

ASX RELEASE

16 July 2018

## KAZIA SHAREHOLDER PRESENTATION

Sydney, 16 July 2018 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to share the slides to be presented to shareholders this evening and on Wednesday at our upcoming shareholder information sessions.

As a reminder, Dr James Garner will present to shareholders in Melbourne and Sydney this week – details below:

<b>Melbourne</b>	Monday 16 July, 5:30 – 7:30 pm Baker McKenzie offices Level 19, 181 William Street Melbourne
<b>Sydney</b>	Wednesday 18 July, 5:30 – 7:30 pm Baker McKenzie offices, Tower 1, level 46, 100 Barangaroo Avenue Sydney

### Briefing webcast and Q+A session:

For those shareholders unable to attend the briefing sessions in person, Kazia will make available the webcast of the Sydney shareholder briefing session within a few days of the event.

[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.

#### Board of Directors

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

**Mr Bryce Carmine** Non-Executive Director

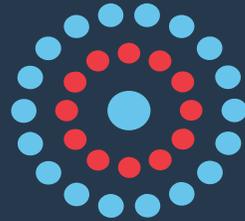
**Mr Steven Coffey** Non-Executive Director

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

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 entered a phase II clinical trial in March 2018. Initial data is expected in early calendar 2019.

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.

For more information, please visit [www.kaziatherapeutics.com](http://www.kaziatherapeutics.com).



**KAZIA**  
THERAPEUTICS



Cancer-focused biotech  
with two clinical-stage  
programs

**Shareholder Information Sessions**

Melbourne, VIC	16 July 2018
Sydney, NSW	18 July 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

1

Cancer drug developer with two distinct therapies in clinical trials

- GDC-0084 currently in phase II trial for brain cancer
- Cantrixil currently in phase I trial for ovarian cancer

2

Well-differentiated assets, with lead program licensed from Genentech

- GDC-0084: targets a critical control mechanism for tumour growth
- Cantrixil: active against treatment-resistant 'cancer stem cells'

3

Publicly-listed company, traded on ASX and NASDAQ

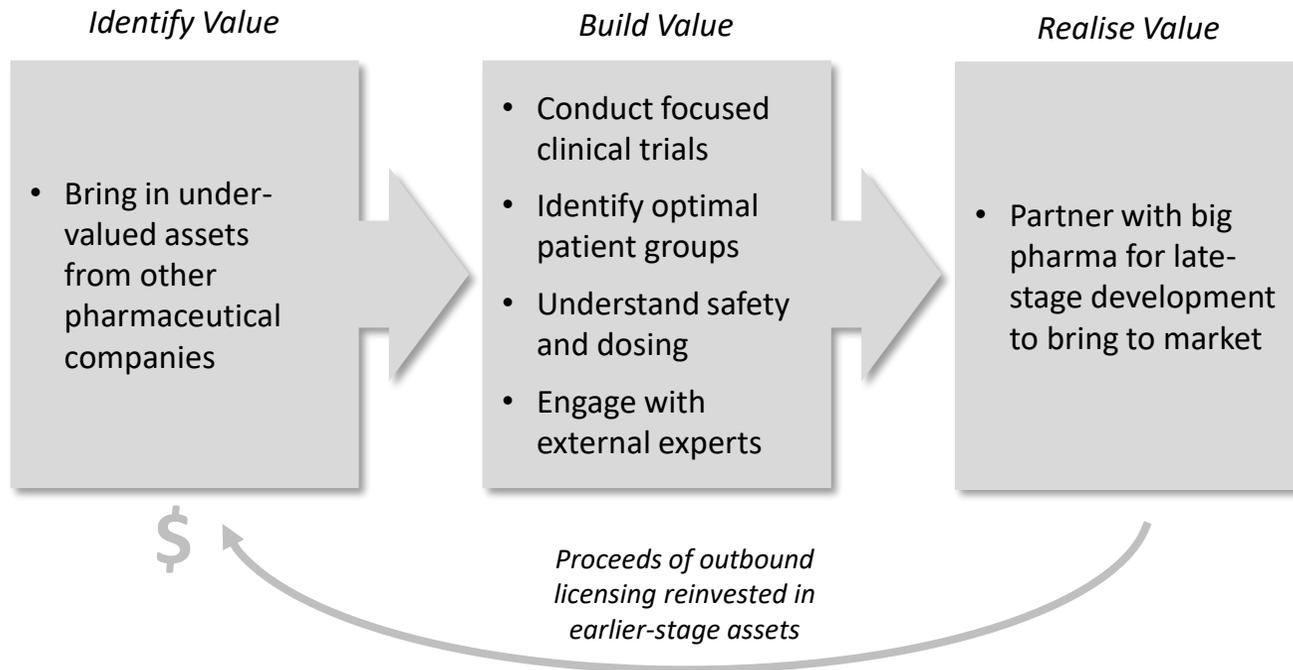
- Market cap ~AU\$ 30 million
- Current assets of ~AU\$ 14.8 million + ~\$7.5 million of NOX securities

4

Experienced team, with extensive international background in big pharma and biotech

# Kazia Corporate Update

# Kazia has implemented a strategy of developing high-quality assets from external sources



**Reduce cycle time and accelerate returns:** 2-4 years to get to value inflection

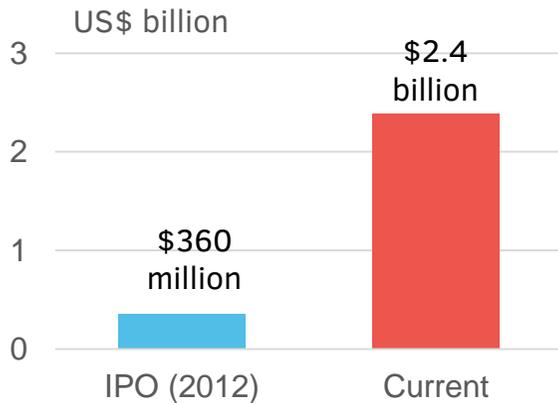
**Improve portfolio strength:** access the best global innovation

**Mitigate risk:** bring in assets which already partially de-risked

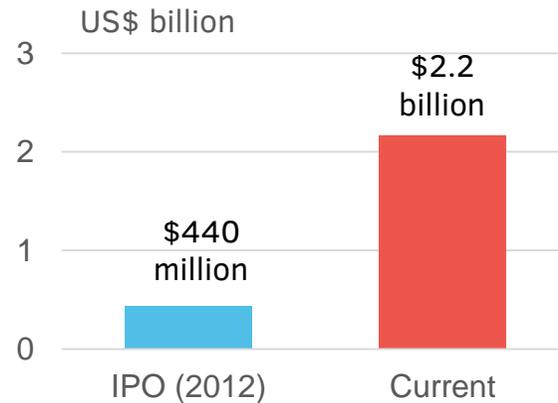
# Other companies have built successful businesses around in-licensed products



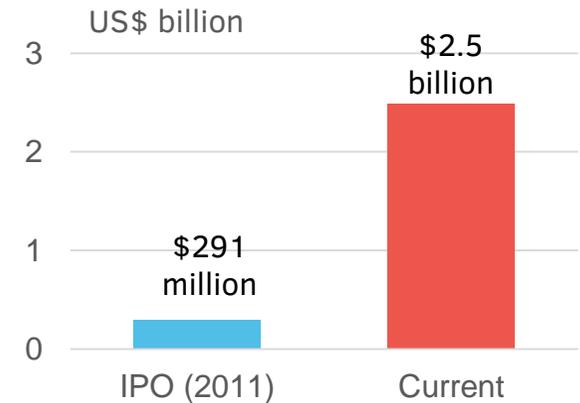
(NASDAQ: TSRO)



(NASDAQ: PBYI)



(NASDAQ: CLVS)



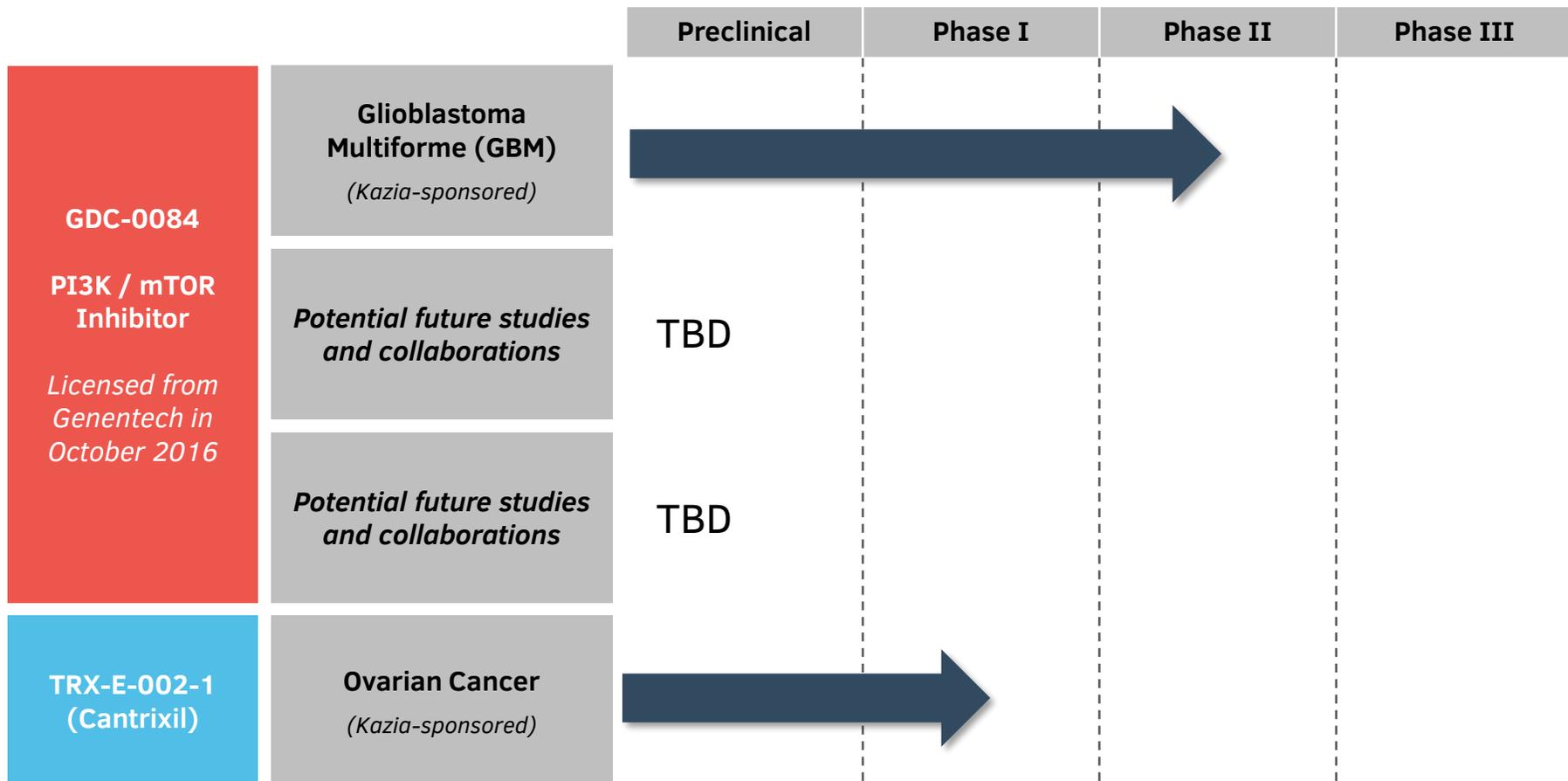
<b>Dec 2010</b>	Licenses rolapitant from Schering-Plough
<b>Jun 2012</b>	Licenses niraparib from Merck
<b>Oct 2015</b>	Submits NDA for rolapitant
<b>Dec 2016</b>	Submits NDA for niraparib

<b>Oct 2011</b>	Licenses neratinib from Pfizer
<b>Sep 2016</b>	Submits NDA for neratinib

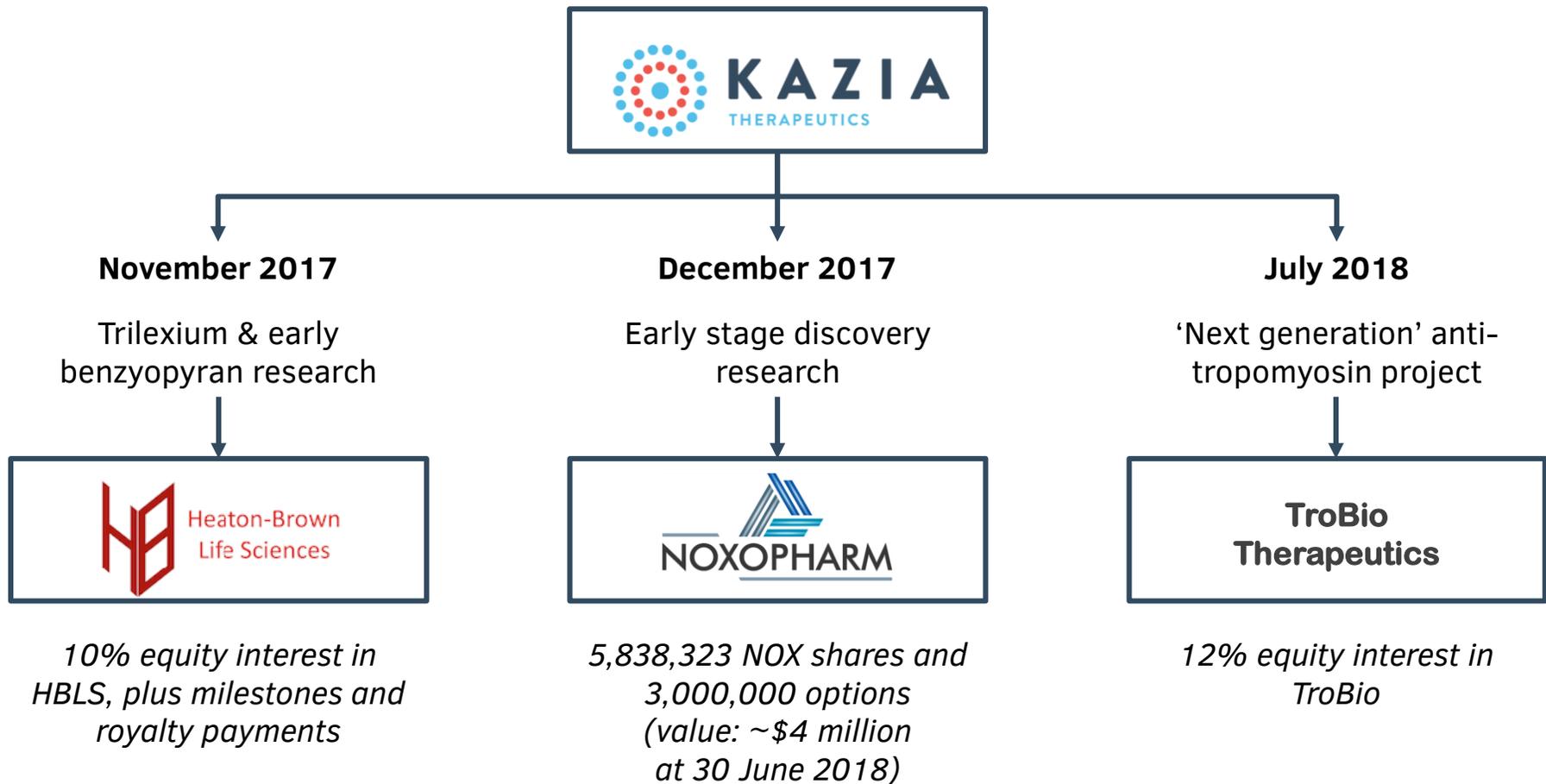
<b>Jun 2011</b>	Licenses rucaparib from Pfizer
<b>Jun 2016</b>	Submits NDA for rucaparib

Source: Bloomberg; Company SEC Filings; Crunchbase

# Our license of GDC-0084 from Genentech has helped us build a promising mid-stage clinical pipeline



# In addition, Kazia has divested non-core intellectual property, providing near-term and long-term value



# Kazia has achieved much in the last three years

Placements in 2H FY2015 raised net proceeds of ~\$47 million

## Key achievements

- Successful licensing of GDC-0084 from Genentech
- Achievement of Orphan Designation for GDC-0084
- Design and implementation of international phase II study for GDC-0084 in glioblastoma under US IND
- Potential exploratory collaborations for GDC-0084 in other indications and patient populations
- Design and implementation of international phase I study for Cantrixil in ovarian cancer under US IND
- Dissolution of CanTx JV and rationalisation of defunct corporate entities
- Evaluation of Anisina through to GLP toxicology (program terminated due to unpromising data)
- Divestment of non-core, early-stage IP to other Australian biotech companies, with participation in any upside
- Granting of patents for Cantrixil in all key jurisdictions
- Substantial corporate restructuring, leading to significant reduction in cost base

# Current funds support work into 2019



*“Whilst the Noxopharm settlement has strengthened our balance sheet significantly, we continue to explore grant funding, licensing opportunities, and equity investment opportunities in the Company. Your Board recognises that it is imperative to carefully balance the interests of our existing investors with the overarching obligation to deliver value-driving data across our key programs.”*

**Iain Ross, Chairman of the Board**  
**Letter to Shareholders – February 2018**



**Kazia is committed to utilising all available mechanisms to fund its R&D programs to value realisation, while safeguarding the interests of existing shareholders**

Source: Kazia Appendix 4D for half-year to December 2017; does not include value of holdings in Noxopharm Limited (\$7.8 million as at 31 December 2017)

# In the near term, Kazia will lodge an F-3 registration with SEC – a common tool for NASDAQ companies

Company	ASX Ticker	Date of F-3 Filing	Amount Registered (US\$)	Amount Raised (US\$)
 PRANA BIOTECHNOLOGY	PBT	2014	\$50 million	\$6 million
		2017	\$50 million	(none yet)
 NOVOGEN	NRT	2015	\$12.5 million	\$12.5 million
 PRIMA BIOMED	IMM	2016	\$60 million	\$5 million
 genetic technologies	GTG	2016	\$100 million	\$6 million
 BENITEC BIOPHARMA	BLT	2017	\$20 million	\$2 million
 mesoblast	MSB	2017	\$180 million	(none yet)

The F-3 registration statement is a useful tool that allows companies to issue NASDAQ securities quickly and cost-effectively, if an attractive investment opportunity should arise

Source: company SEC filings

GDC-0084 Program

Phase II

Glioblastoma Multiforme

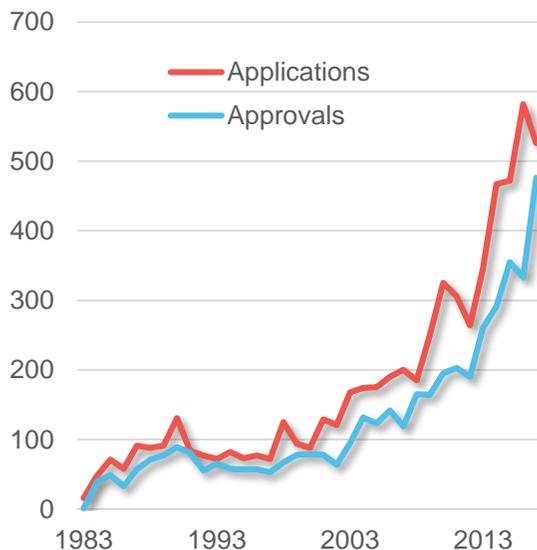
# Orphan designation in February 2018 was an important validation for the GDC-0084 program

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

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

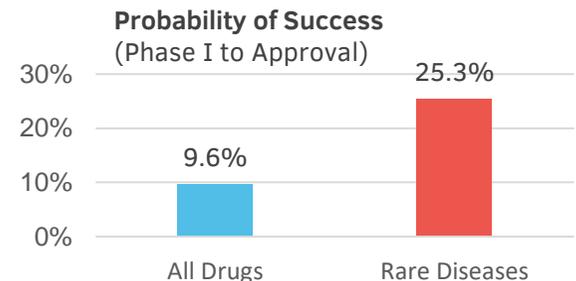
Orphan Designation is usually recognised by investors as value-driving

*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...*



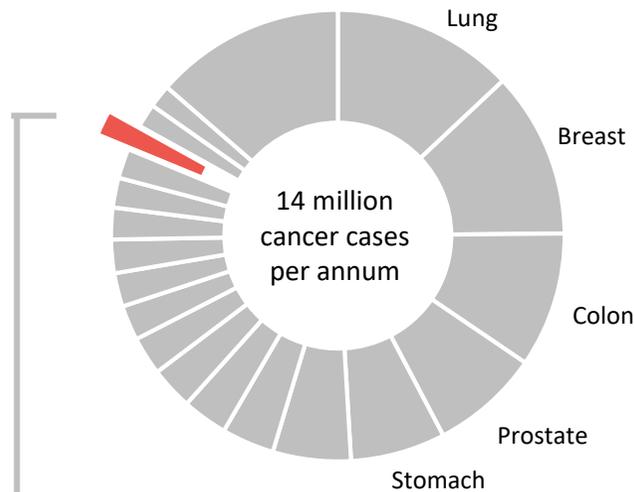
*...and small companies usually see a value inflection when Orphan Designation is granted*

**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

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



## Glioblastoma Multiforme

133,000 cases per annum worldwide

Indicative Market Opportunity

**US\$ 1 billion**

**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**

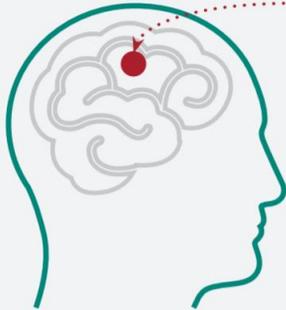
# There is increasing recognition of the need to find treatment options for patients diagnosed with GBM

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

### Glioblastoma

**About GBM:** The most common and most aggressive form of primary brain cancer in adults.



**Symptoms:**  
Headache, nausea, drowsiness and impaired vision.

**Treatment:**  
Treatment path usually consists of surgical resection of the tumour, followed by radiation. Patients then usually have a course of temozolomide (chemotherapy). Unfortunately temozolomide is only effective in about 35% of patients.

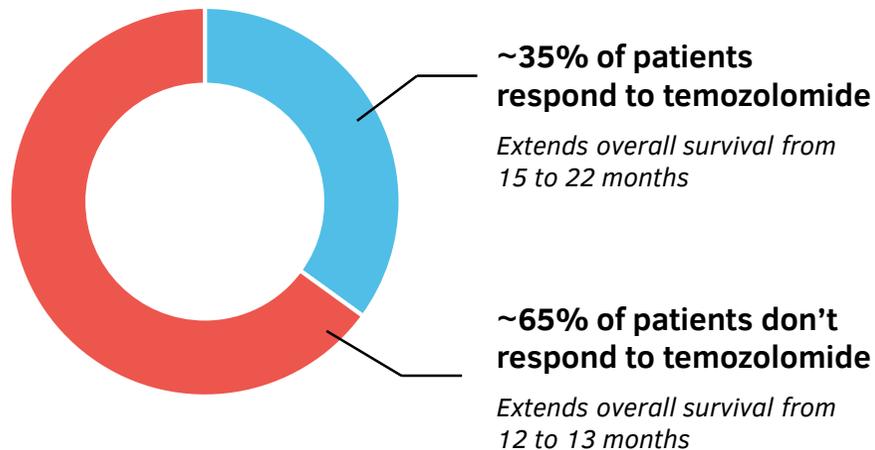
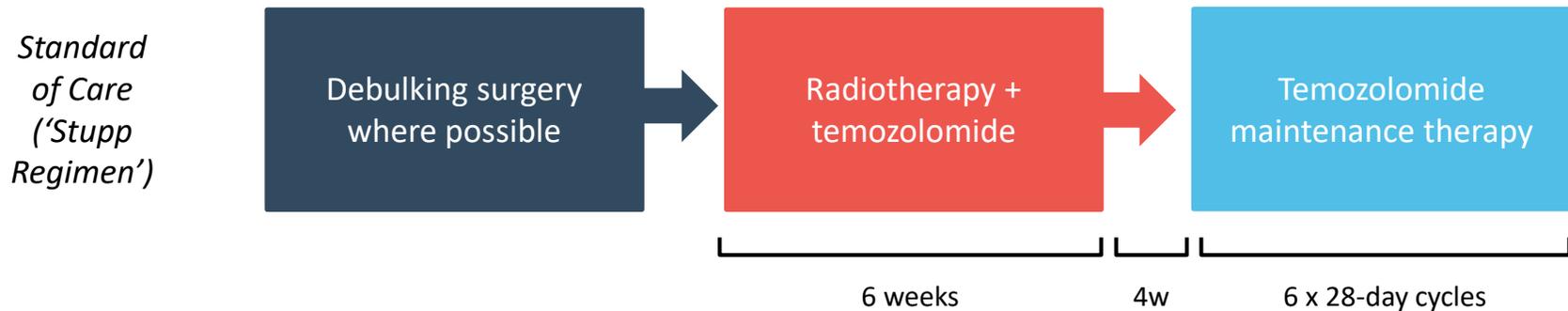
**How common is it:**  
About 133,000 patients per annum worldwide.

**Untreated survival rate:**  
3-4 months

**Median survival rate with best available care:**  
12-15 months



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

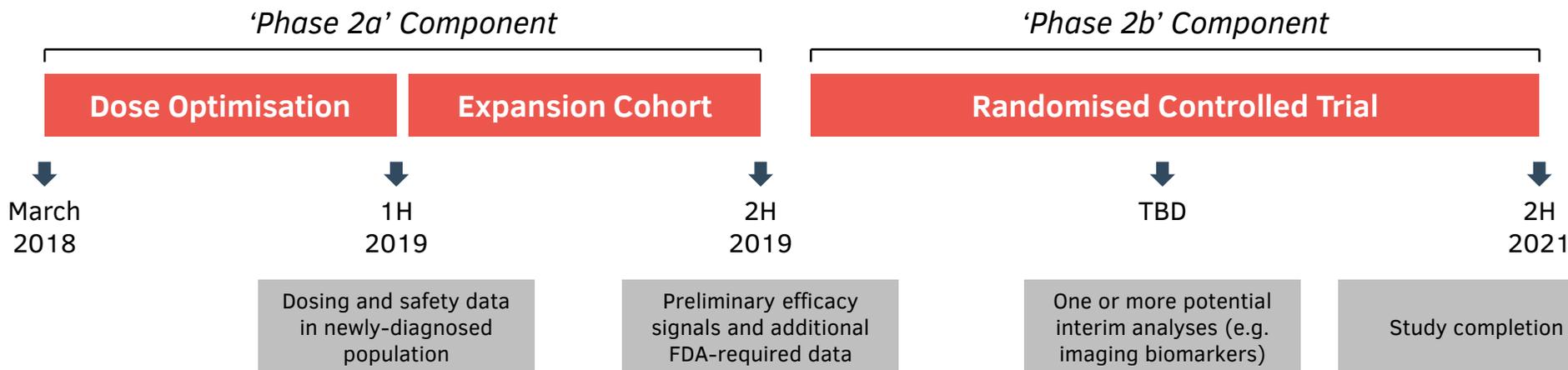


**GDC-0084 is being developed for the ~65% of newly-diagnosed GBM patients who will not response to existing chemotherapy with temozolomide**

*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

# GDC-0084 phase II study design has been simplified to accelerate data readouts

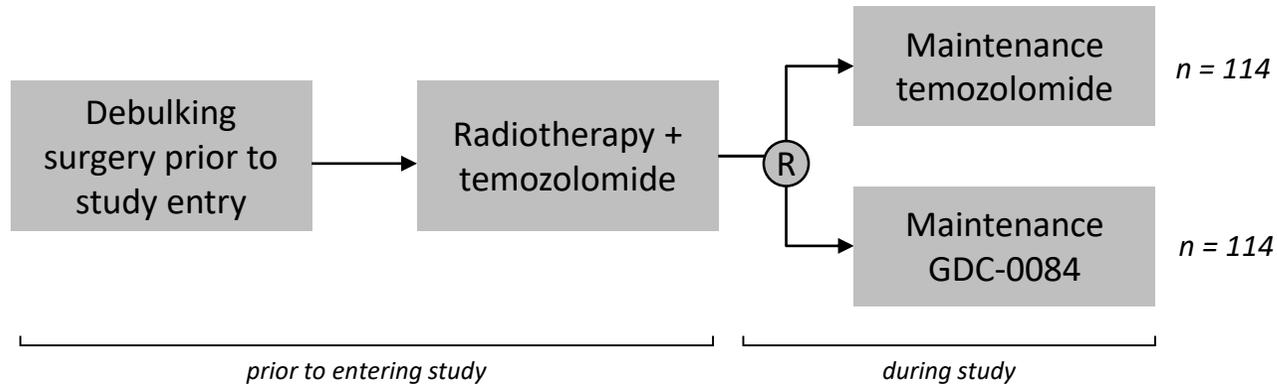


## Key Changes Planned After Investigator Meeting in June 2018 at ASCO

1. Only focus on daily dosing; alternate dosing regimens to be deferred to accelerate completion of phase 2a component
2. MRI and PET scan schedules to be optimised to facilitate clinician and patient convenience and look for early efficacy signals
3. Phase 2a and Phase 2b components to be split into separate studies for efficiency of execution

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

# The 'phase 2b component' (randomised controlled trial) is based on clinician and regulatory feedback



Approximately 60 sites in 5-6 countries

Will target patients who are resistant to temozolomide  
(approximately two-thirds of glioblastoma patients)

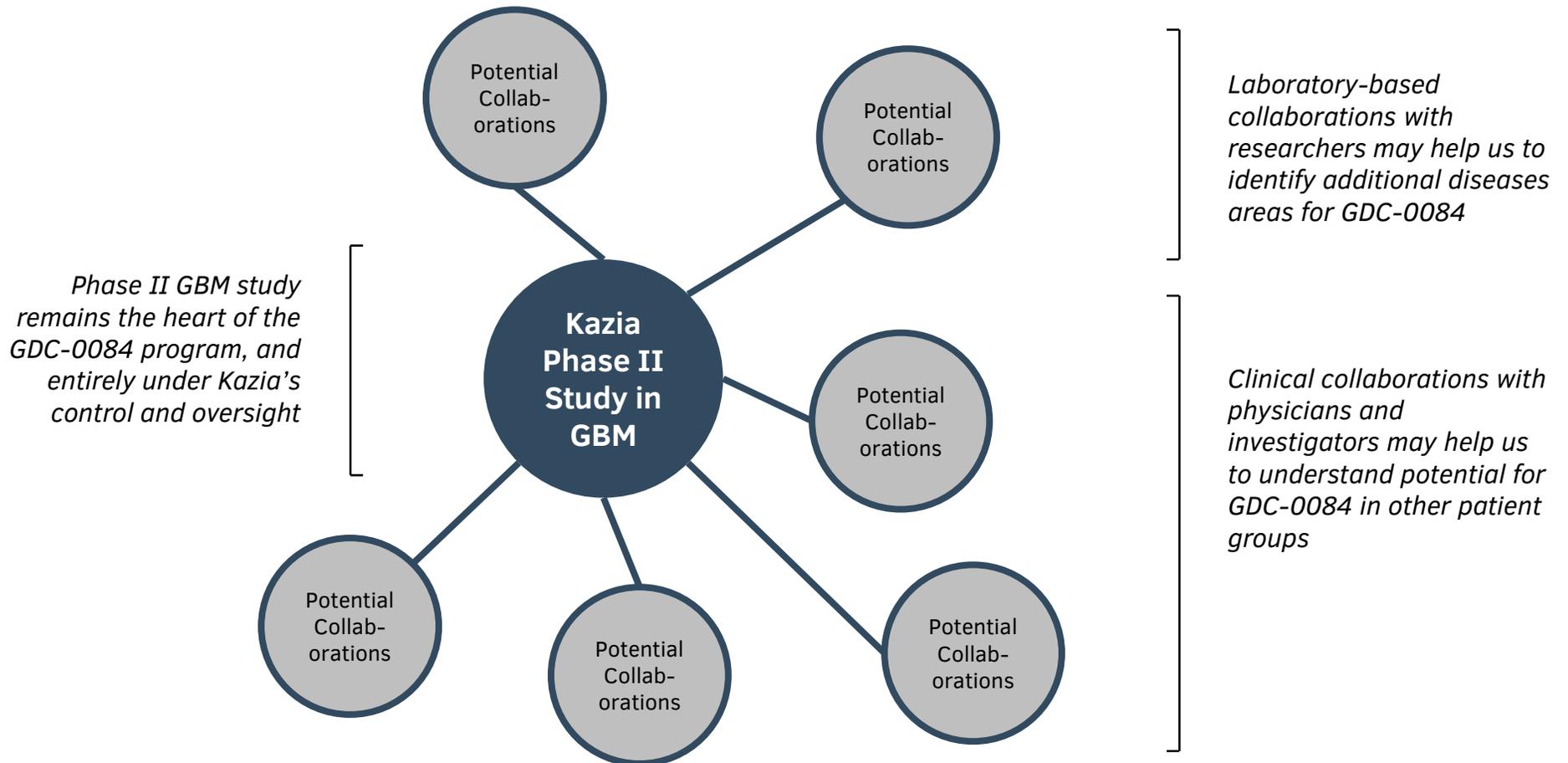
Duration:  
**18 months** recruitment  
**12 months** follow-up

Number of patients:  
approx. **228**  
(114 per arm)

## Regulatory Strategy

- Designed to provide robust evidence of clinical efficacy, using an endpoint, progression-free survival (PFS), that could potentially be approvable
- Goal is to seek accelerated approval prior to completion of a definitive phase III study. Avastin (bevacizumab) was approved for recurrent GBM in this way
- In the interim, Kazia aims to seek special designations (ODD, FTD, etc.) to provide enhanced opportunities for regulatory engagement

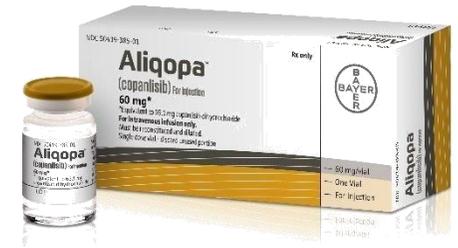
# Kazia is exploring potential collaborations to investigate GDC-0084 in other disease areas



# The PI3K class has been validated by approval of a new therapy in September 2017

PI3K class further validated by approval of Bayer's Aliqopa™ (copanlisib) for lymphoma in Sept 2017

- Two PI3K inhibitors now successfully brought to market
  - Zydelig (idelalisib) [Gilead]
  - Aliqopa (copanlisib) [Bayer]
- Neither drug is brain-penetrant, so are unlikely to rival GDC-0084
- Demonstrates that PI3K is a validated pathway to target for effective treatment of cancer
- Both agents approved by US FDA via 'accelerated approval'



# 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\$ 130 million**  
Market Cap



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

**US\$ 1.2 billion**  
Market Cap



One PI3K inhibitor in phase II human trials

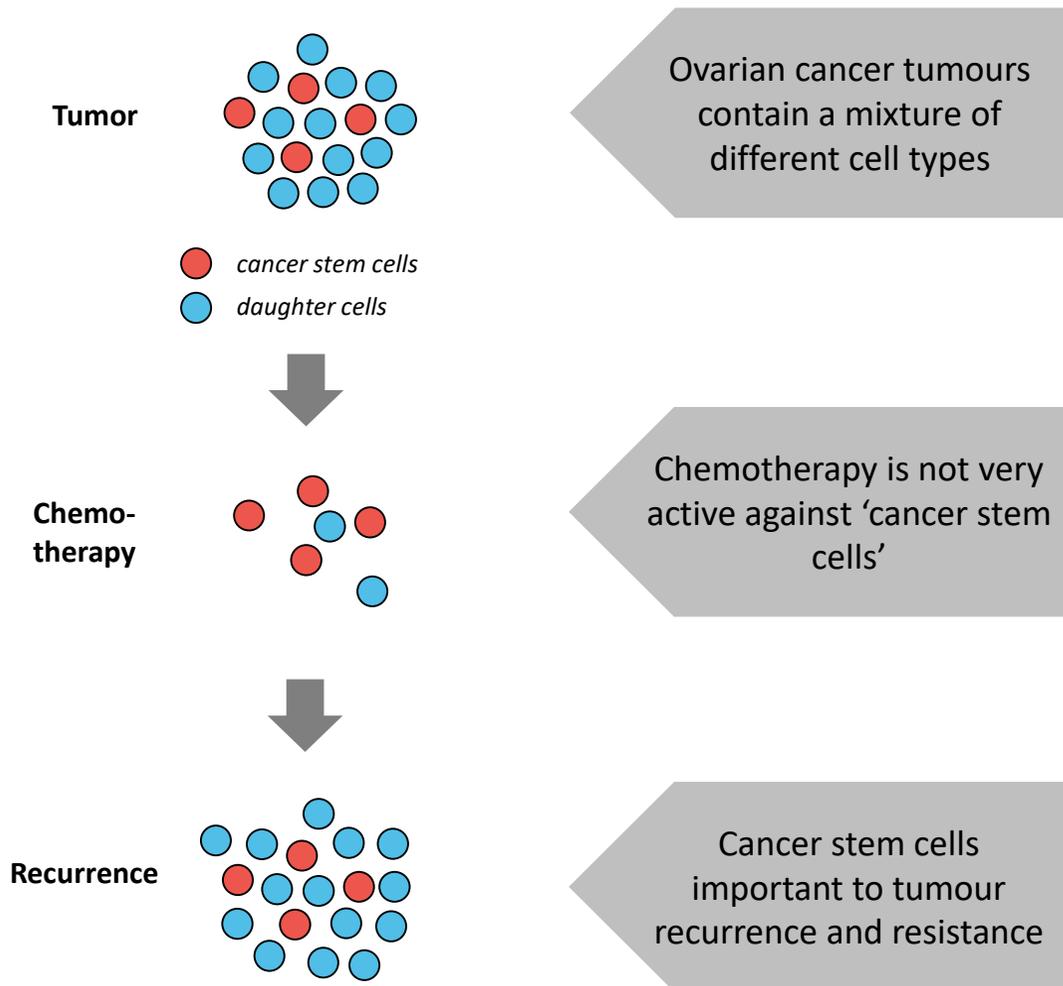
Acquired by big pharma in 2011 for  
**US\$ 375 million**

# Cantrixil Program

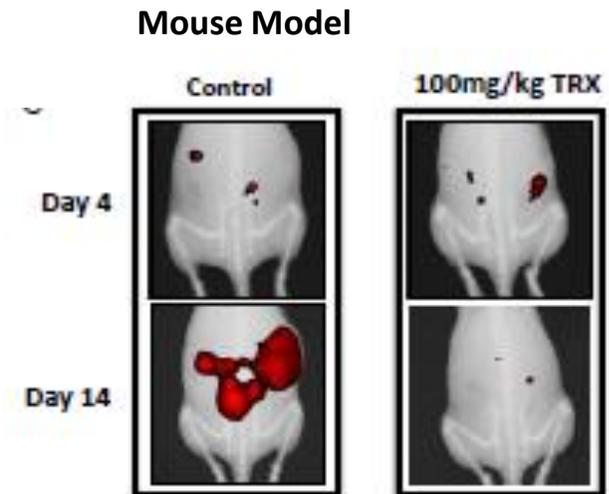
Phase I

Ovarian Cancer

# Cantrixil has been developed to target 'cancer stem cells' which are often resistant to chemotherapy

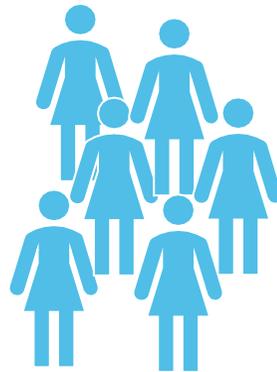
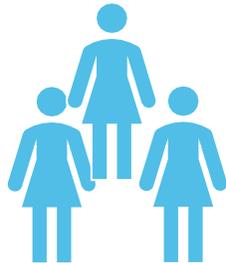


*TRXE-002-1 is active against both regular cancer cells and cancer stem cells, and may therefore help to prevent recurrence*

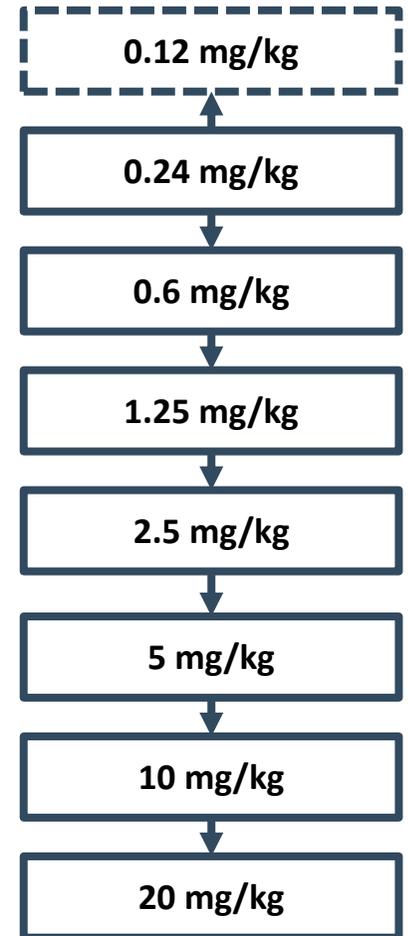


Yale | Data courtesy of Prof Gil Mor, Yale University

# Cantrixil is currently in an ongoing phase I 'dose escalation' study



- Single patient recruited at each dose level until toxicity encountered
- Thereafter, 3 – 6 patients recruited at a given dose level
- Dose where at least one third of patients experience toxicity is defined as the 'maximum tolerated dose'
- Study may recruit between 3 and 42 patients, depending on results seen during the study



# Interim results from 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*

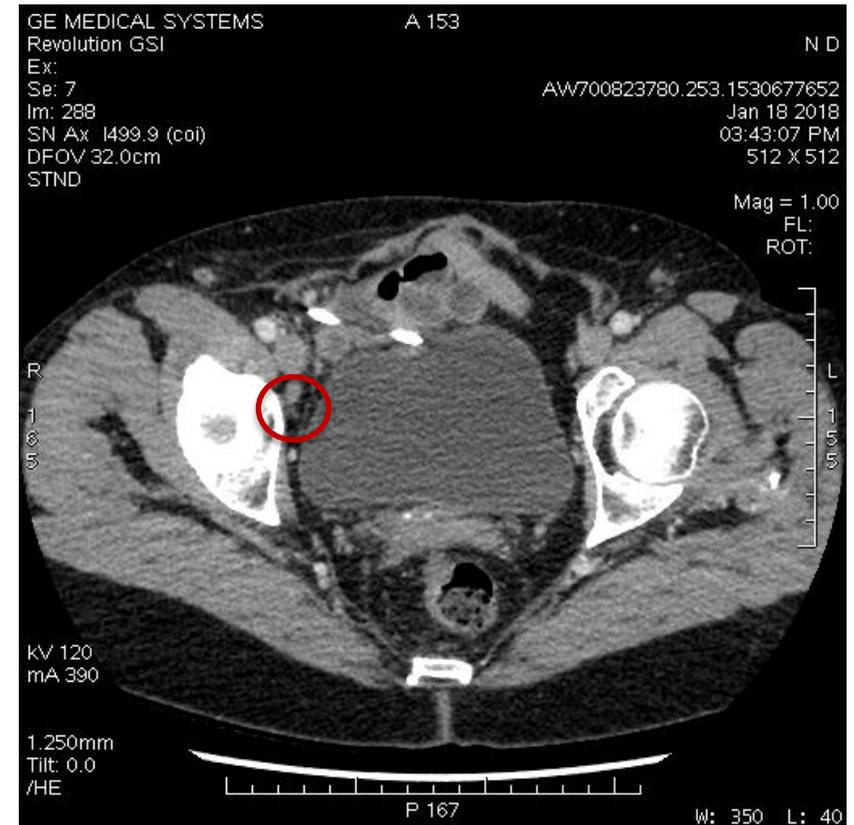
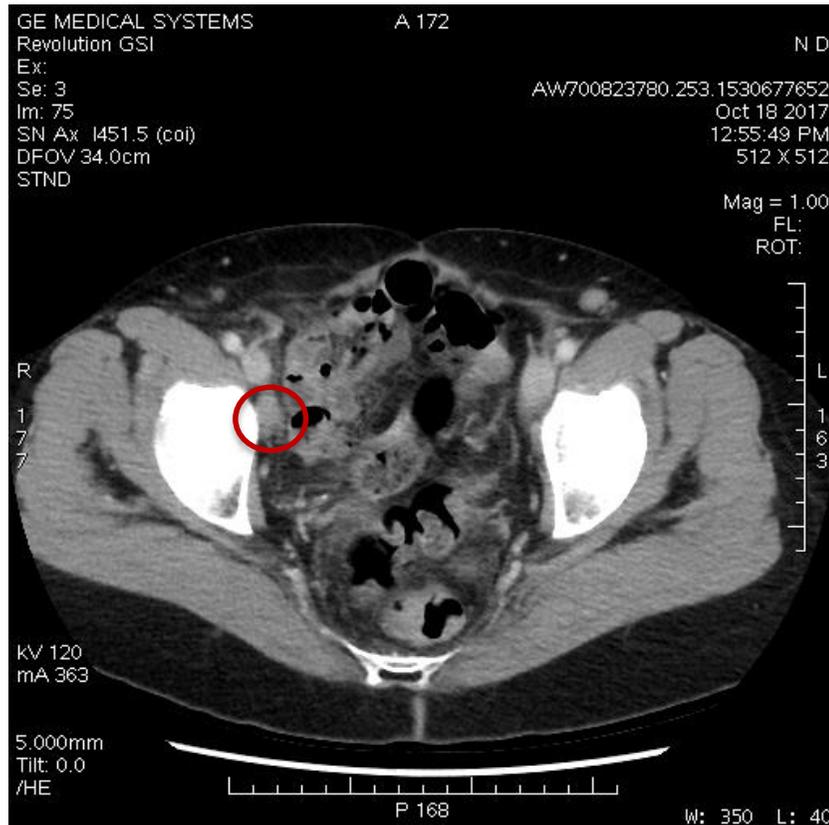
## RECIST Criteria for early-phase oncology studies

<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

# Cantrixil Phase I Study – partial response (1/2)

October 2017 (baseline)

January 2018

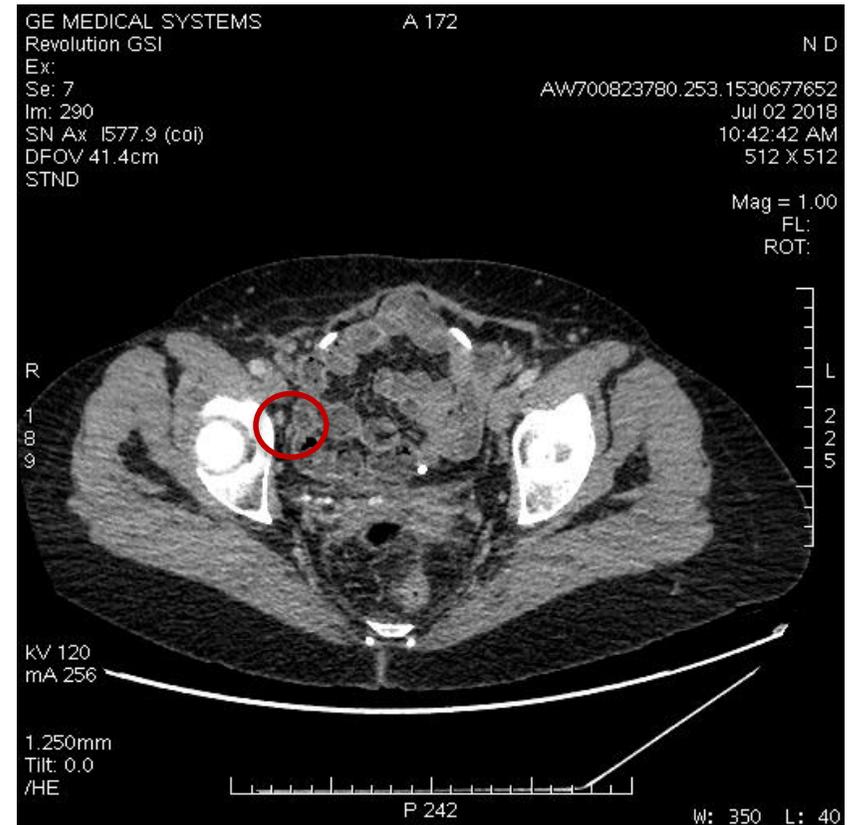
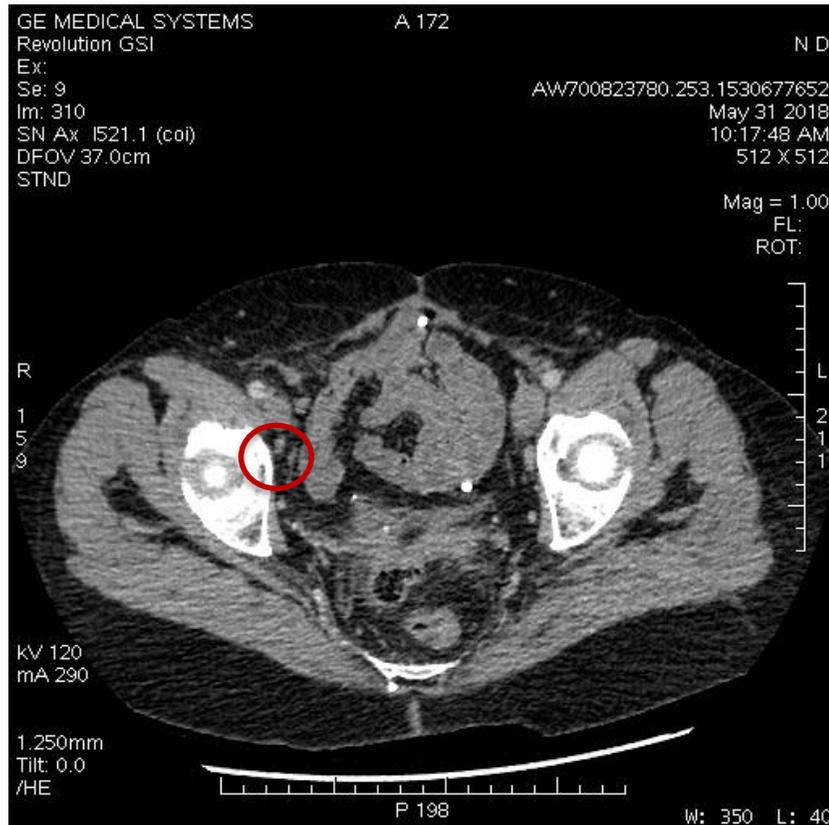


Source: images courtesy of Professor Jim Coward, Icon Cancer Centre

# Cantrixil Phase I Study – partial response (2/2)

May 2018 (end of study participation)

July 2018



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

# Recruitment in the study has been in line with expectations and industry benchmarks

## Indicative Recruitment Metrics for Phase I Studies in Ovarian Cancer

	 KERYX BIOPHARMACEUTICALS, INC.	 astellas	 morphotek	 Boehringer Ingelheim	 Verastem	 OncoMed PHARMACEUTICALS	 NOVARTIS	 KAZIA THERAPEUTICS
<b>Agent</b>	Perifosine	AGS-84M	Farletuzumab	BIBF 1120	VS-6063	OMP-54F28	LDE225	TRX-E-002-1
<b>Trial ID</b>	NCT00431054	NCT00816764	NCT01004380	NCT01314105	NCT01778803	NCT02092363	NCT02195973	NCT02903771
<b>Start Date</b>	Feb-07	Oct-08	Nov-09	Mar-11	Feb-13	Jan-14	Sep-14	Dec-16
<b>End Date</b>	May-12	Jun-10	Oct-12	Apr-16	Feb-15	Dec-17	Sep-17	(Jun-18)*
<b>Duration (months)</b>	63	20	35	61	24	47	36	18
<b>Number of Patients</b>	22	18	15	19	22	37	15	10
<b>Patients per month</b>	0.35	0.90	0.43	0.31	0.92	0.79	0.42	0.56

Source: clinicaltrials.gov

\* Interim analysis only; study remains ongoing

# Next steps for Cantrixil are completion of Part A, and progression to Part B

## Part A: Dose Escalation

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

*Study is currently in late stages of Part A*

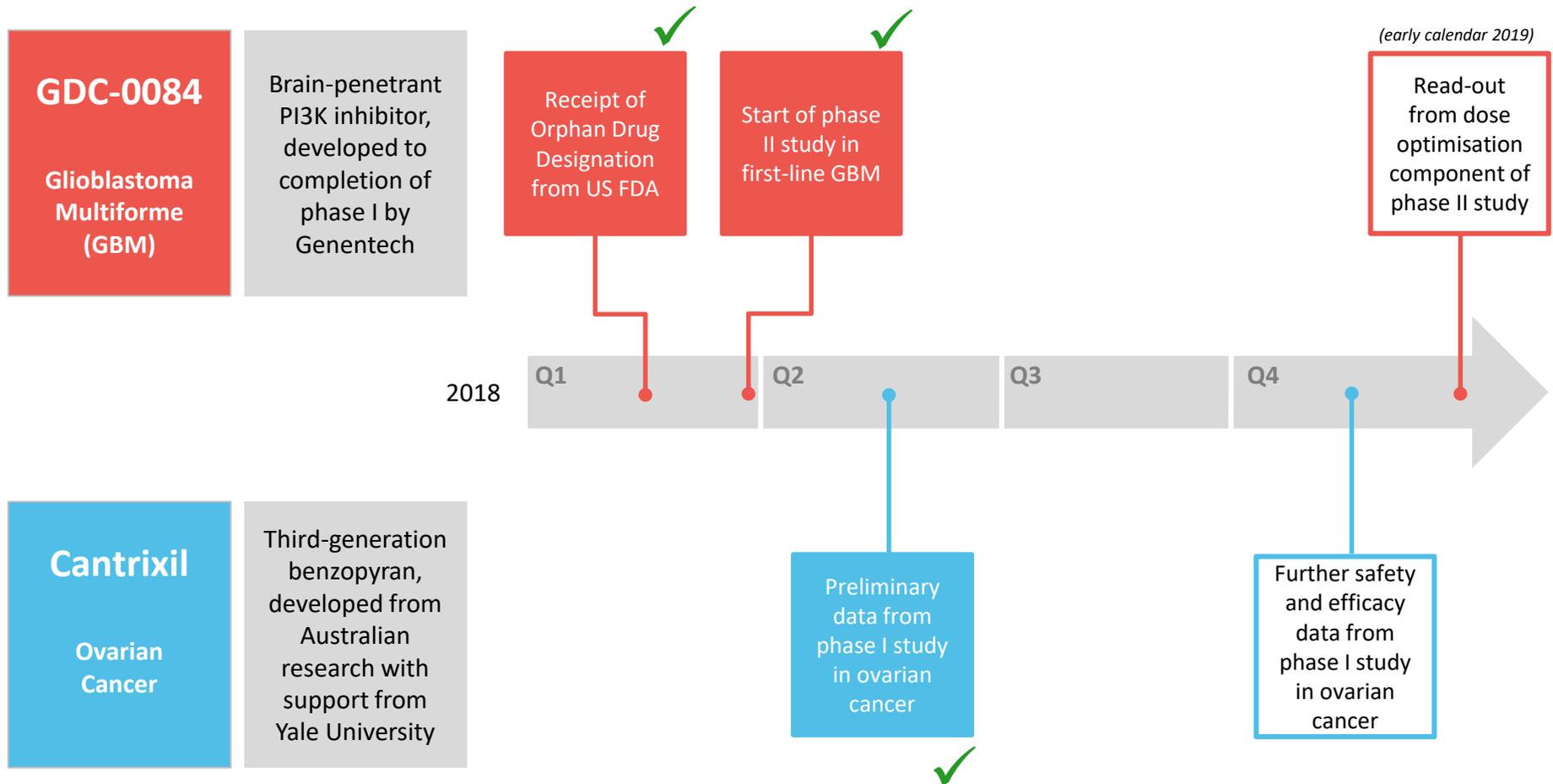
## Part B: Dose Expansion

- 12 patients at MTD
- Seeks to provide potential efficacy signals

*Current forecast is for completion of Part A in 3Q calendar 2018*

# Summary

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



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Cancer drug developer with two distinct therapies in clinical trials

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Well-differentiated assets, with lead program licensed from Genentech

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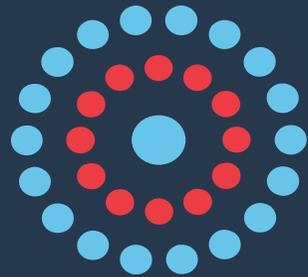
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Publicly-listed company, traded on ASX and NASDAQ

- Market cap ~AU\$ 30 million
- Current assets of ~AU\$ 14.8 million + ~\$7.5 million of NOX securities

4

Experienced team, with extensive international background in big pharma and biotech



**KAZIA**  
THERAPEUTICS

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