

Key Highlights



Receipt of second tranche of US\$819,000 funding from the 2011 Forman Trust



Total funds received by the HOPE® SPV to date of US\$1,888,000

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development and commercialisation of clinically validated cannabis medicines, is pleased to announce, it has received the second tranche of US\$819,000 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), further to the ASX announcement dated 17 August 2023. Receipt of the second tranche of funding from the 2011 Forman Trust brings to total funds received via the SPV to US\$1.888 million. Zelira will manage the SPV as part of its business platform.

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

For further information please contact

Company

Dr Oludare Odumosu Managing Director & CEO

\$\cdot\\$\dagger\$ +1 909 855 0675

Australia

Level 3, 101 St Georges Terrace Perth WA 6000, AUSTRALIA

% +61 8 6558 0886

Fax: +61 8 6316 3337 Renquiries@zeliratx.com

www.zeliratx.com

ACN 103 782 378

Investors

Ronn Bechler

Executive Director, Automic Group

\$ +61 400 009 774

🛱 ronn.bechler@automicgroup.com.au

USA

5110 Campus Drive, Suite 150 Plymouth Meeting, PA 19462 United States Of America

\$\\\$\+14846300650

Zelira Therapeutics Ltd (ASX:ZLD,

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 noncancer pain as well as offering over the counter [OTC] products.

Zelira has established a special purpose vehicle (SPV) to conduct FDA Phase 1, Phase 2 and Phase 3 clinical trials for Zelira's proprietary and patent protected HOPE® 1. Zelira has contributed 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 SPV and US FDA trials for HOPE® 1 in exchange for a cumulative equity interest of 45% of the SPV. Zelira will manage the SPV as part of its business platform. 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 May 2023, Zelira completed an IRB approved strategically designed multi-arm, head-to-head study targeting diabetic nerve pain.

The clinical trial included a comprehensive comparison against the widely recognised and

highly successful multi-billion dollar revenue generating drug Lyrica® (Pregabalin). With the findings underscoring the exceptional efficacy of our treatments in managing pain, with ZLT-L-007 demonstrating the most substantial reduction in pain severity, particularly at the 60-day and 90-day follow-up periods. 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.

Zelira's Rx business generates revenue from its proprietary medication, HOPE. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana. Zelira will also be expanding commercialisation of ZENIVOL® - the world's first clinically validated cannabinoid drug for treatment of chronic insomnia 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. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannabidiol (CBD).

For further information, please visit: zeliratx.com

