ASX RELEASE
31 October 2022

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 31 October 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), 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 2022.

Key Points

- Positive interim data from an ongoing study of paxalisib in combination with whole brain radiotherapy at Memorial Sloan Kettering Cancer Center in New York, NY, was reported at the 2022 Annual Conference on CNS Trials and Brain Metastases, sponsored by the Society for Neuro-Oncology (SNO) and the American Society for Clinical Oncology (ASCO). Data from an initial cohort of nine patients showed all responding to therapy, with a favourable tolerability profile. The study has expanded to Stage 2.
- Final data from Kazia's phase II study of paxalisib in newly diagnosed glioblastoma with unmethylated MGMT promotor status was the subject of an oral presentation by Professor John de Groot, Division Chief of Neuro-Oncology at UCSF, at the European Society of Medical Oncology (ESMO) Annual Meeting in Paris, France. The study reported overall survival of 15.7 months, which compares favourably to the figure of 12.7 months associated with temozolomide, the existing standard of care.
- The Global Coalition for Adaptive Research, who sponsor the GBM AGILE pivotal study of paxalisib in glioblastoma, informed Kazia that paxalisib had not graduated to the second stage. All patients enrolled to the first stage, who are expected to number approximately 150 subjects, will continue in the study per protocol until its completion in 2H 2023.
- Post period, Kazia reported positive preclinical data in melanoma from an ongoing collaboration with the Huntsman Cancer Institute at the University of Utah in Salt Lake City, UT. The data shows potent monotherapy activity, as well as synergy with BRAF and MEK inhibitors, which are standard of care for approximately 50% of patients with BRAF-positive disease.
- FDA granted rare pediatric disease designation (RPDD) to paxalisib for treatment of AT/RT, a rare childhood brain cancer. Among other advantages, this provides a second opportunity for paxalisib to attain a pediatric priority review voucher (pPRV) if approved in AT/RT.

Kazia CEO, Dr James Garner, commented, “The last few months have impressively demonstrated the breadth of opportunity inherent in the paxalisib program. In particular, the interim data from the study at Memorial Sloan Kettering in combination with radiotherapy for brain metastases is extremely exciting. This is an enormous potential indication, with very high unmet need, and we look forward to working with our advisors and collaborators to prospect it more deeply.”

“It is difficult to fully assess recent news from the GBM AGILE study,” he added, “but we continue to view the study as a promising potential path to registration for paxalisib. The patients recruited in Stage 1 are likely to provide a richer data set than that used for the approval of temozolomide. The study remains ongoing, and we are entirely blinded to data, so we look forward to seeing the results of the study in 2H CY2023, at which time we anticipate discussing potential approval strategies with FDA.”

Positive Data in Brain Metastases

Interim data from an ongoing phase I study of paxalisib in combination with whole brain radiotherapy (WBRT) for the treatment of brain metastases (NCT04192981), sponsored by Memorial Sloan Kettering Cancer Center in New York, NY, was presented at the 2022 Annual Meeting on CNS Trials and Brain Metastases in Toronto, ON in August 2022.

The data, which was the subject of a prestigious oral presentation by the lead investigator, Dr Jonathan Yang, reported an initial cohort of nine patients. All patients responded to treatment and tolerability was favourable. On the basis of the positive data, the study has graduated to a second stage, to which recruitment is underway.

Brain metastases are a common complication of many solid tumours, particularly cancers of the breast, lung, and skin. Radiotherapy is a ubiquitous mainstay of treatment, and about 200,000 patients undergo WBRT each year in the United States alone. However, response rates to WBRT are typically substantially less than 50%, and there remains a pressing need for therapies which are able to augment the effect of radiotherapy in this patient group.

Final Phase II Glioblastoma Data Presented at ESMO

Final data from a completed phase II study of paxalisib monotherapy for newly diagnosed glioblastoma patients with unmethylated MGMT promotor status (NCT03522298), sponsored by Kazia Therapeutics, was presented at the annual congress of the European Society for Medical Oncology (ESMO), held in Paris, France, in September 2022.

An oral presentation by Professor John de Groot, Division Chief of Neuro-Oncology at UCSF, and former Director of Clinical Research in the Department of Neuro-Oncology at MD Anderson Cancer Center, summarised the key findings of the study, including an overall survival of 15.7 months, which compares favourably to the figure of 12.7 months which is associated with temozolomide in this patient population. Professor de Groot’s presentation also described key pharmacodynamic data from the study, which helped to substantiate the brain penetration and biological activity of paxalisib. The data built off a previous poster

presentation at the Annual Meeting of the American Society for Clinical Oncology (ASCO), held in Chicago, IL, in June 2022.

Conclusion of Recruitment to GBM AGILE

In August 2022, the company was informed by the Global Coalition for Adaptive Research (GCAR), sponsor of the GBM AGILE pivotal study in glioblastoma, that the paxalisib arm had not met the pre-specified criteria for expansion to Stage 2, and had therefore concluded recruitment with approximately 150 patients enrolled to Stage 1. The study remains ongoing, with patients from Stage 1 continuing on drug and in follow-up according to the protocol.

The study was designed in two stages: a first stage of up to approximately 150 patients, and a second stage of 50 patients. Participating arms undergo a 'graduation analysis' to determine transition from Stage 1 to Stage 2. The specific statistical requirements of the graduation analysis are not public, but they require an experimental therapy to demonstrate a high degree of activity at an early point in the trial.

Kazia remains fully blinded to all study data, so it is not possible at present to assess the performance of paxalisib. Moreover, the study remains ongoing, with additional data collected from enrolled patients until twelve months after the last patient was randomised. As such, the eventual efficacy of paxalisib cannot be estimated from available data. Kazia expects to receive final data from the study in 2H 2023. Should it prove positive at that stage, the company anticipates discussion with FDA to determine the most appropriate path to potential registration.

The company notes that, even without the 50 patients that would have been enrolled to Stage 2, the data set that will eventually emerge from GBM AGILE will comprise approximately 150 patients on paxalisib, and approximately the same number in the control group, in an international randomised controlled trial with an overall survival endpoint. This is more substantial data than that which supported the registration of either temozolomide (the standard of care for newly-diagnosed patients), or Avastin (bevacizumab) (which is approved in certain territories for recurrent patients).

Positive Preclinical Data in Melanoma

In the context of a previously declared strategy to explore the use of paxalisib in cancers outside the central nervous system, Kazia has entered into a number of research collaborations with leading cancer centres. Post period, in October 2022, such a collaboration at the Huntsman Cancer Center of the University of Utah presented preclinical data for paxalisib in melanoma at the 19th International Congress of the Society for Melanoma Research in Edinburgh, Scotland.

The data, which was summarised in a poster presentation by Dr Gennie Parkman, working in the laboratory of Professor Sheri Holmen, demonstrated potent single agent activity for paxalisib and, moreover, synergy with BRAF and MEK inhibitors, which are standard of care

therapies in this disease. Professor Holmen noted that the results were “among the most promising single agent data that we have seen in our research.”

The collaboration remains ongoing, and Kazia expects to share further data in due course. The company is optimistic that further data may support a clinical trial in metastatic melanoma.

Paxalisib Awarded RPDD in AT/RT by FDA

As disclosed in the previous quarter, Kazia received Rare Pediatric Disease Designation (RPDD) from the US FDA for atypical teratoid / rhabdoid tumours (AT/RT), a rare childhood brain cancer with no FDA-approved drug treatment.

RPDD enables the company to seek a pediatric Priority Review Voucher (pPRV) should the drug be initially approved in this indication. Such vouchers are freely tradable and have typically commanded prices in excess of US $100 million. The company had previously secured RPDD in DIPG in August 2020, providing two opportunities to now access the pPRV program.

Positive preclinical data in AT/RT was previously presented at the American Association of Cancer Research (AACR) Annual Meeting in April 2022, and at the International Symposium on Pediatric Neuro-Oncology (ISPNO) in Hamburg, Germany, in June 2022. The data stemmed from an ongoing collaboration with Professor Jeffrey Rubens and colleagues at Johns Hopkins Medical School in Baltimore, MD. The work remains ongoing, with further data anticipated in due course.

PNOC Study of Paxalisib in DIPG Expands Internationally

An ongoing phase II study of paxalisib in combination with ONC201 (Chimerix, Inc) for diffuse intrinsic pontine glioma (DIPG) and diffuse midline gliomas (DMGs) (NCT05009992), sponsored by the Pacific Pediatric Neuro-Oncology Consortium (PNOC) has expanded internationally, with two sites now open in Australia. The study is expected to open additional countries in the near future.

The study is based substantially on preclinical research by Professor Matt Dun at the Hunter Medical Research Institute at the University of Newcastle in Newcastle, Australia. Professor Dun has shown evidence of potent synergy between the two drugs in preclinical models of DIPG, and has reported case studies of children successfully treated with the combination in compassionate use experience.

Financial Position

Kazia closed the quarter to 30 September 2022 with a cash balance on hand of A$5.3 million (approximately US$3.4 million), a decrease of A$1.7 million on the previous quarter. On a conservative forward-looking forecast, the company projects runway to 1Q CY2023. However, the company notes that future expenditure will be significantly reduced due to the removal of costs associated with Stage 2 of the GBM AGILE study. The remaining part of

GBM AGILE is fully-funded and the company anticipates no material further expenditure on the study.

The company continues to periodically use its NASDAQ ATM financing facility in a judicious way to support its operational requirements. The ATM allows the company to raise capital dynamically in the market, with no discount, no warrant coverage, and modest banking fees, allowing it to fund itself with minimal dilution to existing shareholders.

Broad Clinical Program Ongoing

Sponsor	Phase	Indication	Registration
PAXALISIB			
Global Coalition for Adaptive Research	II / III	Glioblastoma	NCT03970447
Weill Cornell Medicine	II	Glioblastoma (*with ketogenesis*)	NCT05183204
Alliance for Clinical Trials in Oncology	II	Brain metastases	NCT03994796
Dana-Farber Cancer Institute	II	Breast cancer brain metastases (*with Herceptin*)	NCT03765983
Dana-Farber Cancer Institute	II	Primary CNS lymphoma	NCT04906096
Pacific Pediatric Neuro-Oncology Consortium	II	DIPG (childhood brain cancer)	NCT05009992
St Jude Children's Research Hospital	I	DIPG	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	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 multiple forms of brain cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of ten clinical trials in this disease. A completed phase II study in glioblastoma reported promising signals of efficacy in 2021, and a pivotal study for registration, GBM AGILE, is ongoing, with final data expected in 2H CY2023. Other clinical trials are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these having reported encouraging interim data.

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, and for atypical teratoid / rhabdoid tumours (AT/RT) in June 2022 and July 2022, respectively.

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.

Forward-Looking Statements

This announcement may contain forward-looking statements, which can generally be identified as such by the use of words such as “may,” “will,” “estimate,” “forward,” “anticipate,” or other similar words. Any statement describing Kazia's future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for results of Kazia’s clinical trials, and Kazia’s strategy and plans with respect to paxalisib. Such statements are based on Kazia’s expectations and projections about future events and future trends affecting our business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including risks and uncertainties associated with clinical trials and product development and the impact of global economic conditions. These and other risks and uncertainties, are described more fully in Kazia’s Annual Report, filed on form 20-F with the SEC, and in subsequent filings to SEC. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this announcement. Actual results could differ materially from those discussed in this announcement.

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	**Quarter ended ("current quarter")**
37 063 259 754	September 2022

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(4,281)	(4,281)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(412)	(412)
	(f) administration and corporate costs	(1,364)	(1,364)
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)		
1.9	**Net cash from / (used in) operating activities**	**(6,057)**	**(6,057)**

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)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	3,680	3,680
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	**Net cash from / (used in) financing activities**	**3,680**	**3,680**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,361	7,361
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,057)	(6,057)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,680	3,680
4.5	Effect of movement in exchange rates on cash held	319	319
4.6	**Cash and cash equivalents at end of period**	**5,303**	**5,303**

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	5,303	5,303
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)**	**5,303**	**5,303**

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	271
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.

7.	**Financing facilities** *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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
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)	(6,057)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,303
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	5,303

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.9

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.

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 through Q1 CY2023. The company is in ongoing discussions with potential investors and partners and, in the meantime, plans to continue to utilise its 'at-the-market' (ATM) facility with Oppenheimer & Co to provide additional funding from time to time.

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.

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.

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 October 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.