



17 August 2023

Zelira initiates HOPE® clinical trial following closing the first round of HOPE SPV fundraise and receipt of cash



HOPE® CLINICAL TRIAL UNDERWAY

Key Highlights

-  First Close of HOPE-SPV funding for a US\$3.25 million commitment, with the execution of definitive agreements to advance autism targeted HOPE® 1 through FDA trials in the USA
-  Receipt of first tranche of US\$1,069,000 from the 2011 Forman Trust and Mr. Malik Majeed

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development and commercialisation of clinically validated cannabis medicines, is delighted to announce it has executed definitive agreements with the 2011 Forman Trust and Mr Malik Majeed, as announced on 22 May 2023, to provide a first tranche of US\$1.069 million of the US\$3.25 million funding for Zelira to conduct FDA clinical trials for Zelira's proprietary and patent protected HOPE® 1 product via a special purpose vehicle (SPV). Zelira will manage the SPV as part of its business platform.

Zelira expects to have subsequent rounds of closings this quarter from its continuing fund raising efforts to support the HOPE® 1 formal FDA clinical program.



Dr Oludare Odumosu, Zelira Therapeutics Managing Director, commented:

We are excited about achieving this new milestone for our company and starting our first formal FDA trial. This receipt of first tranche funding will allow Zelira to commence our formal FDA trials process with our CRO iNGENu for the HOPE Autism Spectrum Disorder program. Looking ahead, Zelira anticipates continued success in our funding efforts for the SPV, facilitating subsequent closures on the balance of the circa US\$35 million capital raise to fund HOPE® 1 FDA trials in the USA and bolstering the financial foundation needed to drive the HOPE ASD program.

Issuer	Zelira-Hope1, LLC - Special Purpose Vehicle
Securities	Convertible note (the "Convertible Note") convertible into common stock at the purchaser's election.
Note Amount	US\$3,250,000 (Phase 1: / 2: US\$1,888,000 / Phase 3 / 4: US\$1,362,000)
Note Interest Rate:	10.0% paid in cash annually in arrears
Note Term	12 months each
Origination Fee	0.5%
Note security	The Notes will be secured by a first ranking security over the assets of the SPV.
Conditions of draw down	<p>The remaining funds will draw down funds upon the achievement of the below milestones:</p> <ul style="list-style-type: none"> • Execution of definitive agreements (achieved) • Enrolment of first patient (FPI) for either its Phase 1 or 2 Clinical Trial • Commencement its Phase 3 Clinical Trial • Enrolment of first patient (FPI) for its Phase 3 Clinical Trial.
Use of funds	Zelira agrees to perform HOPE Phase 1/2 (US\$17,690,400) & Phase 3 (US\$14,067,200) clinical trials, exclusively with iNGENu CRO
Convertibility Option	At the Purchasers' election during the term of the Convertible Note, the Purchasers may convert a portion or all their Convertible Note into a cumulative maximum of 4.23% of shares of the SPV's common stock (the "Conversion").
Conversion Terms	The Convertible Note converts on a fixed ratio per USD drawn down and the conversion price (the "Conversion Price") will be undertaken with no discount to the value 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.

For further information
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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 cannabidiol (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 Curtin 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

