ASX RELEASE
29 July 2022

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 29 July 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 June 2022.

Key Points

- Kazia's at-the-market (ATM) financing facility, operated by Oppenheimer & Company, has raised total gross proceeds to date of US$ 3.2 million (approximately AU$ 4.6 million), at an average price per ADS of US$ 5.94 (AU$ 0.85 per ordinary share), materially expanding the company's operating runway with minimal dilution to existing shareholders.
- Alliance study in brain metastases has transitioned to an expansion stage after promising data in the initial exploratory stage.
- Final data from the phase II study of paxalisib in glioblastoma was presented at the ASCO annual meeting.
- Preclinical data demonstrating synergistic activity in the combination of paxalisib and ONC201 in DIPG, an aggressive childhood brain cancer, was presented at the ISPNO annual meeting.
- Preclinical data demonstrating synergistic activity in the combination of paxalisib with several other experimental cancer therapies in AT/RT, another childhood brain cancer, was presented at the AACR annual meeting.
- FDA granted orphan drug designation (ODD) and, post period, rare pediatric disease designation (RPDD) to paxalisib for treatment of AT/RT. Among other advantages, this provides a second opportunity for paxalisib to attain a pediatric priority review voucher (pPRV) if approved in AT/RT.
- GBM AGILE study has been recruiting ahead of expectations and has opened a paxalisib arm in several European countries.
- The phase I study of EVT801 in patients with advanced cancer continues to recruit well and has successfully cleared the third dose cohort.
- Post period, Kazia has launched a new Scientific Advisory Board (SAB), comprised of leading experts in brain cancer research and novel therapies.

Kazia CEO, Dr James Garner, commented, “This quarter has been characterised by multiple positive data read-outs from the paxalisib program. In particular, the emerging data in childhood brain cancer is very promising. Moreover, the ongoing Alliance study has given us the first indications that paxalisib may also have a role to play in the treatment of brain metastases, which represents a significant unmet medical need and a very substantial commercial opportunity.”

“On the financing front,” Dr Garner continued, “our ATM facility has been extremely successful. We have brought a meaningful amount of capital into the company at no discount, with no accompanying warrants or options, and with very modest fees to our bankers. Alongside the ATM, the company continues to routinely evaluate a number of financing approaches, including equity placements and non-dilutive opportunities such as partnering and grant funding.”

Final Phase II Glioblastoma Data Presented at ASCO

The final data from Kazia’s phase II study of paxalisib in patients with newly diagnosed glioblastoma and unmethylated MGMT status (NCT03522298) was presented at the Annual Meeting of the American Society for Clinical Oncology (ASCO) in Chicago, IL, from 3-7 June 2022.

The poster presentation described an overall survival (OS) in the intent-to-treat (ITT) population of 15.7 months, and a progression-free survival (PFS) of 8.6 months. These data compare favourably with the corresponding 12.7 months and 5.3 months respectively for temozolomide, the existing FDA-approved standard of care, in this patient group. Tolerability was consistent with prior clinical trial experience, with hyperglycemia, mucositis, and rash among the most common toxicities.

Alliance Trial in Brain Metastases Transitions to Expansion Stage

In June 2022, a phase II, genomically-guided clinical trial of paxalisib, among other therapies, in the treatment of brain metastases, sponsored by the Alliance for Clinical Trials in Oncology (NCT03994796), graduated the initial paxalisib arm to an expansion stage in the breast cancer cohort, following positive efficacy and safety signals. Recruitment in two cohorts, lung cancer and other tumours, remain ongoing.

New Preclinical Data in Childhood Brain Cancer

Associate Professor Matt Dun, at the Hunter Medical Research Institute, part of the University of Newcastle, Australia, presented new data describing the rationale for, and efficacy of, the combination of paxalisib with ONC201 (Chimerix, Inc) in the treatment of diffuse intrinsic pontine glioma (DIPG) and diffuse midline gliomas (DMGs) at the 20th Annual International Symposium on Pediatric Neuro-Oncology (ISPNO) in Hamburg, Germany, from 12-15 June 2022.

Dr Dun's data showed that PI3K pathway activation is a common resistance mechanism to ONC201, and the combination of the two drugs was synergistic in animal models of DIPG. Using two aggressive autopsy animal models of DIPG the combination of paxalisib and ONC201 synergistically extended survival from 73 to 100 days (37%) and from 36 to 43 days (19%), respectively. Using two different animal models each representing aggressive DIPG disease the combination of paxalisib and ONC201 demonstrated improved survival from 73 to 100 days (37%) and 36 to 43 days (19%) in each model respectively. These results were assessed to be synergistic in their effect.

The presentation also described two patients who received the combination of ONC201 and paxalisib under compassionate access, and who demonstrated "dramatic reductions in tumour volume and complete resolution of disease symptoms, extending overall survival".

On the basis of this research, a clinical trial (NCT05009992) of the combination commenced recruitment in November 2021 under the sponsorship of the Pacific Pediatric Neuro-Oncology Consortium (PNOC). The study is ongoing, with initial data anticipated in 1H CY2023.

Separately, Assistant Professor Jeffery Rubens at Johns Hopkins University in Baltimore, MD, presented new data at the Annual Meeting of the American Association for Cancer Research (AACR), held in New Orleans, LA, from April 8 – 13, 2022. Dr Ruben's preclinical data described the use of paxalisib in atypical rhabdoid / teratoid tumours (AT/RT), a different and rare form of childhood brain cancer. Paxalisib demonstrated efficacy as a monotherapy and was synergistically active with two other classes of therapy: an HDAC inhibitor and a MAPK inhibitor.

Regulatory Designations in AT/RT

On 17 June 2022, the company announced that the US Food and Drug Administration (FDA) had granted Orphan Drug Designation (ODD) to paxalisib for the treatment of AT/RT. Orphan designation entitles Kazia to an additional period of market exclusivity, during which generic competitors cannot market their products in the United States, as well as a waiver of PDUFA fees, and access to orphan grant opportunities. The company previously received orphan designation for glioblastoma in February 2018 and for malignant glioma in August 2020.

Post period, on 6 July 2022, the company announced that FDA had awarded Rare Pediatric Disease Designation (RPDD) to paxalisib for the treatment of AT/RT. 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.

GBM AGILE Study Opens in Europe

During 2Q CY2022, the GBM AGILE pivotal study (NCT03970447) opened the paxalisib arm in Switzerland and France. The addition of these countries has substantially expanded the pool

of recruiting sites and made the drug available to clinical trial patients in Europe for the first time since the original phase I study. The study opened to recruitment in the US in January 2021, and in Canada in November 2021.

EVT801 Study Clears Third Dose Level

The phase I study of EVT801 in patients with advanced cancer (NCT05114668) continues to recruit well. The drug recently completed the third of up to eight dose levels and has opened recruitment to the fourth dose cohort. To date, the drug appears generally well-tolerated. Depending on how many dose cohorts are required to establish a maximum tolerated dose (MTD), interim data from the study is anticipated in 2H CY2022 or 1H CY2023.

New Scientific Advisory Board Launched

Post period, on 12 July 2022, the company announced the launch of a new Scientific Advisory Board (SAB), comprising four leading experts in brain cancer. The new SAB reflects the late stage of development of paxalisib in brain cancer and has been designed to support imminent initiation of pre-commercial activities for the drug.

The members include Professor Priscilla Brastianos (Harvard Medical School / Massachusetts General Hospital), Professor John de Groot (University of California, San Francisco), Dr Alan Olivero (independent consultant, formerly of Genentech, Inc), and Professor Patrick Wen (Harvard Medical School / Dana Farber Cancer Institute).

ATM Facility Raises US$ 3.2 million (AU$ 4.6 million) in New Capital

Kazia's at-the-market (ATM) financing facility, operated by Oppenheimer & Company, has raised total proceeds to date of US$ 3.2 million (approximately AU$ 4.6 million), at an average price per ADS of US$ 5.94 (AU$ 0.85 per ordinary share), materially expanding the company's runway with minimal dilution to existing shareholders.

Aside from technical trial runs, the facility has been used on five occasions since its inception. On the most active day, the ATM accounted for 4% of the day's trading volume, implying minimal price impact as a result of its use.

Of note, shares issued under the ATM are issued at the spot market price, with no discount, no accompanying warrants or options, and with banking fees approximately half of those associated with more traditional financing methods.

Impact of COVID-19

The company identifies no material impact from the ongoing COVID-19 pandemic to its operations. Given the evolution of the pandemic, the company will hereafter discontinue routine updates on this topic and will notify the market of COVID-related impact only on an as needed basis.

Financial Update

As noted in the accompanying Appendix 4C, the company's cash position as at 30 June 2022 was AU$ 7.36 million, versus AU$ 6.96 million at 31 March 2022, an increase of AU$ 0.4 million. The company calculates an operating runway on a forward-looking basis through 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 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	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 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 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. Seven 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, and for AT/RT in June 2022.

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,” “intend,” “potential,” “prospective,” 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. 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	June 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	(3,834)	(18,191)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(412)	(1,790)
	(f) administration and corporate costs	(583)	(2,784)
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)		
1.9	**Net cash from / (used in) operating activities**	**(4,829)**	**(22,755)**

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)		(2,328)

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**	**-**	**(2,328)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4,056	4,056
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)		
3.10	**Net cash from / (used in) financing activities**	**4,056**	**4,072**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,958	27,587
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,829)	(22,755)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(2,328)

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)	4,056	4,072
4.5	Effect of movement in exchange rates on cash held	1,176	785
4.6	**Cash and cash equivalents at end of period**	**7,361**	**7,361**

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	7,361	7,361
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)**	**7,361**	**7,361**

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	-

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)	(4,829)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,361
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	7,361
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.52

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 Q4 CY2022.

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. The company expects to continue to be able to access capital markets and other funding sources as needed.	

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: 29 July 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.