

ASX RELEASE

8 November 2018

## **KAZIA ANNUAL GENERAL MEETING MATERIALS**

Sydney, 8 November 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide the Chairman's Address and CEO presentation which will be discussed at our Annual General Meeting at 10am this morning.

[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. Initial data was presented in June 2018 and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

### **Board of Directors**

**Mr Iain Ross** Chairman, Non-Executive Director

**Mr Bryce Carmine** Non-Executive Director

**Mr Steven Coffey** Non-Executive Director

**Dr James Garner** Chief Executive Officer, Managing Director

**KAZIA ANNUAL GENERAL MEETING  
8 NOVEMBER 2018**

**CHAIRMAN'S ADDRESS**

Ladies and Gentlemen,

It is my great pleasure to welcome you to the 2018 Annual General Meeting for Kazia Therapeutics Limited. When I spoke at last year's AGM, I referred on several occasions to the enormous potential that all of us on the Board saw in the company. This year, I am proud to be able to point to some real and important achievements, as the company has begun to deliver on that potential. My fellow directors and I remain certain that Kazia's best years are ahead, but we feel that the accomplishments of the past twelve months validate our faith and confidence.

Before I say more, I would just like to make a few remarks in respect of my friend and former director of the company, Ian Phillips. Ian joined the Board of Novogen, as it then was, in 2015, and was instrumental in initiating the transformation process that ultimately led to the company as it is today. Ian was an enthusiastic champion of Kazia, a loyal colleague, and an entertaining raconteur. He passed away on 1 October 2018 at home in New York, and will be sorely missed by all who had the good fortune to know him.

Today's meeting finds the company in the strongest position it has been able to enjoy for some years. Our lead program, GDC-0084, has returned to the clinic, and the phase II clinical study is progressing very well. In addition, we have been almost overwhelmed by interest from clinicians and researchers who wish to explore other uses of the drug. Such collaborations are typically performed substantially at the expense of the institution in question, and so they provide a tremendously cost-effective opportunity for Kazia to gather more data and identify new markets. Two such projects have been launched thus far: a phase I study with St Jude Children's Research Hospital in a form of childhood brain cancer, and a phase II study with Dana-Farber Cancer Institute in breast cancer that has spread to the brain. Both of these are important studies and they each have the potential to add significant economic value to the GDC-0084 asset. We are grateful to have the opportunity to work with top-tier investigators at such prestigious centres.

Meanwhile, the Cantrixil study continues to progress. We reported promising initial data from this study in June, and the drug has now advanced into a dose expansion cohort which should provide an initial understanding of potential efficacy. The substantial progress in this program is testament to the hard work that has been invested over the last three years to move it forward.

I have said on a number of occasions that the first priority of the Board must be to ensure the long-term financing of the company. To that end, we were very pleased in October to be able to secure significant new investment from high-quality sector-specialist institutional funds as well as our largest shareholder. The proceeds of this capital raise will help to strengthen the company's balance sheet, and to progress the R&D programs through four data read-outs

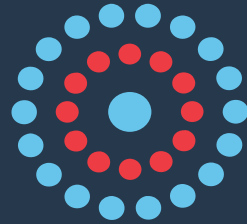
between now and the end of calendar 2019. However, no less important is the validation that this investment represents. The fact that high calibre healthcare professional investors see the company as an attractive investment opportunity is definitive evidence that we are on the right track.

The Board has also been mindful that existing investors have sometimes felt that they had a raw deal in previous capital raises and therefore we have been determined to protect the interests of existing investors to the fullest extent possible. Our recent financing raised just the necessary funds to progress our programs, no more and no less, and was conducted at a modest discount and with no issuance of warrants. We are satisfied that the new investors share our long-term commitment to the company, and a strong desire to see it succeed, and we are delighted to welcome them to the registry.

As part of our commitment to existing shareholders, we have offered the ability for eligible investors to strengthen their position via a Share Purchase Plan, on the same terms that were offered to institutional investors. We recognise that recent market volatility has taken its toll on many investors, and there is no expectation that shareholders should feel obliged to participate. However, if you do so, you will be following some of the best investors in the business, and your commitment will help to secure the future success of Kazia. All of the directors will be participating in the SPP, and I would commend it to you.

In short, these measures leave Kazia in an enviable position. We have, in GDC-0084, one of the most exciting assets in Australian biotech. That asset is currently in three clinical trials, under the oversight of the US FDA, each of which have the potential to generate transformative clinical data. We are well financed through 2019, enabling us to complete the two GDC-0084 and Cantrixil studies that are wholly funded by Kazia. We have a highly-qualified team, led by our CEO, Dr James Garner. We have a highly efficient business, having dramatically cut cost in previous years. And we have the reassurance of knowing that the value of our pipeline is understood and valued by professional investors.

I thank you again for your ongoing support of the company, and ask you to promote its ongoing success by supporting today's resolutions. My fellow directors and I remain dedicated to working on behalf of all shareholders to help Kazia become the company we believe it can be. This year has been remarkable, but we can assure you that the best is yet to come.



**KAZIA**  
THERAPEUTICS



# Presentation to Annual General Meeting of Shareholders

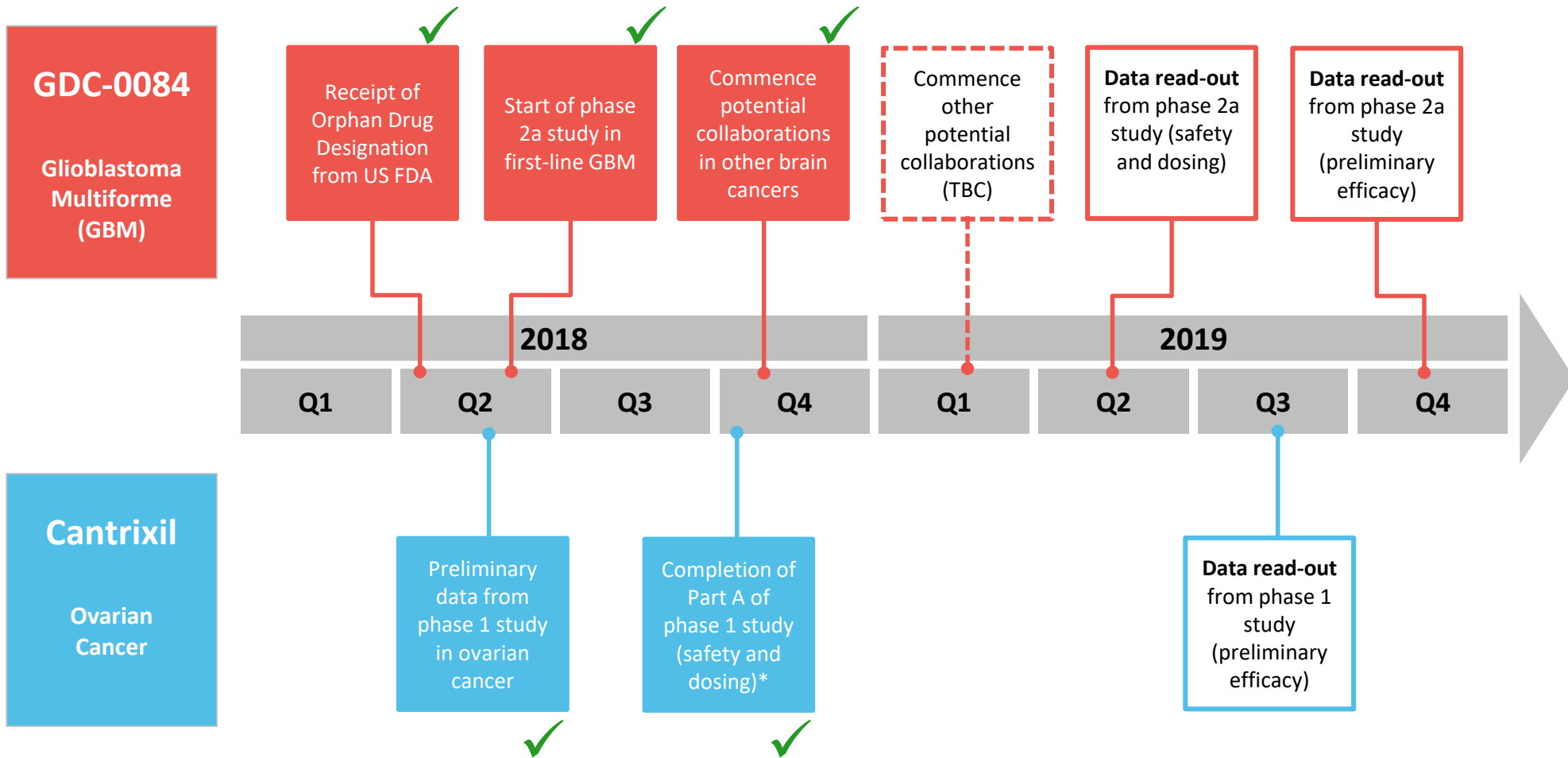
**Dr James Garner**  
**Chief Executive Officer**

8 November 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.

# 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

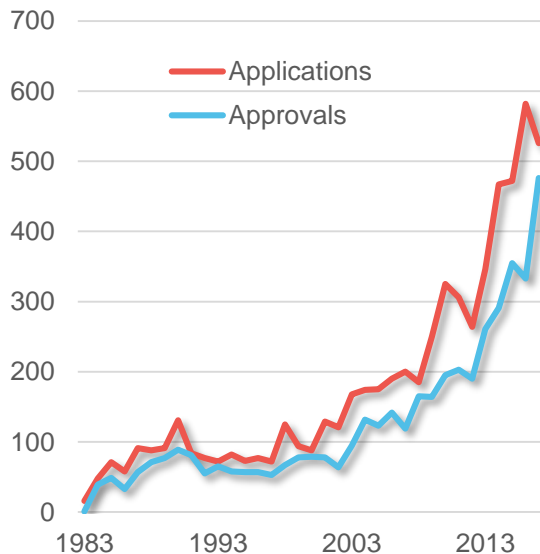
# Orphan designation in February 2018 was an important validation for the GDC-0084 program

FDA Orphan Designation recognises diseases affecting <200,000 Americans pa

Orphan Designation provides benefits to companies throughout a drug's lifecycle

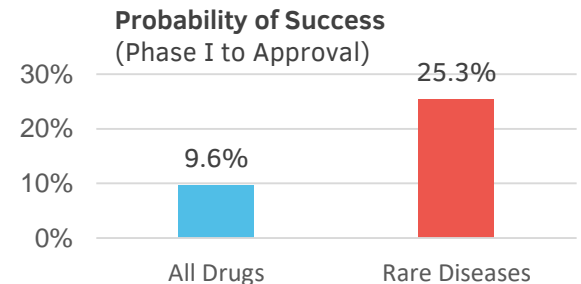
Orphan Designation is usually recognised by investors as value-driving

*Orphan designation is becoming more common for specialised novel drugs, particularly in areas such as oncology*



1. Waiver of PDUFA fees (application fees) at time of submitting an application for marketing authorisation
2. Tax credits for qualified clinical research costs
3. Up to seven years of additional market exclusivity, extending lifetime of product
4. Potential access to orphan drug grants

*Drugs targeting rare diseases are more likely to be approved...*



*...and small companies usually see a value inflection when Orphan Designation is granted*

**8.9%**

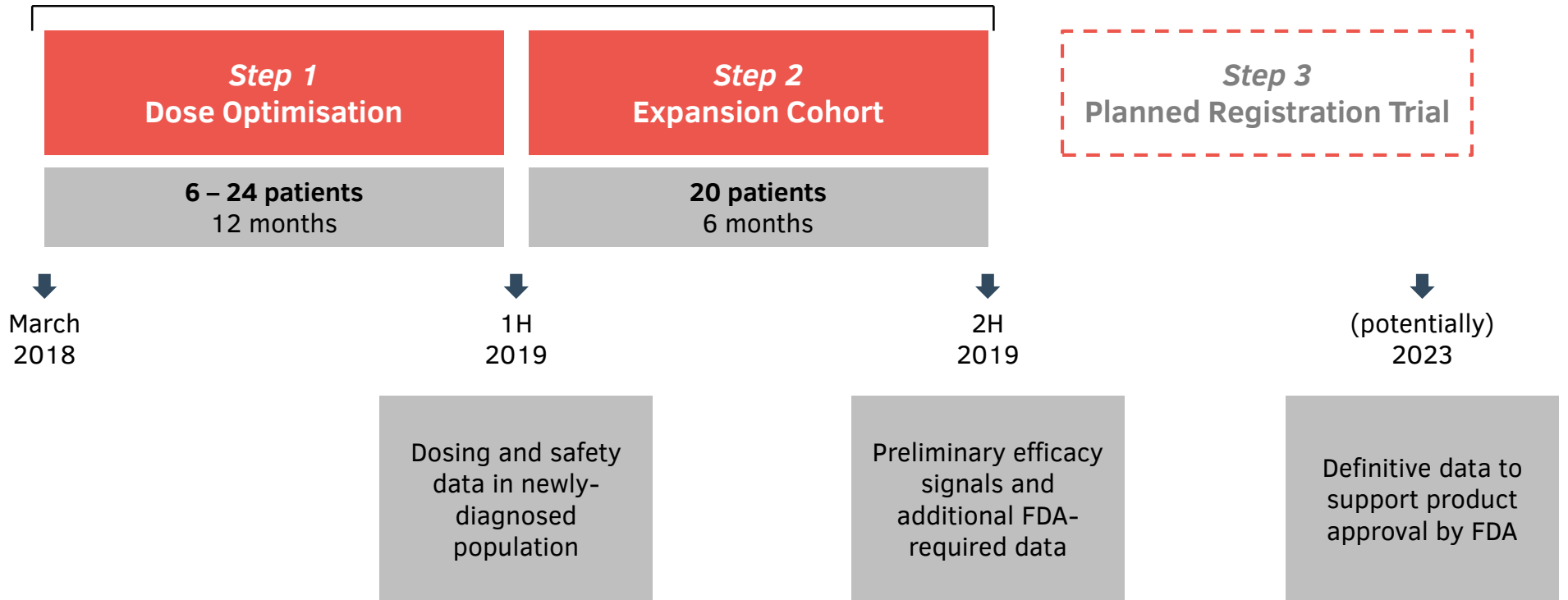
*Average increase in company value with grant of orphan designation*

Source: FDA; BIO; KL Miller (2017). *Orphanet Journal of Rare Diseases*. 12:114



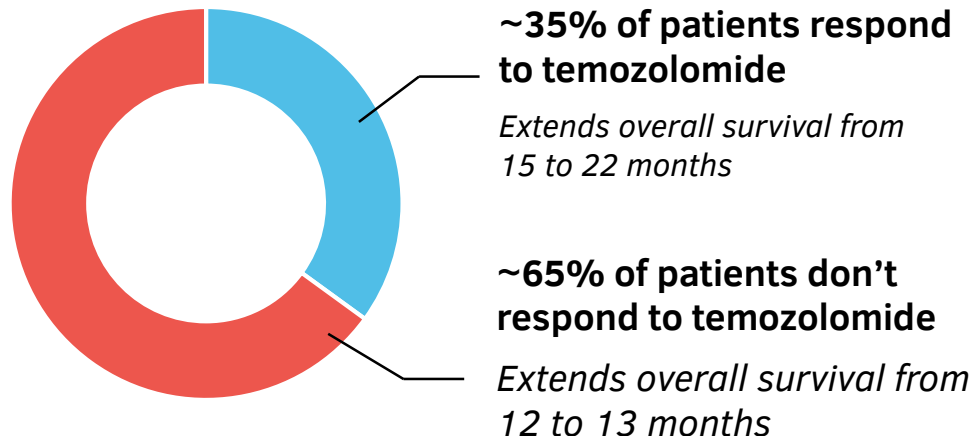
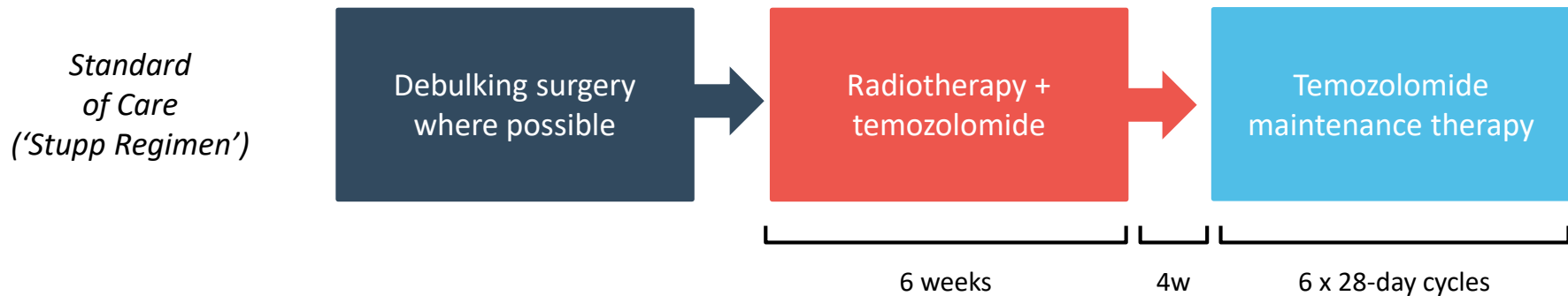
# The phase 2a study of GDC-0084 in glioblastoma is well underway, with the first cohort fully recruited

## 'Phase 2a' Component



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

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

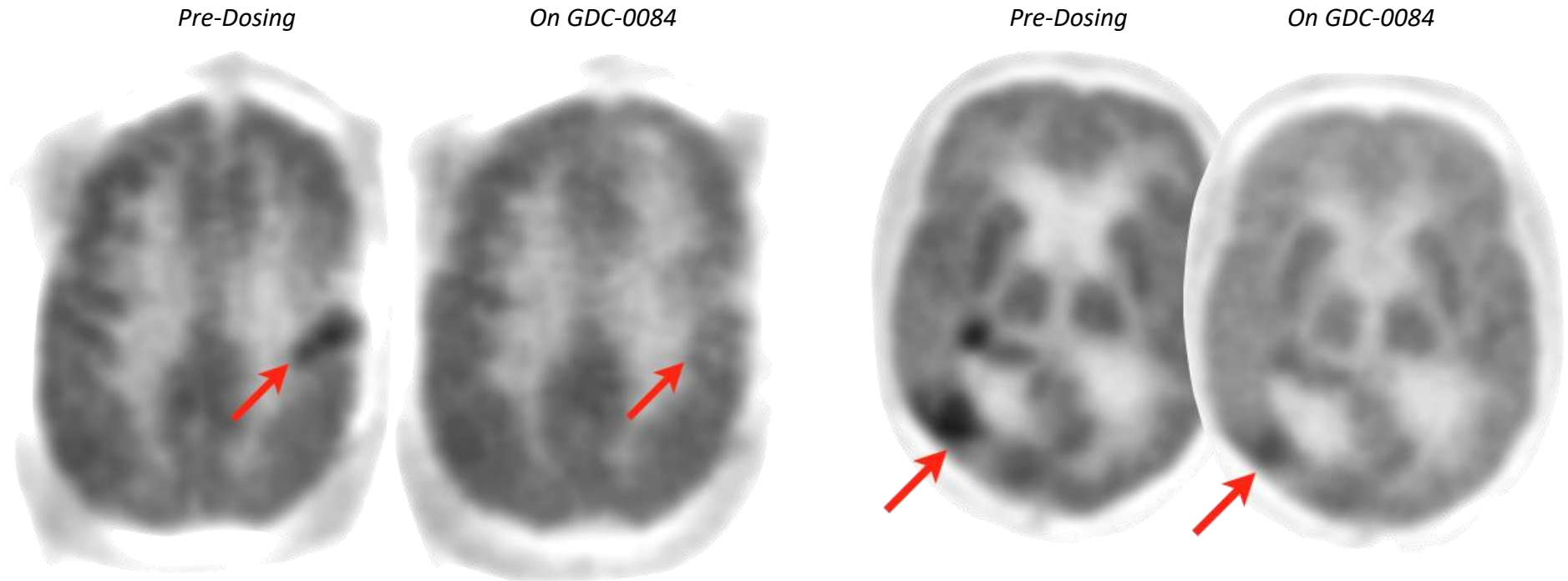


**GDC-0084 is being developed for the ~65% of newly-diagnosed GBM patients who will not respond to existing chemotherapy with temozolomide**

*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

# In 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)



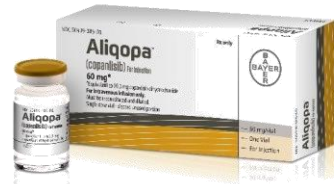
FDA Approved **July 2014** ✓  
(blood cancers)  
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal liver toxicity and diarrhoea ✗



Aliqopa (copanlisib)



FDA Approved **September 2017** ✓  
(blood cancers)  
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal infections ✗



Copiktra (duvelisib)



FDA Approved **October 2018** ✓  
(blood cancers)  
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal infections and diarrhoea ✗



**GDC-0084**



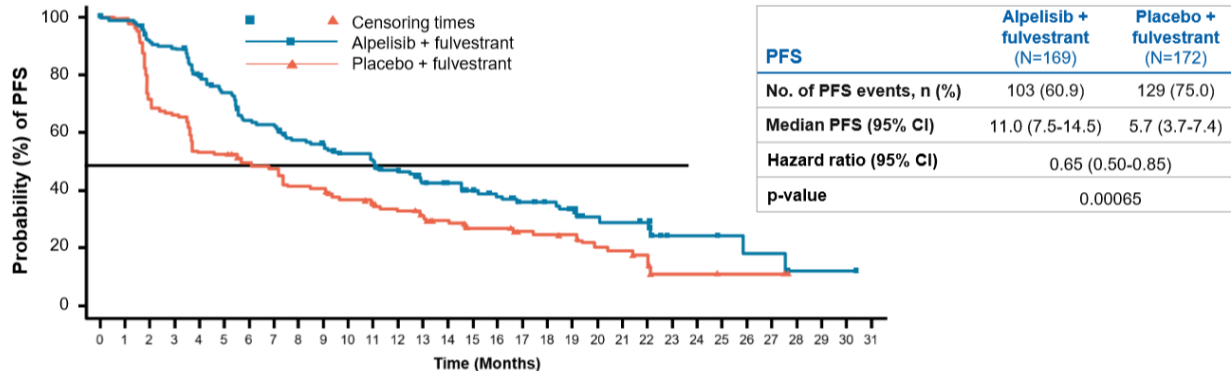
In phase II human trials under US FDA oversight (brain cancer)

Does cross blood-brain barrier ✓

Appears generally safe and well-tolerated thus far ✓

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

## New data at ESMO: Study met primary endpoint of PFS in the *PIK3CA*-mutant cohort



Number of subjects still at risk

Time (Months)	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Alpelisib + Fulv	169	158	145	141	123	113	97	85	82	75	71	62	54	50	43	39	32	30	27	17	16	14	5	5	4	3	3	1	1	1	0	
Placebo + Fulv	172	167	120	111	89	88	80	77	67	66	58	54	48	41	37	29	29	21	20	19	14	13	9	3	3	2	2	2	0	0	0	

Overall survival data immature at this time and will be discussed at a later date.

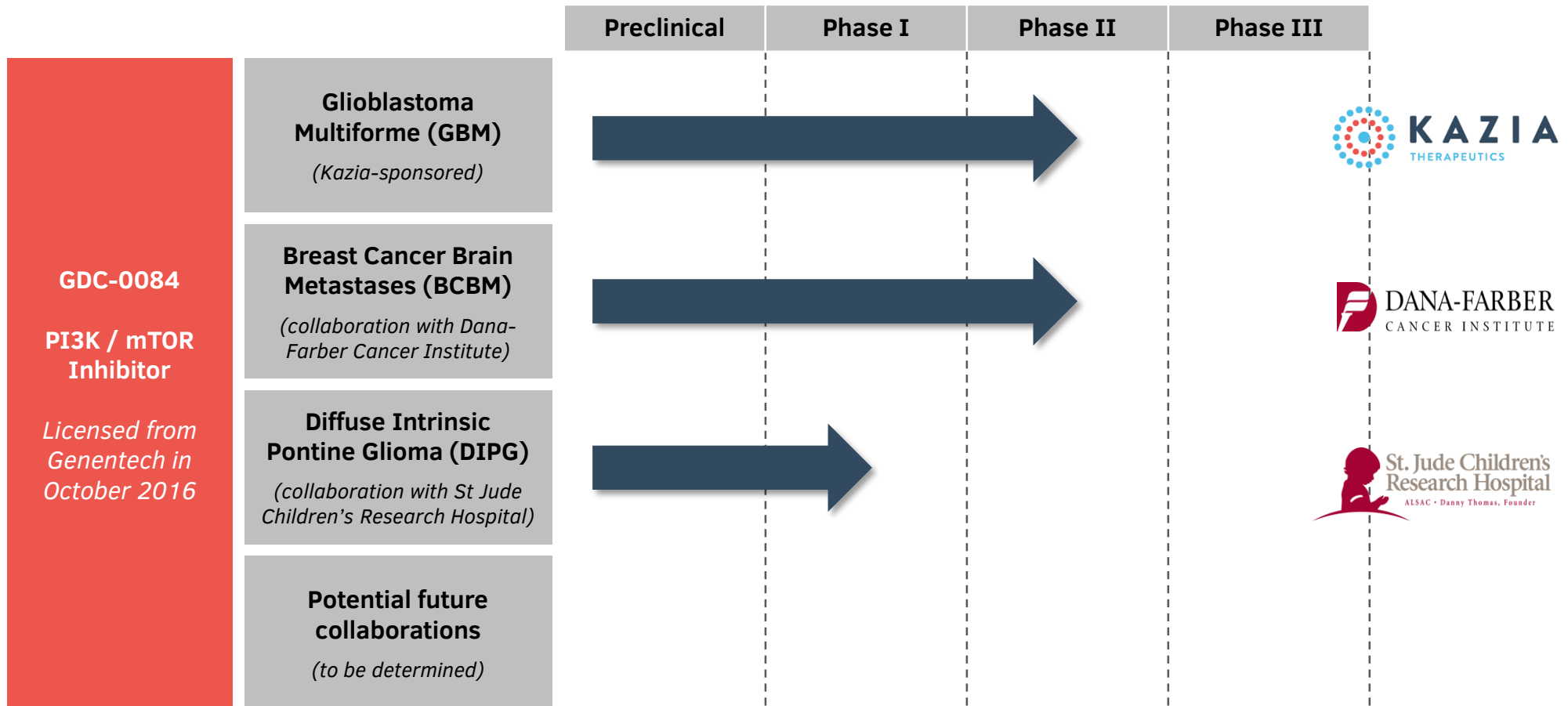
Source: Andre F. Ciruelos EM, Rubovszky G et al. Alpelisib + fulvestrant for HR+, HER2- advanced breast cancer: Results of the Phase III SOLAR-1 trial. Presented at the European Society for Medical Oncology (ESMO) 2018 Congress (Abstract LBA3\_PR) on October 20, 2018.

15 Novartis ESMO Investor Call | October 22, 2018



- 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 progression-free survival from 5.7 months to 11.0 months

# There are now three ongoing human trials with GDC-0084, each in different forms of brain cancer



Cantrixil

Phase I

Ovarian Cancer

# Cantrixil 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**



# Interim results from Part A of phase I study provide encouraging signals for potential safety and efficacy

## Key findings from June 2018 interim analysis

- Study has progressed through most dose levels with only a single patient needed

*Suggests we will be able to give therapeutic doses with acceptable tolerability*
- Three patients out of five (60%) have experienced 'stable disease'

*Suggests drug may have the potential to slow disease progression*
- One patient has experienced a 'partial response' in combination with chemo

*Suggests possibility Cantrixil may be able to help reverse the course of ovarian cancer*

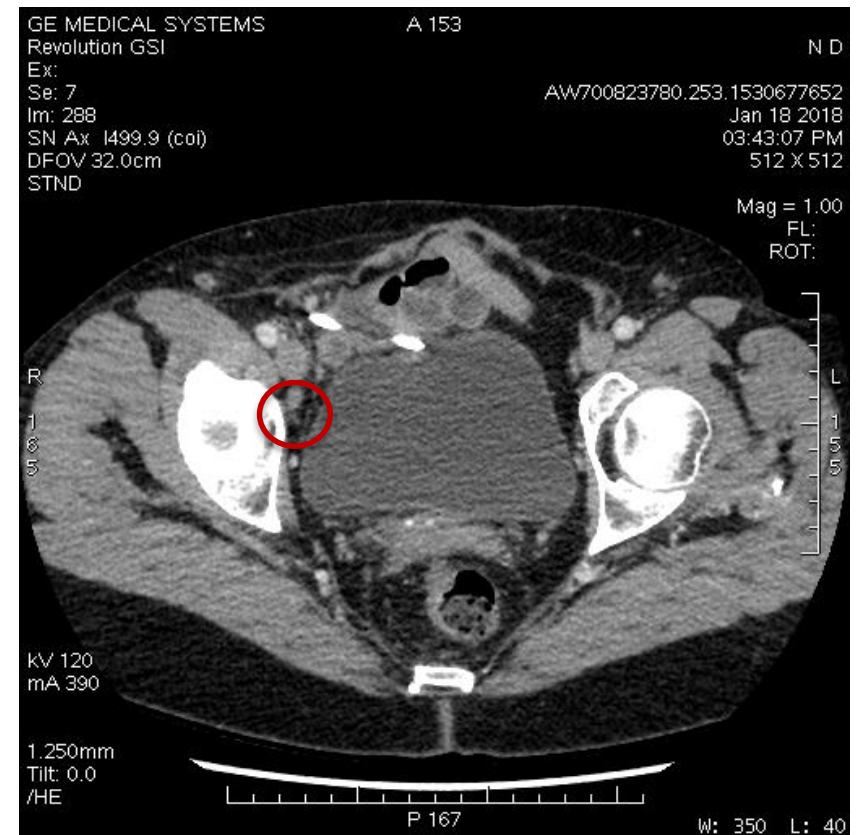
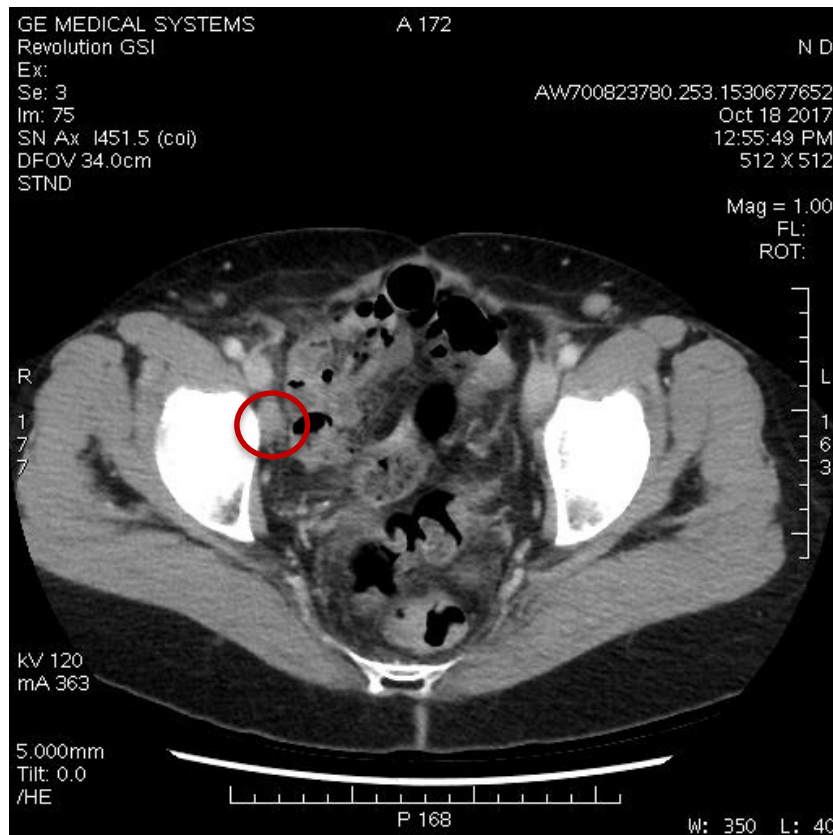
## RECIST Criteria for early-phase oncology studies

<b>CR</b>	<b>Complete Response</b>	Complete disappearance of target lesion on MRI / CT
<b>PR</b>	<b>Partial Response</b>	At least 30% decrease in size of target lesion on MRI / CT
<b>SD</b>	<b>Stable Disease</b>	Between 20% increase and 30% decrease in size of target lesion
<b>PD</b>	<b>Progressive Disease</b>	At least 20% increase in size of target lesion on MRI / CT

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

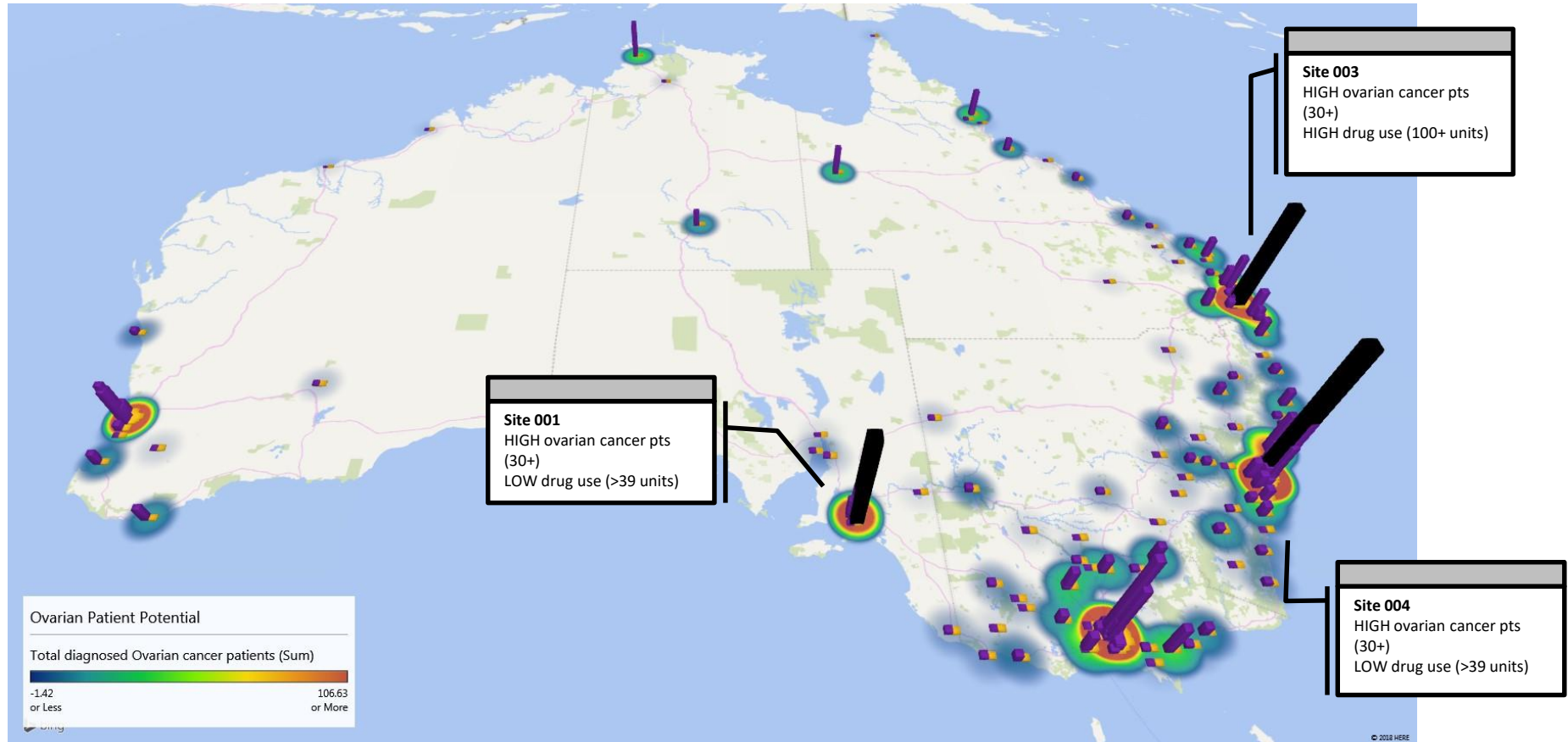
October 2017 (baseline)

January 2018



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

# Kazia is working closely with IQVIA on leading-edge data analytics to identify potential trial patients

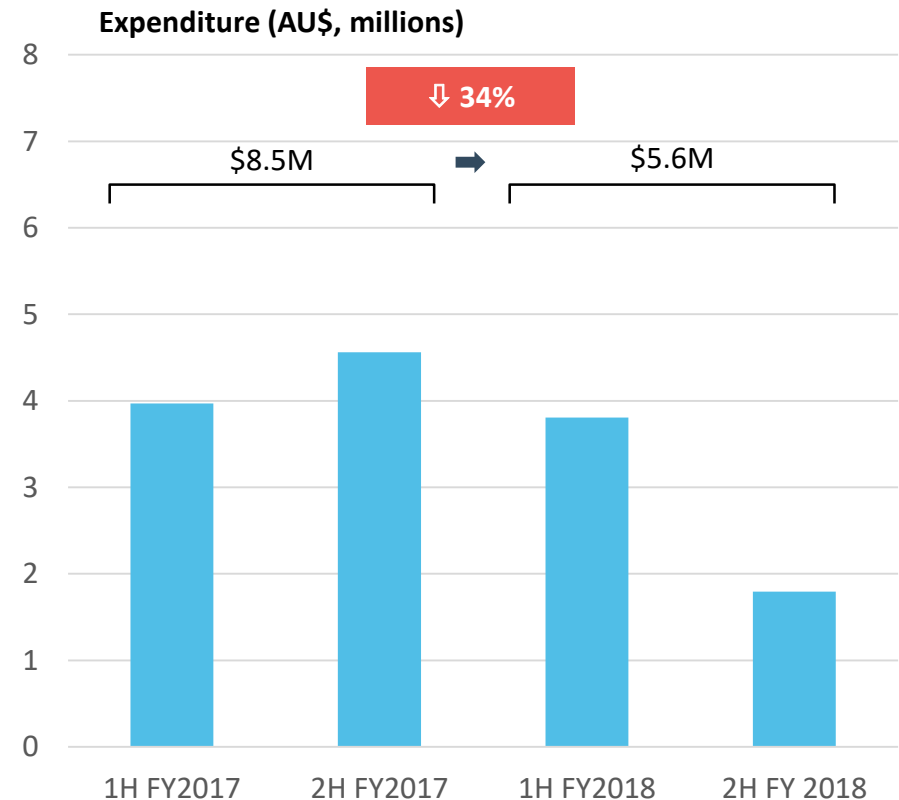
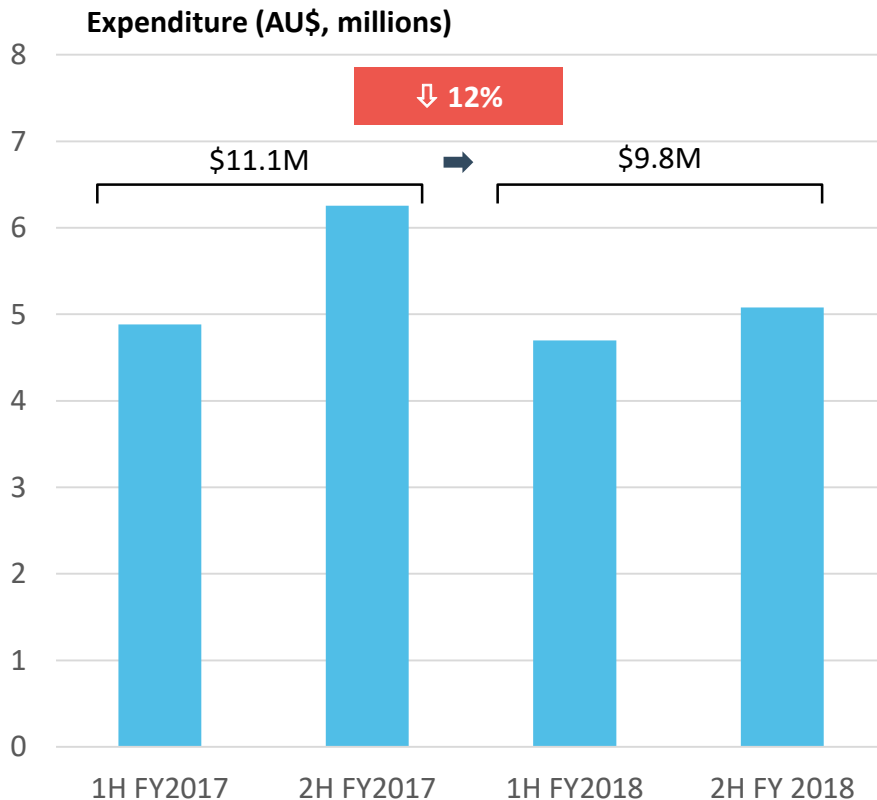


# Company Summary

# Kazia is running efficiently, with majority of funds applied directly to R&D

Largely constant R&D investment...

...against significant reduction in G&A costs



Note: R&D – research and development; G&A – general and administrative

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



\*NOX shares valued as at October 2018

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



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

**US\$ 140 million**  
Market Cap



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

**US\$ 430 million**  
Market Cap



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

**US\$ 400 million**  
Market Cap



One PI3K inhibitor in phase II human trials

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

# Kazia has become a compelling investment proposition

- 1 Lead program, GDC-0084, sourced from Genentech, the world's most successful cancer drug developer
- 2 Class of drugs, PI3K inhibitors, is well-validated and resurgent, but GDC-0084 is uniquely differentiated by ability to cross the blood-brain barrier
- 3 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
- 7 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





# KAZIA

THERAPEUTICS

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