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Zelira<sup>®</sup> develops technology for making free flow powder from cannabinoid distillate and signs new licensing deal

## ZELIRA<sup>™</sup> DEVELOPS TECHNOLOGY AND SIGNS NEW LICENSING DEAL

# Key Highlights

- Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology developed by Zelira
- Cannabinoid capsules developed with Zelira's EDCDM technology demonstrate enhanced dissolution profile compared to current cannabinoid capsules available in market
- Cannabinoid distillate captured in Zelira's matrix technology solves the problem of non-uniformity and separation of cannabinoid from powder bed
- Zelira's EDCDM technology opens new ways to develop pharmaceutical grade solid oral dosage forms such as capsules and tablets
- Foundational licensing deal for EDCDM technology signed with DRCN Holdings, with affiliates operating medical cannabis licenses in Maryland, West Virginia, Pennsylvania and Michigan
  - Zelira to receive an upfront, non-refundable, non-contingent licensing fee of US\$1 million
  - DRCN Holdings has an option for up to 3 years to develop up to 3 commercial products using EDCDM
  - Zelira to receive a 20% royalty on net sales from commercialised products, with minimum of US\$1 million of net sales per annum or either party can cancel the license

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Receipt of the US\$1 million licensing fee will satisfy the milestone for the 393,870,322 Class A Performance Rights on issue **Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)**, a global leader in the research and development of clinically validated cannabinoid medicines, is pleased to announce that it has successfully demonstrated enhanced dissolution of cannabinoids using its enhanced distillate capture and dissolution matrix (EDCDM), and signed a foundation licensing deal for this proprietary technology that includes an upfront non-refundable, non-contingent licensing fee of US\$1 million.

### Enhanced Distillate Capture and Dissolution Matrix (EDCDM)



Up until now, the market has had difficulty in formulating and developing free flow solid oral dosage forms based on cannabinoid distillate. This is due to the non-uniformity of cannabinoid distillate and its separation from the powder bed. EDCDM technology, developed by Zelira, resolves this problem by creating the capacity to capture distillate in a unique and proprietary matrix. When combined with the cannabinoid distillate, it creates a free-flowing powder base for capsules and tablets.



This novel matrix absorbs the distillate into a nano porous silicate particle where the distillate is effectively trapped in the structure of the silicate rendering the powder bed dry. As a result, this prevents the distillate from separating from the powder bed during encapsulation and under the compression forces utilised in tableting.

Comparative analytical testing results demonstrated the efficacy of Zelira's proprietary EDCDM technology in substantially improving average dissolution of cannabinoid capsules with EDCDM technology relative to cannabinoid capsules without the EDCDM technology:

	AVERAGE PERCENT DISSOLVED AT 60 MINUTES		
Formulations	1% Tween 80	Fasted State Simulated Intestinal Fluid (FaSSIF)	Fed State Simulated Intestinal Fluid (FeSSIF)
74.5mg cannabinoid capsules with EDCDM technology	36.5%	18.1%	42.3%
74.5mg cannabinoid capsules without EDCDM technology	8.7%	4.1%	17.1%
Dissolution Improvement Factor (DIF)	4.2X	4.4X	2.5X

Studies conducted in Zelira Laboratory, Pennsylvania, USA.

### **Rapid commercialisation opportunities**

The enhanced dissolution characteristics of Zelira's EDCDM technology provides an opportunity for rapid commercialisation opportunities. A licensing agreement has already been signed with DRCN Holdings to develop products underpinned by Zelira's EDCDM.

### **About DRCN Holdings**

DRCN Holdings LLC (DRCN) is a privately held, vertically integrated parent company with controlling interest in several West Virginian cannabis companies and affiliate cannabis entities in Maryland, Michigan and Pennsylvania. These States have approved legal medical cannabis programs with additional focus on research, development, manufacturing, agricultural genetics, and human clinical trials for cannabinoid-based, FDA approved, prescription medications. DRCN is led by experienced industry experts, Reggie Alston and Neil Cooper, with experience in medical cannabis products, growing, manufacturing, processing and dispensary operations as well as research, development, and technology improvements.



### Licensing agreement with DRCN Holdings

Key terms of the licensing agreement include:

- Zelira to receive an upfront, non-refundable, non-contingent licensing fee of US\$1 million from DRCN Holdings
- DRCN Holdings has an option to designate up to 3 product target profiles for Zelira to develop products for
- 3 year period to exercise product development options, with a possible 2-year extension
- Products must generate a minimum of US\$1 million in Net Sales each year after commercialisation, otherwise, either party has right to cancel license
- Zelira to receive a 20% royalty on Net Sales from commercialised products created under the license



# Zelira Therapeutics Global Managing Director & CEO Oludare Odumosu said:

"We strongly believe that the cannabinoid-based medicine market will scale up significantly when the ability to consistently formulate, validate and commercialise dosage forms that closely resemble current pharmaceutical drugs and in formats such as capsules and tablets, becomes available.

Reflecting Zelira's biopharmaceutical business strategy, we have solved two key issues holding back wider acceptance and usage of cannabinoid medicinal products – the difficulty in formulating solid oral dosage drugs with distillate, and the low rate of dissolution into the body from capsules and tablets. We have now demonstrated that Zelira's proprietary Enhanced Distillate Capture and Dissolution Matrix technology substantially traps the distillate in a free flow powder matrix and increases the rate of dissolution. This is a very exciting development as it opens multiple product development and commercialisation paths for medicinal cannabinoids.

The licensing arrangement with DRCN Holdings reflects the substantial and immediate value of Zelira's technology given the multiple products that can now be commercialised. We look forward to partnering with DRCN Holdings to bring new products to market that enhance peoples' lives.

The success of Zelira's EDCDM, and results showing its efficacy, reinforce Zelira's commitment to world-class science and position as a global biopharmaceutical leader in the development and marketing of clinically validated cannabinoid-based medicines. We have only just started to explore the breadth and depth of Zelira's biopharmaceutical technologies and products in development that we will bring to market soon.

Receipt of the upfront, non-refundable, non-contingent fee under this transaction, will further strengthen Zelira's cash position. This puts the company in an increased strong position to continue to accelerate both our prescription (Rx) and Over The Counter (OTC) businesses/strategies."

Zelira is pleased to announce that, subject to the receipt of the US\$1 million licensing fee from DRCN, the milestones for its 393,870,322 Class A Performance Rights will be met. The milestone for the conversion of these Performance Rights was cumulative revenues from the date of issue of the Performance Rights received by the Company or its subsidiaries from US based product sales of products derived or generated from Ilera Therapeutics LLC exceeding US\$1 million within five (5) years from the date of issue of the Performance Rights.

### **Accounting Treatment**

Following the receipt of confirmation of the upfront, non-refundable, non-contingent licensing fee of US\$1 million, the Company has been working with its auditor to ascertain the correct method of recognising the contract asset. Given that the licensing fee is being paid as consideration for service obligations delivered by the Company and that the performance obligations have been satisfied, the Company is of the view that the receipt of the upfront, non-refundable, non-contingent licensing fee of US\$1 million complies with AASB 15 (Revenue from Contracts with Customers), and as such will recognise the value of the licensing fee as revenue received for contract services provided, with that revenue of AUD\$1.37m (using a USD/AUD exchange rate of \$0.73) to be recognised in November 2021.

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

# For further information please contact

### Company

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### About Zelira www.zeliratx.com



Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) is a leading global biopharmaceutical company manufacturing and marketing cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to access the world's largest and fastest growing markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines for the treatment of a variety of medical conditions in its Rx business, including insomnia, autism and chronic non-cancer pain.



The Company has two proprietary formulations under the HOPE<sup>™</sup> brand that are generating revenues in Australia, Pennsylvania, Louisiana and Washington D.C. with other states in the US expected to follow. Zelira is also generating revenue in Australia from its proprietary and patented Zenivol<sup>™</sup> - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol<sup>™</sup> has successfully completed the first Phase 1b/2a clinical trial for chronic insomnia where it was found to be a safe and effective treatment. This clinical trial is published in the prestigious journal 'Sleep'. In 2020, Zelira partnered with SprinJene<sup>®</sup>Natural to develop and commercialise natural and organic oral care products under the SprinjeneCBD brand, as part of Zelira's OTC business. The SprinjeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids and based on the proprietary and patented technology of Blackseed oil and Zinc.

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