Kazia Therapeutics

Company update

Deep dive into childhood brain cancer

Pharma & biotech

In light of the positive newsflow from Kazia's efforts in addressing adult brain cancer, management is leveraging its niche expertise and experience to address a complex and untapped segment, childhood brain cancer. Due to the challenges in addressing this unmet need, including significant hurdles in enrolling patients for a clinical trial, there is a vacuum of options for those served with this diagnosis. As Kazia is working to pioneer this sub-segment, leveraging its network, in this note we examine the science and attempt to connect the dots on the potential market opportunity and dynamics despite the limited data points to date.

Year end	Revenue (US$m)	PTP* (US$m)	EPADR* (US$)	DPADR (US$)	P/E (x)	Yield (%)
12/20	0.8	(7.8)	(1.04)	0.0	N/A	N/A
12/21	11.0	(3.2)	(0.26)	0.0	N/A	N/A
12/22e	0.0	(17.2)	(1.27)	0.0	N/A	N/A
12/23e	0.0	(19.9)	(1.47)	0.0	N/A	N/A

Note: *Converted at A$1.38/US$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

Positive data on adult brain cancer

Kazia continues to progress its main asset, paxalisib, in addressing adult brain cancer. The company recruited its first patient in the paxalisib arm of the GBM AGILE study in January 2021 and remains on track to recruit approximately 200 patients, with data expected in H2 CY23. The first site outside of the United States (in Canada) became operational in November 2021 and site expansion into Europe and China is planned for Q2 CY22 (partner Simcere's investigative new drug application was approved in China in January 2022). With multiple programs expected to read out in CY22, including studies assessing paxalisib in brain metastases (BMs) in Q2 CY22 (one Phase I and two Phase II trials, sponsored by Sloan-Kettering, the NIH and Dana-Farber, respectively) and interim data from the EVT801 Phase I study in H2 CY22, we foresee several potential inflection points for the company in the coming months. This progress in adult brain cancer trials provides Kazia with the experience and capabilities that would likely make an extension into child brain cancer, an untapped market opportunity, a natural move.

Valuation: Remains unchanged

Our NPV valuation of US$294m or US$22.28 per basic ADR remains unchanged. Kazia reported net cash of US$11.0m (A$15.2m) at the end of December (2021), which we estimate will fund the company into H123 (H2 CY22). We expect the company will need to seek roughly US$51m in financing (including US$22m in FY23 and US$22m in FY24). Kazia established a US$35m at-the-market program in April 2022, which may fulfil a portion of our projected funding needs. The company had gross cash of A$6.958m at 31 March and in its 4C quarterly statement management reported a Q322 operating cash burn rate of A$6.5m.

24 May 2022

Price	**US$5.84**
Market cap	**US$78m**
	ADR/Ord conversion ratio 1:10
Net cash (US$m) at 31 December 2021	11.0
ADRs in issue	13.39m
ADR code	KZIA
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR price performance

52-week high/low	US$12.0	US$5.2

Business description

Kazia Therapeutics is a late-stage clinical pharmaceutical company with lead asset paxalisib (a PI3K inhibitor that can cross the blood-brain barrier, licensed from Genentech), in a pivotal study for GBM. It also recently in-licensed the Phase I drug EVT801, an inhibitor of lymphangiogenesis in tumors.

Next events

ASCO presentation	5 June 2022
ISPNO presentation	11–12 June 2022

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Edison profile page

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Natural extension into child brain cancer

Having established a foothold in adult brain cancer drug development, Kazia's management is well positioned to extend its platform into child brain cancer. To date, the only options for child brain cancer are intensive radiation and chemotherapy and, in cases where possible, surgery. Despite significant advances in these treatment approaches, the possibility of long-term, debilitating side effects highlights a pressing unmet medical need. The challenges of conducting complex clinical trials for adults are compounded in the smaller children population, including recruitment. Having established a strong recruitment and key opinion leader (KOL) network in brain cancer, the company management is able to collaborate with institutions and organizations such as St. Jude Children's Research Hospital. We expect that the current lack of treatment options and the company's progress to date should allow the company to progress in seeking novel solutions to address child brain cancer.

Paxalisib as a targeted therapy for DIPG

Kazia Therapeutics is investigating the use of paxalisib, a dual inhibitor of mTOR and PI3K, in diffuse intrinsic pontine glioma (DIPG), which is primarily a childhood cancer. Based on preclinical data to date, paxalisib has an uncommon ability to effectively cross the blood-brain barrier (BBB), making it well suited for central nervous system (CNS) indications. PI3K and mTOR amplification/overexpression is estimated to be a driver of tumor progression in up to 80% of DIPG tumors, highlighting this as a potential target for chemotherapy in DIPG. Significant activation of the PI3K/mTOR pathway has also been observed in atypical teratoid rhabdoid tumor (ATRT), a highly aggressive form of CNS cancer primarily diagnosed in early childhood (described further below).

Paxalisib has been shown to inhibit tumor growth in a Phase I trial (NCT01547546), demonstrating stable disease in 19 patients (40%) with progressive or recurrent high-grade gliomas (HGGs) with minimal dose-limiting toxicities. Furthermore, the first patient in a Phase II investigator-led study (NCT05009992) for the treatment of DIPG and other diffuse midline gliomas (DMGs) with paxalisib, was dosed in November 2021. This study utilizes an adaptive platform design to study paxalisib in combination with ONC201 (dopamine D2 receptor inhibitor) with or without radiotherapy in the treatment of DMGs. An adaptive platform trial allows multiple interventions to be evaluated simultaneously in a randomized study. Outcomes can be assessed on accrued data rather than a specified sample size and can inform the trial design as initial questions are answered, making the trial open-ended. This design could potentially overcome problems associated with small patient populations in DIPG. Kazia is completing a further Phase I trial, in collaboration with St. Jude Children's Research Hospital, investigating the safety and efficacy of paxalisib in pediatric patients with newly diagnosed DIPG or DMGs after radiation therapy.

Preclinical data from Dr Raabe and Dr Barnett (physician scientists at Johns Hopkins University), presented at the AACR Annual Meeting 2022, has identified strong synergism using a combination of RG2833 (an HDAC1/3 inhibitor) and paxalisib to treat DIPG. Evaluation of this combination is ongoing; however, these finding suggest a new possible combination for paxalisib in treating DIPG.

Encouraging preclinical data in ATRT

Kazia recently presented results at the AACR Annual Meeting 2022, highlighting the effect of certain paxalisib combinations in preclinical ATRT models. The company reported that Paxalisib slowed tumor growth in orthotopic xenograft models of ATRT and extended median survival from 40 to 54 days. Furthermore, paxalisib combined synergistically with clinical asset TAK580 (DAY101, a pan-RAF kinase inhibitor from Day One Biopharmaceuticals, being studied in NCT03429803, NCT04775485) to reduce ATRT cell growth and viability. Additionally, Kazia reported preclinical

findings showing that Paxalisib in combination with RG2833 decreased ATRT cell growth and increased apoptosis. Both combinations were confirmed to be more effective than paxalisib alone in mouse ATRT xenograft pilot studies. We anticipate these findings will form the basis of new clinical trials for the investigation of paxalisib in ATRT as a monotherapy and/or in combination.

Just scratching the surface

Despite the continued innovation of targeted and immunotherapy drugs in adult oncology, there are no meaningful options to address child brain cancer. Using adult glioblastoma (GMB) as a proxy (as childhood cancers are very rare and hence licensing deals in these indications are even more rare), we have summarized comparisons of potential licensing deals for paxalisib in Exhibit 1. From this, licensing deals for kinase inhibitors in GBM appear to range from US$70m to nearly US$400m.

Exhibit 1: Licensing deals for kinase inhibitors in GBM

Deal date	Licensee	Licensor	Generic name	Mechanism of action	Deal value (US$m)	Upfront cash (US$m)
30/01/2018	BridgeBio Pharma	Novartis	infigratinib	Fibroblast growth factor receptor (FGFR) antagonist	112	15
01/02/2018	CANbridge Pharmaceuticals	Puma Biotechnology	neratinib maleate	Epidermal growth factor receptor (EGFR) inhibitor	70	30
11/06/2019	Zai Lab	Deciphera Pharmaceuticals	ripretinib	Platelet-derived growth factor receptor (PDGFR) antagonist	205	20
01/04/2021	Royalty Pharma	GlaxoSmithKline	cabozantinib (S)-malate	AXL inhibitor; vascular endothelial growth factor receptor (VEGFR) antagonist	392	342
01/11/2021	EOC Pharma	Aadi Bioscience	sirolimus (albumin-bound)	Mammalian target of rapamycin (mTOR) inhibitor	271	

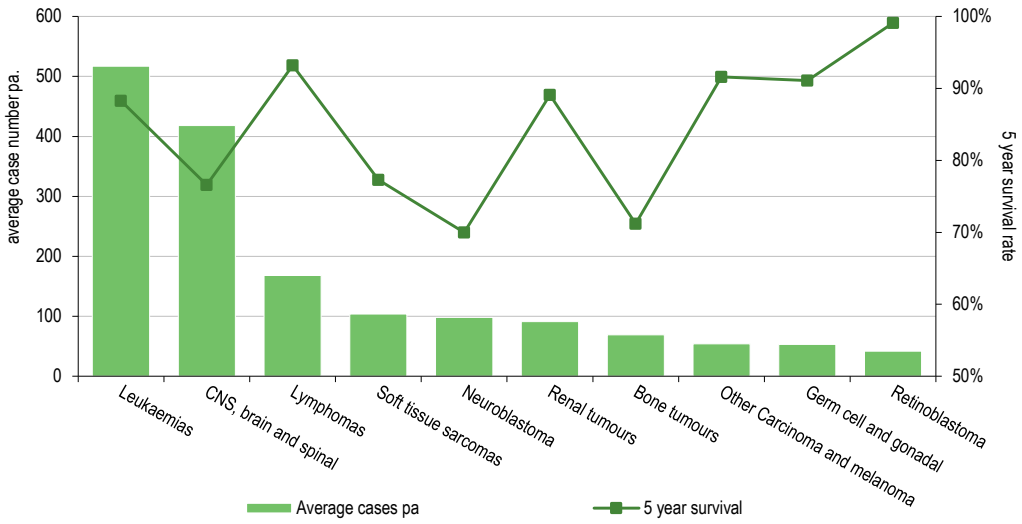
Source: Evaluate Pharma Edison Investment Research

Pediatric oncology: An overview

Childhood cancer is a rare disease

Recent decades have seen the significant innovation of targeted and immunotherapy drugs in the adult oncology space, accompanied by increased survival and quality of life for many patients. Despite this, the field of pediatric oncology is still an area of large unmet medical needs. Childhood cancers of all types are rare: an estimated 10,470 children in the United States under the age of 15 will be diagnosed with cancer in 2022, compared to 1.9 million adults. Exhibit 2 highlights average UK case numbers for the 10 most common pediatric cancers. For biotech and pharmaceutical companies looking to address indications in this field, there are considerable obstacles to overcome. Low patient numbers can result in difficulties filling clinical trials, particularly in less prevalent cancers. Furthermore, many childhood cancers are not observed in the adult population, as they tend to be driven by different factors, hence limiting the read-across from approved chemotherapy agents.

Exhibit 2: Average childhood cancer cases and five-year survival by diagnosis*



Source: Children, teenagers and young adults UK cancer statistics report 2021. Note: *Cases averaged over 1997–2016 in patients <15 years old.

Current standards of care risk chronic health conditions

Owing to the difficulties associated with developing drugs for pediatric oncology, and the absence of targeted therapies in many cases, treatment of childhood cancers often focuses on radiotherapy and the intensification of chemotherapeutic regimens. Optimization of such multimodal treatments commonly succeeds (80% of pediatric oncology patients survive for at least five years after diagnosis), however the surviving children often experience chronic health effects. This is highlighted in a 2006 study that calculated the cumulative incidence of chronic health conditions in childhood cancer survivors as 73.4% by age 30. Serious chronic conditions reported include cardiomyopathy and secondary cancers. Thus, there is a clear unmet medical need for targeted therapies that can avoid the use of intensive chemo- and radiotherapy in pediatric oncology patients.

Incentives exist for pediatric drug developers

To address the problems associated with drug development in pediatric oncology, governments and regulators have implemented a selection of initiatives to incentivize development. For example, in 2012 US Congress expanded the priority review voucher (PRV) program to include drug development in rare pediatric diseases. A drug targeting a qualifying indication that has demonstrated significant improvements in safety and/or efficacy versus standards of care can provide the sponsor with a PRV that can be used for subsequent regulatory applications for other drugs in any indication. Possession of a PRV offers the owner an expedited FDA NDA review process of up to six months (as opposed to a standard NDA review that usually lasts up to 10 months). Importantly, PRVs are transferable and can be sold to other drug developers. As seen in Exhibit 3, this is often for a considerable price, making PRVs a valuable asset to companies they are awarded to. DIPG or other pediatric brain cancer programs studied by Kazia are likely to result in Kazia receiving a PRV if the product eventually gains approval.

Exhibit 3: Recent PRV sales

Company	PRV type	Sold to	Price (US$)	Year
BioMarin	Rare Pediatric Disease	Sanofi and Regeneron	67m	2014
United Therapeutics	Rare Pediatric Disease	AbbVie	350m	2015
Knight	Tropical Disease	Gilead Sciences	125m	2016
Sarepta Therapeutics	Rare Pediatric Disease	Gilead Sciences	125m	2017
Spark Therapeutics	Rare Pediatric Disease	Jazz Therapeutics	110m	2019
BioMarin	Rare Pediatric Disease	Undisclosed	110m	2022

Source: Edison Investment Research

The FDA Orphan Drug Designation (ODD) initiative provides another major incentive for the development of pediatric oncology drugs. Qualifying drugs intend to treat, prevent or diagnose rare conditions or diseases that affect fewer than 200,000 people in the United States. Owing to the rarity of childhood cancers, almost all drugs developed to treat a pediatric oncology indication will qualify for this initiative. An ODD qualifies the recipient for benefits including potential market exclusivity of seven years after approval and tax credits for clinical trials.

Pediatric brain cancers have unmet medical needs

According to the NCI SEER program, brain cancer is the second most common cancer in children, representing ~16% of all new cancer diagnoses in that age group.

Diffuse midline gliomas

A particularly aggressive and invasive high-grade (Grade IV) glioma that mostly affects young children is DIPG (previously known as diffuse midline glioma, DMG). Tumors of this kind are found in an area of the brain known as the pons, a crucial brainstem structure involved in a range of basic human functions such as breathing, hearing, taste, eye movement and balance. DIPG is predominantly diagnosed in children aged five to 10 and rarely occurs in the adult population. While the incidence of DIPG is low (one to two per 100,000 in US, ~300 new pediatric cases per year), most patients will survive less than one year after diagnosis (median overall survival rate 9–11 months). This stark prognosis is due to the highly invasive and aggressive nature of DIPG often making surgical resection impossible, the heterogeneity of DIPG tumors and the lack of FDA approved targeted treatments. Current standard of care for DIPG patients is palliative radiotherapy and despite modern advances in radiology, outcomes for survival have not changed over the past 20 years.

Up to 90% of DIPGs possess a lysine-27 to methionine point mutation in histone 3 (H3K27M), which is strongly correlated with poor prognosis in such patients. Importantly, the H3K27M mutation cooccurs with changes in signaling genes, including receptor tyrosine kinases, transcriptional

regulators, cyclin-dependent kinases, intracellular kinases and tumor suppressors. These mutations may offer attractive targets for new targeted therapy development. A selection of drugs in development for the treatment of DIPG is summarized in Exhibit 4.

Exhibit 4: Targeted therapies in clinical trials for DIPG

Drug	Sponsor/collaborator	Phase	Mechanism of action	Notes
Panobinostat	Pediatric Brain Cancer Consortium	**Phase I – NCT02717455**	Histone deacetylase inhibitor	Initiated in 2016, aims to enroll 53 patients to investigate panobinostat in treating DIPG
Ribociclib	Children's Hospital Medical Center, Cincinnati/ Novartis	**Phase I – NCT03355794**	Cyclin-dependent kinase 4/6 inhibitor	Investigating ribociclib in combination with everolimus (Afinitor) following radiotherapy in newly diagnosed DIPG
Adavosertib	National Cancer Institute	**Phase I – NCT01922076**	Wee1 inhibitor	Investigating adavosertib with or without local radiation therapy in treating newly diagnosed pediatric DIPG
Dasatinib	St. Jude Children's Research Hospital	**Phase I – NCT01644773**	Multi-tyrosine kinase inhibitor	Study completed in March 2019 – dasatinib in combination with crizotinib in treatment of DIPG and HGG. A potential interaction was observed.

Source: clinicaltrials.gov, Edison Investment Research

Atypical teratoid rhabdoid tumor

Atypical teratoid rhabdoid tumor (ATRT) is another highly aggressive (always diagnosed as Grade IV) form of CNS cancer primarily diagnosed in early childhood. Tumors of this type represent the most common malignant CNS cancer in children below one year of age and over 90% of diagnoses are made in children younger than three years. ATRT diagnosis is incredibly rare, with an estimated 596 people living with the cancer in the United States, or ~60 cases reported each year, and only 50 cases ever reported in adults. The primary treatment for ATRT is multimodal and involves maximum safe surgical resection followed by adjuvant chemo- and radiotherapy, which are accompanied by often severe side-effects. Despite this aggressive line of treatment, many patients will become refractory to therapy and the prognosis for ATRT is generally poor, reflected in a relative five-year survival rate of 32.2%.

Most ATRTs are characterized by the loss of function mutations of SMARCB1, a gene important for normal cell differentiation, the loss of which is associated with uncontrolled cell proliferation and tumor growth. There are currently no approved targeted therapies for the treatment of ATRT, however various attractive targets have presented themselves and several drugs have entered clinical trials. Examples include vorinostat (a histone deacetylase inhibitor), alisertib (an aurora kinase A inhibitor), ribociclib (a cyclin-dependent kinase 4/6 inhibitor) and dasatinib (a multi-tyrosine kinase inhibitor).

Exhibit 5: Financial summary

Year end 30 June, IFRS, US$000s	2020	2021	2022e	2023e
INCOME STATEMENT				
Revenue	768.8	11,034.2	19.5	0.0
Cost of Sales	0.0	0.0	0.0	0.0
Gross Profit	768.8	11,034.2	19.5	0.0
R&D	6,879.9	10,537.2	16,282.6	18,565.2
SG&A	2,673.8	5,088.3	3,237.6	3,657.4
EBITDA	(7,809.3)	(3,213.3)	(17,156.6)	(19,878.6)
Normalized operating profit	(7,809.3)	(3,213.3)	(17,156.6)	(19,878.6)
Amortization of acquired intangibles	(785.8)	(916.9)	(1,415.2)	(1,415.2)
Exceptionals	(465.5)	(1,862.5)	(53.7)	0.0
Share-based payments	(189.9)	(461.1)	(928.8)	(928.8)
Reported operating profit	(9,250.5)	(6,453.8)	(19,554.4)	(22,222.6)
Net Interest	0.0	0.0	0.0	0.0
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0
Pre-Tax Profit (norm)	(7,809.3)	(3,213.3)	(17,156.6)	(19,878.6)
Pre-Tax Profit (reported)	(9,250.5)	(6,453.8)	(19,554.4)	(22,222.6)
Reported tax	216.1	351.0	463.2	526.4
Profit After Tax (norm)	(7,626.9)	(3,038.6)	(16,750.2)	(19,407.7)
Profit After Tax (reported)	(9,034.4)	(6,102.9)	(19,091.2)	(21,696.2)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalized)	(7,626.9)	(3,038.6)	(16,750.2)	(19,407.7)
Net income (reported)	(9,034.4)	(6,102.9)	(19,091.2)	(21,696.2)
Basic average number of ADRs outstanding (m)	7.3	11.8	13.2	13.2
EPADR - basic normalized (US$)	(1.04)	(0.26)	(1.27)	(1.47)
EPADR - diluted normalized (US$)	(1.04)	(0.26)	(1.27)	(1.47)
EPADR - basic reported (US$)	(1.24)	(0.52)	(1.44)	(1.64)
Dividend (A$)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	8,992.9	20,794.4	17,929.9	15,065.4
Intangible Assets	8,992.9	15,943.9	14,528.7	13,113.5
Tangible Assets	0.0	0.0	0.0	0.0
Investments & other	0.0	4,850.5	3,401.2	1,951.9
Current Assets	7,720.0	21,297.7	6,197.5	10,173.6
Stocks	0.0	0.0	0.0	0.0
Debtors	979.9	61.1	64.2	0.0
Cash & cash equivalents	6,350.8	19,990.4	4,887.1	8,927.5
Other	389.4	1,246.2	1,246.2	1,246.2
Current Liabilities	(3,672.1)	(6,033.7)	(6,694.6)	(7,360.9)
Creditors	(2,528.2)	(3,574.4)	(4,235.2)	(4,901.6)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	0.0	0.0	0.0
Other	(1,143.9)	(2,459.3)	(2,459.3)	(2,459.3)
Long Term Liabilities	(2,804.8)	(8,630.3)	(8,167.0)	(29,379.7)
Long term borrowings	0.0	0.0	0.0	(21,739.1)
Other long-term liabilities	(2,804.8)	(8,630.3)	(8,167.0)	(7,640.6)
Net Assets	10,235.9	27,428.1	9,265.7	(11,501.6)
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	10,235.9	27,428.1	9,265.7	(11,501.6)
CASH FLOW				
Op Cash Flow before WC and tax	(7,809.3)	(3,213.3)	(17,156.6)	(19,878.6)
Working capital	1,209.5	(4,051.3)	1,643.8	1,653.4
Exceptional & other	216.1	662.8	409.5	526.4
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(6,383.7)	(6,601.8)	(15,103.3)	(17,698.8)
Capex	0.0	0.0	0.0	0.0
Acquisitions/disposals	0.0	0.0	0.0	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	8,796.9	20,368.7	0.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Net Cash Flow	2,413.2	13,766.9	(15,103.3)	(17,698.8)
Opening net debt/(cash)	(3,937.6)	(6,350.8)	(19,990.4)	(4,887.1)
FX	0.0	(127.3)	0.0	0.0
Other non-cash movements	0.0	0.0	0.0	0.0
Closing net debt/(cash)	(6,350.8)	(19,990.4)	(4,887.1)	12,811.7

Source: Company accounts, Edison Investment Research

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