31 August 2022

Zelira® delivers strong growth in revenue, launches multiple products and makes significant progress in clinical validation during FY22

FULL YEAR RESULTS ANNOUNCEMENT
ASX ANNOUNCEMENT

Key FY22 Highlights

Successfully launched multiple new products:

- RAF FIVE™ range of acne treatment products
- Enhanced distillate capture and dissolution matrix (EDCDM) proprietary technology (brand name 'Zyraydi')
- ITURA™ Advance Relief Cream

Achieved further clinical validation milestones:

- HOPE® 1 results of longitudinal, real-world data (RWD) study in autism support safe and effective use
- Zenivol® results of longitudinal, RWD support its effectiveness in managing the treatment of insomnia
- Progressed arm one (enrolment of 20 patients) of a three-arm diabetic nerve pain drug trial, a head-to-head trial against a Big Pharmaceutical company's multi-billion dollar revenue drug

Expanded geographical footprint into highly regulated markets:

- Entered New Zealand - via exclusive distribution agreement with NUBU Pharmaceuticals for Zenivol® and HOPE® 1
- Entered Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest- via exclusive distribution agreement with Adjupharm for Zenivol®, with formal German regulatory approval received (July 2022)

Revenue up 132% to $1.5 million (FY21: $0.7 million)

Successfully raised US$5 million from US fund, Quincy Street Capital LLC, at a 54% premium to the share price at the time, to accelerate growth initiatives

- Post year-end, on 13 July 2022, received formal approval from German regulatory authority BfArM, for commercialisation of Zenivol® by Adjupharm

Zelira Therapeutics Ltd (ASX: ZLDDG, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is pleased to announce its results for the 12 months ended 30 June 2022 (FY22).

Commenting on the Company's FY22 achievements and performance, Global Managing Director & CEO, Dr Oludare Odumosu said:

"We have made significant progress over the past 12 months, delivering on our 'multiple shots on goal' strategy and growth ambition. We launched several new products, entered new and highly regulated global markets, and made significant advancements in clinical validation.

Clinical validation remains core and critical to our growth strategy. We are seeing an acceleration of regulatory reform, with highly regulated markets increasingly approving clinically validated cannabinoid-based medicines. We announced longitudinal, real-world data study results for both HOPE® 1 and Zenivol®, with results supporting the safe and effective use of both our medicines. We also completed the enrolment of 20 patients in the diabetic nerve pain drug trial, representing arm-one of the three-arm trial. This trial will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected products against a multi-billion dollar Big Pharmaceutical company drug.

We successfully commercialised three new products, contributing to our record sales achieved this year. Early strong adoption of the RAF FIVE™ range of acne treatment skincare products is evident in the US market. Launched in September 2021, the skincare products were created to meet the growing demand for differentiated, effective treatments for acne. The RAF FIVE™ line is Zelira's first step into the acne medication market, valued at more than $11 billion worldwide. We will be focusing on rapid market penetration of the RAF FIVE™ products in 2023.

Globally, we expanded into two new markets, New Zealand and Germany, both highly regulated markets. Germany is the first access point to the EU, and in itself, Europe's largest, and one of the world's largest and fastest growing markets for cannabinoid medicines. Following the recent formal regulatory approval of Zenivol® in Germany, we will now continue to progress activities to license Zenivol® into other global markets"

Successfully launched multiple products

RAF FIVE™ September 2021 Zelira launched its five-product RAF FIVE™ acne treatment line in the US. RAF FIVE™ is the only skin care line in the world to feature Zylorma®, a patent-pending acne fighting complex developed by Zelira in partnership with Harvard-trained, Beverly Hills cosmetic dermatologist Dr. Karyn Grossman and noted drug development chemist and executive Dr. Brian Warrington.

Enhanced Distillate Capture and Dissolution Matrix (EDCDM) November 2021 Zelira signed a foundation licensing deal for the proprietary EDCDM technology with DRCN Holdings. The EDCDM technology creates the capacity to capture distillate in a unique and proprietary matrix, with this enhanced characteristic providing for further rapid commercialisation opportunities. Moving forward this technology will go by the brand name 'Zyraydi'

ITURA™ May 2022 In partnership with CVSCM, Zelira launched ITURA™ an Advanced Relief Cream formula using CBD and Hemp Spectra Technology that targets multi-symptoms such as numbness and tingling, muscle cramps, insensitivities and neuropathies including pain associated with Peripheral Artery Disease and diabetes.

Clinical validation milestones achieved in FY22

HOPE® 1 Published a white paper detailing the analysis of longitudinal, RWD study generated from patients using HOPE® 1. Results support the safe and effective use in autism spectrum disorder.

Zenivol® Published a white paper detailing the analysis of longitudinal, real-world data from 94 patients using Zenivol®. The results support Zenivol®'s effectiveness as a therapeutic option to manage chronic insomnia symptoms.

Diabetic nerve pain drug trial

Completed enrolment of 20 patients in the diabetic nerve pain drug trial, representing the first of three arms in the multi arm head-to-head trial against Big Pharmaceutical company's multi-billion dollar revenue drug.

Expanded geographical footprint into two new and highly regulated markets

New Zealand via exclusive 5-year distribution agreement with NUBU Pharmaceuticals for Zenivol® and HOPE® 1 NUBU will be filing for formal New Zealand government registration with the Ministry of Health NZ for both Zenivol® and HOPE® 1

Germany via 5-year exclusive distribution agreement with Adjupharm GmbH (Adjupharm) for Zenivol®. In July 2022, Zenivol® received formal approval from the German regulatory authority BfArM (The Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte) via its German commercialisation partner Adjupharm.

Strong growth in revenue supported by product launches and licencing deals

Total revenue in FY22 was up 132% to $1.5 million (FY21: $0.7 million) comprising:

- Sale of Goods of $0.75 million, up 74% on pcp driven by:
  - Sale of HOPE® 1 and Zenivol® in Australia, up 219%
  - Sale of Oral Care products in the US, up 94%
  - Other sales of new products, including RAF FIVE™
- License Fee of $0.7 million, includes foundation licensing deal for EDCDM
- Project Management fee $0.08 million.

Successful capital raise at a premium value to support growth

Zelira successfully raised US$5 million from US-based family office fund Quincy Street Capital LLC (Quincy Street). At a Group level, the fundraising valued Zelira at A$122.8 million, a 54% premium to the Company's market value at the time of the raise and resulted in Quincy Street becoming a substantial shareholder of Zelira with a holding of 6.3%. The funds raised are being utilised to accelerate growth initiatives, including clinical development and ongoing trials in Australia and US, multiple product commercialisation and market penetration opportunities and additional licencing for Rx (prescription) products and technologies.

Key priorities for 2023

- Clinical development and ongoing trials in Australia and the US
- Additional licensing for Zelira Rx (prescription) products and technologies and expansion of geographical footprint
- Commercialisation of RAF FIVE™ products with a focus on rapid market penetration
- Expansion of Zelira's SprinJeneCBD footprint in the US and emerging global CBD markets

Commenting on the Company's positive outlook, Dr Oludare Odumosu said:

"We are committed to continuing to deliver on our strategic growth initiatives in the coming year. Given the successful early traction we have received for our newly launched products in addition to the growth achieved in our existing products in FY22, we will be very focused on expanding the market penetration of our acne and oral-care product lines as well as securing additional licensing agreements for our prescription products and ECDCM technology in FY23.

I am very excited by the positive prospects of the products we have launched to date, and with the successful capital raised from Quincy Street, we have the balance sheet to support initiatives to drive further growth and product market penetration.

We will continue to progress additional licensing discussions for HOPE® and Zenivol® globally. Having recently received formal approval from the German regulatory authority for Zenivol®, we will look to grow sales of the product in Europe's largest market for cannabinoid-based medicines, and are confident and well positioned to progress licensing activities into other global markets."

Investor briefing on FY22 results and growth initiatives

Chairman Osagie Imasogie and Global Managing Director & CEO Oludare Odumosu, will host a virtual investor briefing on Wednesday 7 September at 10:00am AEST. An accompanying presentation will be made available via the ASX announcement platform prior to the call.

To participate at this briefing, please register via:
https://us02web.zoom.us/webinar/register/WN_b-iLE2iFTmqJ3JGU1_8DPg

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

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About Zelira www.zeliratx.com

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 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 power 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**