

KAZIA THERAPEUTICS

Investor Newsletter

JUNE 2019

From the CEO



Dr James Garner
*CEO and
Managing Director*

Dear Investors,

Since our last newsletter, momentum has continued to build around Kazia's international clinical trial program.

Four of those trials focus on GDC-0084. We are trialling GDC-0084 in glioblastoma, the most common and aggressive form of brain cancer. We reported safety and dosing data from the first part of our phase II trial in May. We were delighted with the results, which reconfirmed the safety of GDC-0084 and identified that a dose 60 mg, which is higher than the 45 mg provided to patients under the phase I trial.

These findings are important as we move into the next stage. We are currently recruiting an additional 20 patients to provide confirmatory efficacy signals. We expect to report results before the end of 2019.

Our inclusion in the Alliance study, announced at the end of last month, is a dramatic and exciting step forward. We are participating alongside Eli Lilly and Genentech in a ground-breaking study led by one of the world's leading researchers in the field, and funded by the US National Cancer Institute. There can be no greater endorsement for GDC-0084 than this kind of commitment, and we are tremendously proud to be playing a part.

We marked World Brain Tumour Day on June 8. In recognition of the day, Professor Matt Dun of the University of Newcastle was featured extensively in the media around his research into DIPG, a rare but aggressive form of childhood brain cancer. More information follows on the next page.

Finally, we showcased positive data from our Cantrixil trial in ovarian cancer in front of a global audience at the American Association for Cancer Research's conference in April.

Thank you for your ongoing support as we forge ahead in what is shaping up to be a very successful year of delivery for Kazia.

James

James Garner

In the News



20 May 2019

Kazia announces participation in NCI-funded Alliance study



6 May 2019

Top-line safety data from GDC-0084 phase II study shows MTD of 60mg



1 April 2019

Part A data from Cantrixil phase I study in ovarian cancer presented at AACR



19 March 2019

Kazia sells shareholding in Noxopharm for \$2.4 million



20 February 2019

Half-year report released

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World Brain Tumor Day

As we do each year, we marked World Brain Tumor Day on 8 June 2019. Our homepage includes a grey ribbon for the month of June to recognise the challenges faced by patients with brain cancer.



It was inspiring to see Professor Matt Dun of the University of Newcastle featured extensively in the media around World Brain Tumor Day. Professor Dun is one of Australia’s leading researchers in DIPG, a rare but aggressive form of childhood brain cancer.

In a video produced by the Hunter Medical Research Institute, Professor Dun describes his very personal motivation to find new treatments for DIPG. He also outlines his own research work with Kazia’s GDC-0084, which has shown promising signals in the laboratory for DIPG and is currently being explored in a human trial in the United States. Professor Dun’s video can be seen [here](#).

Professor Dun was interviewed by Jane Hansen in the [Daily Telegraph](#) on 8 June, and the story was widely syndicated. Of his experiments with GDC-0084, he notes that “we have tested 11 DIPG samples in the lab and they are all sensitive to the drug.”



Professor Dun was also featured on Channel 7’s Sunrise program on 24 June. In the interview, he spoke candidly about his daughter, Josie, who was diagnosed with DIPG in February 2018.



The Kazia team continue to be inspired by the dedication of scientists such as Professor Dun, and we encourage readers to support his efforts through the charity www.RunDIPG.org.

Kazia’s Programs at a Glance

GDC-0084

[NCT03522298](#)

Phase II study in glioblastoma (most common brain cancer) (led by Kazia Therapeutics)

Part A successfully completed; Part B currently recruiting

[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)

Start-Up

[NCT03696355](#)

Phase I study in DIPG (led by St Jude Children’s Research Hospital)

Recruiting

Cantrixil

[NCT02903771](#)

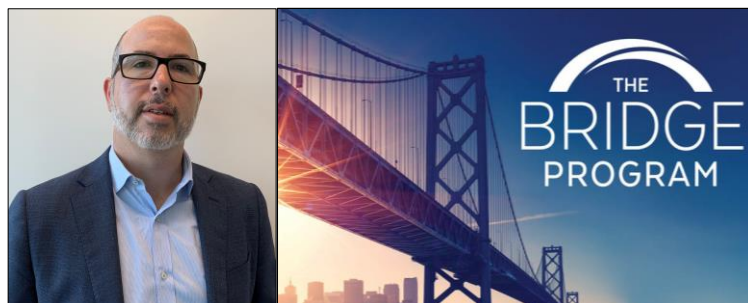
Phase I study in treatment-resistant ovarian cancer (led by Kazia Therapeutics)

Part B approaching full recruitment; data expected 2H 2019

Daniel Berg Invited to Bridge Program

Daniel Berg, Clinical Program Director for Cantrixil, has been selected to join the prestigious Bridge Program, a professional development scheme for high-potential professionals in the Australian drug development industry.

The Bridge Program is administered by Queensland University of Technology and has the support of MTP Connect, pharmaceutical companies, universities, and industry associations. Every year, 100 industry professionals across Australia are invited to join a challenging program of training, networking, and professional development.



Alliance Study in Brain Metastases

In May, Kazia announced that GDC-0084 had been selected for a sophisticated, multi-drug study in metastatic brain cancer (cancer that has spread to the brain from elsewhere in the body). The study is being run by the Alliance for Clinical Trials in Oncology, and funded by the US National Cancer Institute (NCI).

NCI is the largest of the National Institutes of Health (NIH), and has an annual budget of approximately US\$ 4.75 billion. It has contributed to the development of many of the world's leading cancer drugs, including paclitaxel, carboplatin, and GM-CSF. Their website is available [here](#). NCI is regarded as one of the most prestigious and exacting funding bodies for cancer research.

Very few drugs have shown efficacy against brain mets. One key challenge is that most drugs do not cross the 'blood-brain barrier' and so cannot reach the tumour. GDC-0084 is the only drug of its kind that is able to cross the blood-brain barrier, and so it represents a unique opportunity to bring benefit to these patients.

The Alliance study is led by Dr Priscilla Brastianos at Harvard Medical School who is a widely-published expert on brain metastases.



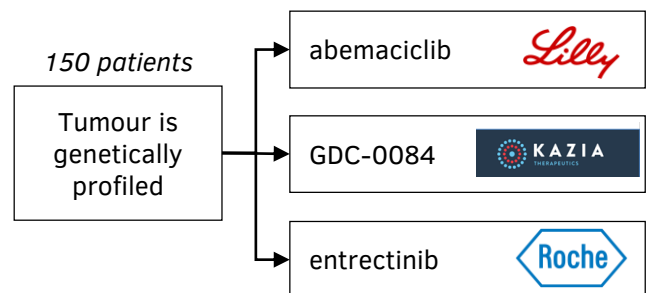
Brain Mets at a Glance

200,000 *Number of new cases of brain mets each year in the United States*

**Melanoma
Lung
Breast** *Most common primary tumours that spread to the brain*

**Surgery
Radiation** *Main treatments currently available to patients with brain mets*

The study exemplifies a leading-edge approach to cancer treatment called 'precision medicine'. The thinking behind precision medicine is that oncologists should treat cancer on the basis of its genetic features, not just its anatomical location. In the Alliance study, patients will be allocated on the basis of the genetic profile of their tumour to receive either GDC-0084 or two other drugs manufactured by Eli Lilly and Roche / Genentech.



Investor Presentations

Kazia CEO, Dr James Garner, has presented to investors in Sydney, Melbourne, and Brisbane at events organised by Proactive Investors and Wholesale Investors. A video of Dr Garner's presentation to Wholesale Investors is available [here](#).



Abemaciclib is already approved by FDA for the treatment of certain forms of breast cancer, and is sold under the trade name Verzenio™. Entrectinib is not yet approved, but it is being tested in a ground-breaking clinical trial that also selects patients based on the genetics of their tumour rather than its anatomical location.

The Alliance study is expected to begin recruitment in July, and will take approximately two years to complete.

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

Upcoming Scientific Conferences



16 – 17 August 2019
Inaugural Brain Metastases Meeting
New York, NY



20 – 24 November 2019
Annual Scientific Meeting
Phoenix, AZ

Spotlight on Clinical Trials



Dr Jeremy Simpson
Clinical Program Director
– GDC-0084

In this interview, Kazia's Dr Jeremy Simpson explains the clinical trial process and reviews Kazia's broad slate of four live clinical trials for the GDC-0084 program

Where are things currently with the GDC-0084 program?

Four clinical trials are currently recruiting patients and gathering data on a day to day basis. All are taking place in the United States under the oversight of the US FDA. Three are phase II studies, and one is phase I. That's a very broad and ambitious slate of work for a company our size! This research is of high interest to oncologists globally, which was reinforced strongly at the recent American Society of Oncology (ASCO) Meeting.

What does the phase of a trial mean?

Traditionally, phase I studies are conducted to understand the safety profile and optimal dosing of a new drug. Phase II studies demonstrate preliminary efficacy, and phase III studies are performed to get the drug registered by regulatory agencies such as FDA or TGA. Only after phase III can we sell the drug and make it widely available to physicians and patients. That said, the terms are a little old-fashioned, and regulators increasingly think in terms of exploratory studies (earlier and experimental) and registrational studies (later and confirmatory).

How does Kazia manage such a diverse program of clinical trials?

We outsource a lot of the operational execution of our trials to specialist 'contract research organisations' (CROs). Kazia designs the studies and oversees the project, but the CROs provide the manpower.

However, three of our studies are run directly by collaborators. We provide input and advice into study design, and keep a close eye on progress, but we don't manage the day-to-day detail. We are working with incredibly prestigious hospitals and trial groups, such as Dana-Farber Cancer Institute, St Jude Children's Research Hospital, and the Alliance for Clinical Trials in Oncology, so it is great to work with the very best in the business.

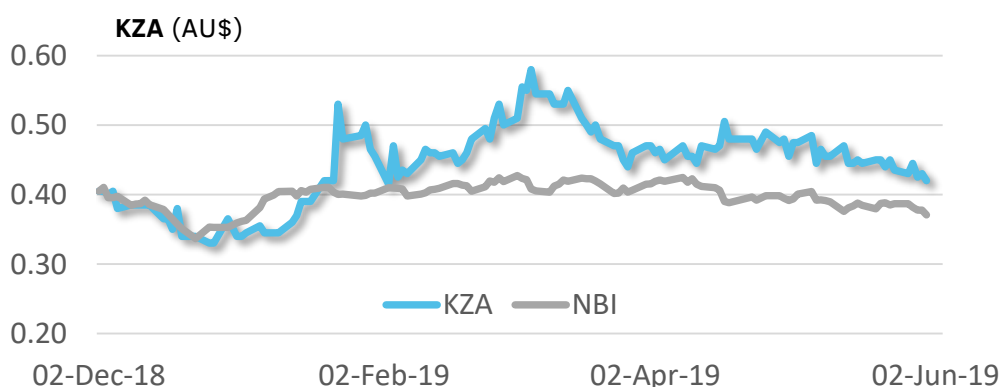
Why is the GDC-0084 program all being conducted in the US?

The US is typically around half of the commercial market for any new cancer drug, so we do all our clinical trials under the oversight of the US FDA such that they are kept familiar with the program and can provide input. The number of patients in the US is also an important consideration, given its large population. As we move towards registration for GDC-0084, we plan to include hospitals in additional countries, including of course Australia!

What are the next steps in the GDC-0084 program?

We should mostly finish the ongoing phase IIa study towards the end of this year. We are already well-advanced in preparation for a registrational study that will hopefully start in the first half of 2020. This will likely involve around two hundred patients and will take a couple of years, which is a very quick path to market by the standard of most cancer drugs. We have a lot of clinicians who are very keen to be a part of the registrational study, so it will be exciting to see it come together!

Market Watch



Market Cap: AU\$ 22 million

52W Range: AU\$ 0.33 – 0.67

Issued Shares: 62 million