE® 1 TRIALS

### Key Highlights

- US-based Cantheon Capital LLC, a global investor focused on the promotion of clinical trial assets with near term catalysts, to invest cornerstone circa US$8.6 million to support HOPE® 1 US FDA clinical trials
- HOPE® 1 special purpose vehicle (SPV) established to facilitate investment to fund HOPE® 1 US FDA clinical trials
- Specialist cannabinoid CRO and FDA experienced iNGENū appointed as CRO for the HOPE® 1 US FDA trials
- Zelira to raise up to an additional circa US$26 million in SPV to fund HOPE® 1 US FDA trials for total gross proceeds of circa US$35 million, and retain a 55% interest in the HOPE® 1 SPV

**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)**, a global leader in the development and commercialisation of clinically validated cannabinoid-based medicines, is delighted to announce that it has received a binding term sheet from Cantheon Capital LLC (**Cantheon**) to provide an initial US$8.6 million 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 a total of circa US$35 million to fund the SVP and US FDA trials for HOPE® 1 in exchange for a 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$35 million 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 (**Cantheon Convertible Notes**) that can be converted into a maximum of 12.93% of the SPV's common stock.

Zelira has also executed a mandate with SW4 Advisors Limited (**SW4 Partners**) to raise the remaining circa US$26 million required for the SVP, on standard commercial terms.

## Summary of the Term Sheet

The Term Sheet gives Cantheon the right to subscribe for circa US$8.6 million in convertible notes in the SPV subject to terms and conditions set out in the Annexure.

The 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.

**Zelira Therapeutics Chairman, Osagie Imasogie, commented:**

"I am very pleased that we are now at the third stage of our LAUNCH, LEARN & DEVELOP strategy for validation and commercialisation of cannabinoid-based medicines. We **LAUNCHED** HOPE® 1 into the market in three US States, Pennsylvania, Louisiana and Washington D.C. approximately three years ago and in Australia in 2020, where it is available to prescribers and patients through the Therapeutic Goods Administration (TGA) Special Access and Authorised Prescriber Schemes for use with the symptoms of Autism Spectrum Disorder (ASD).

During this period, we **LEARNED** from patients who use HOPE® 1 for essential data points – the dose they used, their frequency of dosing, any side effects they experienced, and the efficacy of our product. Zelira, published positive results detailing the analysis of longitudinal, real-world studies (RWD) generated from patients using HOPE®. The results support the safe and effective use of HOPE® 1. In addition, 70% of patients in the study cohort were rated by clinicians as having achieved at least 'moderate' therapeutic effect after 5 months on HOPE® 1. In the state of Pennsylvania, our licensee has sold and dispensed over 9 million doses of HOPE® over the past three years with no negative safety signal. These doses have been bought and paid for, out of pocket, by parents who have administered HOPE® to their children with ASD, on a monthly basis.

Now we are proceeding, with a high level of comfort, based on our learning and RWD, including positive before and after videos of children with ASD that have been administered HOPE®, to the formal **DEVELOPMENT** of HOPE® 1 under the US FDA process. Our target is a potential eventual approval of HOPE® 1 in the US as a drug for ASD, within approximately 36 months from the commencement of our trials. We expect that the next months will be exciting and value enhancing for our patients and shareholders, as we proceed with our clinical development of HOPE® 1."

**Zelira Therapeutics Managing Director, Dr Oludare Odumosu, commented:**

"Zelira continues to deliver on our unique drug development strategy with the decision to advance HOPE® 1 through formal clinical trials and seek FDA approval. We are pleased to have searched for and selected a world class specialist research organisation, iNGENū, to partner with us to drive the clinical and regulatory activities for what we hope will be a successful clinical trial that results in the US FDA approval of HOPE® 1 as a frontline solution for patients living with ASD.

iNGENū, coupled with their US affiliate, Benuvia, have the experience of successfully taking the Syndros® cannabinoid product through the US FDA to approval. In addition, they hold the FDA and DEA licences required to manage schedule 1 products in the US. Lastly, they have an FDA and DEA approved manufacturing site that can supply both our clinical trial and commercial products for what we hope will be an FDA approved product.

In preparing for this US FDA trial, we reformulated HOPE® 1 into a pharmaceutical grade capsule, using our proprietary Zyraydi™ technology. Not only does this provide a more convenient and traditional pharmaceutical dosage form for patients and the market, but it also provides us with additional IP protection for our already patented formulation of HOPE®. Using Zyraydi™ to reformulate HOPE® 1 into a free-flowing powder and then a capsule also provided us with a more competitive cost basis for manufacturing HOPE® 1. We expect to deliver our IND to the FDA by the end of 2023 calendar year."

We are equally pleased that Zelira's unique value proposition resonated strongly with US-based Cantheon Capital, who have agreed to cornerstone the funding required for the SPV."

**Cantheon Capital LLC's General Partner, Aaron Ray, commented:**

"We are glad to support Zelira's innovative Launch, Learn and Develop strategy for clinical validation of cannabinoid medicines. As global investors in this space, we are excited to have the opportunity to fund a product that already has a considerable amount of real-world data for safety and efficacy, with millions of doses having been dispensed to patients over several years before the start of formal FDA clinical trials. This situation is in sharp positive contrast with the traditional situation where formal first in man studies (usually phase 1) FDA trials start with reliance on only animal studies and a hypothesis as to how the study product will do in humans.

In addition, we are pleased that Zelira has appointed iNGENū as its Contract Research Organisation to lead the clinical validation and regulatory registration of the study product with the US FDA. We know iNGENū well and are comfortable that they will partner effectively with Zelira to drive the execution of the required clinical trials and pivotal studies for approval. iNGENū was selected on the basis of their capability and experience as a specialist cannabinoid CRO and their US FDA experience, which enabled them to develop and present an attractive tailored, time efficient and cost-effective approach to Zelira's clinical trial requirements. We look forward to the prospect of a successful investment outcome and launching an approved HOPE® 1 into a multibillion dollar market."

**iNGENū's CEO, Dr. Sud Agarwal stated:**

"iNGENū is uniquely positioned to partner with both Zelira and Cantheon for the clinical development of HOPE® 1 through the US FDA. We have strong footprints in both Australia and the US that span the full range of clinical, regulatory, and manufacturing capabilities for the medicinal cannabinoid industry.

We are pleased to be working with Zelira who are developing pharmaceutical-grade cannabinoids, with a solid, patent-protected focus. We are particularly pleased to be working on the first drug that is specifically developed to target the treatment of ASD symptoms. The two other currently approved drugs for ASD in the US (Risperdal and Abilify) are both antipsychotics, have some challenging dose-related side-effects and could potentially be superceded by a cannabinoid based new drug approval.

We look forward to HOPE® 1 going through the scientific rigor of a clinical trial and reviewing its clinical data."

**This announcement has been approved and authorised for release by the board of Zelira Therapeutics Limited.**

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**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)** Zelira is a leading global biopharmaceutical company in the research, development and commercialisation of clinically validated cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development positioned to enter global markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines in its prescription [Rx] business for the treatment of a variety of medical conditions including insomnia, autism and chronic non-cancer pain as well as offering over the counter [OTC] products.

Zelira's Rx business generates revenue from two proprietary medications, HOPE® and ZENIVOL®. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana.

Zelira is also generating revenue in Australia from its proprietary and patented ZENIVOL® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia. Zelira will also be expanding commercialisation of ZENIVOL® into Germany via its German commercialisation partner Adjupharm GmbH following recent approval from German regulatory authority BfArM.

Zelira's OTC products in the oral and dermatology health care sectors are also generating revenue. Zelira, in partnership with SprinJeneCBD, launched a full line of oral care products, currently generating revenue in the US. The SprinJeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, blackseed oil and zinc utilising proprietary and patented technology. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannnabidiol (CBD).

Zelira has developed Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology under the brand name Zyraydi, that solves the problem of non-uniformity and separation of cannabinoid from powder bed, opening new ways to develop pharmaceutical grade solid oral dosage forms such as capsules and tablets. Zelira will be assessing opportunities for commercialisation of this technology.

The Company conducts its work in partnership with world-leading researchers and organisations which since inception includes Curtain University in Perth, Australia; the Telethon Kids Institute in Perth, Australia; the University of Western Australia, in Perth, Australia; St Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

For further information, please visit: **zeliratx.com**

## About Cantheon Capital, LLC www.cantheoncapital.com

Cantheon Capital supports pharmaceutical and biotech companies who are engaged in clinical trials with capital funding and detailed scientific advice. Cantheon deploys capital to assist biotechs to achieve their drug development goals.

For further information, please visit **www.cantheoncapital.com**

## About iNGENū www.ingenucro.com.au

iNGENū is a globally focused Contract Research Organization working exclusively in the cannabinoid and psychedelic space. In addition to choosing iNGENū for their deep subject matter expertise, international biotechs choose iNGENū to take advantage of:

- an Australian Government 43.5% R and D grant
- rapid clinical trial start-up in under 12 weeks
- performing FDA-focused research prior to opening an IND

For further information, please visit **www.ingenucro.com.au** , **www.benuvia.com**

zelira® THERAPEUTICS

**ANNEXURE 1**
**Terms of Convertible Notes**

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|---|---|
| **Issuer** | Special Purpose Vehicle (to be incorporated) |
| **Securities** | Convertible note (the "Convertible Note") convertible into common stock at the purchaser's election. |
| **Note Amount** | $8,639,400 (Phase 2: $4,716,708 / Phase 3: $3,922,692) |
| **Note Interest Rate** | 10.0% paid in cash annually in arrears |
| **Note Term** | 12 months each |
| **Origination Fee** | 2% |
| **Note security** | The Notes will be secured by a first ranking security over the assets of the SPV. |
| **Conditions of draw down** | The drawdown of funds under the Convertible Notes will be conditional upon:<br>• Execution of definitive documentation;<br>• Commencement of the HOPE Phase 2 clinical trial |
| **Use of funds** | Zelira agrees to perform HOPE Phase 2 ($17,690,400) & Phase 3 ($14,067,200) clinical trials, exclusively with iNGENū CRO, commencing within 90 days. At closing, Zelira will provide Cantheon with a written guaranteed agreement. |
| **Convertibility Option** | At the purchaser's election during the term of the Convertible Note, the purchaser may convert a portion or all their Convertible Note into a cumulative maximum of 12.93% of shares of the SPV's common stock (the "Conversion"). |
| **Conversion Terms** | The Convertible Note conversion price (the "Conversion Price") will be undertaken at a 15% discount to the value of other subsequent cash investors invest in the SPV. Zelira holds 55% of the SPV and the cash investors with a cumulative investment of $34,557,600 shall hold 45% of the SPV. |
| **Closings** | Within 30 days of executing the term sheet unless otherwise agreed |
| **Prepayment** | At the Company's election with 30-days' notice subject to a 3.0% prepayment penalty if completed within the first six months from the closing. |

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