

ASX RELEASE

31 January 2022

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 31 January 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 December 2021.

Key Points

- GBM AGILE study has opened in Canada and has, to date, screened over 1000 patients in the overall study.
- EVT801 phase I study has commenced recruitment in France and has successfully cleared the first dose cohort.
- Phase II study of paxalisib in newly diagnosed glioblastoma has reported final data, with overall survival of 15.7 months confirming a substantial potential treatment advantage over temozolomide, the existing standard of care.

Kazia CEO, Dr James Garner, commented, “Kazia concluded an exceptionally successful 2021, with three major partnering deals, \$15 million in revenue, a very promising lead program now in an international phase III trial, and a strong second asset now in phase I. Our areas of focus in 2022 will include the important work of preparing paxalisib for potential commercialisation and driving what may be transformative data from the broad clinical program that is underway across both our drug candidates.”

Market Activity

The company has received a higher than usual number of queries from shareholders regarding recent movements in the price of the company’s securities. For the avoidance of doubt, the company reiterates that it is not aware of any material, non-public, adverse information which may have impacted share price.

Kazia CEO, Dr James Garner, commented, “The biotech sector has seen a turbulent start to 2022, with the small cap biotech index down 24% in January. Kazia’s fundamentals remain very strong, with two high-quality assets in human trials and cash through to 4Q CY2022. We continue to focus on executing our ambitious plans for both drug candidates and look forward to sharing results with investors in due course.”

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

GBM AGILE Study Expands Internationally

The GBM AGILE pivotal study (NCT03970447) opened to recruitment for the paxalisib arm in Canada in November 2021. The first site to open to the paxalisib arm was Sunnybrook Health Sciences Centre in Toronto, ON. Additional sites are in the process of rolling out.

In December 2021, Kazia Therapeutics and Simcere Pharmaceutical received notice that the IND application for paxalisib in China had been approved. This important regulatory approval is a critical step in launching GBM AGILE in China, and in potentially pursuing other clinical trials of paxalisib. GBM AGILE is expected to open to recruitment in China mid-year.

In January 2022, post-period, the Global Coalition for Adaptive Research (GCAR) announced that GBM AGILE has screened over one thousand patients in the study to date.

EVT801 Phase I Study Underway

The phase I study of EVT801 (NCT05114668) commenced recruitment on 4 November 2021 at the Oncopole centre in Toulouse, France. A second hospital, Centre Leon Berard in Lyons, France, commenced recruitment in January 2022.

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 has been designed to incorporate a wide range of translational biomarkers, which should provide rich data on the pharmacological activity of EVT801 in patients with cancer.

As of 31 January, the study has successfully cleared the first dose level, and has begun treatment at the second dose level.

Completion of Paxalisib Phase II Study

On 3 December 2021, Kazia announced positive top-line final data from a phase II study of paxalisib in patients with newly diagnosed glioblastoma (NCT03522298).

The study reported median overall survival (OS) of 15.7 months in patients treated with paxalisib, 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.

PNOG Study in DIPG Commences Recruitment

In November 2021, the Pacific Pediatric Neuro-Oncology Consortium (PNOG) commenced recruitment to an adaptive phase II study of multiple drug candidates in diffuse midline gliomas (DMGs), including diffuse intrinsic pontine glioma (DIPG) (NCT05009992). DIPG is a rare childhood brain cancer for which there are no FDA-approved drug treatments, and in which median overall survival is less than one year.

The PNOG study is designed to investigate combinations of therapies in the treatment of this very aggressive cancer. In particular, the study will explore combination of paxalisib with ONC201, an investigational drug manufactured by Chimerix, Inc. This combination has shown very promising evidence of potential efficacy in preclinical data.

In August 2020, Kazia received Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) from the US FDA for this patient population.

Management Team Expansion

In November 2021, Dr John Friend joined the Kazia management as Chief Medical Officer. Dr Friend is a seasoned oncology drug developer with more than 25 years of experience in industry, including companies such as Helsinn, Cellectar Biosciences, and Abbott. Dr Friend's focus will be on preparing paxalisib for potential commercialisation and building richer and deeper relationships with clinicians and researchers. Dr Friend is based in New Jersey, in the United States.

In January 2022, immediately post-period, Karen Krumeich was appointed as Kazia's Chief Financial Officer. Ms Krumeich has a dual training in accounting and pharmacy and has worked in the healthcare sector for more than 30 years. Her early career included companies such as Bristol Myers-Squibb and she has more recently served as Chief Financial Officer to several public and private biotech companies. Ms Krumeich will be focused on building relationships with US investors. Ms Krumeich is based in Pennsylvania, in the United States.

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 December 2021 was AU\$ \$15.2 million, versus AU\$ 19.6 million at 30 September 2021. The company calculates runway on a forward-looking basis to 4Q CY2022.

Broad Clinical Program Ongoing

Sponsor	Phase	Indication	Registration
PAXALISIB			
Global Coalition for Adaptive Research	II / III	Glioblastoma	NCT03970447
Weill Cornell Medicine	II	Glioblastoma (with <i>ketogenesis</i>)	NCT05183204
Alliance for Clinical Trials in Oncology	II	Brain metastases	NCT03994796
Dana-Farber Cancer Institute	II	Breast cancer brain metastases (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 (with <i>radiotherapy</i>)	NCT04192981
EVT801			
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 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")

December 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(3,842)	(9,307)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(108)	(516)
(f) administration and corporate costs	(335)	(1,578)
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	10
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	(4,275)	(11,391)

2. Cash flows from investing activities		
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)	-	(1,582)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(f) other non-current assets		
2.2 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)		
2.6 Net cash from / (used in) investing activities	-	(1,582)

3. Cash flows from financing activities		
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	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)		
3.10 Net cash from / (used in) financing activities	17	17

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	19,624	27,587
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,275)	(11,391)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	(1,582)

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	17	17
4.5	Effect of movement in exchange rates on cash held	(177)	558
4.6	Cash and cash equivalents at end of period	15,189	15,189

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

6.	Payments to related parties of the entity and their associates	Current quarter \$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>		

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>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)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(4,275)
8.2 Cash and cash equivalents at quarter end (item 4.6)	15,189
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	15,189
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.55
<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: 31 January 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.