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ASX RELEASE

31 July 2020

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Sydney, 31 July 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 June 2020.

Key Points

- Positive data from phase II study of paxalisib in glioblastoma presented at ASCO and AACR conferences in June 2020
- Paxalisib on track for potential commencement of GBM AGILE registration study in 2H CY2020
- ~$9 million in new capital raised through oversubscribed institutional placement in April 2020 and subsequent share purchase plan in May 2020

Kazia CEO, Dr James Garner, commented, "we are making excellent progress in the development of paxalisib. Following very positive data in recent months, the drug remains on track to commence a phase III study for registration, subject to ongoing funding discussions, and we anticipate that it could enter the market within the next few years. The commercial opportunity in glioblastoma is conservatively estimated at US$ 1 - 1.5 billion per annum. Beyond that, we have studies well underway in other forms of brain cancer, and these could substantially expand the opportunity for paxalisib."

Positive Clinical Trial Data for Paxalisib

Kazia presented an interim analysis of the ongoing phase II study of paxalisib in glioblastoma at the American Association for Cancer Research (AACR) Annual Meeting in June 2020. This analysis determined a median overall survival of 17.7 months for patients treated with paxalisib, which compares favourably to the historical control of 12.7 months for patients treated with temozolomide, the existing standard of care[1]. The analysis also showed a median progression-free survival of 8.5 months, which is similarly encouraging in

[1] ME Hegi, A-C Desirens, T Gorlia, et al. *N Engl J Med* (2005); 352:997-1003

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

comparison to the historical control of 5.3 months associated with temozolomide. The study remains ongoing, and final data is expected in late CY2020 or early CY2021.

Summary of Paxalisib Data in Comparison to Temozolomide (existing standard of care)

	Temozolomide (FDA-approved treatment)	**Paxalisib** (interim phase II data)
Progression-Free Survival (PFS)	5.3 months	8.5 months
Overall Survival (OS)	12.7 months	17.7 months

Note: temozolomide figures are historical controls, and so may not be directly comparable

Broad Clinical Trial Program on Track

In addition to the ongoing phase II study in glioblastoma, four trials of paxalisib in other forms of brain cancer are ongoing.

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
St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
Memorial Sloan Kettering Cancer Center	I	Brain metastases (*with radiotherapy*)	NCT04192981

Impact of COVID-19

The company has been closely attentive to the potential impact of the ongoing COVID-19 pandemic on its activities. To date, there has been only modest operational impact at certain hospitals participating in Kazia clinical trials, with no material impact thus far. Nevertheless, the company continues to exercise a high degree of prudence, and is regularly evaluating emergent operational and financial challenges.

Preparation Well Advanced for GBM AGILE Registration Study

The company has continued to work closely with the Global Coalition for Adaptive Research (GCAR) and with clinicians to bring paxalisib into the ongoing GBM AGILE study. It is expected that GBM AGILE will provide the substantial evidence for FDA approval of paxalisib in glioblastoma. The study remains on track to commence recruitment in 2H CY2020, and the company expects to provide further detail in the near future.

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High Impact Academic Publications

Two peer-reviewed papers concerning paxalisib have recently been published in the prestigious journal, *Clinical Cancer Research* (CCR). CCR is published by the American Association of Cancer Research (AACR) and is ranked the #10 most impactful oncology journal (out of 348 publications) by SCImago.

The first paper, by Wen et al.[2], provides a complete review of the data from the phase I study of paxalisib in recurrent glioma that was performed by Genentech (NCT01547546). The paper concludes that 'these data support the further development of GDC-0084 [paxalisib].' The key results of this study have been previously presented (for example at ASCO in 2016), but their detailed analysis in a high-profile scientific journal provides a canonical reference point for researchers, investors, and partners. Unlike conference posters, such journal publications undergo an exacting process of 'peer review', and only those which represent a significant and reliable contribution to the field are accepted.

The second paper, by Ellingson et al.[3], reports a highly innovative analysis of imaging data from the same phase I study. Professor Ellingson correlates the amount of paxalisib in a patient's body with measurable changes on MRI and PET scans, and connects those changes with clinical outcomes. These data provide a powerful confirmation that paxalisib crosses the blood-brain barrier and inhibits the PI3K pathway, and that this biological activity translates to meaningful changes in disease progression. The work was previously the subject of a prize-winning oral presentation at the Society for Neuro-Oncology (SNO) Annual Meeting in November 2019.

Taken together, these papers substantially reinforce the body of published scientific data for paxalisib and provide new insights into its mechanism of action and potential clinical efficacy.

Regulatory Activity

During 4Q FY2020, the company received confirmation from the United States Adopted Name (USAN) Council that 'paxalisib' had been confirmed as the non-proprietary name for the drug formerly designated GDC-0084. This follows confirmation of paxalisib as the International Non-Proprietary Name (INN) for ex-US territories in December 2019.

Financial Update

As noted in the accompanying Appendix 4C, the company's cash position at 30 June 2020 was AU$ 8.8 million. The company invested AU$ 2.1 million in research and development activities during 4Q FY2020, and incurred G&A expenses of AU$ 0.7 million.

These figures imply that approximately 75% of the company's expenditure is devoted directly to research and development, representing a very high level of operating efficiency.

[2] PY Wen et al. *Clin Cancer Res* 2020;26:1820–28
[3] BM Ellingson et al. *Clin Cancer Res* 2020;26:3135-44

The company would also highlight that, while G&A expenses are incurred fairly evenly throughout the year, cash invested in research and development activities tends to vary considerably by quarter. In particular, the cashflows reported in this Appendix 4C include milestone payments associated with the completion of the Cantrixil phase I study, as well as one-off costs for the set-up of GBM AGILE. Accordingly, it is difficult to draw inferences as to the anticipated expenditure in FY2021.

In April and May 2020, the company raised approximately AU$ 9.0 million (before costs) in an oversubscribed institutional placement and subsequent Share Purchase Plan. The proceeds of these transactions will be used to advance the clinical development of paxalisib towards registration.

Should it be required, the company has contingency plans in place to adjust operational execution of its studies and, as necessary, to conserve cash.

Upcoming Milestones

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

- Commencement of recruitment to GBM AGILE registration study for paxalisib in glioblastoma
- Additional interim data from the ongoing phase II study of paxalisib in glioblastoma
- Interim data from the ongoing phase II study of paxalisib in breast cancer brain metastases at Dana-Farber Breast Cancer Institute
- Interim data from the ongoing phase I study of paxalisib in DIPG at St Jude Children's Research Hospital

The milestones are indicative and may be subject to change.

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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 multiforme, 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 in April 2020, and further data is expected in 2H 2020. Paxalisib was granted orphan designation for glioblastoma by the US FDA in February 2018.

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 is currently undergoing a phase I clinical trial in Australia and the United States. Interim data was presented at the ESMO Congress in September 2019, and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

This document was authorized for release to the ASX by the Board of Directors.

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	30 June 2020

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	(2,071)	(6,951)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(212)	(1,150)
	(f) administration and corporate costs	(482)	(2,186)
1.3	Dividends received (see note 3)		
1.4	Interest received	18	66
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		1,391
1.8	Other (provide details if material)		20
1.9	**Net cash from / (used in) operating activities**	**(2,747)**	**(8,810)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(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 (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)	8,973	12,973
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	(572)	(833)
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**	**8,401**	**12,140**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,110	5,434
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,747)	(8,810)
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)	8,401	12,140
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**8,764**	**8,764**

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	1,264	610
5.2	Call deposits	7,500	2,500
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)**	**8,764**	**3,110**

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	Nil
6.2	Aggregate amount of payments to related parties and their associates included in item 2	Nil

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	Nil	
7.2	Credit standby arrangements	Nil	
7.3	Other (please specify)	Nil	
7.4	**Total financing facilities**	Nil	

7.5	**Unused financing facilities available at quarter end**	Nil

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)	2,747
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8,764
8.3	Unused finance facilities available at quarter end (Item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	8,764
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	3.19

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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:

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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 July 2020.....

Authorised by: .....The 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.

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