

ASX RELEASE

29 October 2021

## QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

**Sydney, 29 October 2021** – 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 30 September 2021.

### Key Points

- GBM AGILE study continues to make good progress, with activation of Canada expected in 4Q CY2021, and activation of Europe and China expected in CY2022.
- EVT801 phase I study remains on track to commence recruitment by end of CY2021. Regulatory approval has been received from the French competent authority.
- Final data from paxalisib phase II study in glioblastoma expected during 4Q CY2021.

Kazia CEO, Dr James Garner, commented, “We have continued to make good progress on all fronts during the third quarter. The last few months have been characterized by a focus on operational matters. As we move towards the end of CY2021, we expect to report a number of important data read-outs, and to commence recruitment to the phase I study of EVT801. Delivery of these milestones will neatly conclude a tremendously productive year for the company.”

### Good Progress in GBM AGILE Pivotal Study

Kazia previously provided an update on progress with the GBM AGILE pivotal study (NCT03970447) in June 2021. Since then, the study has continued to progress well, with almost thirty hospitals in the United States now recruiting to the paxalisib arm. The study is expected to open to the paxalisib arm in Canada during 4Q CY2021, and in Europe and China next year. The respective regulatory submissions in Europe and China have been submitted and are undergoing review by regulatory agencies.

Kazia has brought forward manufacture of an additional batch of paxalisib investigational product, and this is expected to become available for use in the study in 1Q CY2022.

### 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

## **EVT801 Phase I Study on Track to Commence in 4Q CY2021**

On 2 September 2021, Kazia announced that the phase I study of EVT801 had received regulatory approval from L'Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), the French regulatory agency. The study has since also received approval from the Committee for the Protection of Persons (CPP), which serves as a centralised ethics committee for both of the participating sites. Commencement of recruitment to the study is expected by the end of CY2021.

A team of Evotec scientists who led the early development of EVT801 have been working to compile their research into a scientific paper, which is expected to be submitted for publication in a peer-reviewed academic journal during 4Q CY2021.

## **Multiple Data Read-Outs from Paxalisib Program**

The phase II study of paxalisib (NCT03522298) is moving towards completion, and Kazia expects to share top-line final data during 4Q CY2021, as previously indicated. In addition, the company expects to receive initial data from several ongoing investigator-initiated studies and will provide this to investors as soon as it is available.

## **Completion of Human ADME Study**

Kazia indicated in its Appendix 4C for the June quarter that it had initiated a human ADME (absorption, distribution, metabolism, elimination) study to satisfy certain standard regulatory requirements for approval of a new pharmaceutical product (NCT05012670). This study has completed the in-life phase, and all results appear to lie within expected parameters. The company expects to conclude analysis of the study early in CY2022 and to share results with FDA shortly thereafter.

## **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 closely.

## **Financial Update**

As noted in the accompanying Appendix 4C, the company's cash position as at 30 September 2021 was AU\$ 19.6 million, versus AU\$ 27.6 million at 30 June 2021. The company calculates our cash position will finance operations on a forward-looking basis through to 4Q CY2022.

## Broad Clinical Program Ongoing

| Sponsor                                     | Phase    | Indication  | Registration |
|---|----------|---|--------------|
| <b>PAXALISIB</b>                            |          |   |              |
| Kazia Therapeutics                          | II       | Glioblastoma  | NCT03522298  |
| Global Coalition for Adaptive Research      | II / III | Glioblastoma  | NCT03970447  |
| Weill Cornell Medicine                      | II       | Glioblastoma<br>( <i>with ketogenesis</i> )                 | TBD          |
| Alliance for Clinical Trials in Oncology    | II       | Brain metastases  | NCT03994796  |
| Dana-Farber Cancer Institute                | II       | Breast cancer brain metastases<br>( <i>with 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>( <i>with radiotherapy</i> )            | NCT04192981  |
| Kazia Therapeutics                          | I        | Human ADME study in healthy volunteers                      | NCT05012670  |
| <b>EVT801</b>                               |          |   |              |
| Kazia Therapeutics                          | I        | Advanced solid tumours                                      | TBD          |

## 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 other 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 immunoncology agents. A phase I study is expected to begin in CY2021.

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")**

September 2021

| <b>Consolidated statement of cash flows</b>               | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (12<br/>months)<br/>\$A'000</b> |
|---|------------------------------------|---|
| <b>1. Cash flows from operating activities</b>            |                                    |   |
| 1.1 Receipts from customers                               |                                    |   |
| 1.2 Payments for  |                                    |   |
| (a) research and development                              | 5,465                              | 5,465   |
| (b) product manufacturing and operating costs             |                                    |   |
| (c) advertising and marketing                             |                                    |   |
| (d) leased assets   |                                    |   |
| (e) staff costs   | 408                                | 408   |
| (f) administration and corporate costs                    | 1,243                              | 1,243   |
| 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                  |                                    |   |
| 1.8 Other (provide details if material)                   |                                    |   |
| <b>1.9 Net cash from / (used in) operating activities</b> | <b>7,116</b>                       | <b>7,116</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 (progress payment for EVT801)   | 1,582                              | 1,582   |

| Consolidated statement of cash flows |   | Current quarter<br>\$A'000 | Year to date (12 months)<br>\$A'000 |
|--------------------------------------|---|----------------------------|-------------------------------------|
| 2.2                                  | (f) other non-current assets<br>Proceeds from disposal of:<br>(a) entities<br>(b) businesses<br>(c) property, plant and equipment<br>(d) investments<br>(e) intellectual property<br>(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)   |                            |                                     |
| 2.6                                  | <b>Net cash from / (used in) investing activities</b>   | <b>1,582</b>               | <b>1,582</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   |          |          |
| 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)   |          |          |
| 3.10      | <b>Net cash from / (used in) financing activities</b>                                   | <b>-</b> | <b>-</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                             | 27,587  | 27,587  |
| 4.2       | Net cash from / (used in) operating activities (item 1.9 above)              | (7,116) | (7,116) |
| 4.3       | Net cash from / (used in) investing activities (item 2.6 above)              | (1,582) | (1,582) |

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date (12 months)<br>\$A'000 |
|--------------------------------------|--|----------------------------|-------------------------------------|
| 4.4                                  | Net cash from / (used in) financing activities (item 3.10 above) | -                          | -                                   |
| 4.5                                  | Effect of movement in exchange rates on cash held                | 735                        | 735                                 |
| 4.6                                  | <b>Cash and cash equivalents at end of period</b>                | <b>19,624</b>              | <b>19,624</b>                       |

| 5.  | Reconciliation of cash and cash equivalents<br>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | Current quarter<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|--|----------------------------|-----------------------------|
| 5.1 | Bank balances  | 19,624                     | 19,624                      |
| 5.2 | Call deposits  |                            |                             |
| 5.3 | Bank overdrafts  |                            |                             |
| 5.4 | Other (provide details)  |                            |                             |
| 5.5 | <b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>   | <b>19,624</b>              | <b>19,624</b>               |

| 6.  | Payments to related parties of the entity and their associates                          | Current quarter<br>\$A'000 |
|---|---|----------------------------|
| 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 | -                          |
| <i>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.</i> |   |                            |

|   |   |  |
|---|---|--|
| <b>7. Financing facilities</b><br><i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i><br><i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>   | <b>Total facility<br/>amount at quarter<br/>end<br/>\$A'000</b> | <b>Amount drawn at<br/>quarter end<br/>\$A'000</b> |
| 7.1 Loan facilities   | -   | -  |
| 7.2 Credit standby arrangements   | -   | -  |
| 7.3 Other (please specify)  | -   | -  |
| 7.4 <b>Total financing facilities</b>   | -   | -  |
| 7.5 <b>Unused financing facilities available at quarter end</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)  | (7,116)        |
| 8.2 Cash and cash equivalents at quarter end (item 4.6)  | 19,624         |
| 8.3 Unused finance facilities available at quarter end (item 7.5)  |                |
| 8.4 Total available funding (item 8.2 + item 8.3)  | 19,624         |
| 8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>  | 2.75           |
| <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: N/A  |                |
| 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: N/A  |                |
| 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 October 2021 .....

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.