

#### ASX RELEASE

7 January 2019

#### **KAZIA PRESENTATION TO BIOTECH SHOWCASE**

Sydney, 7 January 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide a copy of the presentation which is to be presented by Dr James Garner at Biotech Showcase in San Francisco on Tuesday 8 January 2019.

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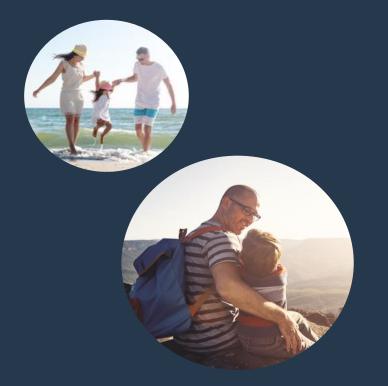
#### About Kazia Therapeutics Limited

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. Licensed from Genentech in late 2016, GDC-0084 is due to enter a phase II clinical trial early in 2018. Initial data is expected in early calendar 2019, and the study is expected to complete in 2021.

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. Initial data is expected in the first half of calendar 2018.





A clinical-stage oncology company with two novel agents in development

Presentation to Biotech Showcase #BTS19

San Francisco, CA 8 January 2019

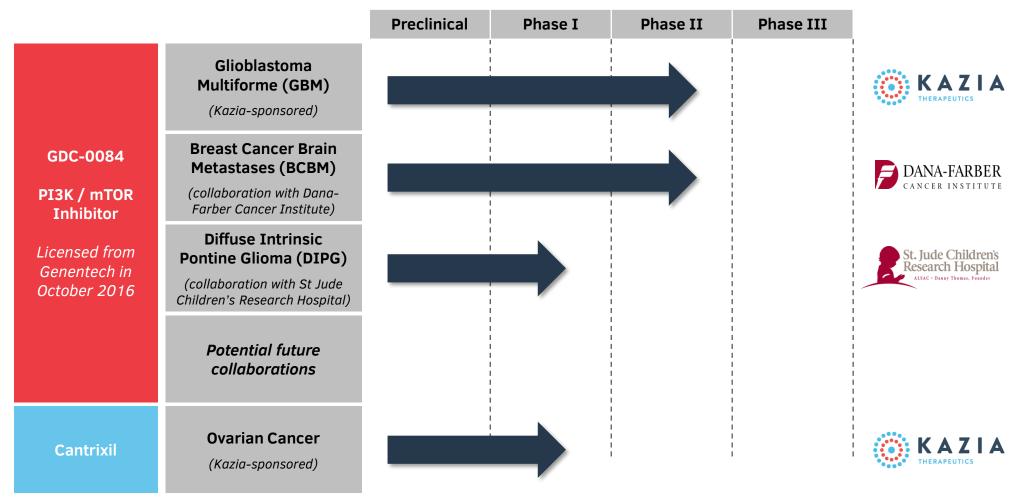
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### **Forward-Looking Statements**

This presentation contains "forward-looking statements" within the meaning of the "safeharbor" 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.



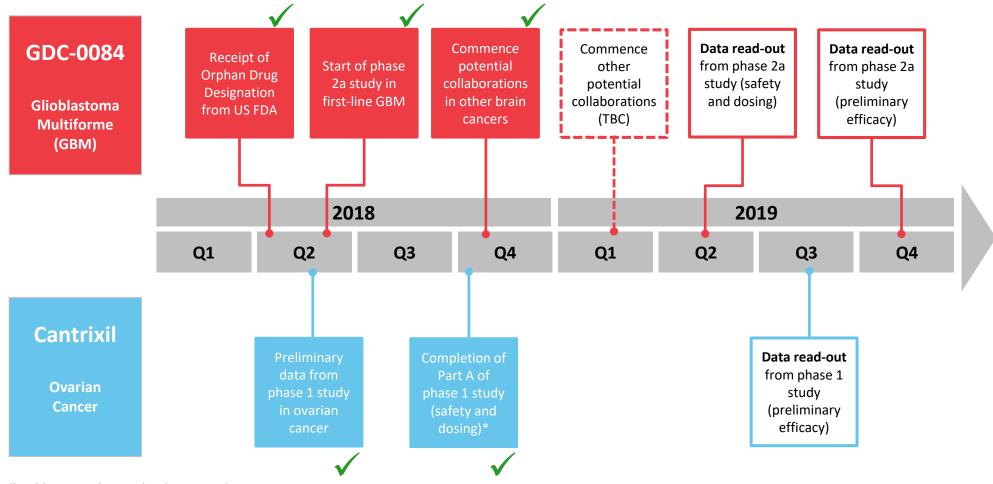
# Kazia has four ongoing clinical trials across two novel programs



Note: All studies performed substantially in US under IND



## Kazia has delivered all milestones for 2018, with high-value data read-outs expected in 2019



\*Full publication plans to be determined

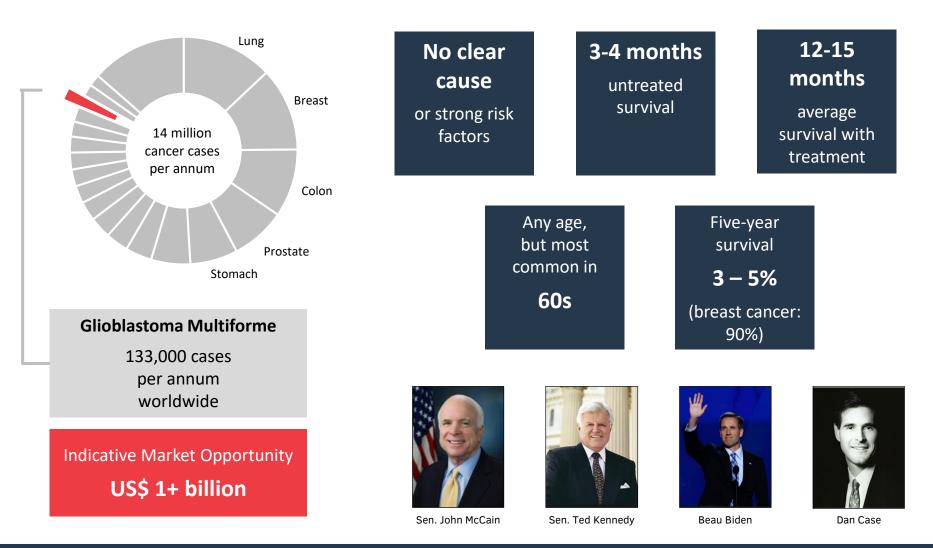


### GDC-0084

Phase II Glioblastoma Multiforme

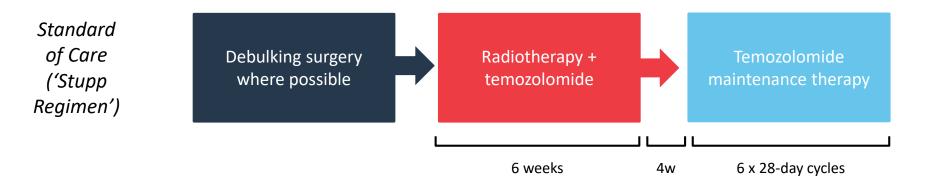


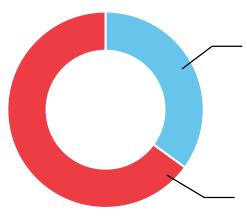
# Glioblastoma (GBM) is the most common and most aggressive form of primary brain cancer





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





#### ~35% of patients respond to temozolomide

*Extends overall survival from 15 to 22 months* 

### ~65% of patients don't respond to temozolomide

*Extends overall survival from 12 to 13 months* 

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

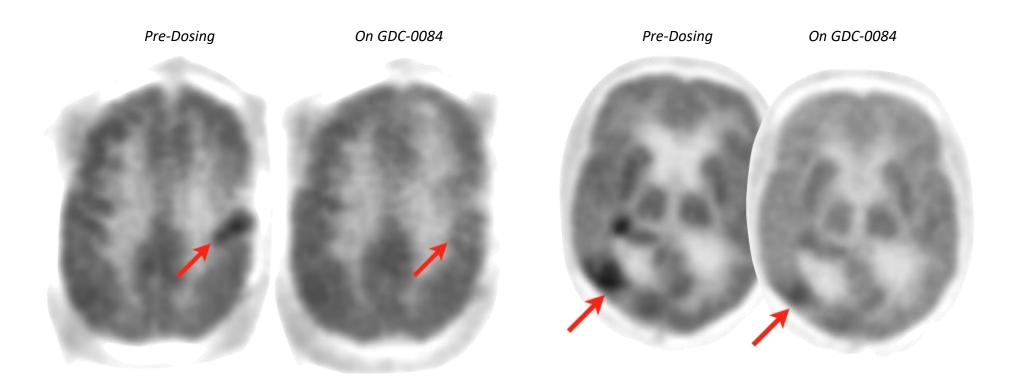


For these patients, there is no effective pharmacological treatment currently available



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

## In GDC-0084 phase 1, 7 / 27 patients (26%) showed a 'metabolic partial response' on FDG-PET



Analysis courtesy of Professor Ben Ellingson, UCLA Brain Tumor Imaging Laboratory

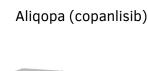


### The PI3K class has been further validated with a third approved therapy, but GDC-0084 is unique



Zydelig (idelalisib)





BAYER





Verastem

Copiktra (duvelisib)

FDA Approved	FDA Approved
September 2017	October 2018
(blood cancers)	(blood cancers)
[accelerated approval]	[accelerated approva
Does <u>not</u> cross	Does <u>not</u> cross
blood-brain barrier	blood-brain barrier
Potentially fatal	Potentially fatal

X



GDC-0084



In phase II human trials under US FDA oversight (brain cancer)

Does cross blood-brain barrier

Appears generally safe and well-tolerated thus far



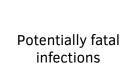
FDA Approved July 2014 (blood cancers) [accelerated approval]

Does not cross blood-brain barrier

Potentially fatal liver toxicity and diarrhoea

X

X



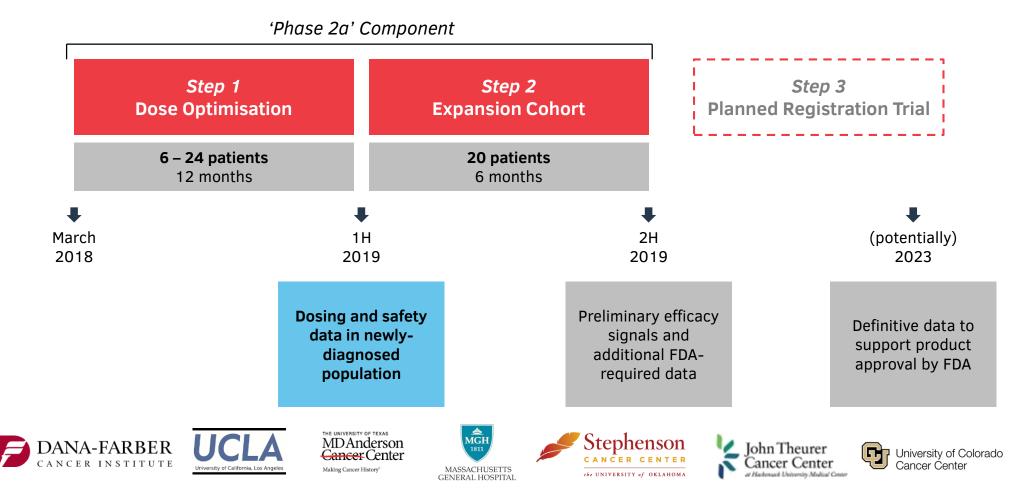
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Potentially fatal infections and diarrhoea

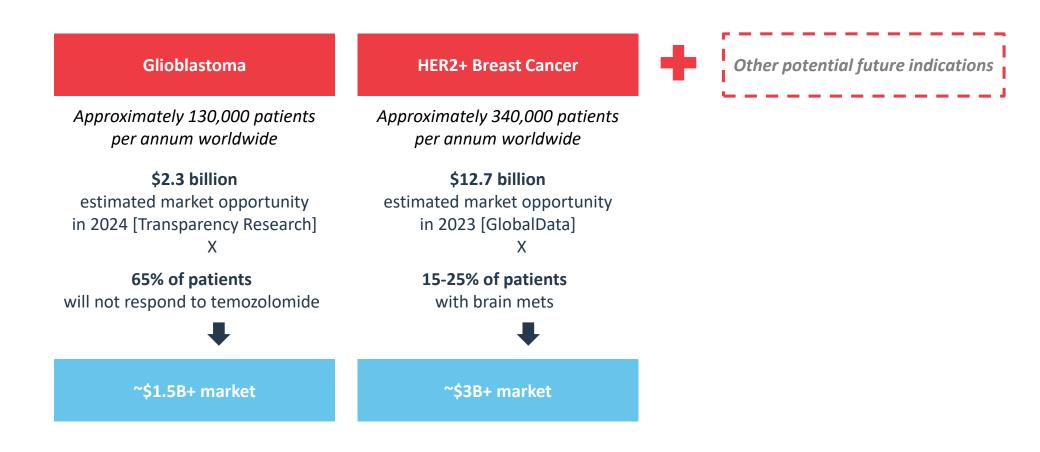
## GDC-0084 is currently in a phase 2a study in GBM, with multiple data-readouts during 2019



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

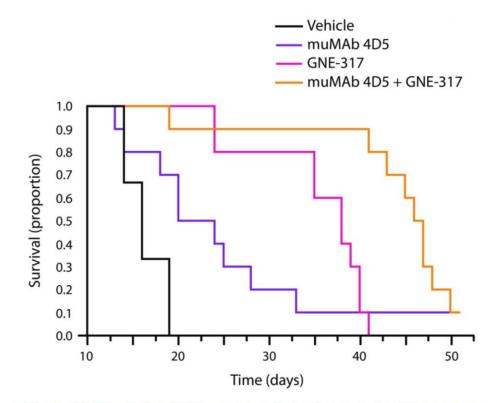


## Brain metastases represent a significant expansion to the commercial opportunity for GDC-0084





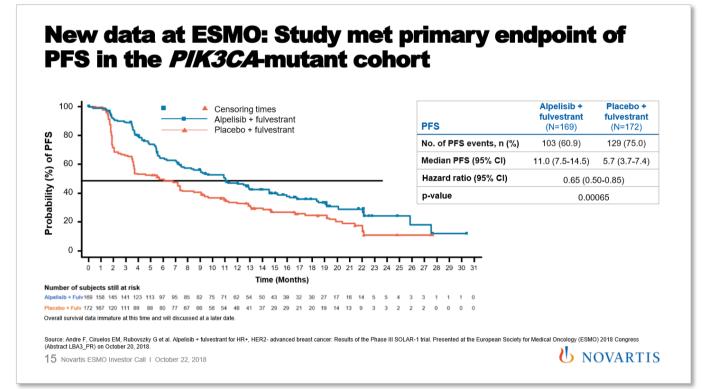
### GDC-0084 analogue has shown good preclinical evidence of activity in breast cancer brain mets



Enhanced survival effect of muMAb 4D5 combined with GNE-317 versus single-agent treatment in mice bearing Fo2-1282 brain lesions. Mice were administered muMAb 4D5 IV weekly (30 mg/kg following a 2× loading dose) and/or 30 mg/kg GNE-317 daily by oral gavage. Treatment was initiated on day 10 and terminated on day 30. *Arrows* denote antibody treatment; *solid line denotes* GNE-317 treatment



## Recent data from Novartis at ESMO showed impressive results for PI3K inhibitor in breast cancer



- Alpelisib (BYL719) is a PI3K inhibitor being developed for breast cancer
- Alpelisib only inhibits the alpha form of PI3K, and was not developed to cross the blood-brain barrier; GDC-0084 inhibits all four types of PI3K and was developed to cross the blood-brain barrier
- ESMO data showed increase in progressionfree survival from 5.7 months to 11.0 months



### **GDC-0084** value proposition is considerable

- Currently in Phase II clinical trials, under IND with US FDA, at leading US centers for brain cancer
- Clear Phase I data, with favourable safety profile and indications of efficacy in late-stage GBM patients
- Clear unmet medial need, with only existing therapy working in ~35% of patients
- Defined >US\$1 billion market potential for GBM alone
- PI3K is a well-validated onco-target, with three existing therapies on market, but GDC-0084 uniquely differentiated by ability to cross blood-brain barrier
- Key inflection point due in 2H 2019, and additional indication investigator studies ongoing with updates in 2019
- High potential for accelerated approval by FDA



### Cantrixil

Phase I Ovarian Cancer





## Cantrixil phase 1 study has now progressed into Part B, and data is expected in calendar 2019

#### **Part A: Dose Escalation**

- 3 to 42 patients in up to 8 cohorts
- Seeks to establish maximum tolerated dose and understand safety profile

#### **Part B: Dose Expansion**

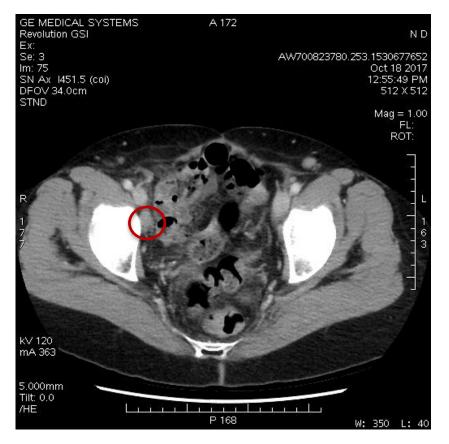
- 12 patients, all at 5 mg/kg
- Seeks to provide potential efficacy signals

- 3 / 12 (25%) patients now enrolled
- Additional US site opening mid-November (Rhode Island, USA)
- Two patients from Part A still receiving treatment



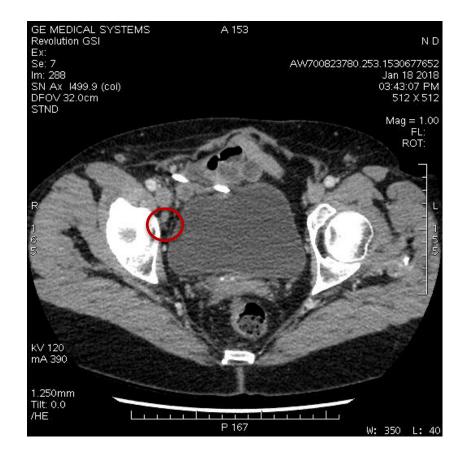
# Part A has already shown evidence of activity with one partial responder to date

#### October 2017 (baseline)



Source: images courtesy of Professor Jim Coward, Icon Cancer Centre

### January 2018

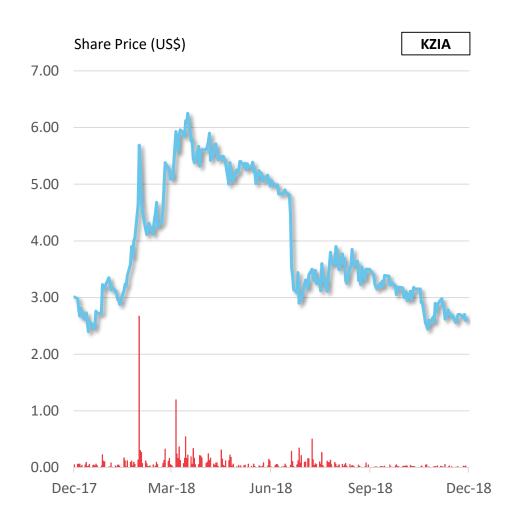




### Corporate Summary



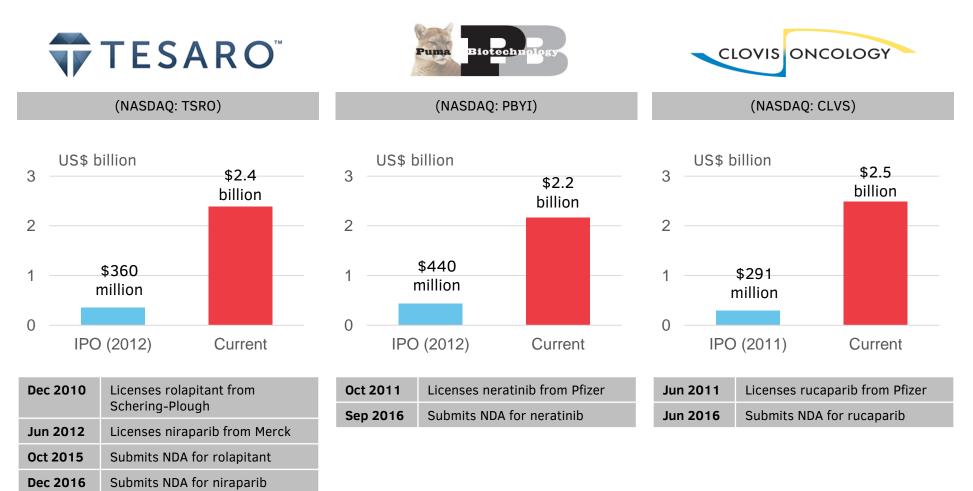
### Kazia is NASDAQ & ASX listed



Current Assets (Jun 18)	) Debt
US\$ 6.9 million	Nil
Market Capitalisation	US\$ 17 million
Listing	NASDAQ: KZIA (1:10 ratio) ASX: KZA
Average Daily Volume	NASDAQ: 0.4% /day ASX: 0.1% /day
Average Daily Value	NASDAQ: US\$ 100K /day ASX: AU\$ 28K /day
Shares on Issue	62 million (25% US, 75% Australia)
Outstanding Options / Warrants	~6 million



## Other companies have built successful businesses around in-licensed products





## Other companies focused on the PI3K pathway have been highly-valued in the market







Calistoga Pharmaceuticals Single asset company with one PI3K inhibitor in phase I human trials

One PI3K inhibitor in phase II human trials, one other drug in phase III, and two in animal testing

One PI3K inhibitor approved in October 2018 for certain blood cancers, one other drug in human trials

One PI3K inhibitor in phase II human trials

US\$ 140 million Market Cap

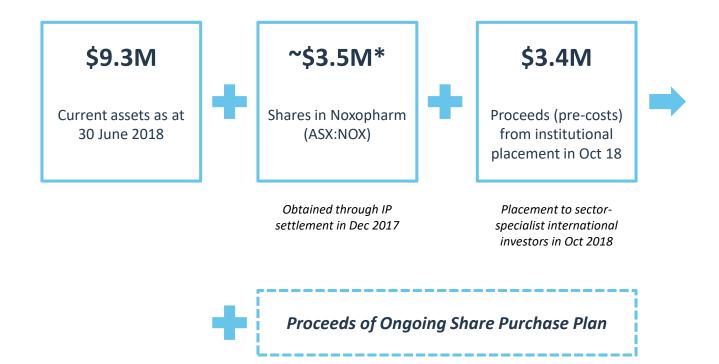
US\$ 430 million Market Cap

US\$ 400 million Market Cap

Acquired by big pharma in 2011 for **US\$ 375 million** 



## Kazia is now well-funded to see both programs through key data read-outs in calendar 2019

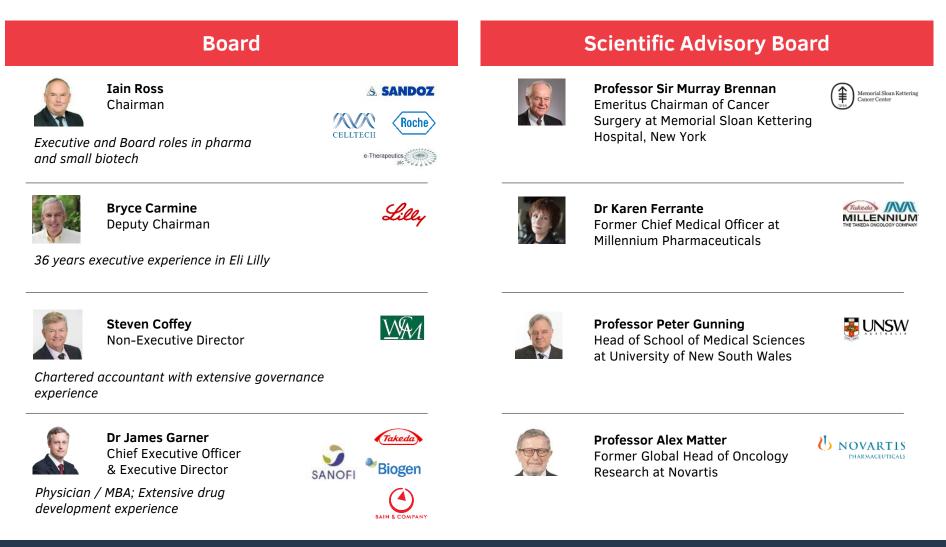


#### **Current funding allows:-**

- Completion of phase IIa GDC-0084 trial
- Completion of phase I Cantrixil trial
- Working capital into calendar 2020
- Multiple opportunities to engage with potential partners and licensees



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





# Kazia has become a compelling investment proposition

- Lead program, GDC-0084, sourced from Genentech, the world's most successful cancer drug developer
- Class of drugs, PI3K inhibitors, is well-validated and resurgent, but GDC-0084 is uniquely differentiated by ability to cross the blood-brain barrier
- Phase I data shows **favourable safety profile and evidence of efficacy**; phase II study underway under FDA oversight and with world-class centers of excellence in brain cancer
- 4 High **unmet need** for new therapies, with only existing drug effective in just 35% of patients and no front-runner among drugs in development
- 5 **Collaborations** progressing in childhood brain cancer and in brain cancer that has spread from elsewhere; largely funded by participating hospitals
- 6 Second program, Cantrixil, in an ongoing phase I study with **preliminary evidence of** activity
- **Four data read-outs** from clinical trials over calendar 2019, with significant potential to drive financial value and potential partnering
- 8 Company is **well-funded** to complete ongoing studies after institutional placement to sector-specialist investors





www.kaziatherapeutics.com