ASX RELEASE

30 July 2021

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 30 July 2021 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), 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 2021.

Key Points

- Kazia has licensed worldwide rights to EVT801, a selective VEGFR3 inhibitor, from Evotec SE, a European drug development company. EVT801 is due to commence a phase I clinical trial in patients with advanced cancer by end of CY2021.
- All upfront payments from outbound partnering transactions in 1Q CY2021 have been received by Kazia.
- A new phase II trial of paxalisib in combination with a ketogenic diet has been launched in collaboration with Cornell University.
- GBM AGILE is recruiting ahead of schedule, with more than two dozen sites now open to the paxalisib arm, and expansion to Europe and China slated for 2H CY2021.

Kazia CEO, Dr James Garner, commented, "The second calendar quarter has been a busy and productive period for Kazia, as we bed down three substantial cross-border licensing deals. We have continued to make great strides with the paxalisib clinical program, with two new studies launching, and a number of important read-outs are slated for the second half. Meanwhile, the EVT801 program is off to a running start, and we are well on track to commence our planned phase I study before the end of calendar 2021. The last two months or so have fully justified our excitement around this new asset, and we are very much looking forward to seeing it in the clinic."

In-License of EVT801 from Evotec

As noted by way of a post-period item in the Appendix 4C for the March quarter, Kazia has, in April 2021, executed a worldwide exclusive licensing agreement with Evotec SE, a leading European drug development company, for EVT801, a small-molecule, orally-available, selective inhibitor of VEGFR3.

The terms of the agreement provide for Kazia to pay Evotec an upfront payment of €1 million, contingent milestone payments, and a tiered single-digit royalty on net sales. In addition to the licensing agreement, Kazia has engaged Evotec under a Master Services Agreement to support various aspects of the drug's ongoing development.

At the time of the license agreement, Kazia provided guidance that it would commence a phase I clinical trial of EVT801 by the end of CY2021. The program remains well on track to meet this milestone. Investigational product for use in the clinical trial has been manufactured. Two hospitals in France have been selected to participate. The study protocol has been submitted for review by L'Agence nationale de sécurité du médicament et des produits de santé (ANSM), the French regulatory agency. Kazia expects to provide further operational updates during 3Q CY2021.

Phase II Clinical Trial of Paxalisib Launched in Collaboration with Cornell University

On 15 June 2021, Kazia announced that it had entered into an agreement with the Joan & Sanford I Weill Medical College of Cornell University in the United States, known generally as Weill Cornell Medicine, to explore the use of paxalisib in combination with ketogenesis for patients with glioblastoma.

A significant and growing body of research has suggested the potential for ketogenic diets to provide benefit in a range of tumour types, including glioblastoma. Unlike healthy tissue, many tumours are poorly able to make the metabolic adaptations necessary to metabolise ketones, and so are dependent on glucose. Removing glucose from the diet thus selectively impairs the tumour while allowing healthy tissue to function normally.

For paxalisib, a second and very specific potential benefit has been identified by Professor Lew Cantley and colleagues, the scientist who originally discovered the PI3K pathway. Professor Cantley's research suggests that insulin may limit the effects of PI3K inhibitors, and that this class of drugs may therefore be more effective if patients can maintain a very low level of insulin in their body. The best way to achieve this is through a ketogenic diet, and through a drug named metformin, and so the Cornell study will examine this combination. Professor Cantley serves as a scientific advisor to the study, and Dr Howard Fine, a highly experienced neuro-oncologist, will serve as Principal Investigator. Recruitment to the study is expected to begin in 2H CY2021.

New Paxalisib Phase II Glioblastoma Data Presented at AACR Conference

In April 2021, Kazia presented new pharmacokinetic (PK) data from its ongoing phase II study of paxalisib in patients with newly diagnosed glioblastoma. The data strongly supported the selection of 60mg per day as the optimal dose, and this is generally being used for subsequent studies. In addition, the data found no substantial difference between taking paxalisib on an empty stomach, versus taking it with food. This implies that paxalisib will not require a limitation in this respect when approved by FDA, simplifying its administration for clinicians and patients.

New Pharmacokinetic (PK) Study Launched to Support NDA Submission to FDA

Kazia has initiated a specialized 'mass-balance study' of paxalisib, also known as an ADME (Absorption, Distribution, Metabolism, Excretion) study. The study will be conducted in the United Kingdom, with the support of several contract research organisations who specialize in such studies.

The purpose of the ADME study is to fully characterize the distribution of paxalisib within the human body, and to measure the rate at which it is eliminated. A single dose of a radio-labelled version of paxalisib will be administered to a small group of healthy volunteers, who are then carefully assessed for approximately one week to measure excretion of the radio-labelled material. This data is expected by FDA as part of a New Drug Application (NDA) and so Kazia has incorporated execution of this study into its development plan for paxalisib, in parallel with GBM AGILE. It is expected that dosing of subjects will occur in August 2021.

Kazia CEO, Dr James Garner, commented, "As we move ever closer to a potential NDA submission for paxalisib, the Kazia team is working hard to build a compelling and exhaustive regulatory dossier. GBM AGILE will of course be the centerpiece of our application, but a substantial amount of supportive information will be required to ensure success. This ADME study is one instance of the broader body of work required to launch a new product, and we are pleased to be performing this project in CY2021 so that the requisite data is available for our NDA filing."

The ADME study is technical in scope and is not expected to provide information of a material nature to investors, but Kazia may provide operational updates from time to time.

Positive Progress Across Paxalisib Clinical Trial Program

In June 2021, Kazia provided an operational update on its clinical trial program. The update noted excellent progress in GBM AGILE, the pivotal study for paxalisib, with approximately two-dozen trial sites open to recruitment in the paxalisib arm at that time. To date, GBM AGILE has screened over 650 patients, and this is expected to accelerate as new sites in new territories come online through 2H CY2021.

Also in June 2021, Kazia announced that the phase II study of paxalisib in primary CNS lymphoma at Dana-Farber Cancer Institute had commenced recruitment. In general, lymphoma has been a very promising indication for PI3K inhibitors, with four of the five FDA-approved agents targeting some form of this disease. As the only brain-penetrant PI3K inhibitor in mainstream development, paxalisib has unique potential in the form of this disease that occurs within the central nervous system, and so the Dana-Farber study will examine this new use of the drug. Dr Lakshmi Nayak, a neuro-oncologist with extensive clinical research experience, will serve as Principal Investigator.

Kazia's own phase II study of paxalisib in glioblastoma has completed dosing, with the final patient on study drug having now experienced disease progression, after approximately 2.3 years on treatment. Kazia will now work with the investigators to bring the study to a conclusion and to seek publication of final data in a high-quality scientific journal.

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.

Broad Clinical Program Ongoing

Sponsor	Phase	Indication	Registration
Kazia Therapeutics	II	Glioblastoma	NCT03522298
Global Coalition for Adaptive Research	II / III	Glioblastoma	NCT03970447
Weill Cornell Medicine	II	Glioblastoma (*with ketogenesis*)	TBD
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	TBD
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	NCT04192981
Kazia Therapeutics	I	Human ADME study in healthy volunteers	TBD

Financial Update

As noted in the accompanying Appendix 4C, the company's cash position as at 30 June 2021 was AU$ 27.6 million, an increase on the 3Q FY2021 balance of AU$ 19.7 million. The increase principally reflects revenues from partnering transactions, as previously disclosed by the company.

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. Eight additional studies are active 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.

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 is expected to begin in CY2021.

For more information, please visit www.kaziatherapeutics.com or follow us on Twitter @KaziaTx.

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 2021

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	7,428	12,689
1.2	Payments for		
	(a) research and development	(3,159)	(18,713)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(406)	(1,462)
	(f) administration and corporate costs	(646)	(2,685)
1.3	Dividends received (see note 3)		
1.4	Interest received	5	42
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		1,018
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**3,222**	**(9,111)**

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 (12 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)	4,239	28,108
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**	**4,239**	**28,108**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	19,655	8,764
4.2	Net cash from / (used in) operating activities (item 1.9 above)	3,222	(9,111)
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)	4,239	28,108
4.5	Effect of movement in exchange rates on cash held	471	(174)
4.6	**Cash and cash equivalents at end of period**	**27,587**	**27,587**

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	21,087	21,087
5.2	Call deposits	6,500	6,500
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)**	**27,587**	**27,587**

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)	3,222
8.2	Cash and cash equivalents at quarter end (item 4.6)	27,587
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	27,587
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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:

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:

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:

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 July 2021.....

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.