ASX ANNOUNCEMENT

31 July 2023

Clinical validation milestone achieved in Q4 FY2023 with Zelira's diabetic nerve pain drug outperforming Big Pharma drug

QUARTERLY ACTIVITIES REPORT FOR Q4 FY2023
ASX ANNOUNCEMENT

Key Highlights

- Announced top line results of the IRB-approved trial with Zelira's proprietary diabetic nerve pain drug (ZLT-L-007) outperforming Big Pharmaceutical company's multi-billion-dollar annual revenue drug, Lyrica®
  - Results demonstrate ZLT-L-007 outperformed Lyrica® achieving a significant reduction in NRS pain scores (symptom severity)
  - ZLT-L-007 found to be safe and well tolerated
  - Additional insights from full study will be reported as they become available in FY23-24
- Secured additional US$3.25 million investment in HOPE® Special Purpose Vehicle (SPV)
  - Total amount raised to date US$11.85 million
  - Zelira will continue to raise up to an additional US$22 million to fund FDA clinical trials
- Appointed Dr. Donna Gentile O'Donnell as Non-Executive Director
  - Follows Non-Executive Director resignation of Ms. Lisa Gray

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is pleased to provide this quarterly activities report alongside its Appendix 4C for the three months ended 30 June 2023 (Q4 FY2023).

Commenting on the operational progress in Q4 FY2023, Global Managing Director & CEO, Dr Oludare Odumosu said:

We were thrilled to announce over the fourth quarter the positive top line results of the IRB approved trial in the United States for our ZLT-L-007 product, which is a significant achievement for clinical validation of our proprietary patent protected diabetic nerve drug treatment. The findings showed that Zelira's drug, ZLT-L-007, materially outperformed a major multi-billion dollar Big Pharma drug, Lyrica®, as an effective treatment for diabetic nerve pain management, as measured by NRS pain scores. The results also confirmed our drug to be safe and well tolerated.

Lyrica® is a commercially available pain medicine that has historically achieved peak annual sales of approximately US$5 billion. Having comparatively positive results compared to Lyrica®, evidences the magnitude of the market potential ahead of us.

The compelling trial results also marks a significant milestone in our Launch, Learn and Develop strategy, providing us with a high level of confidence to further progress our diabetic drug to formal FDA clinical trials, gain regulatory approval and most importantly, achieve our end goal of providing patients with the best possible treatment for pain relief.

Over the fourth quarter we also continued to increase investment into the HOPE®1 SPV, securing an additional US$3.25 million of funding and welcoming The 2011 Forman Investment Trust and Mr. Malik Majeed as co-partners into the SPV. The additional funding has positioned us to be able to start the formal HOPE® 1 FDA trial process, working with our CRO and partner iNGENu.

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Zelira's proprietary diabetic nerve pain drug (ZLT-L-007) outperformed Big Pharmaceutical company's multi-billion-dollar annual revenue drug, Lyrica®

Zelira successfully completed an IRB-approved multi-arm head-to-head study of its proprietary diabetic nerve pain drug ZLT-L-007 against a major Big Pharmaceutical company's multi-billion-dollar annual revenue drug, Lyrica®.

Topline results demonstrate that ZLT-L-007 outperformed Lyrica®, achieving a significant reduction in NRS pain scores, indicating a decrease in symptom severity.

ZLT-L-007 was found to be safe and well-tolerated, meeting the primary endpoint for safety with no Serious Adverse Events (SAE).

The study also met secondary endpoints, including significant decreases in Visual Analog Scale (VAS) and Short form McGill scores, among others.

Additional insights from the full study will be reported, as they become available, during FY 2023-2024.

Secured additional US$3.25 million investment in HOPE® SPV

Zelira secured an additional US$3.25 million of funding into the HOPE® SPV, increasing the total amount raised to US$11.85 million.

Zelira will continue to raise up to an additional US$22 million to complete the funding of HOPE® 1 US FDA trials in autism for a total of approximately US$35 million.

Non-Executive Director Appointment

Dr. Donna Gentile O'Donnell was appointed Non-Executive Director effective 1 June 2023.

Donna has led a diverse and successful career in health care, life sciences and public service concentrated in the Greater Philadelphia area.

Zelira will seek shareholder approval to issue 95,000 unlisted options, to acquire ZLD shares, to Dr. O'Donnell at an exercise price of $1.15 and expiring 3 years from the date of issue, subject to vesting conditions as part of her remuneration package.

Dr O'Donnell's appointment follows the resignation of Ms. Lisa Gray as Non-Executive Director effective 31 May 2023.

Operational activities

The performance in Q4 FY2023 reflects Zelira's continuous focus on our clinical validation strategy.

Financial snapshot

Cash receipts of $0.173 million (Q3 FY2023: $0.077 million) were mainly driven by Sales in our OTC product lines with SprinJene CBD and RAF Five.

The Company's net cashflow used in operations for Q4 FY2023 was $1.347 million. Operational expenses mainly comprised:

- Product manufacturing and operating costs of $17k, slightly down from $30k in Q3 FY2023
- Research and development of $113k, down from $258k in Q3 FY2023
- Advertising and marketing of $286k, in line with $278k in Q3 FY2023
- Staff costs of $509k, down from $614k in Q3 FY2023
- Administrative and corporate costs of $514k, down from $1,122k in Q3 FY2023
- Variations in costs reflect timing of payments.

The Company's net cashflows from investing activities of $71k represents sale of Melodiol Global Health Ltd (ASX:ME1) (formally Creso Pharma Ltd) shares during the quarter.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C, payments to related parties of $224k comprised Director Services of $192k and Non-Director Services including Accountancy Fees of $21k and Company Secretarial Services of $11k.

As at 30 June 2023, the Company had a cash position of $146k.

Zelira is making significant progress towards execution of the definitive agreements with respect to the HOPE® SPV funding totalling US$11.85 million. Zelira anticipates income generated through management and associated services provided to the SVP will provide sufficient working capital to continue its operations and meet its business objectives.

Strategy and outlook

Commenting on Zelira's operational strategy and growth outlook, Dr Odumosu said:

This quarter has seen us achieve a new benchmark for clinical validation, running a trial against a Big Pharma Drug that has shown, via compelling results, that our cannabinoid-based medicines, are well positioned to compete in the wider pharmaceutical drug market.

The next step of our diabetic nerve drug, ZLT-L-007, will be to evaluate further progression in formal FDA clinical trials as part of our Launch, Learn and Develop strategy. We enter this phase with confidence following the positive clinical data received.

Following further additional funding in the HOPE® 1 SPV, we are now positioned to commence the FDA clinical trials for HOPE® 1.

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

For further information please contact

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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's 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 cannabidiol (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 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.

The Company conducts its work in partnership with world-leading researchers and organisations which since inception includes Curtin 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**

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