

**ASX RELEASE** 

11 October 2018

#### PRESENTATION TO FINANCE NEWS NETWORK INVESTOR EVENT

Sydney, 11 October 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to release an investor presentation to be made today at the Finance News Network Investor Briefing at 12.30pm in Sydney.

[ENDS]

#### **About Kazia Therapeutics Limited**

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, GDC-0084 entered a phase II clinical trial in March 2018. Initial data is expected in early calendar 2019. GDC-0084 was granted orphan designation for glioblastoma by the US FDA in February 2018.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells, and is being developed to treat ovarian cancer. TRX-E-002-1 is currently undergoing a phase I clinical trial in Australia and the United States. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.





Cancer-focused biotech with two clinical-stage programs

Presentation to Finance News Network Investor Event

Sydney, NSW 11 October 2018

### **Forward-Looking Statements**

This presentation contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements, including changes from anticipated levels of customer acceptance of existing and new products and services and other factors. Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. The Company has no obligation to sales, future international, national or regional economic and competitive conditions, changes in relationships with customers, access to capital, difficulties in developing and marketing new products and services, marketing existing products and services update the forward-looking information contained in this presentation.



### **Investment Highlights**

- Cancer drug developer with two distinct therapies in clinical trials
  - GDC-0084 in phase II trial for brain cancer
  - Cantrixil in phase I trial for ovarian cancer
- Lead program, GDC-0084, acquired from Genentech following their strategic deprioritisation and now in phase II under Kazia
- Experienced team, with extensive international background in big pharma and biotech
- Four value-driving clinical data read-outs between now and end of 2019, with potential upside around planned collaborations in other forms of cancer



### Kazia strategy to develop high-quality assets from external sources

# Identify Value

 Bring in undervalued assets from other pharmaceutical companies

#### **Build Value**

- Conduct focused clinical trials
- Identify optimal patient groups
- Understand safety and dosing
- Engage with external experts

Proceeds of outbound licensing reinvested in earlier-stage assets

#### Realise Value

 Partner with big pharma for latestage development to bring to market





### A strong team brings international experience in big pharma and early-stage biotech

#### **Board**



**Iain Ross** Chairman

Executive and Board roles in pharma

& SANDOZ

CELLTECH









and small biotech

**Bryce Carmine Deputy Chairman** 



36 years executive experience in Eli Lilly



**Steven Coffey** Non-Executive Director



Chartered accountant with extensive governance experience



**Dr James Garner** Chief Executive Officer & Executive Director

Physician / MBA; Extensive drug

development experience







#### **Scientific Advisory Board**



**Professor Sir Murray Brennan Emeritus Chairman of Cancer** Surgery at Memorial Sloan Kettering Hospital, New York





**Dr Karen Ferrante** Former Chief Medical Officer at Millennium Pharmaceuticals





**Professor Peter Gunning** Head of School of Medical Sciences at University of New South Wales



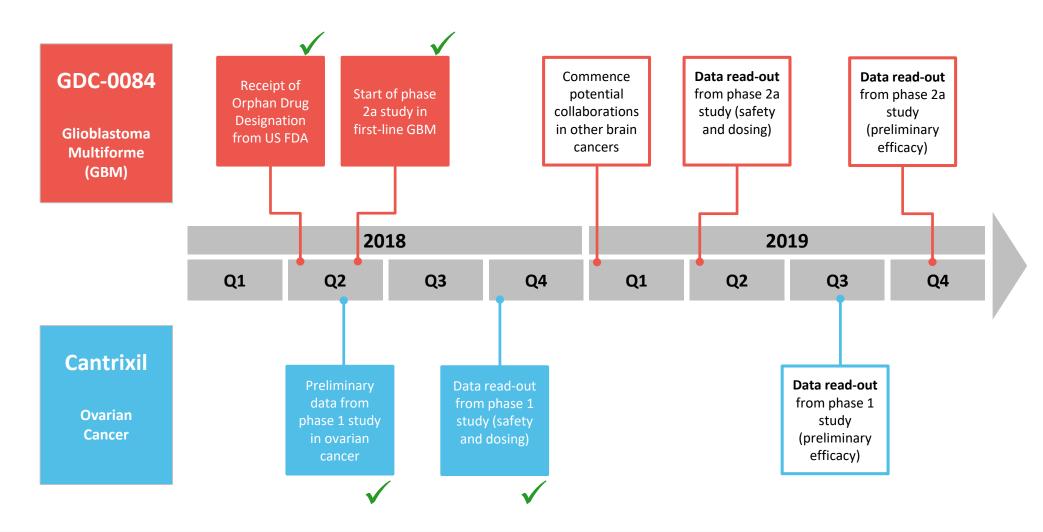


**Professor Alex Matter** Former Global Head of Oncology Research at Novartis





## Two clinical programs, with value-driving inflection points providing impactful newsflow during 2018-19

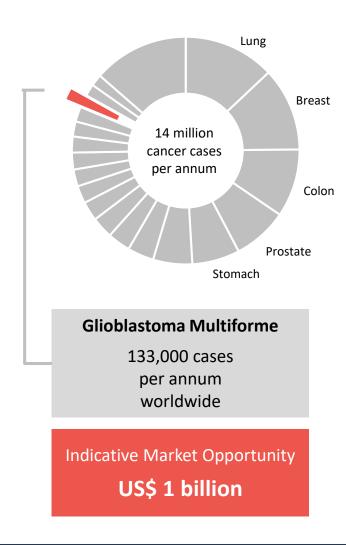


### Kazia is NASDAQ & ASX listed with ~\$9.3M of current assets at 30 June 2018





## Glioblastoma (GBM) is the most common and most aggressive form of primary brain cancer



No clear cause or strong risk factors **3-4 months**untreated
survival

12-15
months
average
survival with
treatment

Any age, but most common in

60s

Five-year survival

3 - 5%

(breast cancer: 90%)

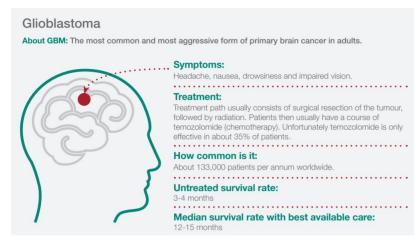
Most common drug treatment is temozolomide (Temodar®), used after surgery and radiotherapy

Ineffective in approximately two-thirds of patients → huge unmet need

### There is increasing recognition of the need to find treatment options for patients diagnosed with GBM

Growing public attention for brain cancer highlights need for new treatment options

- Senator John McCain's diagnosis in July 2017 highlighted glioblastoma and focused attention on the need for new treatments
- Australian Brain Cancer Mission launched in October 2017, with funding from Cure Brain Cancer Foundation, Federal Government, and Minderoo Foundation
- TV personality, Carrie Bickmore, launched 'Beanies for Brain Cancer' after losing her husband to the disease









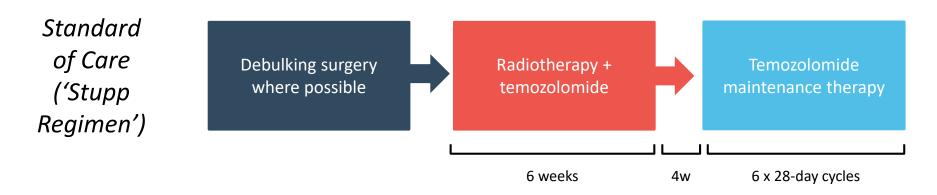


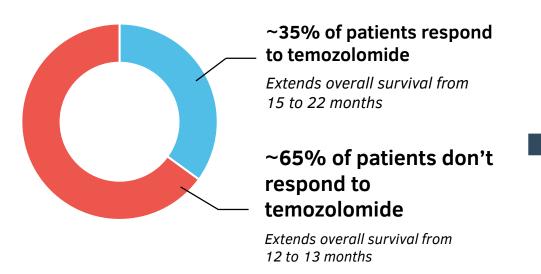






## Current standard of care is essentially ineffective in approximately 65% of GBM cases





GDC-0084 is being developed for the ~65% of newly-diagnosed GBM patients who will not respond to existing chemotherapy with temozolomide

For these patients, there is no effective pharmacological treatment currently available

Source: ME Hegi, A-C Diserens, T Gorlia, et al. (2005). N Engl J Med 352:997-1003



## The PI3K inhibitor class is well-validated, but GDC-0084 is the only brain-penetrant drug in GBM

Two marketed products in the PI3K class validate this approach to treating cancer

 Two PI3K inhibitors now successfully brought to market, both in specific forms of blood cancer



- Demonstrates that PI3K is a validated pathway to target, and can yield effective cancer therapies
- Both agents approved by US FDA via 'accelerated approval' without waiting for a full phase 3 study

GDC-0084 is essentially unique in being able to cross the blood-brain barrier

- Neither of the two approved drugs can cross the blood-brain barrier and neither will ever be a treatment for brain cancer
- GDC-0084 was designed specifically for brain cancer, so it has been engineered to cross the BBB very effectively, and this has been shown in animal and human data
- Encouraging Phase I data in late stage patients now looking to treat earlier stage GBM patients



### Phase I of GDC-0084 established dosing and showed favourable safety

#### Safety

- Phase I safety trial conducted by Genentech
- 47 patients enrolled with advanced glioma (grade 3/4); average of three prior lines of therapy
- Most common adverse events were oral mucositis and hyperglycemia (common effects of PI3K inhibitors)
- No evidence of liver, bone marrow, kidney toxicity, or mood disturbances
- Data presented at American Society for Clinical Oncology annual meeting in Chicago, June 2016

#### **Efficacy Signals** Comparison **GDC-0084** 40% 21-52% Arresting Achieved in studies of **Tumour Growth** 'stable disease' Avastin in similar patients Median 21% **Potentially** progression-free Remained on study Delaying survival of for >3 months **Progression** 1 month\* Potentially better 26% predictor of clinical **Slowing Tumour** Showed 'metabolic response than Metabolism partial response'

on FDG-PET











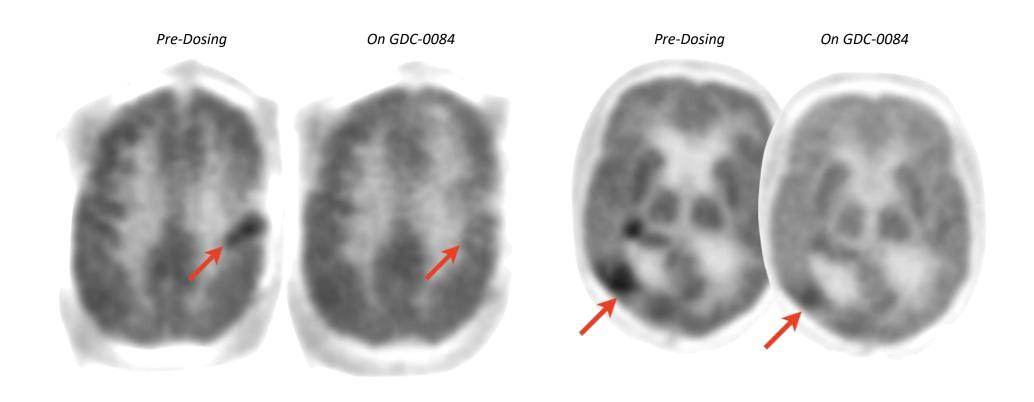
MRI<sup>†</sup>



<sup>\*</sup> Taal et al., Lancet Oncology (2015): ORR and mPFS of Lomustine in 2L GBM were 2/41 (5%) and 1 months, respectively (n = 46)

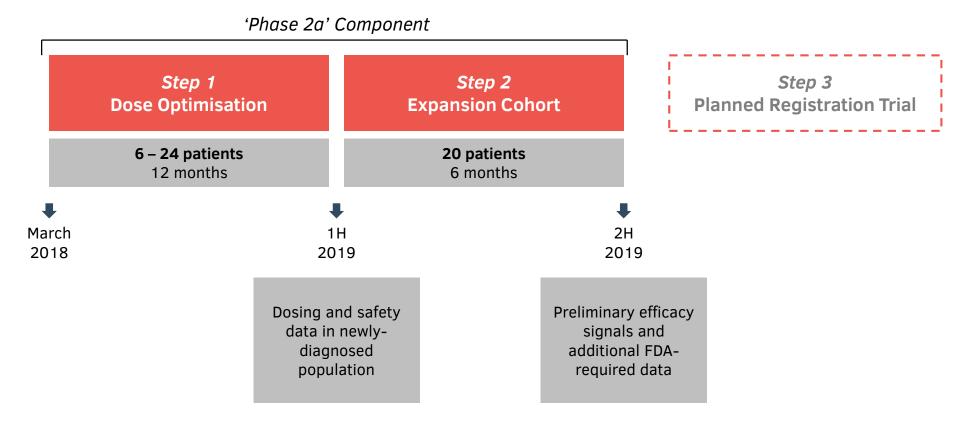
<sup>†</sup> Schwarzenberg J, et al. Clin Cancer Res; 20(13); 3550-9

## In GDC-0084 phase I, 7 / 27 patients (26%) showed a 'metabolic partial response' on FDG-PET





## Multipart GDC-0084 phase II design allows for frequent data read-outs to inform partnering and early approval













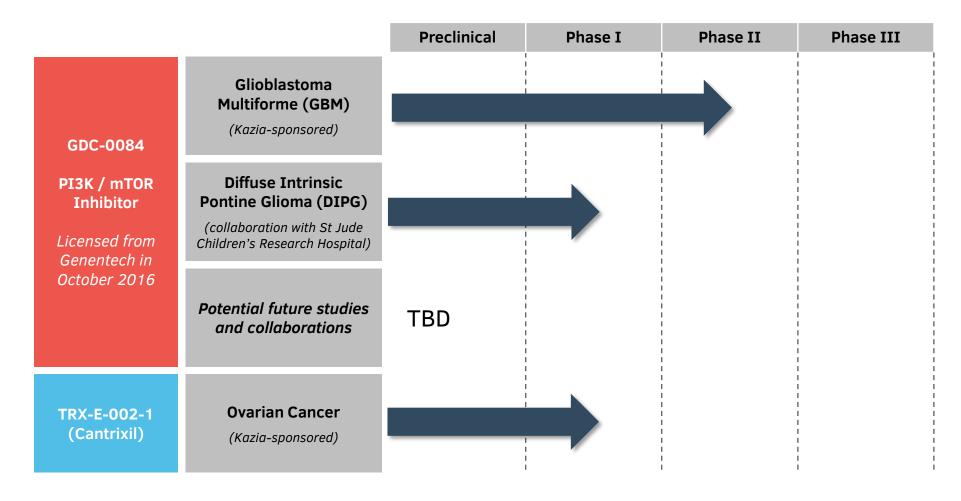




Note: timelines are estimated, and subject to periodic revision based on recruitment performance and treatment effect



## Recent collaboration with St Jude, a leading US paediatric hospital, expands GDC-0084 into childhood brain cancer







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