ASX RELEASE
31 January 2023

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 31 January 2023 – 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 31 December 2022.

Key Points

- Final data from Kazia's phase II clinical trial of paxalisib in glioblastoma was presented at the annual meeting of the Society for Neuro-Oncology (SNO). The data shows a median overall survival for paxalisib in this population of 15.7 months, which compares favourably with the figure of 12.7 months reported for temozolomide, the existing standard of care.
- A phase II clinical trial of paxalisib in children and young adults with diffuse midline gliomas, run by the Pacific Pediatric Neuro-Oncology Consortium (PNOC) has expanded internationally, with two sites open in Australia and additional sites opening in several other countries. Initial data from the study is anticipated in CY2023.
- In October 2022, 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.
- In December 2022, Kazia disclosed an ongoing collaboration with the Queensland Institute of Medical Research (QIMR) to examine novel uses of paxalisib in multiple solid tumours, including breast cancer. The collaboration has already been the subject of a patent filing, and discussions are ongoing regarding potential transition to clinical trials.
- In December 2022, preclinical data for EVT801, Kazia's second pipeline molecule, was published in the journal *Cancer Research Communications*. The data summarises the substantial evidence base for EVT801's pharmacological activity, and describes its potential as a combination agent with immuno-oncology therapies such as Keytruda® (pembrolizumab) and Opdivo® (nivolumab).

- Post period, Kazia announced the completion of a successful institutional financing and sophisticated investors round which raised gross proceeds of AU$ 4.5 million. Part of the transaction remains subject to the approval of shareholders at an Extraordinary General Meeting on 24 February. A Share Purchase Plan is ongoing for eligible investors.

Kazia CEO, Dr James Garner, commented, "After a productive fourth quarter, we are pleased that the company is now financed to the second half of CY2023. This is a critical year for the company in terms of data delivery, and the proceeds of our recent financing leave us well positioned to focus on delivering a broad range of potential catalysts. We are very grateful to the existing investors who have continued to support the company through this round."

Final Phase II Glioblastoma Data Presented at SNO

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 meeting of the Society for Neuro-Oncology (SNO), held in Tampa, FL, from 17-20 November 2022.

The presentation reviewed data that had been previously summarised at the Annual Meeting of the American Society for Clinical Oncology (ASCO), held in Chicago, IL, in June 2022, and at the Annual Congress of the European Society for Medical Oncology (ESMO), held in Paris, France, from 9-13 September 2022. The key findings included a median overall survival of 15.7 months, which compares favourably to the figure of 12.7 months that has been reported for temozolomide, the existing standard of care.

Also at the SNO conference, Professor Matt Dun of the Hunter Medical Research Institute at the University of Newcastle gave an invited oral presentation on his research with the combination of paxalisib and ONC201 (Chimerix, Inc) in the treatment of diffuse midline gliomas (DMGs), an aggressive group of childhood brain cancers which includes diffuse intrinsic pontine glioma (DIPG). Professor Dun described the high level of synergy between the two drugs, and touched on positive clinical outcomes from compassionate use experience.

Expansion of PNOC Phase II Study in Childhood Brain Cancer

In October 2022, Kazia announced expansion of the PNOC022 study to Australia. The study began recruitment in November 2021 and is investigating the combination of paxalisib with ONC201 in the treatment of children and young adults with diffuse midline gliomas (DMGs).

The study is currently open to recruitment at 22 sites globally, including the Sydney Children's Hospital, the Royal Children's Hospital Melbourne, and the Queensland Children's Hospital in Brisbane. The study has also opened at sites in Israel, the Netherlands, and Switzerland. Recruitment is ongoing.

Positive Preclinical Data for Paxalisib 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. 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.

Positive Preclinical Data for Paxalisib in Immunotherapy Combination

In December 2022, Kazia announced the existence of a research collaboration with the Queensland Institute of Medical Research, to explore the use of paxalisib as an immunomodulator in the treatment of solid tumours. This work potentially identifies a novel mechanism of action for the drug, and consequently has been patented to secure novel intellectual property.

The research is led by Professor Sudha Rao, a leading expert in the field of transcriptional biology, who has collaborated closely with other academic centres and with industry partners to explore the activity of novel therapies on the immune system.

Potentially, the project may enable the use of paxalisib in solid tumours such as breast cancer, and may support use of the drug in combination with immuno-oncology therapies such as Keytruda® (pembrolizumab) and Opdivo® (nivolumab). The research remains ongoing.

Positive Preclinical Data for EVT801

In December 2022, scientists working for and with Evotec SE, Kazia's licensing partner for EVT801, published a summary of their preclinical research on the drug in the prestigious journal, Cancer Research Communications.

The paper outlines the substantial body of evidence supporting the activity of EVT801 as an anti-cancer therapy, and includes comparative data against several approved therapies with similar mechanisms of action. The paper also presents combination data with several immuno-oncology agents, showing evidence of substantial synergy.

Kazia Raises AU$ 4.5 Million from Existing Investors

Post period, in January 2023, Kazia announced the completion of an equity placement to four existing sophisticated and institutional investors, which raised gross proceeds of AU$ 4.5 million. The funds will be used by the company to progress its pipeline, which comprises two novel drug candidates in nine clinical trials, and is expected to secure runway into 2H CY2023.

The transaction was priced at AU$ 0.11 per share, representing a 13% premium to the 15-day volume-weighted average price (VWAP), and was not accompanied by the issuance of associated warrants, options, or other structures.

Under ASX Listing Rule 7.1, part of the transaction will be dependent on the approval of shareholders, which will be sought at an Extraordinary General Meeting (EGM) scheduled for 24 February 2022. All shareholders are encouraged to vote their proxies in advance of the EGM.

The company has provided an opportunity for existing eligible retail shareholders to strengthen their position on the same terms as the existing institutional placement via a Share Purchase Plan (SPP). The SPP allows eligible shareholders to apply for up to $30,000 of new shares in Kazia, in defined increments, and will remain open until 24 February. The SPP has been launched primarily to ensure the equitable treatment of retail holders in comparison to institutional holders, and so neither a target nor a cap have been set. However, the company reserves the right to conclude the SPP early, or to scale back subscriptions, if it considers it appropriate to do so given the demand.

All shareholders are referred to the company's ASX announcements of January 2023, to the company website, and to individual shareholder information that has been distributed to all eligible shareholders in respect of the EGM and the AGM.

Financial Position

Kazia closed the quarter to 31 December 2022 with a cash balance on hand of AU$ 4.4 million, versus $5.3 million in the previous quarter. It should be noted however that this figure does not include any part of the proceeds of the company's $4.5 million financing, which was announced in January 2023, and therefore is no longer substantially reflective of the company's cash position or runway.

The reduced cash burn relative to previous quarters reflects in part the company's ongoing cost reduction efforts, which were announced at the Annual General Meeting, and which seek to reduce expenditure in CY2023 by at least 50% relative to 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	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 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,” “future,” “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 and data related to Kazia’s clinical and preclinical trials, and Kazia’s strategy and plans with respect to its programs, including paxalisib and EVT801. Such statements are based on Kazia’s expectations and projections about future events and future trends affecting its 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 and preclinical trials and product development, related to regulatory approvals, and the related to 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 with the 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.

This announcement was authorized for release to the ASX by Dr James Garner, CEO and Managing Director, on behalf of the Board.

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	December 2022

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	(1,449)	(5,730)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(422)	(834)
	(f) administration and corporate costs	(892)	(2,256)
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**	**(2,763)**	**(8,820)**

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 (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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	2,171	5,851
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**	**2,171**	**5,851**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,303	7,361
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,763)	(8,820)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,171	5,851
4.5	Effect of movement in exchange rates on cash held	(320)	(1)
4.6	**Cash and cash equivalents at end of period**	**4,391**	**4,391**

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	4,391	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)**	**4,391**	**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	253
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)	(2,763)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,391
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	4,391

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.6

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: On 16 January the company announced a placement to professional and sophisticated investors raising A$4.5 million and the launch of an associated Share Purchase Plan for eligible shareholders. The company is now financed to the second half of CY2023.

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 January 2023.....

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.