EDISON

Kazia Therapeutics

FY19 results and update

GDC-0084 gets a fifth collaboration

Pharma & biotech

Kazia Therapeutics' FY19 financial results show cash of A$5.4m and an operational cash use of A$6.7m. The 20-patient efficacy cohort in the lead GDC-0084 Phase IIa study should report data in Q419. Kazia has announced a new trial collaborating with the prestigious MSK hospital in NY to look at GDC-0084 in PI3K mutated brain metastases in conjunction with radiotherapy. Initial efficacy data from the Cantrixil ovarian cancer Phase I is also due in Q419. Our base-case value, updated for year-end cash, is A$137m.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/18	2.9	(11.0)	(22.2)	0.0	N/A	N/A
06/19	1.5	(7.7)	(12.9)	0.0	N/A	N/A
06/20e	1.5	(8.7)	(14.0)	0.0	N/A	N/A
06/21e	1.5	(11.1)	(17.9)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptionals and share-based payments.

Efficacy indications for GDC-0084 by late 2019

Kazia is recruiting a 20-patient expansion cohort in its current GDC-0084 Phase II study at a 60mg dose – higher than the 45mg used by Genentech. GDC-0084 has a provisionally assigned official name, paxalisib, subject to final confirmation. The initial data may be available by Q419. If positive, this could trigger a Phase IIb randomised study and potential partnering by 2023. We assume as our base case scenario that this might be adequate for approval in 2024 as patients resistant to the current standard therapy, temozolomide, have no other therapies available.

New metastatic trial for GDC-0084 with radiotherapy

Memorial Sloan Kettering Cancer Center (MSK) in New York supported by Kazia will lead a Phase I trial of GDC-0084 combined with radiotherapy to treat solid brain metastases with a genetic alteration. This has a dose ranging phase followed by cohort expansion. It may report data in H221. The PI3K pathway inhibited by GDC-0084 enables cells damaged by radiation to survive rather than enter apoptosis (cell death) so blocking PI3K might boost the efficacy of radiotherapy.

Cantrixil efficacy indications possible by late 2019

Cantrixil is also in a cohort expansion stage with 12 patients recruited and data due in Q4. Initial data in April was very promising, with one partial responder and five stable disease patients treated. Cantrixil, an intra-peritoneal injection of a novel cytotoxic agent, could become a standard treatment for third-line ovarian cancer patients who now have few therapy alternatives and very poor prognosis.

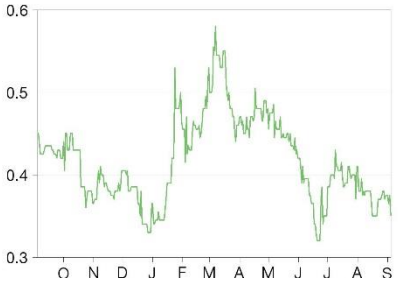
Valuation: Core scenario updated value of A$137m

Kazia is aiming for an accelerated 2023 GDC-0084 approval and 2024 launch, based on Phase IIb/III data. Kazia had A$5.4m cash at 30 June 2019, about A$2m more than our forecast. It will need to raise funds in H219. We estimate ~A$15–20m will be needed to fully fund the GDC-0084 Phase IIb/III study that could start in 2020. Progression of Cantrixil is assumed to require a partner. We maintain our base case 2024 launch scenario but update the value for actual YE cash giving A$137m (A$2.20/share) with a delayed 2026 launch alternative scenario-adjusted value of A$86m (A$1.38/share).

5 September 2019

Price	**A$0.35**
Market cap	**A$22m**
	US$0.76/A$
Cash (A$m) at 30 June 2019	5.4
Shares in issue	62.17m
Free float	90%
Code	KZA
Primary exchange	ASX
Secondary exchange	Nasdaq

Share price performance



%	1m	3m	12m
Abs	(7.9)	(10.3)	(22.2)
Rel (local)	(5.3)	(13.5)	(25.2)
52-week high/low	A$0.58		A$0.32

Business description

Kazia Therapeutics is an ASX- and Nasdaq-listed biotechnology company. It is developing the PI3K/mTOR inhibitor GDC-0084 for drug-resistant brain cancer and Cantrixil for ovarian cancer.

Next events

Cantrixil Phase I preliminary efficacy data	Q419
GDC-0084 Phase IIa preliminary efficacy	Q419

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Edison profile page

Two novel anti-cancer drugs

Kazia Therapeutics is an Australian biotechnology company focused on oncology drug development, listed on both the ASX (KZA) and Nasdaq (KZIA). It has two products in development: GDC-0084 for brain tumours and Cantrixil for refractory ovarian cancer.

GDC-0084 for brain cancer

GDC-0084 is an inhibitor of the membrane-bound signalling enzyme PI3K (phosphoinositide 3 kinase). GDC-0084 now has a provisionally assigned official name, paxalisib, subject to final confirmation. On activation (phosphorylation) by cell surface receptors, PI3K creates a chemical signal to activate both a cell growth pathway and, importantly, the cell survival pathway that blocks cell suicide: apoptosis (Yu and Cui 2016). GDC-0084 is also a moderately potent inhibitor of mammalian target of rapamycin (mTOR) kinase, one of the downstream targets of PI3K signalling.

The PI3K pathway is interesting, compared to other growth signalling systems like MEK-ERK (as activated by the HER2 receptor (blocked by Herceptin) as it responds to changes in the levels of external growth hormones and does not have any signal amplification stage. PI3K is 'switched on' when growth hormone, is detected (for example, by HER 2) and deactivated by an 'off switch': PTEN (phosphatase and tensin homolog).[1]

Blocking PI3K therefore potentially slows cell growth and might encourage cancer cells damaged by radiotherapy or chemotherapy to die. Direct PI3K inhibition is not cytotoxic. Kazia notes that PI3K inhibition in preclinical studies and early clinical data can cause tumour shrinkage. Nonetheless, in our view, it is probably clinically optimal to combine PI3K inhibition with other therapies, such as chemotherapy or radiation. PI3K is found as multiple isoforms and mutations, which makes pharmaceutical targeting more complex (Thorpe et al, 2015).

GDC-0084 was licensed from Genentech in 2016 after a monotherapy Phase I safety and tolerability study showed a good profile at a 45mg dose and indicated retardation of late-stage glioblastoma (GBM) growth with possible shrinkage in some cases; the trial was not an efficacy study, see our June 2019 Note, page 3 for a detailed discussion. Kazia's development focus, Exhibit 1, is on brain cancers as GDC-0084 crosses the blood-brain barrier. Also, brain cancers are very hard to treat and are a frequent complication in up to 30% of metastatic cancer patients.

In primary brain and metastatic brain cancers, there are big needs for new treatments. Glioblastoma remains an active development area with 286 trials of various type ongoing. The best current option is if neurosurgery can debulk the tumour. It is, however, very difficult to surgically remove the entire tumour without causing massive brain injury. Some tumours are inaccessible or too widespread. Radiation therapy is frequently used, but damages surrounding neural tissues. Proton beam therapy is accurate but expensive and places are very limited. Hence, brain tumours invariably reoccur.

The standard chemotherapy is the alkylating agent temozolomide (TMZ). TMZ has excellent brain penetration and will directly damage DNA. However, about 61% of GBM patients produce the enzyme O^6-methylguanine-DNA methyltransferase (MGMT) as they have an unmethylated MGMT gene promoter. MGMT repairs the DNA damage done by TMZ making patients resistant and most gain only minimal benefit (Jiapaer et al, 2018). If GDC-0084 can retard brain tumour growth in TMZ refractory patients, it could find a widespread, standard role.

[1] PTEN mutations are well-known and common oncogenic mutations as they cannot deactivate 'active' PI3K so an active signal persists too long.

Exhibit 1: GDC-0084 trials

Indication	Phase	Size	NCT	Sponsor	Next steps	Data
Newly diagnosed GBM (open label dose and efficacy)	II	66	NCT03522298 (record Sept 2018)	Kazia	MTD determined at 60mg. Now entered a 20-patient dose expansion phase with possible data update in late 2019. Adjuvant treatment given after surgery and radiotherapy with the cell killing agent temozolomide (TMZ) in TMZ resistant patients.	Q419
Genetic testing in brain metastases	II	150	NCT03994796	ACTO** Genentech NCI	This is a three-arm study testing three targeted therapies, CGC-0084 among them. Endpoint will be objective response rate. Due to start in H2 CY19 but not yet recruiting.	Q321
Breast cancer brain metastases (open label parallel assignment)	II	47	NCT03765983	Dana-Faber	A daily 45mg dose of GDC-0084 given with Trastuzumab every three weeks. The trial has two arms, one without surgical resection, the other with presurgical therapy followed by resection. Progress update H2 CY19.	Q421
DIPG* Children (open label paediatric)	I	41	NCT03696355	St Jude	GDC-0084 will be given 8–12 weeks after radiotherapy. Initial dose escalation then a cohort expansion.	Q121
PI3K-mutated brain metastases	I	18–30	TBA	MSK	In combination with radiation therapy. There will be an initial dose escalation followed by a cohort expansion	H221

Source: Edison Investment Research. Note: *DIPG = diffuse intrinsic pontine glioma. **Alliance for Clinical Trials in Oncology.

Current Phase II

In the ongoing Phase II (NCT03522298) a higher GDC-0084 dose (60mg) than Genentech determined (45mg) has been set as the new maximum tolerated dose (MTD). The patients have been predicted to be TMZ resistant as they produce MGMT. All patients undergo prior surgical tumour debulking and combined radiation and TMZ therapy using the Stupp regimen (Stupp *et al* 2005). [2] There was an initial GDC-0084 dose escalation Phase IIa stage, now complete.

The trial is now in a Phase IIb cohort-expansion efficacy stage with 20 patients at a 60mg dose. Patients receive GDC-0084 until disease progression or an unacceptable toxicity, whichever occurs first. The outcome might be announced by December 2019. As this is a small, open-label, safety study with no comparator arm, the outcome is indicative, but not confirmatory, of potential efficacy.

Next-step – randomised Phase IIb/III

If tolerability and signs of efficacy are seen in the current Phase IIb expansion cohort, Kazia aims to run a randomised, comparative Phase IIb/III study in 228 patients with recently diagnosed GBM. This study will compare maintenance therapy with GDC-0084 vs standard-of-care TMZ. Patients will first undergo surgery to remove the bulk of the tumour followed by a radiation therapy combined with TMZ (Stupp regimen). Patients will be then randomised to receive maintenance therapy with either GDC-0084 or TMZ.

The aim is to delay recurrence of the cancer so the trial will measure progression free survival (PFS) or overall survival (OS). The average of five literature median PFS and OS values in GBM patients with an unmethylated MGMT promoter is PFS of 5.2 months and an OS of 13.8 months (June 2019 Note). This Phase IIb/III might be sufficient for regulatory approval by 2024, although this can be better judged when the outcome of the current cohort expansion data is known.

Other GDC-0084 trials and the new MSK collaboration

Kazia is also evaluating, using a series of alliances, the use of GDC-0084 in metastatic brain cancer and childhood disease. This spreads the clinical and financial risks, but such third-party

[2] Introduced in 2005, Stupp regimen is now the standard of care in glioblastoma. It involves firstly surgical tumour debulking and secondly, combined radiation and TMZ therapy followed, third stage, by six cycles (each of one month) of adjuvant TMZ The Stupp regimen gives two-year survival rates of 26.5% as against 10.4 months with radiotherapy alone – these patients were not stratified for TMZ resistance.

In the Kazia study, the third TMZ monotherapy phase is replaced by GDC-0084 monotherapy as, since these patients have the MGMT resistance profile, they are unlikely to benefit from TMZ monotherapy.

studies can become prolonged. Some of these are structured as initially dose ranging with an 'expansion' cohort. One study (NCT03765983) is in breast cancer metastases combined with Herceptin but at a lower 45mg dose than currently used by Kazia.

The latest MSK-sponsored study, Exhibit 1, is a combination with radiotherapy; the St Jude paediatric trial (NCT03696355) uses GDC-0084 two to three months after radiotherapy. Radiotherapy is standard in brain tumour surgery either post-surgery or if surgical intervention is not feasible. However, 30–50% of patients still progress. A mutation associated with progression is PI3KCA (Samuels and Waldman 2010). This makes the PI3K protein permanently active so sending a constant growth and survival signal. The incidence of this mutation is still not well defined and the literature on this is very limited and based on primary tumour types. The percentage of mutated brain cases will vary depending on the primary cancer type that has metastasized.

Other PI3K products

Outside brain cancers, other companies are developing PI3K inhibitors (Zhao et al 2017); for example, Aliqopa (copanlisib, Bayer) is approved as an iv infusion for the treatment of adult relapsed follicular lymphoma and Zydelig (idelalisib, Gilead) is approved as an oral treatment for chronic lymphocytic leukaemia (CLL) and follicular lymphoma. Copiktra (duvelisib, Verastem) was approved in October 2018 again for leukaemia (CLL) and some lymphomas.

In 2019, the FDA approved Piqray (alpelisib, Novartis) as an oral combination therapy with fulvestrant for metastatic breast cancer therapy for patients with the PI3KCA mutation. This is the same mutation as in the MSK trial discussed above. Use requires a genetic test, which is commercially available. The approval was based on a progression-free survival of 11 months vs 5.7 months on fulvestrant alone; this shows that any effect of GDC-0084 is likely to be disease control not as a cell killing chemotherapy agent. The overall response rate, a secondary endpoint, improved from 16.2% to 37.5%. These other products show that PI3K inhibitors work and can gain regulatory approval.

In glioblastoma, Roche/Genentech has a Phase I PI3K pathway inhibitor (Ipatasertib[3]) in a combination dose and safety trial (NCT03673787, data, if released, Q121). No other PI3K inhibitor brain cancer studies have progressed.

Cantrixil for ovarian cancer

Cantrixil is a novel chemotherapy agent: TRX-E-002-1. It was discovered by Novogen working with Yale. Its mechanism of action has been recently investigated. TRX-E-002-1 is claimed to be cytotoxic to undifferentiated stem-like cancer cells and also to differentiated (more 'mature') cancer cells. Although various targets are proposed there is no definitive evidence of the mode of action (Stevenson et al 2018). Lack of a clear biochemical mode of action is not a clinical drawback – if it works – and a generalised, multi-target effect might help prevent cancer resistance developing.

TRX-E-002-1 is combined with cyclodextrin polymer (Dexolve) to give Cantrixil,[4] presumably as its solubility is limited and this provides a standard way to solubilise and stabilise the product. Cantrixil is given as a weekly intra-peritoneal[5] administration so in effect a depot dose. It will slowly dissolve

[3] Ipatasertib (GDC-0068) inhibits Protein Kinase B (also called Akt), a key signalling enzyme downstream of PI3K that is activated by the phosphorylated lipids (such as phosphatidylinositol (3,4,5)-trisphosphate) created by PI3K. Ipatasertib should have similar biochemical effects to GDC-0084 although clinical profiles will differ.

[4] Note that Cantrixil is a company brand name and its generic and brand names are likely to differ.

[5] This is a fluid filled, narrow cavity between the muscles of the abdomen and a membrane that encapsulates the intestines and, in women, ovaries. It normally acts to protect the intestines. Presumably some level of TRX-E-002-1 will diffuse into the abdomen and have an anti-tumour effect on an ovarian cancer mass. It may also stop penetration of the peritoneal cavity by the tumour.

and create a therapeutic reservoir in the abdominal cavity. As an intraperitoneal formulation, it will, if approved, mostly be a specialist hospital product.

A Phase I trial of Cantrixil in ovarian cancer, Exhibit 2, is expected to report preliminary efficacy data from a 12-patient expansion cohort in H219. These patients receive monotherapy at the maximum tolerated dose of 5mg/kg determined in April 2019.

Exhibit 2: Cantrixil clinical trials

Indication	Phase	NCT	Sponsor	Next steps	Data
Ovarian cancer	I	NCT02903771	Kazia	Efficacy from 12-patient expansion cohort	October 2019

Source: Edison Investment Research

Ovarian cancer accounts for 22,400 new cases and 14,100 deaths in the US each year, with a five-year survival rate of 47%. The majority of those diagnosed already have distant metastases, which is associated with a 28.9% five-year survival rate. The expansion cohort data will enable the potential role of Cantrixil in ovarian cancer to be better assessed. Initial data was presented in April.

The likely role for Cantrixil on current data is as a therapy for patients who are platinum refractory or who become platinum resistant over time. On current third-line therapy, such patients have a PFS of approximately 3.5 months and OS of 12 months so there is a major unmet medical need.

If Cantrixil shows signs of having good cytostatic or cytotoxic activity when the trial reports, it could be a relatively easy niche product to develop further given the large medical unmet need in refractory ovarian cancer. It is possible that a robust case could be made for investing in further internal development. However, refractory ovarian cancer is a notoriously difficult cancer to treat with typical response rates to topotecan and paclitaxel in the 10–15% range with overall survival of approximately 12 months and no breakthroughs apparent.

Valuation

The value, last revised in June 2019, varies depending on the approval, pathway and launch date of GDC-0084. Our assigned clinical probability of success for GDC-0084 is 25% (or 20% depending on the indication). Other trials have a 20% probability. We assume Kazia pays a royalty of 10% of net sales to Genentech.

GDC-0084 2024 base case

Our base case valuation of A$137m (updated from A$135m to include actual year-end cash) models a GDC-0084 market launch in 2024 following a single Phase IIb pivotal study. This scenario assumes that GDC-0084 is out-licensed to a marketing partner in 2023 in a deal that includes US$40m upfront and US$120m in clinical and regulatory milestone payments. In this scenario, global sales for GBM reach US$1,050m in 2030.

This scenario is equivalent to A$2.20/share and A$2.11/share after diluting for options and convertible notes. Kazia is also listed on Nasdaq under the code KZIA, with each Nasdaq-listed ADR representing 10 ordinary shares. Our undiluted base case valuation equals US$16.50 per ADR at current exchange rates.

GDC-0084 2026 alternative scenario

An alternative scenario for GDC-0084 assumes a market launch in 2026 because a Phase III study is needed for FDA approval. Although partnering in 2023 is still assumed, Kazia receives a lower 15% royalty rate and a smaller US$20m upfront payment due to the risk and cost of the Phase III; other deal terms remain as before. On these revised assumptions, the valuation becomes A$86m (adjusted for actual year-end cash) or A$1.38/share (undiluted).

Cantrixil

Currently, we assign Cantrixil a 10% probability of overall clinical success and assume a $600m market in refractory ovarian cancer. These estimates will be revised once the current trial data is available. A 5% royalty to Yale is assumed.

Financials

Kazia had A$5.4m cash on 30 June 2019. The operational FY19 cash use was A$6.8m after R&D tax rebates of A$1.4m. This was funded by the sale of a shareholding in Noxopharm for A$2.4m and by raising A$3.8m net (A$4.1m gross less A$0.3m costs) in new equity. In addition, A$1.25m of equity was issued (non-cash) as a milestone connected with the purchase of Glioblast (acquisition of GDC-0084). This led to a net cash outflow of A$0.5m for the year.

Although Kazia reported income of A$1.5m (vs A$13m in FY18) this was mostly a tax rebate. In FY18 there was a large legal settlement (A$8.4m) with Noxopharm and a further (A$2.2m) tax rebate plus non-cash items and grants. Currently, Kazia does not have partnering income. We have now treated the FY18 Noxopharm settlement as an exceptional item to give a clearer picture of true costs. Fewer non-cash items were charged in FY19 vs FY18 but a fair value change of A$1.8m was made (A$1.1m in FY18). On this analysis, management carefully controlled cash costs in FY19. We still project higher cash costs in FY20 and FY21 as larger clinical trials need to be funded. The projected loss appears to reduce because no non-cash adjustments are included in the forecast.

We expect year-end cash to be sufficient to support operations through H2 CY19 but some further funding will be needed by Q4 CY19 as any partnering deals are probably not before H2 CY20. We estimate Kazia will need additional funds of A$15–20m from mid-CY20 to finance the GDC-0084 Phase IIb GBM study planned to start probably in mid CY20. We have not assumed funding for a Phase II Cantrixil study. To cover this, we have assumed additional long-term debt of A$5m in FY20 and a further A$11m in FY21 in our forecasts, but this could be from equity or partnering.

Exhibit 3: Financial summary

A$000s	2018	2019	2020e	2021e
Year end 30 June	AASB	AASB	AASB	AASB
PROFIT & LOSS				
Sales, royalties, milestones	693	34	0	0
Other (includes R&D tax rebate)	2,200	1,431	1,500	1,500
Revenue	2,893	1,465	1,500	1,500
R&D expenses	(9,774)	(6,476)	(7,200)	(9,100)
SG&A expenses	(4,051)	(2,594)	(3,000)	(3,500)
Other	0	0	0	0
EBITDA	(10,932)	(7,604)	(8,700)	(11,100)
Operating Profit (before amort. and except.)	(11,142)	(7,711)	(8,700)	(11,100)
Intangible Amortisation	(1,336)	(1,084)	(1,000)	(1,000)
Exceptionals	8,411	0	0	0
Operating Profit	(6,687)	(10,568)	(9,700)	(12,100)
Net Interest	119	0	0	0
Profit Before Tax (norm)	(11,023)	(7,711)	(8,700)	(11,100)
Profit Before Tax (reported)	(6,344)	(10,568)	(9,700)	(12,100)
Tax benefit	305	298	0	0
Profit After Tax (norm)	(10,718)	(7,413)	(8,700)	(11,100)
Profit After Tax (reported)	(6,039)	(10,270)	(9,700)	(12,100)
Average Number of Shares Outstanding (m)	48.4	57.5	62.2	62.2
EPS - normalised (c)	(22.2)	(12.9)	(14.0)	(17.9)
EPS – diluted (c)	(21.1)	(12.4)	(13.5)	(17.2)
EPS reported (c)	(12.5)	(17.9)	(15.6)	(19.5)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	18,915	13,662	12,662	11,662
Intangible Assets	14,579	13,494	12,494	11,494
Tangible Assets	1	0	0	0
Investments	4,335	168	168	168
Current Assets	9,260	7,514	3,814	3,714
Stocks	0	0	0	0
Debtors	2,535	1,711	1,711	1,711
Cash	5,956	5,433	1,733	1,633
Other	768	370	370	370
Current Liabilities	(3,888)	(1,900)	(1,900)	(1,900)
Creditors	(2,067)	(1,764)	(1,764)	(1,764)
Short term borrowings	0	0	0	0
Other	(1,821)	(136)	(136)	(136)
Long Term Liabilities	(5,046)	(5,081)	(10,081)	(21,081)
Long term borrowings	0	0	(5,000)	(16,000)
Other long-term liabilities	(5,046)	(5,081)	(5,081)	(5,081)
Net Assets	19,242	14,195	4,495	(7,605)
CASH FLOW				
Operating Cash Flow	(8,780)	(6,714)	(8,700)	(11,100)
Net Interest	119	0	0	0
Tax	0	0	0	0
Capex	0	0	0	0
Acquisitions/disposals	150	2,359	0	0
Equity Financing	0	3,816	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(8,511)	(539)	(8,700)	(11,100)
Opening net debt/(cash)	(14,455)	(5,956)	(5,433)	3,267
HP finance leases initiated	0	0	0	0
Other	13	16	0	0
Closing net debt/(cash)	(5,956)	(5,433)	3,267	14,367

Source: Kazia Therapeutics accounts, Edison Investment Research

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