



31 January 2022

## Zelira continues to deliver on its growth plans



### QUARTERLY ACTIVITIES REPORT FOR Q2 FY2022 ASX ANNOUNCEMENT

#### Key Highlights



Stable cash receipts in Q2, with substantial growth to occur in Q3

- Q2 cash receipts from customers of \$0.341 million, relatively stable (Q1 FY2022: \$0.362 million)
- \$1.635 million received soon after quarter end, comprising a \$1.292 million refund under the Australian Federal Government's Research and Development Tax Incentive Scheme, and \$0.342 million<sup>1</sup> partial receipt of the US\$1 million EDCDM technology licensing fee (with the balance to be paid in Q3)



Commercialisation continuing to accelerate

- Expansion into New Zealand via exclusive distribution agreement with NUBU Pharmaceuticals for Zenivol® and Hope™
- Successfully demonstrated enhanced dissolution of cannabinoids using Zelira's enhanced distillate capture and dissolution matrix (EDCDM) and signed a foundation licensing deal for this proprietary technology



Research underpinning new products

- Successfully supported Levin Health's receipt of ethics approval for Phase 2A clinical trial for chronic pain
- Clinical trial results of Zelira's Phase 1 published in the peer-reviewed journal "Pain and Therapy"



US\$5 million raised from US-based family office, at a substantial premium to stock market value, to accelerate growth initiatives

- Values Zelira and its share of associated entities at A\$122.8 million<sup>2</sup>

**Reference:** 1. US\$250k of the US\$1 million upfront, non-refundable, non-contingent license fee in relation to Zelira's EDCDM technology license fee, and using a US\$ / A\$ exchange rate of 0.73. 2. Based on the placement price of Zelira's ordinary shares and the value of Zelira Dermatology at the investment value, and using a US\$ / A\$ exchange rate of 0.73.



**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)**, a global leader in the development of clinically validated cannabinoid medicines, is pleased to provide this quarterly activities report alongside its Appendix 4C for the three months ended 31 December 2021 (Q2 FY2022).



**Commenting on the operational progress in Q2 FY2022, Zelira's Global Managing Director & CEO, Dr Oludare Odumosu said:**

"With commercialisation continuing to ramp up, Zelira delivered a solid second quarter operationally. Cash receipts were stable, with substantial growth in cash receipts to occur in the current third quarter given the operational initiatives successfully executed over the first half of FY2022. Our strategy of having multiple shots at goal is delivering, with sales momentum gaining for current products in market, and new products being clinically tested and launched. With access to Germany and New Zealand via additional distribution agreements with the largest medicinal cannabinoid distributors in each market, we are well placed to continue our growth trajectory through FY2022.

Zelira is known as a leader in cannabinoid research and development for the medicinal cannabis market, and this was further strengthened over Q2. We successfully supported Levin Health's receipt of ethics approval for Phase 2A clinical trial for chronic pain and had the clinical trial results of Zelira's Phase 1 published in the peer-reviewed journal 'Pain and Therapy'.

Zelira's entry into the highly-regulated New Zealand medicinal cannabis market is further testament of Zelira's capabilities as a world class pharmaceutical developer and formulator and commitment to producing the highest quality, evidence-based cannabinoid medicines. Our partnership agreement with NUBU aligns to Zelira's global expansion strategy across our Rx [Pharmaceutical] portfolio, with NUBU, New Zealand's largest medicinal cannabis distribution company, having existing strategic partnerships in place with many of New Zealand's largest pharmacy groups. 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. We solved the two key issues holding this back via Zelira's proprietary Enhanced Distillate Capture and Dissolution Matrix technology. 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 were delighted to welcome US-based fund, Quincy Street, onto the register at an exciting time for Zelira. The capital raised, undertaken at a substantial premium to the stock's trading price, was a strong signal of the fundamental value a sophisticated and experienced investor saw in our scientifically based cannabinoid products that were already in market and coming to market, as well as our growing biopharmaceutical portfolio. We have an ambitious product development and sales growth strategy that we are executing on. The funds raised have not only introduced a new US-based fund onto our register, but more importantly, provided us with the capital to more aggressively roll out our growth strategy with a target of reaching financial breakeven."



### **Receipts from customers to substantially grow in Q3 FY2022**

Zelira generated quarterly cash receipts of \$0.341 million in Q2 FY2022 underpinned by sales of SprinjeneCBD and consulting payments, relatively stable to Q1 FY2022's \$0.362 million.

### **Q3 FY2022 will see substantial growth in cash receipts from customers**

\$0.342 million has already been received in the first two weeks of Q3 FY2022, being partial receipt of the US\$1 million EDCDM technology licensing fee.

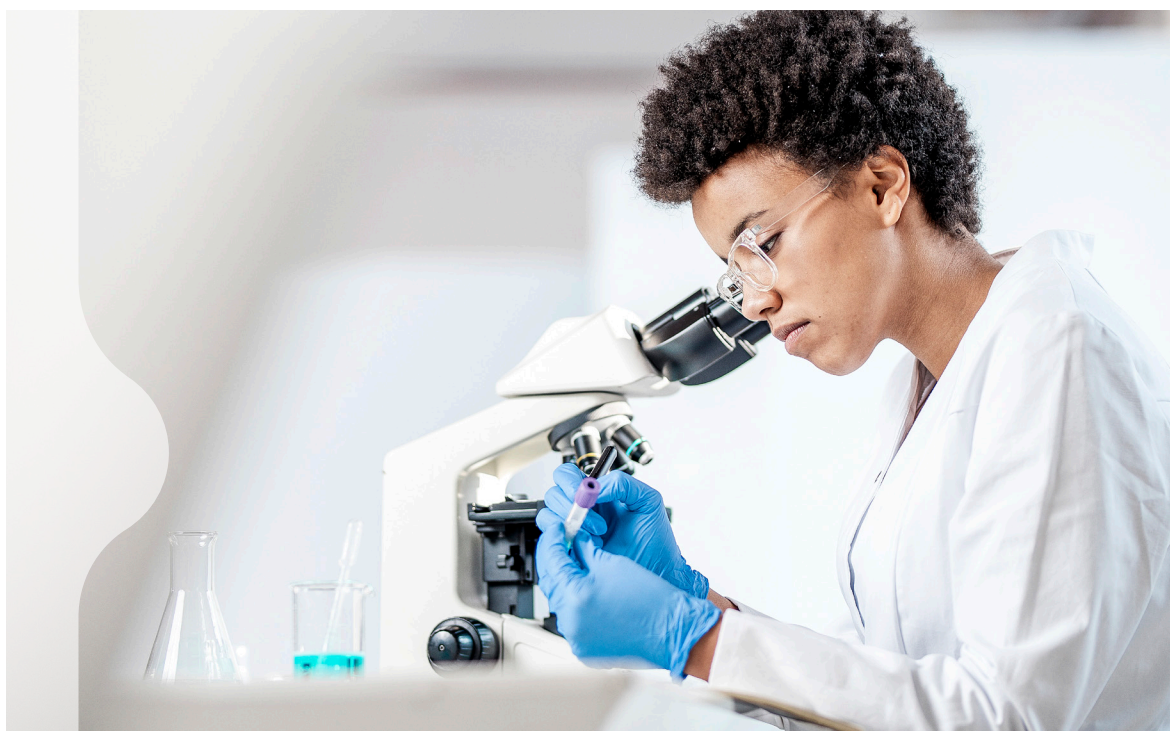
The US\$750k balance of the EDCDM license fee will be paid in the current quarter, generating another circa A\$1.0 million in cash receipts (depending on exchange rates at the time) in Q3.

With a suite of new products launched in H1 FY2022, Zelira is well placed to generate further growth in cashflows and revenue via its diversified income streams.

### **Receipt of R&D refund in Q3 FY2022**

Subsequent to the end of Q2, Zelira received a \$1.292 million refund under the Australian Federal Government's Research and Development Tax Incentive Scheme.

The funds will be used to support the growth in recent launched products including Zenivol® for Insomnia, HOPE™ for Autism and an additional CBD-Toothpaste into global markets, and also to advance Zelira's ongoing clinical and product development programs.





## **Commercialisation continuing to accelerate**

### **Expansion into New Zealand via exclusive distribution agreement with NUBU Pharmaceuticals for Zenivol® and Hope™**

Zelira has expanded into New Zealand via a 5-year exclusive distribution agreement with NUBU Pharmaceuticals ("NUBU"), New Zealand's largest medicinal cannabis distribution company.

This distribution agreement expands the availability of Zenivol®, Zelira's clinically validated cannabinoid-based insomnia medication, beyond Australia and Germany, and HOPE™ beyond Australia and the United States, into the highly regulated and tightly held New Zealand market, further expanding Zelira's global footprint for its Rx business.

NUBU will be filing for formal New Zealand government registration with the Ministry of Health NZ for both Zenivol® and HOPE™.

To retain exclusivity, NUBU is required to purchase annual minimum quantities of Zenivol® and HOPE™ totalling over A\$2.6 million (with A\$178,000 in Year 1) for New Zealand over the 5-year term of the distribution agreement.

### **Successfully demonstrated enhanced dissolution of cannabinoids using Zelira's enhanced distillate capture and dissolution matrix (EDCDM) and signed a foundation licensing deal for this proprietary technology**

In November 2021, Zelira announced that it had 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 included an upfront non-refundable, non-contingent licensing fee of US\$1 million.

Historically 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. Zelira's EDCDM technology resolved 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.

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 (see announcement of 3 November 2021).

The enhanced dissolution characteristics of Zelira's EDCDM technology provides an opportunity for rapid commercialisation opportunities. A licensing agreement was signed with DRCN Holdings to develop products underpinned by Zelira's EDCDM (see announcements of 3 November 2021 and 10 January 2022).



## Research underpinning new products

### Successfully supported Levin Health's receipt of ethics approval for Phase 2A clinical trial for chronic pain

In December 2021, Zelira announced it had successfully project managed ethics approval for a Phase 2a clinical trial to evaluate the efficacy of its licensed patented cannabinoid formulation, ZTL-106, in treating patients with chronic pain. Levin Health licensed ZTL-106 from Zelira and are the sponsors of the trial being undertaken at La Trobe University's Sport and Exercise Medicine Research Centre (Melbourne, Australia).

This outcome further cements Zelira's ability to design and have approved clinical trials with medicinal cannabis products.

### Clinical trial results of Zelira's Phase 1 published in the peer-reviewed journal "Pain and Therapy"

In December 2021, Zelira also announced that the St Vincent's Hospital Melbourne (SVHM) Department of Addiction Medicine research team that undertook the open label dose escalation trial, which results were originally announced on 14 July 2020, in chronic non-cancer pain patients had the results of its trial published in the peer-reviewed journal [Pain And Therapy](#).

The publication of these trial results is further testament of Zelira's world class pharmaceutical development and formulation and commitment to producing the highest quality, evidence-based cannabinoid medicines. Zelira has also leveraged the knowledge gained from this work to support the development of the proprietary formulation licenced to Levin Health (refer above) and to inform the design of other chronic non-cancer pain trials.

### US\$5 million raised from US-based family office at a premium value to accelerate growth initiatives

In October 2021, Zelira raised a total of US\$5 million from Quincy Street Capital LLC (Quincy Street), a US-based family office fund, comprising:

- US\$3.5 million (A\$4.79 million<sup>2</sup>) via a placement of fully paid ordinary shares at A\$0.06 per share (Placement), a 54% premium to the stock's 19 October 2021 closing price
- 1 unlisted option for every 2 ordinary shares issued, expiring 2 years from the date of issue with an exercise price of A\$0.09 per option
- US\$1.5 million (A\$2.05 million<sup>2</sup>) via an equity investment in Ilera Derm LLC (Zelira Dermatology) for a 3% shareholding in that company, valuing Zelira Dermatology at US\$50 million.

Following the fundraising, Quincy Street became a substantial shareholder in Zelira with a 6.3% shareholding.

The funds raised will be used to accelerate Zelira's growth initiatives, including:

- Clinical development and ongoing trials in Australia and the US
- Additional licensing for Zelira Rx products and technologies
- 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.



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**Commenting on the successful capital raising, Founder & Chairman Osagie Imasogie said:**

“This capital raise was a strong signal of the fundamental value a sophisticated and experienced US-based investor saw in our scientifically based and clinically validated cannabinoid products that are already in market and coming to market, as well as our growing biopharmaceutical portfolio that provides several shots on goal.”

The valuation at which this raising was undertaken, a very substantial premium to the Company’s stock market valuation, highlights the substantial inherent value of our business. With multiple attractive opportunities in front of us and a strong capital position, we are aggressively rolling out our growth strategy to enable financial breakeven by the end of this calendar year.”

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## Operational activities

The Q2 FY2022 performance reflects Zelira's focus on the expansion of commercialisation activities, with quarterly cash receipts relatively stable as new partners and channels were activated. Zelira's commercialisation program underpinned the launch of a suite of new cannabinoid-based products in the quarter, building off product launches in Q1 FY2022, with further products targeted for launch over the remainder of FY2022.

## Financial snapshot

The Company's net cashflow used in operations for Q2 FY2022 was \$2.492 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of \$996k, up from \$437k in Q1 FY2022, reflecting the growing sales and market opportunities for Zelira's clinically validated products
- Research and development of \$300k, relatively similar to \$305k in Q1 FY2022
- Staff costs of \$631k, slightly up on \$598k in Q1 FY2022
- Administrative and corporate costs of \$642k, substantially down on \$912k in Q1 FY2022, due to lower legal expenses.

Zelira was also pleased to receive \$0.344 million following the exercise of 11 million options. Furthermore, Zelira issued a total of 38 million options to executives and employees to further incentivise growth, align interests with shareholders and promote retention.

Cash receipts of \$0.341 million (Q1 FY2022: \$0.362 million) were mainly generated from sales of SprinjeneCBD Toothpaste and consulting payments. A further \$1.635 million was received soon after quarter end, comprising:

- \$1.292 million refund under the Australian Federal Government's Research and Development Tax Incentive Scheme
- \$0.342 million partial receipt of the EDCDM technology licensing fee (US\$250k of US\$1 million) with the balance to be paid in the current quarter.

## Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of approximately \$201k comprised Director Services of \$189k and Non-Director Services – corporate advisory services of \$12k.

As at 31 December 2021, the Company had a cash position of \$7.62 million.



### **Well positioned to continue growth trajectory**

Zelira's commercialisation plans continued to be delivered on, with revenues being generated from multiple products already launched in Australia, US and UK, while expanding into new geographies Germany and New Zealand. Zelira is continuing to progress additional licensing discussions for HOPE™ and Zenivol® in the US, while looking to conclude ongoing negotiations to expand distribution of these products into other global markets.

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

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](http://www.zeliratx.com)



**Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF)** is a leading global biopharmaceutical company developing 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™ 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™ - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol™ has successfully completed the first Phase 1b 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® 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 including 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.