

ASX RELEASE

29 April 2022

## QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

**Sydney, 29 April 2022** – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an oncology-focused drug development company, is pleased to provide an update on the ongoing development of its product candidates for the quarter ending 31 March 2022.

### Key Points

- Encouraging new preclinical data for paxalisib in a rare childhood brain cancer is among five abstracts presented at AACR Annual Meeting.
- Phase II study of paxalisib in combination with metformin and ketogenesis has commenced recruitment.
- Company has launched an ‘at-the-market’ financing facility with Oppenheimer & Co, allowing Kazia to respond rapidly and cost-effectively to investor interest in US market.

Kazia CEO, Dr James Garner, commented, “the company has kept up good momentum in the first quarter, with significant progress across both paxalisib and EVT801 programs. In particular, we were excited to see new data for paxalisib presented at the AACR Annual Meeting, which has the potential to significantly expand our opportunity in childhood brain cancer. We already have an ongoing clinical trial in DIPG, and we are now exploring potential avenues forward in a second form of childhood brain cancer. Paxalisib has become one of the most interesting drug candidates in this field, and we look forward to working with clinicians and researchers to further explore the drug in this group of patients.”

### New Preclinical Data in AT/RT and DIPG Presented at AACR

Scientists working in the laboratory of Assistant Professor Jeffrey Rubens at Johns Hopkins University (JHU) in Baltimore, MD, presented two posters at the Annual Meeting of the American Association of Cancer Research (AACR), held from 8 – 13 April 2022 in New Orleans, LA. The posters described positive preclinical data for paxalisib in a rare childhood brain cancer known as atypical teratoid / rhabdoid tumours (AT/RT).

In addition to demonstrating monotherapy activity in this disease, the researchers showed evidence of substantial synergy with examples of two new classes of cancer therapies:

#### Board of Directors

**Mr Iain Ross** Chairman, Non-Executive Director

**Mr Bryce Carmine** Non-Executive Director

**Mr Steven Coffey** Non-Executive Director

**Dr James Garner** Chief Executive Officer, Managing Director

RG2822, an HDAC inhibitor, and TAK580, a MAP kinase inhibitor. In aggregate, the data define a potential new opportunity for paxalisib in the treatment of this disease, which currently has no FDA-approved therapies.

A separate team at JHU presented a poster describing preclinical data for paxalisib in combination with RG2822 for DIPG. Research by several teams of scientists, most notably Professor Matt Dun at the Hunter Medical Research Institute in Newcastle, Australia, has demonstrated the activity of paxalisib in this very aggressive childhood brain cancer, both as monotherapy, and in combination, and the JHU data demonstrates an additional combination strategy that may provide further clinical benefit.

### **Final Study Report Received for Phase II Study of Paxalisib in Glioblastoma**

Post-period, in April 2022, Kazia received the final clinical study report for the phase II clinical trial of paxalisib in newly diagnosed glioblastoma patients (NCT03522298), marking definitive completion of this trial.

In December 2021, the company reported top-line data from the study. Patients treated with paxalisib demonstrated a median overall survival (OS) of 15.7 months, which compares very favourably to the figure of 12.7 months associated with temozolomide, the existing standard of care, in this patient population. The median progression-free survival (PFS) was reported at 8.4 months, which similarly compares very well to the figure of 5.3 months associated with temozolomide.

The safety profile of paxalisib was similar to that observed in other clinical trials, with hyperglycaemia (high blood sugar), mucositis (mouth ulcers), and rash among the most common toxicities. The maximum tolerated dose in newly diagnosed GBM patients was confirmed as 60mg, administered once daily.

An abstract describing the data has been accepted for presentation at an upcoming oncology conference, and Kazia expects to share further information with stakeholders at that time.

### **Phase II Study of Paxalisib in Combination with Ketogenesis Commences Recruitment**

In February 2022, the company announced initiation of recruitment to a phase II study of paxalisib in combination with metformin and a ketogenic diet for glioblastoma (NCT05183204) had commenced recruitment at Weill Cornell Medical Center, under the leadership of Dr Howard Fine.

The study builds upon research by Professor Lew Cantley, who discovered the PI3K pathway. Professor Cantley's subsequent research has shown that PI3K inhibition and insulin are antagonistic, and that activity of drugs which inhibit the PI3K pathway may be enhanced by achieving a very low level of insulin in the patient's blood. Both metformin and a ketogenic diet are effective tools to achieve a low-insulin state, and so they have been combined with paxalisib in this study. Initial data is provisionally anticipated in 1H CY2023.

## **EVT801 Phase I Study Design and Biomarker Strategy Presented at AACR**

A further two poster presentations described the innovative trial design and biomarker strategy for the phase I study of EVT801 in patients with advanced cancer (NCT05114668).

The phase I study will initially examine the safety, tolerability, and pharmacokinetics of EVT801 administered as monotherapy, using a 'dose escalation' design. Once a maximum tolerated dose is determined, the study will expand and enrol additional patients in two distinct populations (renal cell carcinoma and soft tissue sarcoma) to better elucidate the clinical activity of the drug. The study commenced recruitment in November 2021 and is currently enrolling patients at two sites in France: Oncopole in Toulouse and Centre Léon Bérard in Lyons.

The study employs a rich suite of biomarkers, including detailed analysis of immunological activity following administration of EVT801, and AI-enhanced interpretation of CT scans. It is hoped that the substantial body of data yielded by these investigations will help to provide greater insight into, and confidence in, the further development of the drug.

## **Launch of 'ATM' Facility with Oppenheimer & Co.**

Post-period, the company announced in April 2022 that it had entered into an agreement with Oppenheimer & Co, an investment bank based in New York, NY, to implement an 'at-the-market' (ATM) facility.

ATMs are a common financing instrument that allow companies to directly place registered securities to investors via the company's NASDAQ listing. The instrument can allow the company to rapidly and cost-effectively respond to investor interest.

Investors are referred to the company's announcement of 26 April 2022 for further information.

## **Impact of COVID-19**

The company has no revisions to its prior guidance concerning COVID-19. At present, there is limited operational impact, but Kazia continues to monitor the situation.

## **Financial Update**

As noted in the accompanying Appendix 4C, the company's cash position as at 31 March 2022 was AU\$ 6.9 million, versus AU\$ 15.2 million at 31 December 2021. The company calculates runway on a forward-looking basis to 4Q CY2022.

### Broad Clinical Program Ongoing

| Sponsor                                     | Phase    | Indication   | Registration |
|---|----------|--|--------------|
| <b>PAXALISIB</b>                            |          |  |              |
| Global Coalition for Adaptive Research      | II / III | Glioblastoma   | NCT03970447  |
| Weill Cornell Medicine                      | II       | Glioblastoma<br>(with <i>ketogenesis</i> )                 | NCT05183204  |
| Alliance for Clinical Trials in Oncology    | II       | Brain metastases   | NCT03994796  |
| Dana-Farber Cancer Institute                | II       | Breast cancer brain metastases<br>(with <i>Herceptin</i> ) | NCT03765983  |
| Dana-Farber Cancer Institute                | II       | Primary CNS lymphoma                                       | NCT04906096  |
| Pacific Pediatric Neuro-Oncology Consortium | N/A      | DIPG (childhood brain cancer)                              | NCT05009992  |
| St Jude Children's Research Hospital        | I        | DIPG   | NCT03696355  |
| Memorial Sloan Kettering Cancer Center      | I        | Brain metastases<br>(with <i>radiotherapy</i> )            | NCT04192981  |
| <b>EVT801</b>                               |          |  |              |
| Kazia Therapeutics                          | I        | Advanced solid tumours                                     | NCT05114668  |

## **About Kazia Therapeutics Limited**

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Eight additional studies are active in various forms of brain cancer. Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno-oncology agents. A phase I study commenced recruitment in November 2021.

For more information, please visit [www.kaziatherapeutics.com](http://www.kaziatherapeutics.com) or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Kazia Therapeutics Limited

**ABN**

37 063 259 754

**Quarter ended ("current quarter")**

March 2022

| Consolidated statement of cash flows                      | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$A'000 |
|---|----------------------------|---------------------------------------|
| <b>1. Cash flows from operating activities</b>            |                            |                                       |
| 1.1 Receipts from customers                               |                            |                                       |
| 1.2 Payments for  |                            |                                       |
| (a) research and development                              | (5,050)                    | (14,357)                              |
| (b) product manufacturing and operating costs             |                            |                                       |
| (c) advertising and marketing                             |                            |                                       |
| (d) leased assets   |                            |                                       |
| (e) staff costs   | (863)                      | (1,379)                               |
| (f) administration and corporate costs                    | (623)                      | (2,201)                               |
| 1.3 Dividends received (see note 3)                       |                            |                                       |
| 1.4 Interest received                                     |                            |                                       |
| 1.5 Interest and other costs of finance paid              |                            |                                       |
| 1.6 Income taxes paid                                     |                            |                                       |
| 1.7 Government grants and tax incentives                  |                            | 10                                    |
| 1.8 Other (provide details if material)                   |                            |                                       |
| <b>1.9 Net cash from / (used in) operating activities</b> | <b>(6,536)</b>             | <b>(17,927)</b>                       |

|  |       |         |
|--|-------|---------|
| <b>2. Cash flows from investing activities</b>           |       |         |
| 2.1 Payments to acquire or for:                          |       |         |
| (a) entities   |       |         |
| (b) businesses   |       |         |
| (c) property, plant and equipment                        |       |         |
| (d) investments  |       |         |
| (e) intellectual property (milestone payment for EVT801) | (746) | (2,328) |

| <b>Consolidated statement of cash flows</b> |  | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (9<br/>months)<br/>\$A'000</b> |
|---|--|------------------------------------|--|
| 2.2   | (f) other non-current assets<br>Proceeds from disposal of: |                                    |  |
|   | (a) entities   |                                    |  |
|   | (b) businesses   |                                    |  |
|   | (c) property, plant and equipment                          |                                    |  |
|   | (d) investments  |                                    |  |
|   | (e) intellectual property                                  |                                    |  |
|   | (f) other non-current assets                               |                                    |  |
| 2.3   | Cash flows from loans to other entities                    |                                    |  |
| 2.4   | Dividends received (see note 3)                            |                                    |  |
| 2.5   | Other (provide details if material)                        |                                    |  |
| <b>2.6</b>                                  | <b>Net cash from / (used in) investing activities</b>      | <b>(746)</b>                       | <b>(2,328)</b>                                 |

|             |   |          |           |
|-------------|---|----------|-----------|
| <b>3.</b>   | <b>Cash flows from financing activities</b>   |          |           |
| 3.1         | Proceeds from issues of equity securities (excluding convertible debt securities)       |          |           |
| 3.2         | Proceeds from issue of convertible debt securities                                      |          |           |
| 3.3         | Proceeds from exercise of options   |          | 17        |
| 3.4         | Transaction costs related to issues of equity securities or convertible debt securities |          |           |
| 3.5         | Proceeds from borrowings  |          |           |
| 3.6         | Repayment of borrowings   |          |           |
| 3.7         | Transaction costs related to loans and borrowings                                       |          |           |
| 3.8         | Dividends paid  |          |           |
| 3.9         | Other (provide details if material)   |          |           |
| <b>3.10</b> | <b>Net cash from / (used in) financing activities</b>                                   | <b>-</b> | <b>17</b> |

|           |  |         |          |
|-----------|--|---------|----------|
| <b>4.</b> | <b>Net increase / (decrease) in cash and cash equivalents for the period</b> |         |          |
| 4.1       | Cash and cash equivalents at beginning of period                             | 15,189  | 27,587   |
| 4.2       | Net cash from / (used in) operating activities (item 1.9 above)              | (6,536) | (17,927) |
| 4.3       | Net cash from / (used in) investing activities (item 2.6 above)              | (746)   | (2,328)  |

| <b>Consolidated statement of cash flows</b> |  | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (9<br/>months)<br/>\$A'000</b> |
|---|--|------------------------------------|--|
| 4.4   | Net cash from / (used in) financing activities (item 3.10 above) |                                    | 17   |
| 4.5   | Effect of movement in exchange rates on cash held                | (949)                              | (391)  |
| <b>4.6</b>                                  | <b>Cash and cash equivalents at end of period</b>                | <b>6,958</b>                       | <b>6,958</b>                                   |

| <b>5.</b>  | <b>Reconciliation of cash and cash equivalents</b><br>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | <b>Current quarter<br/>\$A'000</b> | <b>Previous quarter<br/>\$A'000</b> |
|------------|---|------------------------------------|-------------------------------------|
| 5.1        | Bank balances   | 6,958                              | 15,189                              |
| 5.2        | Call deposits   |                                    |                                     |
| 5.3        | Bank overdrafts   |                                    |                                     |
| 5.4        | Other (provide details)   |                                    |                                     |
| <b>5.5</b> | <b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>  | <b>6,958</b>                       | <b>15,189</b>                       |

| <b>6.</b> | <b>Payments to related parties of the entity and their associates</b>                   | <b>Current quarter<br/>\$A'000</b> |
|-----------|---|------------------------------------|
| 6.1       | Aggregate amount of payments to related parties and their associates included in item 1 | -                                  |
| 6.2       | Aggregate amount of payments to related parties and their associates included in item 2 | -                                  |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

| <b>7. Financing facilities</b>  | <b>Total facility amount at quarter end \$A'000</b> | <b>Amount drawn at quarter end \$A'000</b> |
|---|---|--|
| <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>   |   |  |
| 7.1 Loan facilities   | -   | -  |
| 7.2 Credit standby arrangements   | -   | -  |
| 7.3 Other (please specify)  | -   | -  |
| <b>7.4 Total financing facilities</b>   | <b>-</b>  | <b>-</b>                                   |
| <b>7.5 Unused financing facilities available at quarter end</b>   |   | <b>-</b>                                   |
| 7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well. |   |  |
|   |   |  |

| <b>8. Estimated cash available for future operating activities</b>  | <b>\$A'000</b> |
|---|----------------|
| 8.1 Net cash from / (used in) operating activities (item 1.9)   | (6,536)        |
| 8.2 Cash and cash equivalents at quarter end (item 4.6)   | 6,958          |
| 8.3 Unused finance facilities available at quarter end (item 7.5)   |                |
| 8.4 Total available funding (item 8.2 + item 8.3)   | 6,958          |
| <b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>   | <b>1.06</b>    |
| <i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>                            |                |
| 8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:   |                |
| 8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?   |                |
| Answer: Yes   |                |
| 8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?                        |                |
| Answer: The company calculates cash runway on the basis of a forward-looking forecast to Q4 CY2022.   |                |
| The company is in ongoing discussions with potential investors and partners and has, in the meantime, instituted an 'at-the-market' (ATM) facility with Oppenheimer & Co to provide the opportunity to receive additional financing cashflow. |                |
| 8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?   |                |
| Answer: Yes.  |                |
| <i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>  |                |

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 29 April 2022.....

Authorised by: .....Board of Directors .....

(Name of body or officer authorising release – see note 4)

### Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.