KAZIA THERAPEUTICS

Investor Newsletter

FEBRUARY 2019

From the CEO

Dr James Garner
CEO and
Managing Director

Dear Investors,

2019 is certain to be an exciting year for Kazia, with at least four high-value data read-outs from clinical trials expected during the year.

For GDC-0084, we will finalise the optimal dose level for further development in glioblastoma, the most aggressive form of brain cancer. If we can dose higher than in Genentech's phase I study, that would be great news, bringing the potential for higher efficacy. Later in the year, we will report initial efficacy data. This will be a tremendously important milestone for investors and potential partners.

Meanwhile, the Cantrixil study in ovarian cancer has picked up the pace and is due to report full data from Part A in the first half, followed by efficacy data from the expansion cohort in the second half. We are very proud to have had an abstract accepted for the prestigious AACR conference in April in the United States.

On the corporate side, 2019 has been off to a breakneck start for the Kazia team, commencing with a presentation at Biotech Showcase, part of the JP Morgan Annual Healthcare Conference in San Francisco in the first week of January. We were delighted by the level of investor and partnering interest in Kazia at the conference, and took over 40 meetings in four days.

This is an exciting time for companies developing PI3K inhibitors (such as GDC-0084). The third commercial product in the class was approved in October 2018. At the same time, Novartis presented very strong data for their PI3K inhibitor in breast cancer. And in January of this year, TG Therapeutics received the coveted 'breakthrough designation' (BTD) from the US FDA for their drug for lymphoma. GDC-0084 is unique in its ability to cross the blood-brain barrier, but these successes from comparable drugs provide very welcome encouragement for our program.

Best wishes,

James

James Garner

In the News

15 January 2019
Kazia receives $2.2 million in cash via the Australian R&D tax rebate scheme

8 November 2018
Kazia AGM results in all resolutions supported by shareholders

22 October 2018
Phase II GDC-0084 study starts with Dana-Farber in breast cancer brain mets

18 October 2018
Placement of $3.4M to primarily institutional investors

3 October 2018
Phase I GDC-0084 study starts with St Jude Hospital in DIPG

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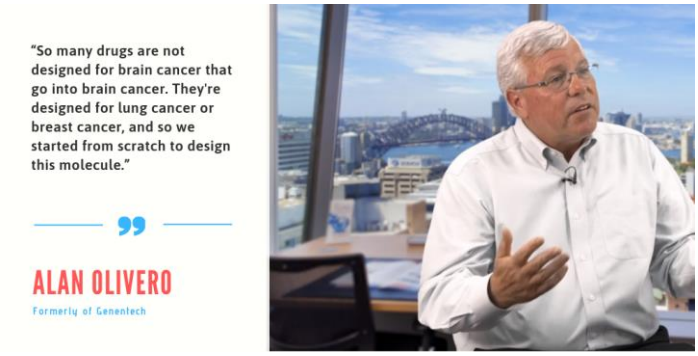
Visit by Dr Alan Olivero

Dr Alan Olivero, the inventor of GDC-0084 and former head of the PI3K program at Genentech, visited Sydney, Australia in December 2018 and met with the Kazia team, as well as attending a private luncheon with institutional investors and analysts.

During his visit, Dr Olivero was interviewed by journalists at Boardroom Media, and a video of the wide-ranging discussion can be accessed at the Kazia website.



Kazia's Programs at a Glance

GDC-0084	
NCT03522298 Phase II study in glioblastoma (most common brain cancer) (*led by Kazia Therapeutics*)	Recruiting well for Part A; initial data expected in 1H 2019
NCT03765983 Phase II study in breast cancer brain metastases (*led by Dana-Farber Cancer Inst.*)	Recruiting
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*)	50% recruited to Part B; efficacy data in 2H 2019

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

Kazia to present Cantrixil at AACR

Cantrixil has been selected for presentation at the upcoming American Association of Cancer Research (AACR) annual meeting in Atlanta, GA in early April.

The presentation will cover Cantrixil's ongoing phase I clinical trial in ovarian cancer, which is due to complete in 2019.

AACR is one of the most prestigious cancer research meetings in the world, and is closely watched by pharmaceutical companies, investors, and clinicians. Kazia looks forward to discussing the Cantrixil study with delegates. The presentation will be shared with investors as soon as the conference embargo is lifted and the abstract will subsequently be published in the full conference proceedings.

Meanwhile, the phase I study of Cantrixil in ovarian cancer is progressing well. All patients in Part A have completed treatment, and Kazia is exploring the best routes for further publication of this data.

At the time of writing, the expansion cohort (Part B) has treated six out of twelve planned patients, with a further three in screening. Recruitment is expected to conclude in the first half of calendar 2019.

Kazia at Biotech Showcase

Kazia CEO, Dr James Garner, gave a presentation to investors at Biotech Showcase in San Francisco January 2019, in which he outlined the strength of Kazia's pipeline and the rich newsflow expected in the year ahead.

Following his presentation, Dr Garner was interviewed by senior financial journalists at Proactive Investors and Investing News, where progress with the company's clinical programs was discussed.

Admission to Biotech Daily Index

Kazia was very gratified to be admitted in December 2018 to the Biotech Daily Top 40 Index, which tracks Australia's leading life sciences companies.

An industry journal-of-record, Biotech Daily began operations in November 2005. About 90 percent of the ASX listed biotechnology companies subscribe to Biotech Daily, along with Governments, universities, research institutions, major pharmaceutical companies, funding organizations, private and public unlisted companies, and IR/PR firms.

The Biotech Daily Top 40 began in 2005 with comprehensive data going back to June 2006. Biotech Daily assesses companies for admission on the basis of interesting and good science, benefit to human kind, competence of board and management and finally as an arbiter only, market capitalization.

Research Update

Have we Met?

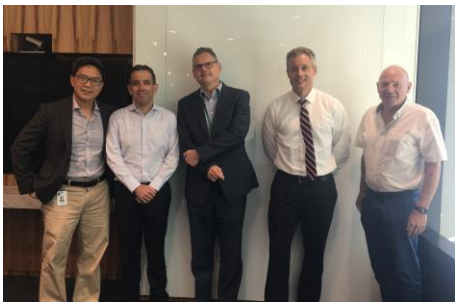
Dr Franziska Ippen, working with Professor Priscilla Brastianos at Harvard Medical School, presented a poster at the Society for Neuro-Oncology (SNO) Annual Meeting in New Orleans in November 2018, describing preclinical work with GDC-0084 in breast cancer brain metastases (BCBM, or 'brain mets', i.e. breast cancer that has spread to the brain).

Dr Ippen's research concluded that GDC-0084 caused growth inhibition in BCBM cell lines and was highly active in tumours with mutations in the PI3K pathway (around 70% of cases). The abstract was published in the journal Neuro-Oncology.

So What? Brain mets represent an enormous unmet medical need, being both common and highly resistant to treatment. Dr Ippen's research encourages the view that GDC-0084 may help to treat this group of patients. A phase II study in BCBM is underway at Dana-Farber Cancer Institute in the United States.

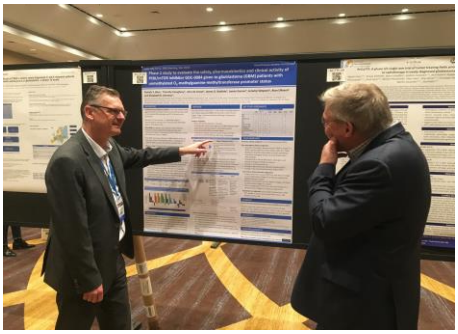
International Collaboration

The Kazia team were honoured to host a meeting in Sydney in January 2019 between Professor Carlo Palmieri of the University of Liverpool, and distinguished Australian scientists from the Garvan Institute and the University of Adelaide. The focus of the discussion was on the potential role for PI3K inhibitors in breast cancer.



Let It SNO

Kazia's Dr Jeremy Simpson also presented a poster at the SNO Annual Meeting, describing the ongoing phase II study of GDC-0084 in glioblastoma. It received considerable interest from delegates and can be downloaded from the Kazia Website.



Targeting DIPG

Dr Ryan Duchatel, a member of Professor Matt Dun's team at the University of Newcastle, presented a poster at the Garvan Signalling Symposium in November 2018. The poster described leading-edge preclinical research with GDC-0084 in DIPG, a rare and aggressive form of childhood brain cancer.

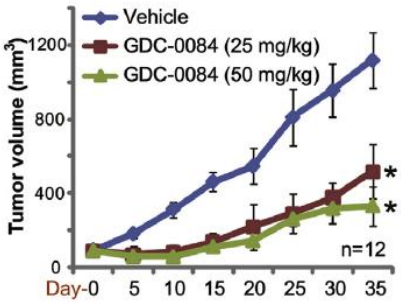
The Newcastle data showed GDC-0084 to be broadly active in DIPG cell lines, and in fact suggested even greater sensitivity to the drug in DIPG than in glioblastoma.

So What? The Newcastle research points to a persuasive case for GDC-0084 in this form of childhood brain cancer. A phase I study in DIPG is currently underway at St Jude Children's Research Hospital in the United States.

Skin in the Game

Dr Ling Ding-Tao and colleagues at the Second Affiliated Hospital of Soochow University in Suzhou, China, recently published preclinical data examining GDC-0084 in mouse models of squamous cell carcinoma (SCC), a common form of skin cancer.

Dr Ling's results show GDC-0084 to be highly active against these models of skin cancer, more so than other PI3K inhibitors tested, but was largely non-toxic to healthy skin cells. An abstract is available from the journal's website.



So What? While skin cancer is not a strategic priority for Kazia at present, these data help to confirm the relevance of the PI3K pathway to a wide range of cancers, and further validate GDC-0084 as a broadly active anti-cancer agent.

Upcoming Scientific Conferences

29 March – 3 April 2019
American Association of Cancer Research
Atlanta, GA

31 May – 4 June 2019
American Society for Clinical Oncology
Chicago, IL

Spotlight on Manufacturing

David Cain
Head, Chemistry, Manufacturing & Controls (CMC)

In this interview, Kazia's David Cain explains the complex series of tasks required to provide GDC-0084 capsules to a clinical trial patient

Where does Kazia make GDC-0084?

Kazia has partnered with world-class Contract Manufacturing Organisations (CMOs) to manufacture GDC-0084. Our CMOs are experts in oncology drug development and are based in the United States, Europe, and Canada.

Is it difficult to make the drug?

There are no very specific factors that make GDC-0084 more difficult to make than other drugs. However, pharmaceutical manufacture is highly regulated, and our CMOs have to observe very rigorous standards known collectively as Good Manufacturing Practice (GMP). They are regularly audited by customers such as Kazia, or by regulatory authorities such as the US FDA, or by EU Qualified Persons in Europe.

What is required to manufacture GDC-0084, and how often does Kazia manufacture?

We received substantial inventory of GDC-0084 as part of our original transaction with Genentech. However, the material needs to be manufactured into capsules for use in clinical trials. We do this according to projected clinical trial needs, and have manufactured two batches to date, with further runs planned in the near future.

Presumably the capsule manufacture is the easy part?

Not quite! There are many complex steps, including micronisation of the drug substance, blending with excipients (inert ingredients), and filling of the capsules to ensure patients get exactly the prescribed dose. Kazia spent many months developing the precise formulation to be used in our trials. The capsules are then subject to rigorous quality control tests, using validated analytical methods that we took over and adapted from Genentech. We also need to show that they remain stable under a variety of conditions, including extremes of temperature and humidity.

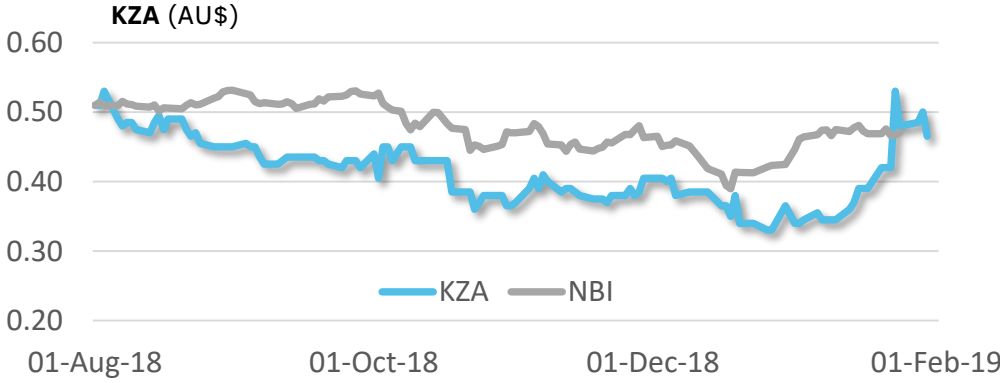
How long do GDC-0084 capsules last for?

The drug substance and finished capsules are actually very stable. At present, we have material that is approach five years old which is still entirely within specifications. Our stability studies are ongoing as we continue to monitor the stability of GDC-0084..

How do you get GDC-0084 to the hospitals that are participating in the trial?

The final steps include labelling (often in multiple languages), warehousing, and distribution, and each of these is a highly regulated process. Specialist couriers distribute GDC-0084 directly to hospital pharmacies, using validated shipping containers and temperature monitors to ensure that the drug arrives undamaged. Upon receipt, the pharmacy will verify that the correct drug has been received, and only then can the medical team begin administering GDC-0084 to patients.

Market Watch



Market Cap: AU$ 29 million

52W Range: AU$ 0.33 – 0.80

Issued Shares: 62 million