Investor Newsletter

May 2018

Dear investors,

Earlier this week, we recognised World Ovarian Cancer Day, an initiative that reminds us of the pressing need for new therapies for this very challenging disease. The Kazia team is proud to be working with some of the leading clinicians in the field to bring forward our potential new therapy, Cantrixil, which is currently in a Phase I clinical study.

At the time of writing, the study continues to progress well, and we expect to report initial data in the second quarter of calendar 2018. The study is designed in such a way that the first information we learn will primarily be around safety, and in particular, the 'maximum tolerated dose', but the study will then move into an expansion component that we hope will provide some preliminary understanding of potential efficacy.

This newsletter contains an illuminating interview with Associate Professor Jim Coward, Lead Investigator for the study, on page 4.

Meanwhile, our GDC-0084 program in glioblastoma, a highly aggressive form of brain cancer, commenced a Phase II study in March. This is a disease with very limited treatment options, and thanks to the excellent work of the drug's inventors at Genentech, we believe GDC-0084 may be an important new option for patients and clinicians.

At this stage, we expect the GDC-0084 study to provide initial data early in calendar 2019. Elsewhere in this newsletter, my colleague Dr Jeremy Simpson, Program Director for GDC-0084, takes us behind the scenes with his description of what is involved in the start-up of a major international clinical trial.

It has been encouraging to see our efforts attract growing interest from the media and from the investment community. We have provided some detail on recent media coverage in this newsletter for the convenience of investors. The hopes and expectations of cancer patients are at stake whenever we speak about our work, and we try to always be mindful of the responsibility that imposes, but equally we think it is important to share the enthusiasm and the pride that all of us on the Kazia team feel towards our work.

Coming months will see us make further clinical progress on both the Cantrixil and GDC-0084 programs. It is a tremendously exciting time for the company, and we thank you for your ongoing support.

Best wishes,

James

Dr James Garner

News Summary

Highlights from our recent company announcements:

- 29 March 2018: Start of phase II clinical study of GDC-0084 (brain cancer)
- 23 February 2018: FDA orphan drug designation received for GDC-0084
- 19 February 2018: Receipt of $4 million R&D tax rebate
- 17 November 2017: Novogen becomes Kazia Therapeutics
- 13 November 2017: Out-licensing of programs to Heaton Brown Life Sciences

Upcoming Events

- 20-21 June 2018: Gold Coast Investment Showcase, Surfers Paradise, Queensland

Visit the Kazia website homepage to follow future events.

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GDC-0084 Phase II trial starts

On 29 March 2018, Kazia announced that it had initiated an international Phase II clinical trial of its lead program, GDC-0084. Click here to view the media release or view the trial announcement by visiting the ASX Announcements section in the Investor Centre on our website at www.kaziatherapeutics.com.au

Following the announcement, Dr James Garner was interviewed on CommSec's Executive Series and we released an interview with Stuart Roberts, Senior Analyst at NDF Research. If you're reading this electronically, you can click on the images below in this newsletter to view those videos. Alternatively, visit the Media Centre on our website. Links to other publications on GDC-0084 have been included behind the logos at the bottom of this page.

CommSec's Tom Piotrowski interviewing Dr James Garner, 3 April 2018

NDF Research Senior Analyst Stuart Roberts interviews Dr James Garner, 5 April 2018

About GDC-0084

An important factor for any brain cancer drug is its ability to cross the blood brain barrier. GDC-0084 is unique in that is has been designed from the ground up as a brain cancer drug, and was shown in Phase I trials to cross the blood brain barrier in humans.

In the Phase II trial, GDC-0084 will be evaluated in comparison with the current mainstay of pharmacological treatment, which is called temozolomide. We know that roughly one third of patients are resistant to temozolomide and it is that population that we are hoping to treat with our drug. For more information on glioblastoma and the way that GDC-004 works, view our article called "GDC-0084 and glioblastoma multiforme" via the Media Centre -> Insights section on our website.

Watch our animation which explains what glioblastoma is and how GDC-0084 works

Initially, a number of predominantly US-based clinical trial sites will be used in the study, under an Investigational New Drug (IND) filing with the US Food and Drug Administration. The first trial site will be The Stephenson Cancer Center at the University of Oklahoma.

The start of the trial follows our announcement in February that Kazia had received Orphan Drug Designation (ODD) from the US Food and Drug Administration for GDC-0084. Benefits of ODD include tax credits, fee waivers and an extension of exclusivity once an orphan drug is on market, before similar drugs are able to be registered.

In April, NDF Research published updated analyst coverage on Kazia. View the new report via the Analyst Reports section of our website at: www.kaziatherapeutics.com

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Interview with **Dr Jeremy Simpson**

While commencement of the Phase II trial of GDC-0084 represented a major milestone for shareholders, it is easy to neglect the hundreds of small, but important tasks that led us to that point. In this interview Kazia's Dr Jeremy Simpson provides some insights on the long journey to commencement of a clinical trial.

How do you expect patients to respond to GDC-0084?

We never know quite how patients will respond, but there are some good reasons to hope that they will show benefit in the GDC-0084 study.

First, the drug has the benefit of some top-class work by the team at Genentech, one of the most successful companies in the world when it comes to new cancer drugs.

Second, we know from the Phase I study that the drug shows some encouraging signs of activity and a favourable safety profile.

Third, the study should be attractive to patients because the drug is oral and appears so far to be fairly well tolerated, and they continue to receive most of their standard care.

Finally, we have worked with some of the world-leading experts in the field to design a very high-quality clinical program. Personally, I'm really excited to be a part of it.

Why open the GDC-0084 study in the US versus Australia?

The first part of the study will look at optimising the dosing, and for purely practical reasons it makes most sense for us to start this work in the US. Apart from anything else, we are working with many of the physicians who participated in the Genentech Phase I study, and it is great to have their continuing engagement.

The US is clearly a very important eventual market for the drug, and we have met with FDA and consulted widely with clinicians and advisors to make sure that it is suited to the requirements of the US regulatory environment.

Nevertheless, Australia is also a great place to run clinical trials, and I have been working on studies here for almost 25 years. Once the study completes the initial dose optimisation component, we anticipate expanding it to include Australia, Europe, and perhaps Asia-Pacific.

Is it challenging to find patients for the study?

Finding patients is always a competitive process, but we expect this study to recruit well. We are already getting requests and enquiries from patients and their families.

All the hospitals we work with are experienced clinical trial centres, and we work with each of them to develop a comprehensive recruitment plan.

What is the role of a CRO?

We are a very lean company, so working with a Contract Research Organisation (CRO) allows us to access a global team of highly-experienced professionals as and when we need them. Altogether, there are well over a hundred people involved in the study at any one time, and it is much more efficient for us to engage those resources only when we need them. Like many of the team, I have a great deal of first-hand experience with a wide range of CROs, and so an important part of my job is to help them do their job.

How did you determine endpoints for the Phase II clinical trial?

There is a large body of regulatory guidance and scientific opinion about how best to measure the effects of a new cancer drug. We have designed our study in recognition of that body of work.

Aside from safety, we will be measuring efficacy of the drug in the form of progression-free survival (PFS). This is a well-established trial endpoint, especially in brain cancer, and one advantage is that it provides a quicker read-out than some other trial endpoints.

We will also be exploring a wide range of other endpoints so as to learn as much as possible about how best to use GDC-0084.

Unfortunately, glioblastoma has a poor prognosis and patients often progress quite quickly. Nevertheless, we want to make sure our data is as comprehensive and robust as possible, so it will likely take several years to achieve a definitive result. However, we are working with the clinicians to try and provide a number of checkpoints and interim read-outs along the way, so we should be able to share a good perspective of study progress at regular intervals.

What excites you about the Phase II trial?

I have worked with big pharma companies and small biotechs over almost a 25 year period, and this has been one of the really exciting programs that I have had the opportunity to be involved with.

One area that gives me a real buzz is the thought of Kazia punching above our weight in implementing such a study. We are working with the world's best physicians and research teams, at a level comparable to any global pharmaceutical company.

When I speak with the physicians, I see the passion and desire to work with GDC-0084 in their eyes, and in my experience that is always a critical indication of success.

I am also hugely excited by the other potential uses for GDC-0084 beyond glioblastoma and into other kinds of cancer treatment. We are already getting ideas and expressions of interest from leading research teams across the globe and it will be exciting to discuss some of these ideas further while the core glioblastoma program progresses.

Doing our part for #WOCD

Did you know that May 8 was World Ovarian Cancer Day?

Ovarian cancer unfortunately remains a hard disease to treat. According to Ovarian Cancer Australia, 1,400 women are diagnosed in Australia each year and 1,000 women each year die from the disease.

We hope that through our potential new therapy, Cantrixil which is currently subject of a Phase I clinical trial for patients with recurrent ovarian cancer, we might be able to offer a new treatment option.

In honour of #WOCD, we caught up with the Lead Investigator on our Cantrixil trial, Professor Jim Coward (pictured, right), who gave us his thoughts on the need for new treatment options.

Professor Coward, who is both a trained scientist and a clinician, said ovarian cancer treatment was far behind that of the more publicised breast and cervical cancers.

“More needs to be done in developing novel clinical trials to help enhance the survival rates for women with ovarian cancer,” Dr Coward said.

“We’re really only gaining small steps in understanding ovarian cancer – how it evolves, how the tumour behaves once its established, where it originates – and making small gains subsequently in developing effective treatments.

“Many women wrongly assume that when they’re getting their Pap test, they’re also getting screened for ovarian cancer. While there are a couple of ways doctors currently test for ovarian cancer, these processes are controversial.

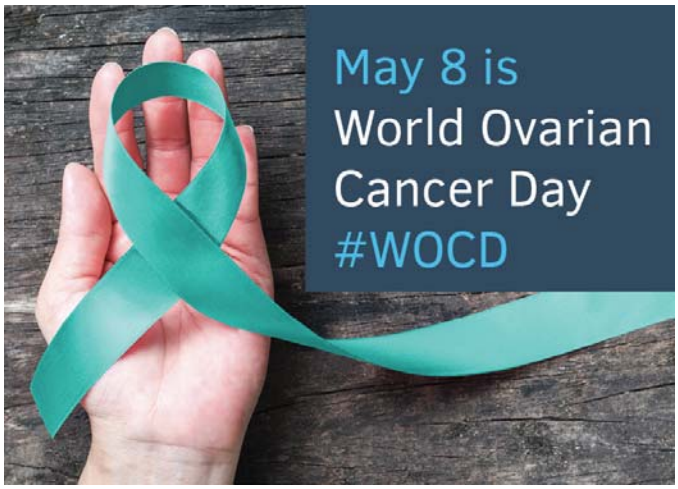
“Ovarian cancer presents late and in late stages. If we could be on the front foot with it, treatments are likely to be more effective.

“Ovarian cancer needs a greater national focus and a unified approach to screening.”

Read an interview with Dr Coward in the Daily Telegraph.

More information

It’s good to be informed. For information on the signs and symptoms of Ovarian Cancer, visit the resources section at Ovarian Cancer Australia’s website at www.ovariancancer.net.au.



Recent media

To read through coverage of World Ovarian Cancer day and our Cantrixil Phase I trial, please click the links below.

Herald Sun

Trials start on new treatment for ovarian cancer, the silent killer in Australia

The Courier Mail

New hope for deadliest of the female cancers

To read a longer article on Kazia and its corporate transformation, please click on the link below.

STOCKHEAD

Kazia wants to cure the disease that delivered the Trump presidency

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