INVESTOR NEWSLETTER

MARCH 2021

Dr James Garner
CEO and
Managing Director

Dear Investors,

The last few months have seen Kazia pass a critical watershed in its development as a company, and that has been the transition of paxalisib into a pivotal study for registration.

Our drug is now on a path to approval, and to a share of a commercial market estimated at US$ 1.5 billion per annum. More importantly, we may provide the first new drug for newly-diagnosed glioblastoma in more than two decades and, with it, hope to patients all around the world.

This matters in ways that are much more than merely symbolic.

For one thing, much of our day-to-day work now focuses on preparing a 'new drug application' (NDA) to the US FDA. We are collecting additional data, refining our manufacturing, and increasing interactions with FDA.

For investors, there is a corresponding shift, although it may not be quite so obvious. The question is no longer 'does paxalisib work?' That has been answered, as best as it can be for now, and resoundingly in the affirmative. The question now is 'how will the company commercialise this?' The best science is worth nothing if it can't successfully be brought to patients.

We will have more to say on this in the near future, but our various regulatory approvals last year show that Kazia can manage the technical elements of an NDA. And our recent partnership with Oasmia for Cantrixil demonstrates the company's capabilities in licensing and business development.

The year ahead will not look like last year, but it will be no less important for paxalisib, and for Kazia. We look forward to sharing progress with you.

James

Dr James Garner

In the News

1 March 2021
Kazia licenses Cantrixil to Oasmia Pharmaceutical AB of Sweden

24 February 2021
Kazia releases Half-Year Report showing cash balance of AU$ 19.4M

7 January 2021
GBM AGILE pivotal study commences recruitment to paxalisib arm

10 December 2020
Kazia signs LOI with PNOC for new clinical trial in DIPG

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Upcoming New Data

Kazia will be presenting new interim data from the ongoing phase II study of paxalisib in glioblastoma to the Annual Meeting of the American Association for Cancer Research (AACR), which will be held virtually from 10-15 April and 17-21 May 2021.

The focus of the poster presentation will be on pharmacokinetic (PK) data from the study. An important objective has been to understand the right dose for future use, and to establish the difference between taking paxalisib on an empty stomach compared to taking it after food. The AACR poster is expected to discuss these results.

Kazia will make the poster available via the company website, in the usual way, as soon as it comes out of embargo, which is expected to be around 10 April 2021.

In addition, Professor Jim Coward has been invited to give a prestigious oral plenary presentation on the final data from the phase I study of Cantrixil in ovarian cancer. Cantrixil was licensed to Oasmia Pharmaceutical AB of Sweden in March 2021.

Kazia's Trials at a Glance

Paxalisib (GDC-0084)	
NCT03522298 Phase II study in glioblastoma (most common brain cancer) (*led by Kazia Therapeutics*)	Recruitment complete **New Data: April 2021**
NCT03970447 Pivotal study in glioblastoma (GBM AGILE) (*led by GCAR*)	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*)	Recruiting
NCT03696355 Phase I study in DIPG (*led by St Jude Children's Research Hospital*)	In Follow-up
NCT04192981 Phase I study in brain mets. (*led by Memorial Sloan Kettering Cancer Center*)	Recruiting
{TBC} Phase II study in primary CNS lymphoma (*led by Dana-Farber Cancer Inst.*)	In Start-up

Research Update

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

In November 2020, Kazia presented an update on emerging efficacy data from the ongoing phase II study of paxalisib in patients with newly-diagnosed glioblastoma.

The key results included a progression-free survival (PFS) of 8.4 months, which compares favourably to an historical figure of 5.3 months for temozolomide, the existing standard of care, and an overall survival (OS) of 17.5 months, versus 12.7 months for temozolomide.

These figures were based on an analysis of all participating patients (n=30), up to the time of data cut-off.

The magnitude of potential treatment benefit suggested by these data was considered highly encouraging. Moreover, the consistency with previous interim analyses helped to provide greater confidence around the reliability of the data.

The study remains in follow-up, with final data expected during CY2021.

Dr Chris Tinkle from St Jude Children's Research Hospital presents interim analysis of paxalisib phase I in DIPG

At the same conference, Dr Chris Tinkle, lead investigator for the phase I study of paxalisib in DIPG, shared an interim analysis of data from that study at an oral presentation.

The study showed paxalisib to be generally safe and well tolerated in a paediatric population, with dosing roughly comparable to adults on a proportional basis.

The study did not yet demonstrate a survival benefit, although there was a potential signal in PFS. The investigators reiterated their belief that combination therapy was likely to be required for a significant treatment advantage in this disease.

St Jude Children's Research Hospital (Memphis, TN)

New Home for Cantrixil

Kazia has licensed worldwide rights for Cantrixil to Oasmia Pharmaceutical AB, a Swedish specialty pharmaceutical company.

Cantrixil was developed by Kazia's predecessor company, Novogen Limited, and has recently completed a phase I clinical trial in ovarian cancer.

The data from the phase I study have been encouraging – Cantrixil has shown benefit in a very late-stage, treatment-resistant group of patients. However, Kazia has taken the view that the further development of Cantrixil will be better served by a larger company with a specialist focus on ovarian cancer.

Oasmia has a marketed product in ovarian cancer, Apealea® (paclitaxel micellar), and is planning to build a pipeline in this disease area.

Kazia will receive a US$ 4 million upfront payment for the transaction, up to US$ 42 million in milestones, and a double-digit royalty on commercial sales.

For More Information

Visit Oasmia's website at:-
https://www.oasmia.com/en/

FDA Approves Fifth PI3K Inhibitor

In February 2021, TG Therapeutics (NASDAQ: TGTX) announced FDA approval of its Ukoniq® (umbralasib) for certain forms of blood cancer.

Ukoniq was approved via the FDA's accelerated approval mechanism, which allows for promising drugs in high-need diseases to be made available prior to completion of a traditional phase III study.

The approval of Ukoniq brings the total number of FDA-approved PI3K inhibitors to five. This has become an extremely well-validated and class of cancer drugs.

However, none of the five approved therapies have any evidence of being able to cross the blood-brain barrier, and so none of them are likely to ever be treatments for brain cancer.

Paxalisib continues to be a member of a very well-proven class, but with a unique point of differentiation.

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

FDA Special Designations
A User Guide

In August 2020, paxalisib was awarded several 'special designations' by FDA. What are these designations and what do they mean?

Orphan Drug Designation (ODD) ✓

Orphan designation recognises drugs that are intended to treat diseases which affect less than 200,000 Americans per annum.

Orphan drugs receive a waiver of fees at the time of an NDA, as well as an extra period of exclusivity, separate from their patent protection. The scheme is designed to encourage development of drugs for less common diseases, such as brain cancer.

Fast Track Designation (FTD) ✓

The Fast Track scheme aims to accelerate development of promising drugs for high-need diseases.

Companies can use FTD to increase their frequency of interaction with FDA, to undertake a 'rolling NDA' submission (where information is submitted as it becomes available rather than all at the end), and to request accelerated approval at the time of NDA.

Breakthrough Designation (BTD)

BTD is essentially an enhanced version of FTD, and is awarded to drugs with very high potential in diseases where the need for new therapies is substantial.

FDA takes an active involvement in guiding the development of drugs with BTD, and priority review is automatic. Only about 20-30 drugs receive BTD each year.

Priority Review

FDA usually reviews NDA filings in 12-14 months. Drugs which are intended to treat diseases for which there is a high unmet need can apply for Priority Review, which reduces the review period to six months.

The majority of cancer drugs receive priority review, and it is typically applied for at the time of NDA.

Rare Pediatric Disease Designation (RPDD) ✓

RPDD was established to incentivise the development of drugs for childhood illnesses. If a drug with RPDD is approved for that childhood illness, the company can request a 'pediatric priority review voucher' (pPRV).

The PRV is generally not used for the original drug, since it will often earn priority review anyway. However, the PRV can be used on another drug and even sold. If a drug for, say, hypertension, with >$1 billion in expected sales, can be approved six months faster, the value is substantial. PRVs trade between companies for hundreds of millions of dollars.

Spotlight on Finance

Gabrielle Heaton
Finance Director

Gabrielle Heaton describes her role, and how a pre-revenue company such as Kazia manages its money

How did you come to work at Kazia?

I am an accountant by training. I have worked extensively in the healthcare sector, and was CFO of a private healthcare group before coming to Kazia. I joined the company in early 2017 to help build the new business. I find it exciting to work with very science-driven companies, and it is important to me to think that our work brings benefit to patients.

What are some of the challenges about working in a biotech company?

Kazia is still pre-revenue, which means that it does not yet make regular sales income. Companies like ours typically go through several rounds of financing before they start to generate income independently.

This means that we have to pay very close attention to budgets and to planning. I work closely with every member of the team to understand exactly what their projected expenditure is, and to make sure that we are well-financed to cover those expenses.

When do you think Kazia will become financially self-sufficient?

For most companies like ours, this is a process that happens in stages rather than all at once. However, the recent sale of Cantrixil to Oasmia demonstrates that we can monetise our R&D. The US$ 4 million initial payment will be invested into the paxalisib program.

What are the most complex aspects of your job?

Kazia is listed on two stock exchanges – ASX and NASDAQ – so we have to comply with both Australian and US reporting. It sometimes seems like we are always working on a statutory report! However, the positive aspect of this is that, as Kazia grows, we are already compliant with the bulk of relevant international requirements, and so we won't have to face the complex reporting transitions that other companies sometimes go through.

In addition, most of Kazia's expenditure takes place in the United States, because that is where our clinical trials are being conducted. We put a lot of effort into managing our exchange rate risk, and through this we have achieved a level of certainty in terms of our projected outflows. As we now begin to receive inflows in US$ (via our recent Oasmia license deal), this helps us to further balance the risk.

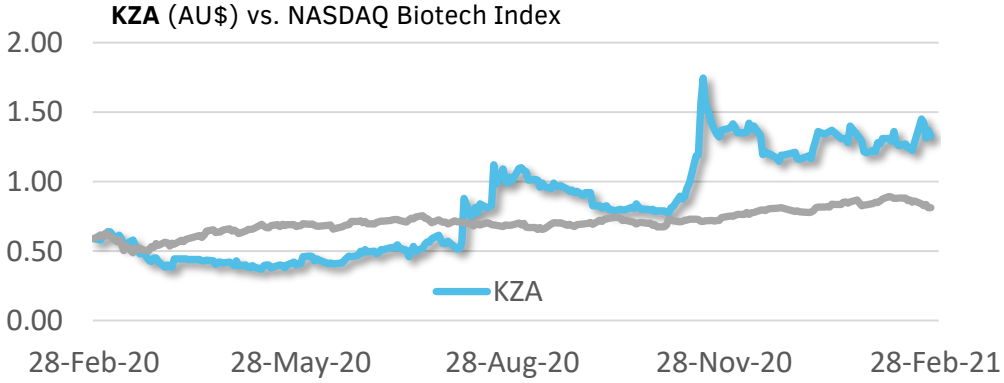
What have been some recent milestones in Kazia's finances?

The company is in better shape than it has been for a very long time. Our recent half-year report lifted the 'emphasis of matter' that biotech companies usually carry. Put simply, our auditors no longer question our ability to remain a going concern. This is relatively uncommon for pre-revenue biotechs, and a big step forward!

What are you most proud of in your work?

I have had friends affected by glioblastoma. If the work we are doing can make a difference to their lives, then that will be a very good result indeed.

Market Watch



Market Cap: AU$ 167 million

52W Range: AU$ 0.37 – 1.75

Issued Shares: 126 million