16 July 2024

Zelira secures leading patents for HOPE® 1 and HOPE® 2 formulations targeting Autism Spectrum Disorder

LEADING PATENTS SECURED

Key Highlights

- Zelira confirms it has secured patents for HOPE® 1 and HOPE® 2 formulations from the Australian Government's Commission of Patents and the US Patent and Trademark Office (USPTO).
- These patents cover drugs that are designed to treat cluster symptoms associated with Autism Spectrum Disorder (ASD).
- The broad patents fortify Zelira's competitive edge in the central nervous system (CNS) therapeutic space and significantly enhance its patent portfolio.
- Zelira expects additional patent grants within the HOPE® portfolio from the US Patent and Trademark Office (USPTO) later this calendar year.

Zelira Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF), a global leader in the development and commercialisation of clinically validated cannabis medicines, confirms it has successfully secured patents for its HOPE® 1 and HOPE® 2 formulations, designed to treat cluster symptoms associated with Autism Spectrum Disorder (ASD). The patents are a significant milestone for the Company and further strengthen Zelira's HOPE® program.

The patents have been granted by both the Australian Government's Commission of Patents and the US Patent and Trademark Office (USPTO), marking a major advancement in Zelira's mission to provide innovative therapeutic solutions through its patent protected proprietary drugs.

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

CEO/Global MD of Zelira Therapeutics, Dr Oludare Odumosu said:

Securing these pivotal patents for our HOPE® 1 and HOPE® 2 formulations was a major advancement for Zelira. The achievement not only strengthens our innovative efforts in treating ASD but also bolsters our ongoing drug development and clinical validation initiatives. Our HOPE® FDA drug program is now well on its way, making significant progress with a positive pre-IND meeting recently conducted with the FDA. These patents reinforce our commitment to delivering impactful therapeutic solutions and fortify our competitive edge in the CNS therapeutic space. We are excited to continue this journey, attracting strategic investments and advancing our mission to deliver transformative therapeutic solutions globally.

The patent details are as follows:

Australian Government Commission of Patents

- **Patentee**: Ilera Therapeutics LLC
- **Patent No.**: 2020232029
- **Application No.**: 2020232029
- **Term**: 20 years from the filing date, expiring on 9 March 2040

In Australia, the issued claims provide broad coverage for both the HOPE® 1 and HOPE® 2 formulations and their uses in treating autism. Claim 18 corresponds to the HOPE® 1 formulation, claim 5 to the HOPE® 2 formulation, and claims 1-4, 6-17, and 19-20 cover methods of using these formulations to treat specific symptoms of ASD such as agitation, anxiety, self-stimulatory behaviour, and communication.

US Patent and Trademark Office (USPTO)

- **Patentee**: Ilera Therapeutics LLC
- **Patent Application No.**: 17/468,023
- **Patent No.**: 11,622,957
- **Term**: 20 years from the filing date, expiring 7 September 2041

The USPTO granted broad claims, including:

- **Claim 20**: A method of improving communication in patients with ASD by administering a pharmaceutical composition comprising a Cannabinoid Profile with THC and CBD at a 5:1 ratio by weight, and a Terpene Profile with α-Caryophyllene (BCP), Myrcene, and α-Bisabolol.
- **Claims 21-34**: Detailed variations and specifications regarding the percentages and compositions of the Terpene and Cannabinoid Profiles, and the flavoring of the pharmaceutical composition

Zelira expects additional patent grants within the HOPE® portfolio from the US Patent and Trademark Office (USPTO) later this calendar year. These forthcoming patents should further solidify the Company's intellectual property and expand its capabilities in treating ASD. By enhancing the HOPE® portfolio, the Company will be able to offer a more comprehensive range of therapeutic solutions, reinforcing its leadership in the CNS therapeutic space and driving continued growth in our cannabinoid-based medicines pipeline.

For further information please contact

Company
Dr Oludare Odumosu
Managing Director & CEO
+1 909 855 0675
oodumosu@zeliratx.com

Investors
Gabriella Hold
Executive Director, Automic Group
+61 411 364 382
gabriella.hold@automicgroup.com.au

Australia
Level 3, 101 St Georges Terrace
Perth WA 6000, AUSTRALIA
+61 8 6558 0886
Fax: +61 8 6316 3337
enquiries@zeliratx.com
www.zeliratx.com
ACN 103 782 378

USA
5110 Campus Drive, Suite 150
Plymouth Meeting, PA 19462
United States Of America
+1 484 630 0650

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 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**