



MARCH 2020

Dr James Garner
CEO and
Managing Director



Dear Investors,

This year is a critical one for Kazia: our lead program, paxalisib, will make the transition into a pivotal study for registration. This is the final inflection point on the way to a commercial product, and a hugely exciting step for the program. We are now on a direct track to a marketing approval.

Our planned pivotal study is GBM AGILE, and we are already hard at work on setup activities. Like so much in the paxalisib program, GBM AGILE is highly innovative, and we think it provides the perfect path to market for our drug. We are delighted and honoured to be joining, and we expect to begin recruitment of patients in the second half of this calendar year.

In the meantime, 2020 has been highly productive for Kazia, with great progress across all of our clinical trial programs. Our phase II study in glioblastoma has completed recruitment, well ahead of schedule. The other four studies of paxalisib are open to recruitment, and the Cantrixil phase I study will shortly complete clinical activities. We expect to report new clinical data from both programs during the next two months.

We recognise that these activities take place against the background of the global COVID-19 outbreak. Kazia has proactively implemented pandemic preparedness measures, and we remain in very close contact with all our partners to ensure that our clinical trials are not disrupted. As a pre-revenue company, we are in a certain sense insulated from much of the immediate economic impact, but our first priority is to ensure that patients in our clinical trials continue to be fully supported.

2020 will be an exciting and important year for Kazia, and we look forward to keeping shareholders regularly updated as the year progresses.

Dr James Garner

In the News



19 February 2020
Half-Year Report published, showing strong progress in R&D



11 December 2019
Kazia accepted to join GBM AGILE; start-up work commences



25 November 2019
Kazia presents initial interim efficacy data from GDC-0084 phase 2 study



28 October 2019
Kazia raises \$4M in oversubscribed institutional placement

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We announced on 6th March 2020 that Kazia had had an abstract accepted to the prestigious AACR annual conference, which was scheduled for 24 – 29 April 2020 in San Diego, CA.

Our abstract focused on an interim data analysis from the ongoing phase II study of paxalisib in glioblastoma. The company previously presented data at the Society for Neuro-Oncology (SNO) Annual Meeting in November 2019, and this data had provided very promising indications of potential efficacy.

The AACR conference has since been cancelled due to the coronavirus pandemic. Kazia regrets the loss of an important academic meeting, but fully supports the organisers in this difficult decision.

In place of the data that would have been presented at AACR, Kazia plans to electively release top-line interim data during March or April 2020 via the ASX announcement platform.

We will be working with our consultants and advisors to distil the key data points for this interim read-out, and will look forward to sharing an update with shareholders at the earliest opportunity.

Professor Ben Ellingson wins Award for Retrospective Analysis of Paxalisib Data

Professor Ben Ellingson (UCLA) presented a ground-breaking analysis of data from the phase I study of paxalisib at the Society for Neuro-Oncology (SNO) annual meeting in November 2019.

Professor Ellingson’s cutting-edge work linked the concentration of paxalisib in the blood to measurable changes on brain scans, and to potential clinical efficacy. The project won the inaugural neuro-imaging award at the conference.



Kazia’s Programs at a Glance

Paxalisib (GDC-0084)

[NCT03522298](#)

Phase II study in glioblastoma (most common brain cancer) (led by Kazia Therapeutics) Recruitment complete **New Data: March / April 2020**

[NCT03765983](#)

Phase II study in breast cancer brain metastases (led by Dana-Farber Cancer Inst.) Recruiting

[NCT03994796](#)

Phase II study in brain mets. (led by Alliance for Clinical Trials in Oncology) Recruiting

[NCT03696355](#)

Phase I study in DIPG (led by St Jude Children’s Research Hospital) Part A successfully completed; Part B currently recruiting

[NCT04192981](#)

Phase I study in brain mets. (led by Memorial Sloan Kettering Cancer Center) Recruiting

Cantrixil

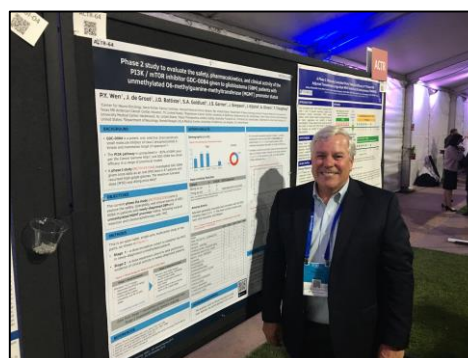
[NCT02903771](#)

Phase I study in treatment-resistant ovarian cancer (led by Kazia Therapeutics) Recruitment complete **New Data: March / April 2020**

Kazia presents initial interim efficacy data from phase II study in glioblastoma

At the same conference, Kazia presented a poster reporting interim efficacy data from the ongoing phase II study of paxalisib in glioblastoma. Using data from the first nine patients, a median progression-free survival (PFS) of 8.4 months was determined, which compares very favourably with the historical standard of care, temozolomide, which is associated with a median PFS of 5.3 months.

This data strongly suggests that paxalisib may be successful in delaying progression of this very aggressive cancer. At the time of analysis, only two patients in the study had passed away, so it was not yet possible to determine median overall survival. In the future, any indication that survival exceeds the 12.7 months associated with current standard of care treatment will be a dramatic finding.



Dr Alan Olivero, inventor of paxalisib, at the SNO Conference in November 2019

An **AGILE** Pivot

Kazia has released details of the clinical trial which will provide a path-to-market for paxalisib.

GBM AGILE is a 'platform study' set up by leading experts in brain cancer to facilitate approval of new drugs in glioblastoma. It runs over a period of years, and companies can insert their drugs into it in order to generate the clinical data required for registration. The study is strongly supported by FDA, and is managed operationally by the Global Coalition for Adaptive Research (GCAR), a non-profit group dedicated to pioneering innovative clinical trial designs in high-need disease areas.



Professor Tim Cloughesy (UCLA) is the Principal Investigator for GBM AGILE, and a current investigator on the paxalisib phase II study

GBM AGILE is already up and running: the first drug to enter the study began in mid-2019. It is expected that paxalisib will be the second drug to join, and recruitment of patients to the paxalisib arm will begin in the second half of 2020.

Kazia is built on a highly collaborative business model, where clinical data is developed in close partnership with clinicians, researchers, and other institutions, with sharing of cost and workload. GBM AGILE is the fastest, most cost-effective, and most efficient path to market for paxalisib, and a fitting final chapter to its development.

For More **Information**

Visit the Global Coalition for Adaptive Research (GCAR), the non-profit entity that runs GBM AGILE www.gcaresearch.org

View GBM AGILE on clinicaltrials.gov www.clinicaltrials.gov/ct2/show/NCT03970447

Read about GBM AGILE's novel clinical trial design https://cancerres.aacrjournals.org/content/77/13_Supplement/3594.short
<https://clincancerres.aacrjournals.org/content/24/4/737.abstract>

Learn more via the National Brain Tumor Society <https://braintumor.org/our-research/gbmagile/>

Q&A

Q. What are the advantages of GBM AGILE, compared to Kazia running its own study?

A. GBM AGILE is a larger and more sophisticated study than any one company could likely establish. It is strongly supported by clinicians and FDA. The use of innovative approaches such as a shared comparator arm mean that the study will be faster and more cost-effective.

Q. How many patients will be recruited?

A. GBM AGILE is an 'adaptive' study, which means that it will recruit only the number of patients required to provide a definitive answer. Up to 200 patients may receive paxalisib, but the number may be considerably fewer if the efficacy of the drug exceeds expectations, and that could result in substantial savings in time and cost.

Q. Is paxalisib at a disadvantage by being the second drug to join the study?

A. All the drugs which join GBM AGILE will be assessed against a common control arm, but they won't be compared to each other. GBM AGILE is not a 'winner takes all' study. Rather, it is hoped that, over time, several new therapies could emerge from the study and be approved for widespread use in patients.

Q. Does this mean that Kazia no longer intends to seek a partner for paxalisib?

A. Kazia's strategy of seeking a partner to commercialise paxalisib remains unchanged. Having a clearly-defined path to registration that is strongly supported by FDA can only increase the attractiveness of paxalisib to potential partners.

Q. What will it cost for paxalisib to participate in GBM AGILE?

A. The commercial arrangements for the study remain confidential, but the cost of GBM AGILE is expected to be substantially less than the cost of Kazia conducting a standalone study.

Q. Will GBM AGILE only run in the United States?

A. GBM AGILE is currently open only in the US, but it is planned to open in other territories as well, potentially including Australia.

Q. When will GBM AGILE start recruiting patients to the paxalisib arm?

A. We expect to start recruitment in 2H CY2020.

Sign up for **Email Updates**

Make sure to keep in touch with everything that is happening at Kazia by signing up for email updates via the Kazia Website, or email us asking to be added at info@Kaziatherapeutics.com

Spotlight on Corporate Governance



Kate Hill
Company Secretary

In this interview, Kate Hill explains the role of the company secretary and the central focus that Kazia places on corporate governance

Please tell us about your background, and how you came to be Company Secretary at Kazia.

I left Deloitte nearly four years ago, after 20 years as a partner, in order to follow a passion to help build growing companies. My first role was with Kazia, and I have now been part of the team for over three and a half years.

In addition to my position with Kazia, I am a non-executive director of two listed companies, and the non-executive Chair of a third. In all of my roles I am passionate about governance and risk management in a way which enhances the value of the organisation – that is, built into the smooth running of the business, rather than getting in the way of the underlying operations of the company.

What does the Company Secretary role encompass?

I am the person with responsibility for governance and corporate conduct, and I advise the board and the CEO in this regard. This involves making sure that the Company is compliant with the various rules and regulations which apply to us, but at the same time my aim is to make sure we are not buried in bureaucracy.

I also co-ordinate the activities of the Board of Directors, and an important part of my role is to ensure that the Board is in a position to operate as an efficient and effective decision-making body.

Why are governance and corporate conduct so important?

Corporate conduct is really a way of thinking of Kazia as a corporate citizen: we want to be of good standing in the community so that we attract quality investors and collaborators. Governance is concerned with how the business is run, including how objectives are set and achieved, how risk is monitored, and how performance is optimised. Good governance provides the foundation for a high-performing organisation, and preserves and strengthens shareholder confidence. Focusing on these factors helps to build long-term value in the business.

What about communications with shareholders?

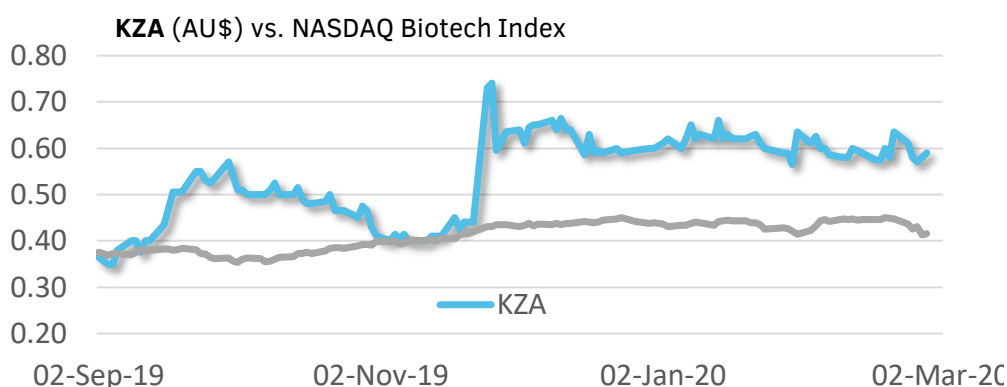
We are listed on both ASX and NASDAQ, so there is a complex process for making sure we comply with our continuous disclosure requirements on both markets. Essentially we are required to announce “market sensitive” information, that is, any information which would be expected to have a material impact on our share price.

We are also conscious that the ASX and SEC platforms are not to be used for more minor matters, so we have a series of other mechanisms to communicate with our shareholders, such as this newsletter, investor briefing sessions, and videos of interviews with our CEO, where we can add more detail and context to the publicly available information. We also keep our shareholders informed via the media, including social media.

What is your proudest accomplishment at Kazia?

In 2017 we did a lot of work to relaunch the company as a clinical oncology business with a portfolio of assets. This included renaming and rebranding, consolidating the shares and tidying up the balance sheet. We do not have a lot of resources and I'm proud that we achieved this transformation successfully but utilising a very small amount of investors' funds.

Market Watch



Market Cap: AU\$ 43 million

52W Range: AU\$ 0.32 – 0.74

Issued Shares: 72 million