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ASX RELEASE

29 January 2021

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 29 January 2021 – 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 31 December 2020.

Key Points

- GBM AGILE pivotal study opened to recruitment for the paxalisib arm, placing the drug on a direct path to commercialisation
- Completion of an AU$ 25 million financing round in October 2020 leaves the company well-funded to commence GBM AGILE pivotal study; initial one-off start-up fee of US$ 5 million paid on execution
- New clinical collaboration launched with Pacific Pediatric Neuro-Oncology Consortium (PNOC) to investigate paxalisib as combination therapy in DIPG
- Interim analysis of paxalisib phase II study in glioblastoma presented at Society for Neuro-Oncology (SNO) Annual Meeting, directionally confirming earlier results
- Interim analysis of paxalisib phase I study in DIPG presented at SNO Annual Meeting, showing favourable safety and tolerability
- Final top-line data from Cantrixil phase I study in ovarian cancer released; definitive study publication in draft

Kazia CEO, Dr James Garner, commented, “the December quarter has been defined by two critical achievements: a financing round that will substantially fund the GBM AGILE pivotal study for paxalisib, and the subsequent commencement of recruitment to that study. We are now, in common parlance, a ‘phase III company’, with our lead program on a direct path to a potential FDA approval, and that elevation in status is beginning to be reflected in a much broader and deeper level of investor engagement.”

Commencement of GBM AGILE Pivotal Study

On 16 October 2020, immediately following a successful $25 million financing round, Kazia executed a definitive agreement with the Global Coalition for Adaptive Research (GCAR) to execute the paxalisib arm of the GBM AGILE pivotal study (NCT03970447). Positive data

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

from this study is expected to support the registration of paxalisib as a new therapeutic for glioblastoma.

GBM AGILE has been established by leading clinicians and researchers in the glioblastoma field to expedite the approval of promising new therapies for the disease. It is an adaptive study, in which the number of patients recruited is constantly adjusted according to emerging data. Through this and other efficiencies, GBM AGILE lowers the cost of developing a new drug in glioblastoma by a very substantial margin, while still providing gold-standard clinical data to support registration.

GBM AGILE is currently active at 35 sites in the United States and will shortly be opening in Canada. Expansion to EU and China is expected during CY2021.

Successful Capital Raise Provides AU$ 25 Million in New Funding

As noted in the company's previous Appendix 4C, 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 implement the GBM AGILE pivotal study.

New Study in DIPG

On 10 December 2020, Kazia announced that it had signed a Letter of Intent (LOI) with the Pacific Pediatric Neuro-Oncology Consortium (PNOC) to include paxalisib in a new clinical trial of multiple therapies in combination for patients with DIPG and other diffuse midline gliomas (DMGs).

The PNOC study will also include ONC-201 (Oncoceutics, Inc) and panobinostat (SecuraBio, Inc) and will explore treatments in various combinations using an adaptive design.

Of note, the PNOC study has built off an extensive body of laboratory research undertaken by Associate Professor Matt Dun at the Hunter Medical Research Institute in Newcastle, NSW. The Dun laboratory research is expected to be published in a peer-reviewed academic journal during 1H CY2021.

Kazia's participation in the PNOC study incurs no direct cost to Kazia, beyond provision of study drug and administrative support. Implementation is subject to approval by FDA and relevant institutional review boards, and to execution of a definitive agreement between Kazia and the University of California, San Francisco (UCSF) on behalf of PNOC.

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Interim Data from Phase II Study in Glioblastoma & Phase I Study in DIPG

Kazia reported new interim data from the ongoing phase II study of paxalisib in glioblastoma (NCT03522298) at the Society for Neuro-Oncology (SNO) Annual Meeting in November 2020.

The interim analysis of all patients in the study (n=30) showed a progression-free survival (PFS) of 8.4 months, and an overall survival (OS) of 17.5 months. These numbers compare favourably with the historical control: corresponding figures of 5.3 months and 12.7 months, respectively, are reported with temozolomide, the only FDA-approved standard of care in newly diagnosed glioblastoma.

At the same meeting, Dr Chris Tinkle and colleagues gave an oral presentation on interim data from their ongoing phase I study of paxalisib as monotherapy in patients with DIPG and DMGs (NCT03696355). The study had recruited 27 patients and reported generally favourable safety and tolerability with paxalisib, having determined a maximum tolerated dose (MTD) in children of 27 mg/m^2.

There was not, at the time of analysis, a clear signal of efficacy, which was unsurprising given that the primary focus of the study was safety and tolerability. However, the authors reported a progression-free survival at 6 months (PFS6) of 96%, which compares favourably to an historical control of 58%.

Final Top-Line Data from Cantrixil Phase I Study in Ovarian Cancer

On 9 December 2020, Kazia reported top-line final data from the completed phase I study of Cantrixil (TRX-E-002-1) in advanced ovarian cancer. In total, 25 patients were recruited at hospitals in the United States and Australia. An MTD of 5 mg/kg was determined, with the key side effects being abdominal pain and gastro-intestinal symptoms.

Among 16 evaluable patients, one patient demonstrated a complete response (CR) according to RECIST criteria, and two patients demonstrated partial responses (PRs), making an overall response rate (ORR) of 19%.

Kazia is currently working alongside the investigators to produce a manuscript for submission to a peer-reviewed academic journal.

Receipt of $1.02 million R&D Tax Rebate

On 14 December 2020, Kazia received $1.02 million via the Australian R&D Tax Rebate scheme.

Completion of Unmarketable Parcel Share Sale Facility

As announced to ASX on 2 November 2020, Kazia launched an unmarketable parcel share sale facility in which parcels of less than AU$ 500 in value could be resumed and re-sold, with the benefits accruing to the holder.

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This facility closed as planned on 18 December 2020, with 243,784 shares being purchased from shareholders and sold on market for an average price of $1.37 per share. The proceeds from the sale of these shares is to be distributed to those shareholders during the first week of February 2021. As a result of the facility, a total of 1,860 shareholders have left the register, and a number of other shareholders took the opportunity to consolidate their holdings.

Impact of COVID-19

The company has no revisions to its prior guidance concerning COVID-19, but envisages a systematic review with investigators during 1Q CY2021. At present, there is limited operational impact, but Kazia continues to monitor the situation closely.

Broad Clinical Program Ongoing

Sponsor	Phase	Indication	Registration
Kazia Therapeutics	II	Glioblastoma	NCT03522298
Global Coalition for Adaptive Research	II / III	Glioblastoma	NCT03970447
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
Pacific Pediatric Neuro-Oncology Consortium	N/A	DIPG	TBD
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	NCT04192981

Financial Update

As noted in the accompanying Appendix 4C, the company's cash position as at 31 December 2020 was AU$ 19.366 million. The company invested AU$10 million in research and development activities during 2Q FY2021, including an initial one-off fee of US$ 5M (~AU$ 6.5M) to commence the GBM AGILE pivotal study, and incurred G&A expenses of AU$ 0.5 million.

On the basis of cash at 31 December 2020 and expenditure during the quarter, the Appendix 4C reflects 1.92 quarters of available funding. However, as noted above, the company incurred substantial one-off payments in 2Q FY2021 associated with commencement of the GBM AGILE pivotal study for paxalisib. As a result, expenditure in this quarter is unrepresentative of ongoing spend.

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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 GBM AGILE, a pivotal study in glioblastoma, in October 2020. 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.

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. 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

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Name of entity

Kazia Therapeutics Limited

ABN	**Quarter ended ("current quarter")**
37 063 259 754	December 2020

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	(10,037)	(11,134)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(521)	(722)
	(f) administration and corporate costs	(512)	(1,468)
1.3	Dividends received (see note 3)		
1.4	Interest received	16	32
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	1,018	1,018
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(10,036)**	**(12,269)**

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		

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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)	23,597	23,609
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**	**23,597**	**23,609**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,543	8,764
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,036)	(12.269)
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)	23,597	23,609
4.5	Effect of movement in exchange rates on cash held	(738)	(738)
4.6	**Cash and cash equivalents at end of period**	**19,366**	**19,366**

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	11,366	543
5.2	Call deposits	8,000	6,000
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)**	**19,366**	**6,543**

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.

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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)	(10,036)
8.2	Cash and cash equivalents at quarter end (item 4.6)	19,366
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	19,366
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.93

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: Not at all – the December quarter saw the outflow of a prepayment of USD5m for the start of the GBM Agile trial, as well as significant start up expenses associated with that trial. Adjusting only for the deposit, the cash outflow would have been approx. AUD7m lower and the cash balance approx. AUD7m higher, yielding a result of 7 quarters of cash available.

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: Please note the response to question 8.6.1. The Company believes it has sufficient cash to fund the operations for the remainder of calendar 2021.

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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 as described above	

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 January 2021.....

Authorised by: .....Board of Dirctors .....
(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.

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