ASX RELEASE

30 October 2020

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 30 October 2020 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide an update on the ongoing development of its product candidates for the quarter ending 30 September 2020.

Key Points

- Paxalisib granted special designations by US FDA: Rare Pediatric Disease Designation in DIPG, Orphan Designation in glioma, and Fast Track Designation in glioblastoma
- New clinical collaboration launched with Dana-Farber Cancer Institute: a phase II study in primary CNS lymphoma, led by Dr Lakshmi Nayak
- Post-period: completion of a ~$25 million financing round and execution of definitive agreement with GCAR to commence GBM AGILE pivotal study

Kazia CEO, Dr James Garner, commented, "the September quarter has been highly productive: we have launched a new clinical study, and we have seen important recognition by FDA of the drug's potential in several forms of brain cancer. These achievements leave us ideally positioned as we now transition into the GBM AGILE pivotal study in glioblastoma. The remainder of this year, and the year ahead, are likely to be rich in data read-outs and in operational progress, as we see paxalisib move rapidly towards commercialization."

FDA Special Designations Awarded

In August 2020, Kazia received Rare Pediatric Disease Designation (RPDD) from the US FDA for paxalisib in the treatment of diffuse intrinsic pontine glioma (DIPG). RPDD is designed to support and encourage the development of drugs for rare childhood illnesses. The key benefit of it the program is that it allows for the sponsor company to receive a priority review voucher (PRV) at the time of an application for marketing authorization in the paediatric disease. The PRV can be sold to another company and used for any new drug, and such transactions have historically commanded prices between US$ 68 and 350 million.

Also in August 2020, Kazia received Fast Track Designation (FTD) from the US FDA for paxalisib in the treatment of glioblastoma. FTD is designed to expedite development of

pharmaceutical products which demonstrate the potential to address unmet medical needs in serious or life-threatening conditions. It provides Kazia with substantially enhanced access to FDA, including the ability to submit a 'rolling NDA', in which components of the new drug application can be filed as they become available, increasing efficiency and reducing risk in the approval process.

In addition, and also in August 2020, Kazia received Orphan Drug Designation (ODD) from the US FDA for paxalisib in the treatment of glioma. This encompasses both DIPG and glioblastoma. The company previously received ODD for the narrower indication of glioblastoma in February 2018. ODD provides access to certain grant funding, a waiver of PDUFA fees at the time of NDA submission (currently approximately US$ 3 million per indication), and a period of data exclusivity which augments the patent protection.

The achievement of these milestones leaves the paxalisib program well-optimised from a regulatory standpoint:-

	Glioblastoma	**DIPG**
Orphan Drug Designation	February 2018	August 2020
Fast Track Designation	August 2020	
Rare Pediatric Disease Designation	n/a	August 2020

New Phase II Study in Primary CNS Lymphoma

In September 2020, Kazia launched a new clinical collaboration with Dana Farber Cancer Institute. Under the terms of the collaboration, Dr Lakshmi Nayak will lead a phase II investigator-initiated clinical trial in primary CNS lymphoma. Dr Nayak is an extensively published clinical researcher in this field, and Dana Farber has a world-leading specialist unit for treatment and research of this disease. Primary CNS lymphoma is a form of brain cancer that affects approximately 1,500 patients per annum in the United States. It is considered a high-potential target for paxalisib, since three of the four FDA-approved PI3K inhibitors are used to treat forms of lymphoma outside the central nervous system.

Broad Clinical Trial Program on Track

Sponsor	**Phase**	**Indication**	**Registration**
Kazia Therapeutics	II	Glioblastoma	NCT03522298
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	TBD
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	NCT04192981

Post-Period Events – Successful Capital Raise

On 1 October 2020, Kazia launched a one-for-three accelerated non-renounceable entitlement offer to raise approximately $25 million, before fees. The transaction was fully-underwritten by Bell Potter Securities Limited. The accelerated institutional component closed on 2 October 2020, raising approximately $16.4 million from institutional investors, representing approximately a 70% take-up. The retail component closed on 20 October 2020, raising a further $8.8 million, with approximately 32% take-up.

This financing leaves the company well-funded to execute the GBM AGILE pivotal study.

Post-Period Events – GBM AGILE Moves into Operational Phase

On 16 October 2020, the company executed a definitive agreement with the Global Coalition for Adaptive Research (GCAR) to commence paxalisib's participation in the GBM AGILE pivotal study in glioblastoma.

GBM AGILE is an international, multi-drug platform study, designed to expedite the approval of new medicines for glioblastoma. It is run independently of any individual company, under the leadership of some of the world's premier experts in the field. The study is already ongoing, with thirty sites in the United States and Canada participating, and the first drug is Bayer's Stivarga® (regorafenib). Paxalisib will be the second drug to enter the study. First patient in to the paxalisib arm is expected to occur in early Q1 CY2021.

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 2020 was AU$ 6.5 million. The company invested AU$ 1.6 million in research and development activities during 1Q FY2021, and incurred G&A expenses of AU$ 0.6 million.

On the basis of cash at 30 September 2020 and expenditure during the quarter, the Appendix 4C reflects almost three quarters of available funding. However, immediately post-period, the company executed a fully underwritten capital raise which yielded approximately $25 million in new capital, before fees. As a consequence, the company's operations are well-funded for the foreseeable future.

Upcoming Milestones

The key milestones for the next two quarters are as follows:-

- Additional interim data from the ongoing phase II study of paxalisib in glioblastoma (November 2020 – SNO Annual Meeting)
- Initial interim data from the ongoing phase I study of paxalisib in DIPG at St Jude Children's Research Hospital (November 2020 – SNO Meeting)
- Initial interim data from the ongoing phase II study in breast cancer brain metastases at Dana-Farber Cancer Institute (precise timing remains uncertain due to COVID-related disruption of conference schedules)
- Top-line final data from the completed phase I study of Cantrixil in ovarian cancer
- First patient in (FPI) to GBM AGILE registration study for paxalisib in glioblastoma (planned for each Q1 CY2021 in order to avoid Christmas and New Year period)

These milestones are indicative and may be subject to change.

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is paxalisib (formerly GDC-0084), a small molecule 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 entered a phase II clinical trial in 2018. Interim data was reported most recently at AACR in June 2020, and further data is expected in 2H 2020. Five additional studies are in start-up or ongoing 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.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells and is being developed to treat ovarian cancer. TRX-E-002-1 has completed a phase I clinical trial in Australia and the United States with the final data expected in the second half of calendar 2020. Interim data was presented most recently at the AACR conference in June 2020. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

For more information, please visit www.kaziatherapeutics.com.

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	30 September 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,623)	(1,623)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(217)	(217)
	(f) administration and corporate costs	(409)	(409)
1.3	Dividends received (see note 3)		
1.4	Interest received	16	16
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**	**(2,233)**	**(2,233)**

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		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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)	12	12
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**	**12**	**12**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,764	8,764
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,233)	(2,233)
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 (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	12	12
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**6,543**	**6,543**

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	543	1,264
5.2	Call deposits	6,000	7,500
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)**	**6,543**	**8,764**

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)	(2,233)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,543
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	6,543
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.93

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: Cash outflows are likely to increase as the Company proceeds with the GBM Agile trial

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 raised $25.2 million (before costs) in October 2020 in order to provide funding for the GBM Agile trial, as well as further working capital.

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: .....30 October 2020.....

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.