

ASX RELEASE 6 April 2022

RESPONSE TO SEC LETTER

Sydney, 6 April 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), a late stage, oncology-focused drug development company, advises the receipt of a letter from the United States Securities and Exchange Commission (SEC) commenting on the Company's Form 20-F for the fiscal year ended June 30, 2021. The letter relates to disclosures of financial information in the Company's annual SEC financial filing. The Company is pleased to provide the attached response to the letter from SEC.

For More Information, Please Contact:-

<u>In the United States:</u> <u>In Australia:</u>

Joe Green Jane Lowe Edison Investor Relations IR Department

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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 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.

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

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

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 <u>www.kaziatherapeutics.com</u> or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.



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April 5, 2022

United States Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attention: Christine Torney

Vanessa Robertson

Re: Kazia Therapeutics Ltd

Form 20-F for the fiscal year ended June 30, 2021

Filed October 7, 2021 File No. 000-29962

Ladies and Gentlemen:

Kazia Therapeutics Ltd (the "Company") is providing this letter in response to comments (the "Comments") received from the staff of the U.S. Securities and Exchange Commission's Division of Corporation Finance (the "Staff") by letter dated March 22, 2022, with respect to the Company's Annual Report on Form 20-F that was filed on October 7, 2021.

Set forth below is the Company's response to the Comments, which for your convenience we have incorporated into this response letter. Capitalized terms used in this response letter but not otherwise defined in this response letter shall have the meanings set forth in the Annual Report.

Form 20-F for the fiscal year ended June 30, 2021

<u>Item 5. Operating and Financial Review and Prospects</u> <u>A. Operating Results</u>

Expenses, page 22

1. Please provide us with proposed disclosure to be included in future periodic reports which separately quantifies your research and development expense by project. If you do not track your research and development costs by project, disclose that fact as well as why you do not maintain and evaluate research and development costs by project.

We acknowledge your comment and propose to disclose research and development expense by project in our future periodic reports in the following format (disclosures shown for FY21 report for illustrative purposes):

A\$'000	FY21	FY20
Paxalisib		
- Phase II trial	1,941	3,690
- GBM Agile trial	8,148	1,523
- other paxalisib	966	670
EVT801	1,098	_
Cantrixil	429	1,673
R&D salaries	694	854
Amortisation of licensed assets	1,265	1,084
Total R&D expense	14,541	9,494



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<u>Item 18. Financial Statements</u> <u>Note 5. Revenue, page F-20</u>

2. Please tell us your consideration of providing disclosure of the out-license agreements with Oasmia and Simcere to separately quantify upfront payments and milestone payments by type, as these both appear to be material agreements.

We offer the following comments in relation to this question:

- It is the Company's view that we have complied with the disclosure requirements of IFRS 15 in our annual report on Form 20-F
- We note that disclosure of the revenue earned from our out-license agreements with Oasmia and Simcere appears on pages 40 41 of our annual report on Form 20-F, showing that all revenue received in fiscal 2021 represents up front payments.
- In future periodic reports, we will give consideration to providing additional voluntary disclosure in Note 5 to the financial statements, separately identifying upfront payments and milestone payments by type.

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We appreciate your consideration.

Please feel free to contact me via email gabrielle.heaton@kaziatherapeutics.com.

Yours sincerely,

/s/ Gabrielle Heaton

Gabrielle Heaton

Director, Finance & Administration