Kazia Therapeutics

Cantrixil AACR poster

Cantrixil efficacy data presented at AACR

Pharma & biotech

Kazia Therapeutics presented encouraging data from the Cantrixil Phase I study in a poster at American Association for Cancer Research (AACR) this week. Five of the nine evaluable patients (56%) showed stable disease at the completion of monotherapy treatment and one patient achieved an ongoing partial response to Cantrixil plus paclitaxel therapy. The extension cohort has already recruited nine of 12 subjects; data likely H219. Kazia's primary focus is on GDC-0084, which is in three clinical studies in brain cancers. Initial data from the Phase IIa study in glioblastoma are expected in Q219. We increase our valuation range to between $64m and $111m.

Year end	Revenue (US$m)	PTP (US$m)	EPADR (US$)	DPADR (US$)	P/E (x)	Gross Yield (%)
06/17	6.5	(8.3)	(1.73)	0.0	N/A	N/A
06/18	9.9	(4.8)	(0.95)	0.0	N/A	N/A
06/19e	2.3	(10.5)	(1.91)	0.0	N/A	N/A
06/20e	2.3	(9.4)	(1.52)	0.0	N/A	N/A

Note: Converted at A$1/US$0.76 for the table above and throughout the note.

Cantrixil shows evidence of anti-cancer activity

The poster presented at the AACR conference reported encouraging evidence from the Phase I study that Cantrixil acts to inhibit tumor growth when administered to ovarian cancer patients by intraperitoneal infusion. We see the likely future development of Cantrixil as being for use in combination chemotherapy in either the first-line or second-line setting, so it was encouraging to see it was well tolerated when administered in combination with five different chemotherapy agents after the first two cycles of monotherapy treatment were completed. The ongoing extension cohort will expand the data set regarding the safety and anti-cancer activity of Cantrixil.

GDC-0084 still the primary focus – first data Q219

Kazia is conducting three clinical studies of GDC-0084 in brain cancer or brain metastases, including two studies in collaboration with the prestigious US-based Dana Farber Cancer Institute and St Jude Children's Research Hospital. Initial safety data from the Phase IIa study in glioblastoma (GBM) are expected in the current quarter, with preliminary efficacy data in Q419.

Valuation: Increased to $64–111m

We increase our indicative valuation range to $64–111m or $10.31–17.82 per ADR (vs $63–105m, $10.51–17.57 per ADR), under either post-Phase III approval or accelerated approval scenarios for GDC-0084. We have rolled forward our model and have made adjustment for the sale of the Noxopharm shareholding for $1.8m (vs our previous valuation of $2.7m). We estimate that cash of $4.1m at 31 December 2018 plus the Noxopharm sale proceeds will fund activity into H219, by which time preliminary data from the GDC-0084 Phase IIa are expected to have read out. We estimate that Kazia will need additional funds in the order of $11-15m to fully fund the GDC-0084 Phase IIb study.

1 April 2019

Price	**$3.34**
Market cap	**$21m**
	ADR/Ord conversion ratio 10/1
Net cash ($m) at 31 December 2018	4.1
ADRs in issue	6.2m
ADR code	KZIA
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR share price performance

52-week high/low	$5.90	$2.20

Business description

Kazia Therapeutics is an ASX- and NASDAQ-listed biotechnology company. It is developing the PI3K/mTOR inhibitor GDC-0084 for brain cancer and Cantrixil for ovarian cancer. GDC-0084 was in-licensed from Genentech in 2016.

Next events

GDC-0084 safety and dosing data	Q219
Cantrixil Phase I preliminary efficacy data	Q319
GDC-0084 Phase IIa preliminary efficacy	Q419

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Edison profile page

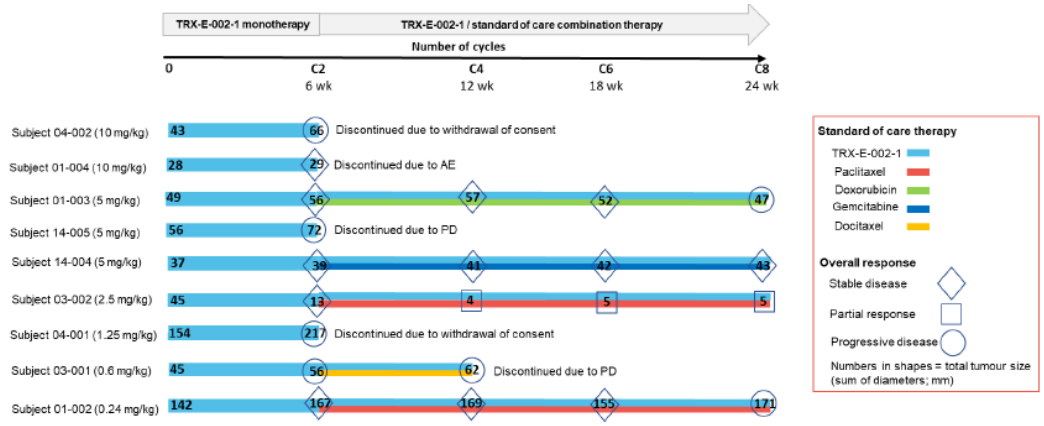
Encouraging efficacy in Cantrixil dose-escalation study

Kazia presented a poster summarizing the safety and efficacy of data from the dose escalation cohorts of the Phase I study of intraperitoneal Cantrixil (TRX-E-002-1) at the AACR conference held from 29 March to 3 April 2019 in Atlanta, Georgia. The study recruited women with ovarian, fallopian tube or primary peritoneal cancer who had failed at least two prior lines of therapy, including standard platinum-based therapy (eg cisplatin, carboplatin or oxaliplatin).

The key new information in the poster is that it reports for the first time the efficacy data on all nine evaluable subjects. The company had previously reported that the maximum tolerated dose (MTD) had been identified as 5mg/kg and that three of the first five evaluable patients achieved stable disease at the end of the six-week monotherapy treatment period and that one of these subjects went on to experience a partial response when treated with Cantrixil in combination with paclitaxel. The company has noted that the 5mg/kg dose is well within the range that was expected to be effective based on preclinical studies.

The poster presentation shows that five of the nine subjects (56%) who had received at least three weekly doses (one cycle) of Cantrixil achieved stable disease when evaluated six weeks after treatment commenced (Exhibit 1). The 56% stable disease rate in this larger body of patients is consistent with the 60% rate reported for the first five patients.

Exhibit 1: Tumor evaluation of Cantrixil dose-escalation cohorts

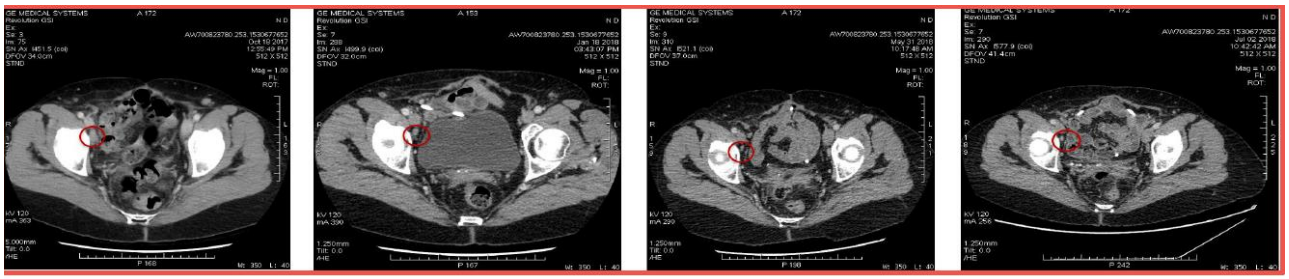


Source: Kazia Therapeutics

Exhibit 1 shows that subject 03-002 experienced substantial tumor shrinkage during the six-week period when she was treated with Cantrixil at 2.5mg/kg as a monotherapy. The sum of tumor diameters, the standard tumor measurement used in the RECIST[1] response criteria, shrank from 45mm to 13mm. While there was a substantial reduction in tumor burden, the level of the CA125 cancer marker in the bloodstream had increased and this patient was considered to have had stable disease rather than a tumor response at six weeks. At the completion of Cantrixil monotherapy the patient subsequently received six cycles (18 weeks) of treatment with 2.5mg/kg Cantrixil combined with paclitaxel. The tumors continued to shrink and the CA125 levels declined during the combination treatment period and 12 weeks after entering the study the patient had achieved a partial response. The response was ongoing at the end of the 24-week follow-up period when the patient exited the study. Exhibit 2 shows that the tumor shrinkage was maintained at a further assessment two months after the end of the study.

1 RECIST= Response Evaluation Criteria in Solid Tumours

Exhibit 2: Progressive tumor reduction over an extended period observed in one patient



A. Oct 2017 (baseline) B. Jan 2018 (end Cycle 4) C. May 2018 (end of study) D. Jul 2018 (follow up)

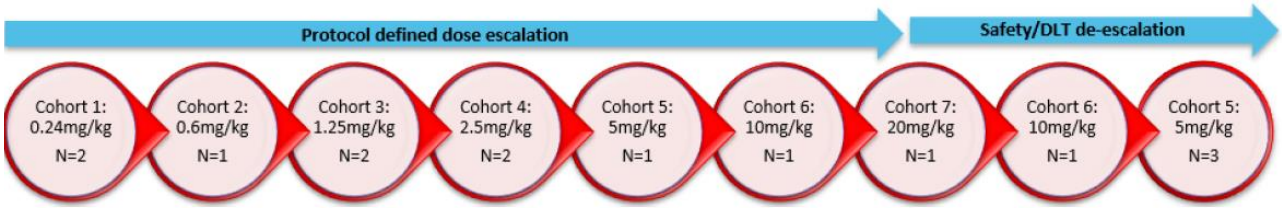
Source: Kazia Therapeutics

Manageable adverse event profile at MTD

The main purpose of the study was to determine the MTD and to investigate the safety of Cantrixil. In total, 14 subjects were enrolled and 11 received at least one dose of Cantrixil infused into the abdominal cavity (intraperitoneal administration) and were evaluated for safety. Nine subjects received at least three doses and were evaluated for efficacy.

Exhibit 3 shows that dosing escalated all the way to 20mg/kg, the highest planned dose, before the first dose limiting toxicity was observed. The dose was then de-escalated in two steps to 5mg/kg, which was identified as the MTD. The dose limiting toxicity was ileus syndrome (temporary arrest of intestinal peristalsis) and safety signals of bowel obstruction and abdominal pain.

Exhibit 3: Dose escalation and de-escalation in study cohorts

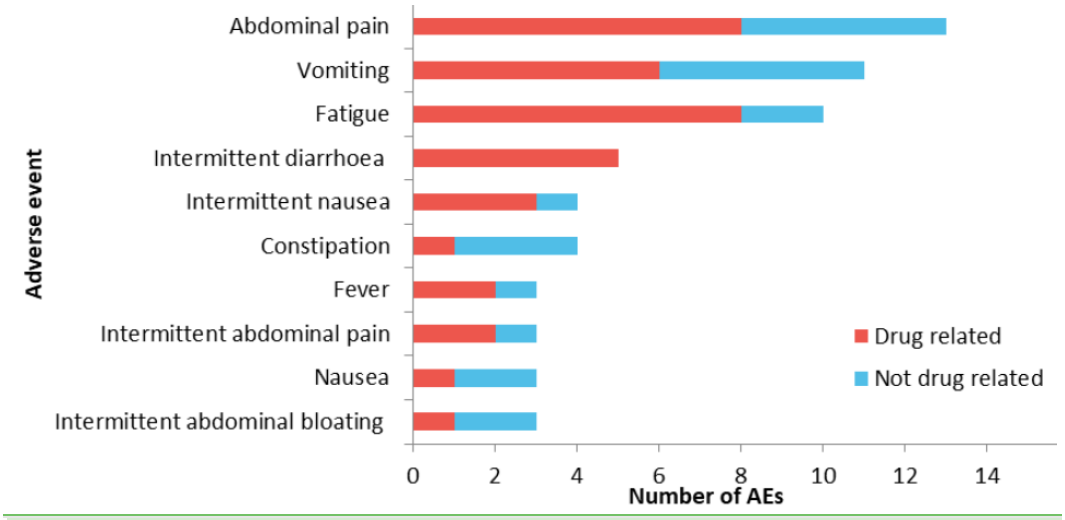


Source: Kazia Therapeutics

Exhibit 4 shows that a total of 161 adverse events were recorded, 66 of which were considered to be drug related. There were 12 serious adverse events recorded, only three of which were drug related: ileus syndrome, abdominal pain and worsening of abdominal pain.

It is notable that most of the adverse events were gastrointestinal. Treatment centers have strategies in place to manage side effects such as pain, nausea and vomiting, but those strategies were not used in this study because the investigators did not want to mask any adverse events.

Exhibit 4: Top 10 most frequent adverse events

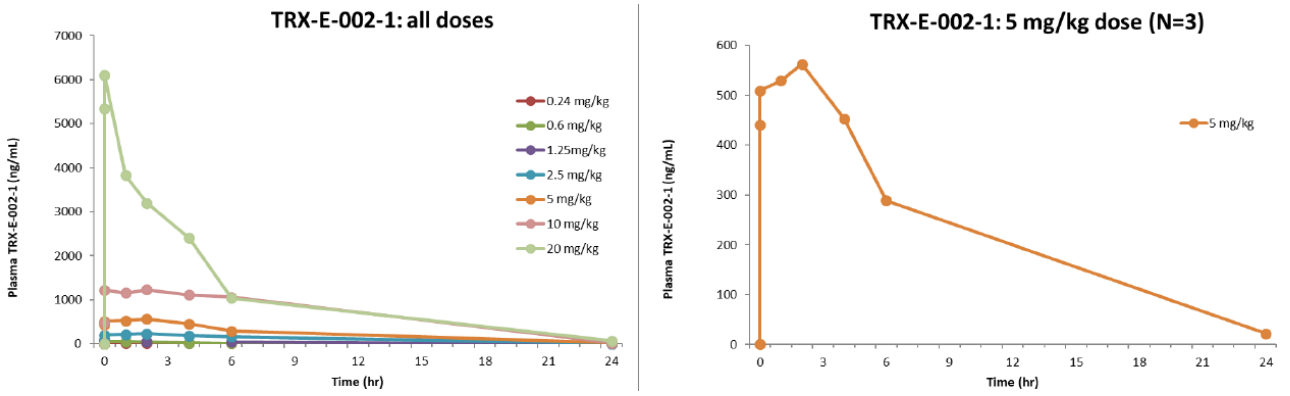


Source: Kazia Therapeutics. Note: AE: adverse event.

PK data show rapid absorption and clearance from the blood

Pharmacokinetic (PK) data shows that Cantrixil is rapidly absorbed following intraperitoneal administration. Levels in the bloodstream peaked around three hours after administration and then declined to very low levels after 24 hours. Intraperitoneal administration exposes abdominal organs to higher levels of the drug than other parts of the body.

Exhibit 5: Cantrixil (TRX-E-002-1) dose concentration profile



Source: Kazia Therapeutics

Recruitment of Cantrixil extension cohort well advanced

Kazia is recruiting a 12-patient expansion cohort, which is being treated with Cantrixil monotherapy at the MTD of 5mg/kg. As of March 2019, nine of the 12 patients have been recruited. Kazia expects to fully recruit the expansion cohort in Q219 and report initial efficacy data in H219.

The 56% of subjects with stable disease at the end of the monotherapy treatment period and the substantial reduction in tumor size seen in one patient receiving combination therapy are encouraging signs that Cantrixil inhibits tumor growth. However, it is not yet clear whether the efficacy is sufficient for it to be a commercially successful product. The expansion cohort will provide additional data to help assess the safety and potential efficacy of Cantrixil.

Future options for Cantrixil: First- or second-line combos

Kazia's overall business strategy is to in-license drug candidates then add value by conducting early to mid-stage clinical development, before out-licensing or selling the program to a partner who would conduct late-stage development.

Therefore, we expect the company to seek a partner for late-stage development of Cantrixil. Depending on the level of interest from potential pharma partners and on Kazia's available financial resources, it could also seek a partner for the next stage of Cantrixil development. Another option would be for Kazia to conduct a small study if there is a particular question that potential pharma partners want to have addressed before they commit to a transaction.

We suspect the next steps in Cantrixil's development will be strongly influenced by discussions with potential partners, which will enable Kazia to learn what additional data partners would require before they could decide whether to seek to in-license or acquire the program. Discussions with the Scientific Advisory Board and clinicians, including trial investigators, will also be influential.

Cantrixil has shown encouraging signs of efficacy as a single agent and good tolerability when used in combination with standard second-line therapies. These two factors mean Cantrixil is likely to be well suited to use in combination therapy.

If the data from the expansion cohort are sufficiently encouraging and there is sufficient interest from potential partners, we suspect the likely next step would to be to test Cantrixil in combination with the investigator's choice of standard chemotherapy drugs in either a first- or second-line setting.

Kazia's primary focus remains on GDC-0084

Kazia's lead drug candidate is GDC-0084, an orally administered small molecule phosphoinositide 3-kinase (PI3K) inhibitor that targets an important growth-signaling pathway in cancer cells, which it in-licensed from Genentech in October 2016. The drug was specifically developed to cross the blood-brain barrier and target GBM, which is an aggressive brain cancer with poor patient survival and for which there are few effective therapies. However, its ability to cross the blood-brain barrier means it is also expected to be effective against other forms of brain cancer and against brain metastases of cancers that originated elsewhere in the body.

Kazia is investigating GDC-0084 in three separate clinical studies, which include one company-sponsored study and two studies conducted in collaboration with prestigious US-based cancer research centers. The three studies are summarized briefly below.

GDC-0084 dose optimization Phase IIa in GBM

Kazia commenced recruitment of a company-sponsored dose optimization Phase IIa study of GDC-0084 in recently diagnosed GBM patients in March 2018. Once the MTD in first-line patients has been identified, an expansion cohort of 20 patients will be treated at that dose. The expansion cohort will undergo intensive monitoring to better understand the pharmacokinetic and toxicity profile of the drug, before the randomized controlled Phase IIb study commences.

The Phase IIa study will be followed by a randomized Phase IIb trial comparing GDC-0084 to standard temozolomide (TMZ) chemotherapy. The study will target the 61% of GBM patients where the tumor cells have an unmethylated O6-methylguanine methyltransferase (MGMT) promoter, as this patient population receives only minimal benefit from treatment with TMZ and is in urgent need of more effective therapies.

Initial dosing and safety data from the Phase IIa study are expected in Q219, with preliminary efficacy signals likely to be reported in Q419.

Breast cancer brain metastases with Dana-Farber

The first of the collaborative studies is a Phase II trial with the Dana-Farber Cancer Institute to investigate GDC-0084 in combination with Herceptin in women with HER2-positive breast cancer who have developed brain metastases. Genentech showed that GDC-0084 improves survival in this indication in animal studies and a successful Phase III study for Novartis's BYL719 validates targeting PI3K in breast cancer.

DIPG childhood brain cancer with St Jude

The second collaboration is with St Jude Children's Research Hospital in a Phase I study of GDC-0084 in the aggressive childhood brain cancer diffuse intrinsic pontine glioma (DIPG). Although the number of patients with this disease is small, the fact that there are no approved treatments for this aggressive cancer could open up pathways to an accelerated approval or Breakthrough Designation. Approval could also earn a valuable FDA pediatric priority review voucher.

Valuation

We have revised our valuation of Kazia to reflect the sale of the shareholding in Noxopharm for $1.8m (before costs) vs our previous valuation of $2.7m. Kazia's remaining unlisted Noxopharm options were valued at $0.2m at 31 December 2018. We have adjusted the share count to include the 0.3m ADRs issued to Glioblast shareholders in November 2018 upon meeting the first milestone (initiation of dosing in the phase II study), relating to the in-license of the GDC-0084 technology and the acquisition of Glioblast in 2016.

Our base case valuation, which models a GDC-0084 market launch in 2026 following completion of a Phase III trial, has increased to $64m (previously $63m). Our valuation is equivalent to $10.31/ADR undiluted (vs $10.51/ADR) and $9.92/ADR after diluting for options and convertible notes. Kazia's primary listing is on the ASX under the code KZA; each NASDAQ-listed ADR represents 10 ordinary shares. Our undiluted base case valuation equals A$1.36 per ASX-listed ordinary share at current exchange rates.

Our base-case valuation assumes a 40% likelihood that GDC-0084 is out-licensed to a marketing partner in 2021 after reporting positive PFS data from the Phase II trial, in a deal that includes US$20m upfront and US$120m in clinical and regulatory milestone payments. We also assume that Kazia pays a royalty of 10% of net sales to Genentech and that global sales for GBM reach US$1,050m in 2030.

Exhibit 6 shows our base-case market assumptions for GDC-0084 and Cantrixil and the contribution of product royalties and milestone payments to the rNPV, which have not changed since our last note. We have offset the risk-adjusted trial cost against milestone revenue for each drug, rather than against royalty revenue. This understates the contribution of the milestone payments to the rNPV and overstates the contribution of royalties.

Exhibit 6: Kazia base case valuation (assumes confirmatory GDC-0084 pivotal trial required)

	Likelihood (%)	rNPV ($m)	rNPV/ ADR ($)	Assumptions
GDC-0084; GBM	25%	13.7	2.21	Global peak sales* of $1,050m from GBM (11,500 US cases/year, 61% unmethylated MGMT** promoter, 80% penetration); pricing of $50k. Global sales 2x US sales; launch 2026; assumes receives 15% royalty on sales, pays away 10% of royalty to Genentech.
GDC-0084; brain metastases in HER2+ breast cancer	20%	5.8	0.94	Global peak sales of $600m (233,000 US breast cancer cases/year, 37% HER2+, 7% develop brain metastases, 50% penetration); pricing of $50k. Global sales 2x US sales; launch 2026; assumes receives 15% royalty on sales, pays away 10% of royalty to Genentech.
GDC-0084; DIPG	20%	0.4	0.07	Global peak sales of $45m (275 US DIPG cases/year, 80% penetration); pricing of $50k. Global sales 2x US sales; launch 2026; assumes receives 15% royalty on sales, pays away 10% of royalty to Genentech.
Ovarian and other abdominal cancers: Cantrixil	10%	22.6	3.63	Global peak sales of $680m from ovarian cancer (14,300 US deaths/year, 30% penetration) and bowel cancer (50,300 US deaths, 25% develop malignant ascites, 20% penetration); pricing of $50k. Global sales 2x US sales; launch 2025; assumes receives 15% royalty on sales, pays away 5% of revenue to Yale.
GDC-0084 milestones		12.4	1.99	Assumes potential licensing upfronts and milestones total $140m ($127m net of payments to Glioblast and Genentech; $38m after risk adjustment).
Cantrixil milestones		15.3	2.46	Assumes potential licensing upfronts and milestones total $140m ($23m after risk adjustment); assumes 5% of upfront and milestone payment paid away to Yale.
SG&A		-8.6	-1.39	
Portfolio total		**61.6**	**9.90**	
Noxopharm options book value		0.2	0.02	
Net cash at end FY19e		2.4	0.38	
Enterprise total		**64.1**	**10.31**	

Source: Edison Investment Research. Note: *Peak sales in actual dollars in forecast year. ** MGMT = methylguanine-DNA methyltransferase gene. We assume that the addressable markets grow at 4% per year. Launch dates listed are calendar years (in some cases the launch will be in the financial year following the calendar year stated).

We have also valued Kazia under an alternative accelerated approval scenario for GDC-0084, which assumes a market launch in 2023 and that Kazia receives a higher 20% royalty rate and a larger US$40m upfront payment because the data are ready for filing, with other deal terms the same as for the post-Phase III approval base case scenario. Exhibit 7 shows that accelerated approval for GDC-0084 would increase our valuation for Kazia to $111m (previously $105m) or $17.82/ADR (undiluted).

Exhibit 7: Kazia valuation in GDC-0084 accelerated approval scenario

	Likelihood (%)	rNPV ($m)	rNPV/ ADR ($)	Assumptions
GDC-0084 – GBM	25%	44.5	7.16	As per Exhibit 2, except 2023 launch (vs 2026) and 20% gross royalty on sales (vs 15%).
GDC-0084 – brain metastases in HER2+ breast cancer	20%	11.2	1.81	As per Exhibit 2, except 20% gross royalty on sales (vs 15%).
GDC-0084; DIPG	20%	0.8	0.13	As per Exhibit 2, except 20% gross royalty on sales (vs 15%).
GDC-0084 milestones		22.5	3.61	Assumes potential licensing upfronts and milestones total $160m ($147m net of payments to Glioblast and Genentech; $48m after risk adjustment). Milestones received earlier than base case (final milestone in 2023 vs 2026).
GDC-0084 total		**79.1**	**12.72**	
Remainder of portfolio		29.2	4.70	
Portfolio total		**108.3**	**17.42**	
Noxopharm options book value		0.2	0.02	
Net cash at end FY19e		2.4	0.38	
Enterprise total		**110.8**	**17.82**	

Source: Edison Investment Research. Note: Launch dates listed are calendar years.

Financials

Kazia had $4.1m cash at 31 December 2018 and has subsequently raised $1.8m (before costs) through the sale of its shareholding in Noxopharm. We expect the available funds to be sufficient to support operations into H2 CY19, by which time preliminary efficacy data from the GDC-0084 Phase IIa studies are expected to read out. However, if is there is any slippage on the timelines, funds may need to be raised in H2 CY19 before the GDC-0084 Phase IIa trial reads out. We

estimate that Kazia will need additional funds of $11–15m to finance the GDC-0084 Phase IIb GBM study.

We have revised our FY19 financial forecasts to account for the ~$1.5m loss on the sale of the Noxopharm shareholding for $1.8m (gross) vs its valuation of $3.3m at the end of FY18.

Exhibit 8: Financial summary

US$000s	2016	2017	2018	2019e	2020e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Sales, royalties, milestones	0	0	0	0	0
Other (includes R&D tax rebate)	2,786	6,508	9,872	2,336	2,294
Revenue	2,786	6,508	9,872	2,336	2,294
R&D expenses	(7,519)	(8,463)	(7,428)	(6,998)	(7,192)
SG&A expenses	(3,301)	(5,761)	(6,181)	(3,300)	(3,563)
Other	0	0	0	0	0
EBITDA	(8,034)	(7,716)	(3,737)	(7,961)	(8,460)
Operating Profit (before GW and except.)	(8,110)	(7,806)	(3,897)	(7,961)	(8,461)
Intangible Amortization	(1,003)	(62)	(1,016)	(1,108)	(997)
Exceptionals	(432)	0	0	0	0
Operating Profit	(9,546)	(7,868)	(4,912)	(9,069)	(9,458)
Net Interest	308	(392)	91	45	24
Profit Before Tax (norm)	(8,805)	(8,260)	(4,822)	(10,544)	(9,434)
Profit Before Tax (reported)	(9,237)	(8,260)	(4,822)	(9,024)	(9,434)
Tax benefit	0	151	232	0	0
Profit After Tax (norm)	(8,805)	(8,109)	(4,590)	(10,544)	(9,434)
Profit After Tax (reported)	(9,237)	(8,109)	(4,590)	(9,024)	(9,434)
Average Number of Shares Outstanding (m)	42.7	46.8	48.4	55.3	62.2
Average Number of ADRs Outstanding (m)	4.27	4.68	4.84	5.53	6.22
EPS - normalized (c)	(21.61)	(17.33)	(9.49)	(19.07)	(15.18)
EPS - diluted	(21.61)	(17.33)	(9.49)	(19.07)	(15.18)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Earnings per ADR - normalized (c)	(216.1)	(173.3)	(94.9)	(190.7)	(151.8)
Earnings per ADR - diluted (c)	(216.1)	(173.3)	(94.9)	(190.7)	(151.8)
Dividend per ADR (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	1,084	12,487	14,376	10,132	9,211
Intangible Assets	625	12,098	11,080	9,972	8,975
Tangible Assets	450	372	1	1	77
Investments	10	17	3,295	160	160
Current Assets	25,908	14,805	7,037	5,415	3,446
Stocks	0	0	0	0	0
Debtors	151	3,240	1,927	2,470	2,424
Cash	25,424	10,986	4,527	2,361	438
Other	333	580	584	584	584
Current Liabilities	(1,088)	(4,092)	(2,955)	(4,054)	(4,188)
Creditors	(988)	(1,423)	(1,571)	(2,670)	(2,804)
Short term borrowings	0	0	0	0	0
Other	(100)	(2,669)	(1,384)	(1,384)	(1,384)
Long Term Liabilities	(117)	(3,943)	(3,835)	(3,918)	(9,998)
Long term borrowings	0	0	0	0	(6,080)
Other long term liabilities	(117)	(3,943)	(3,835)	(3,918)	(3,918)
Net Assets	25,788	19,257	14,624	7,575	(1,529)
CASH FLOW					
Operating Cash Flow	(9,411)	(8,879)	(6,673)	(7,086)	(7,950)
Net Interest	308	189	91	45	24
Tax	0	0	0	0	0
Capex	(399)	(15)	0	(76)	(76)
Acquisitions/disposals	2	(5,394)	114	1,775	0
Equity Financing	594	(13)	0	3,177	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(8,906)	(14,113)	(6,469)	(2,166)	(8,003)
Opening net debt/(cash)	(33,722)	(25,424)	(10,986)	(4,527)	(2,361)
HP finance leases initiated	0	0	0	0	0
Other	608	(326)	10	0	0
Closing net debt/(cash)	(25,424)	(10,986)	(4,527)	(2,361)	5,642

Source: Kazia Therapeutics accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of US$0.76 to A$1. Novogen reports statutory accounts in Australian dollars. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

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