

Kazia Therapeutics Limited (KZIA)
Rating: Buy

 Sean Lee
 212-356-0521

slee@hcwresearch.com

 Swayampakula Ramakanth, Ph.D.
 212-356-0544
sramakanth@hcwresearch.com

 Arthur He, Ph.D.
 646-975-6958
ahe@hcwresearch.com

 Sean Kang
 646-975-6952
skang@hcwresearch.com
A Unique PI3K Inhibitor for Brain Tumors; Initiate With Buy and \$17 PT

Stock Data		01/04/2021		
Price		\$8.98		
Exchange		NASDAQ		
Price Target		\$17.00		
52-Week High		\$15.85		
52-Week Low		\$2.37		
Enterprise Value (M)		\$57		
Market Cap (M)		\$88		
Public Market Float (M)		6.3		
Shares Outstanding (M)		12.6		
3 Month Avg Volume		484,202		
Short Interest (M)		0.02		
Balance Sheet Metrics				
Cash (M)		A\$31.00		
Total Debt (M)		A\$0.00		
Total Cash/Share		A\$2.46		
Book Value/Share		A\$1.49		
<i>Cash (M): Pro forma</i>				
EPS (A\$) Diluted				
Full Year - Jun	2019A	2020A	2021E	
1st Half	(0.11)	(0.09)	(0.06)	
2nd Half	(0.07)	(0.08)	(0.06)	
FY	(0.18)	(0.17)	(0.13)	
Revenue (A\$M)				
Full Year - Jun	2019A	2020A	2021E	
1st Half	1.2	0.7	0.6	
2nd Half	0.4	0.4	0.8	
FY	1.6	1.1	1.4	



Paxalisib is a unique PI3Ki effective against GBM. Kazia Therapeutics is a clinical-stage oncology company developing novel therapies against brain cancer. The company's lead product is paxalisib, an oral pan-PI3K/mTOR dual inhibitor that can cross the blood-brain barrier to destroy glioblastoma multiforme (GBM) cells. Kazia reported positive interim results from an ongoing Phase 2 study in Dec. 2020, which showed that patients with newly diagnosed GBM and unmethylated MGMT status (50-65% of all GBM) treated with paxalisib on top of standard-of-care (SoC) achieved 60% improved progression-free survival and 40% improved overall survival vs. patients treated with SoC alone. Furthermore, in our view, paxalisib has one of the cleanest safety profiles among PI3K inhibitors and it has been well-tolerated in nearly 100 patients. If approved, we believe paxalisib could become the new SoC for MGMT-unmethylated GBM patients. The drug is being evaluated in the GBM AGILE adaptive pivotal study, which costs significantly less than a traditional Phase 3 study and could report topline results as early as YE2023. We expect paxalisib to launch in 2025 and generate risk-adjusted revenues of A\$401M by FY2030.

Additional indications provide avenue for growth. Beyond GBM, Kazia is also exploring several additional indications that we believe paxalisib is well-suited for, including DIPG and brain metastases caused by breast cancer. In December 2020, the company's partners at St. Jude Children's Hospital reported that the drug is safe for pediatric DIPG patients and has some encouraging early signs of efficacy. We note that the FDA has granted the drug the Rare Pediatric Disease Designation for this indication, which could lead to a priority review voucher with a potential value of over \$100M for Kazia, if approved. We believe breast cancer brain mets, which is being investigated in a Phase 2 study, could become the largest indication for paxalisib in the future with up to 70,000 new cases each year in the U.S. alone.

A catalyst-rich 2021. Kazia and its collaborators are currently running six clinical studies of paxalisib across multiple different indications. Over the next 12 months, we expect Kazia to report results from four of these clinical programs which could become significant catalysts for the stock: (1) the initial results from the Phase 2 study in breast cancer brain mets from Dana-Farber in 1H21; (2) the initial results from the Phase 2 study in brain mets by the Alliance group in 1H21; (3) the initial results from the Phase 1 study in brain mets by Sloan Kettering in 1H21; and (4) the final results from the company's Phase 2 study in newly diagnosed GBM in mid-2021.

Valuation and risks. We are initiating coverage of KZIA with a Buy rating and 12-month price target of \$17 per ADS. We derive our price target based on a risk-adjusted net present value (rNPV) analysis of projected future royalty revenues from paxalisib, assuming an 14% discount rate and a 0% terminal growth rate. We derive an rNPV of A\$374M for the product and add in *pro forma* net cash and cash equivalents of A\$31M, to arrive at a 12-month price target of \$17 per diluted ADS. At that time point, we project the company to have a total of 130M shares of common stock, or 13M ADS. Risks include, but are not limited to: (1) clinical; (2) commercial; (3) financial; (4) pandemic; and (5) intellectual property.



Company Overview

Kazia Therapeutics is a clinical-stage biotech company headquartered in Sydney, Australia and is focused on developing novel therapies for the treatment of cancer. While the company was initially established back in 1994 as Novogen Limited, it had a completely different focus to the oncology drug development company that is Kazia today. In 2016, the company underwent a transformation by bringing a new management team and acquiring new assets, culminating in a name change to Kazia Therapeutics in November 2017. Since then, the company has rapidly expanded its development programs and now has six ongoing clinical studies (Exhibit 1). The company's lead product candidate, paxalisib (formerly GDC-0084), is a small molecule inhibitor of the Phosphoinositide 3-kinases (PI3K) signaling pathway and is designed to treat aggressive cancers of the central nervous system (CNS) including glioblastoma multiforme (GBM). The company licensed paxalisib from Genentech, a subsidiary of Roche (RHHBY; not rated), in 2016 and is currently conducting a Phase 2 study of paxalisib for the treatment of newly diagnosed GBM. In the latest results presented in November 2020, patients who were treated with paxalisib achieved a median progression-free survival (mPFS) of 8.4 months and a median overall survival (mOS) of 17.5 months, which compare favorably to historical mPFS of 5.4 months and mOS of 14.4 months for similar patients. In our view, paxalisib could become a game-changer in the GBM space and reach the market as early as 1H25, and generate risk-adjusted revenues of A\$401M by 2030. In addition to GBM, the company is also developing paxalisib for the treatment of additional neurological malignancies including DIPG and brain metastases. We note that over the last 12 months, there have been several positive data releases which have led to a 94% appreciation in Kazia's stock price (January 2, 2020 to December 31, 2020), compared to a 42% appreciation in the broader NASDAQ composite. We expect the company to reach several additional clinical milestones in the next 12 months (Exhibit 2), which we believe could become further catalysts for the stock.

Exhibit 1: Select Products From Kazia Pipeline, December 2020

Summary of trials				
Asset	Sponsor	Phase	Indication	Registration
GDC-0084	Kazia Therapeutics	II	Glioblastoma	NCT03522298
	Alliance for Clinical Trials in Oncology	II	Brain metastases	NCT03994796
	Dana-Farber Cancer Institute	II	Breast cancer brain metastases (with Herceptin)	NCT03765983
	St Jude Children's Research Hospital	I	DIPG (childhood brain cancer)	NCT03696355
	Memorial Sloan Kettering Cancer Center	I	Brain metastases (with radiotherapy)	(TBA)
Cantrixil	Kazia Therapeutics	I	Ovarian Cancer	NCT02903771

Source: Kazia presentation.

Exhibit 2: Milestones Expected Over the Next 12 Months

Product	Upcoming Milestone Event	Expected Timing	Expected Impact
Paxalisib	Start of patient recruitment in the GBM AGILE study	CY1Q21	Low
Paxalisib	Start of patient recruitment in the Phase 2 PCNSL study at Dana-Farber	CY1Q21	Low
Paxalisib	Start of patient recruitment in the Phase 2 DIPG study by PNOG	CY1Q21	Low
Paxalisib	Initial results from Phase 2 BCBM study at Dana-Farber	CY1H21	Medium
Paxalisib	Initial results from Phase 2 brain mets study by Alliance Group	CY1H21	Medium
Paxalisib	Initial results from Phase 1 brain mets study at Sloan-Kettering	CY1H21	Medium
Paxalisib	Final results from Phase 2 GBM study by Kazia	CY1H21	High

Source: H.C. Wainwright estimates.

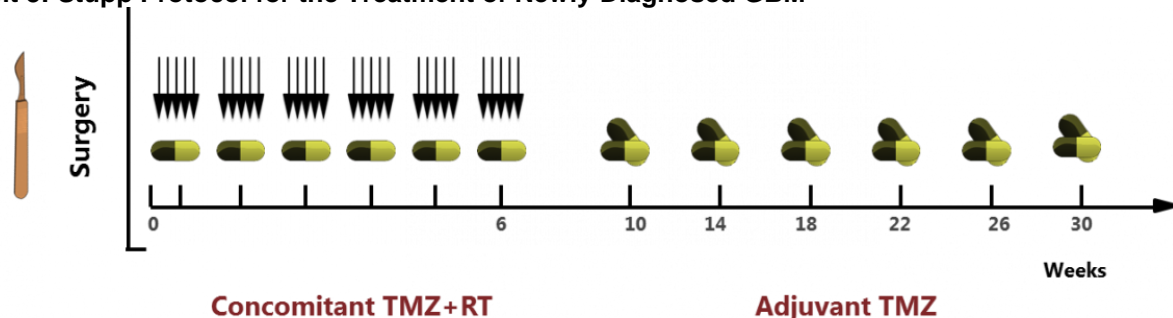
Investment Thesis

Our bullish view on Kazia Therapeutics is based on our positive perception of the following factors: (1) GBM is an indication with significant unmet need; (2) paxalisib belongs to a proven class of therapies and is uniquely able to target brain tumors; (3) paxalisib has demonstrated efficacy against GBM and a clean safety profile; (4) there is potentially an accelerated path to approval; and (5) paxalisib could be used against a broad range of brain tumors.

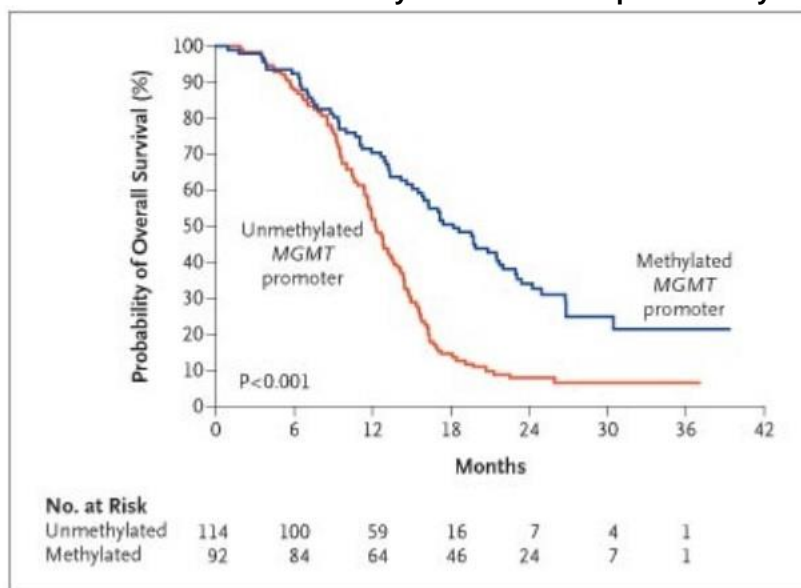
1. GBM is a disease with significant unmet medical need. In recent years, major advances have been made in the treatment of many cancers. However, GBM remains a stubbornly difficult-to-treat disease where available therapies including immunotherapies have had little impact. It is the most common type of primary brain tumor and its hallmark is a heterogeneous cancer cell population with several unique attributes; GBM cells are known to be highly aggressive in infiltrating surrounding tissue, angiogenic, prone to secondary mutations, and are generally resistant to chemotherapy. Each year, approximately 11,000 patients are diagnosed with GBM in the U.S., with a median age of diagnosis of 65, and an additional 20,000 new patients are diagnosed in the EU plus U.K. For GBM patients, their clinical prognosis is usually grim. The survival time for untreated patients is usually less than five months, while those treated with the current standard of care therapies can only expect to survive 12-14 months. For older patients in particular, overall survival is often measured in weeks.

The standard of care treatment for newly diagnosed GBM is the Stupp protocol and it has remained unchanged since 2005. It almost always begins with maximum possible surgical resection of the tumor, which attempts to clear all tumor and surrounding tissue unless it is near a vital, inoperable area of the brain. While surgery can often remove most of the tumor mass and alleviate many of the symptoms, it is almost never able to fully clean out all residual tumor cells. Therefore, surgical resection is most often followed by a combination of radiotherapy (RT) with chemotherapy agents such as temozolomide (TMZ) in order to kill the residual cells (Exhibit 3). However, despite these efforts, virtually all GBM patients still eventually recur, with over 90% of patients experiencing tumor recurrence at the same site as the primary tumor, and often with a very aggressive disease pattern. In particular, the TMZ has been shown to be particularly ineffective in treating GBM patients who have the epigenetic modification of an unmethylated MGMT (O[6]-methylguanine-DNA methyltransferase) promoter, who comprise approximately 50-65% of all GBM patients. Compared to patients with methylated MGMT, whose median overall survival is around 22 months, unmethylated patients have a far lower median overall survival of only around 12 months when treated with the standard of care therapies (Exhibit 4). Over the last 20 years, dozens of chemotherapy, targeted therapy, and immunotherapy agents have been tried in this indication, and none were able to provide any survival benefit beyond a few weeks. Therefore, we believe GBM remains an indication with a significant unmet medical need, especially for patients who have an unmethylated MGMT promoter status.

Exhibit 3: Stupp Protocol for the Treatment of Newly Diagnosed GBM

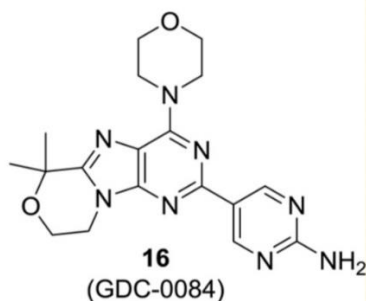


Source: gliotrain.eu, accessed December 2020.

Exhibit 4: Patients with Unmethylated MGMT Respond Poorly to Standard of Care

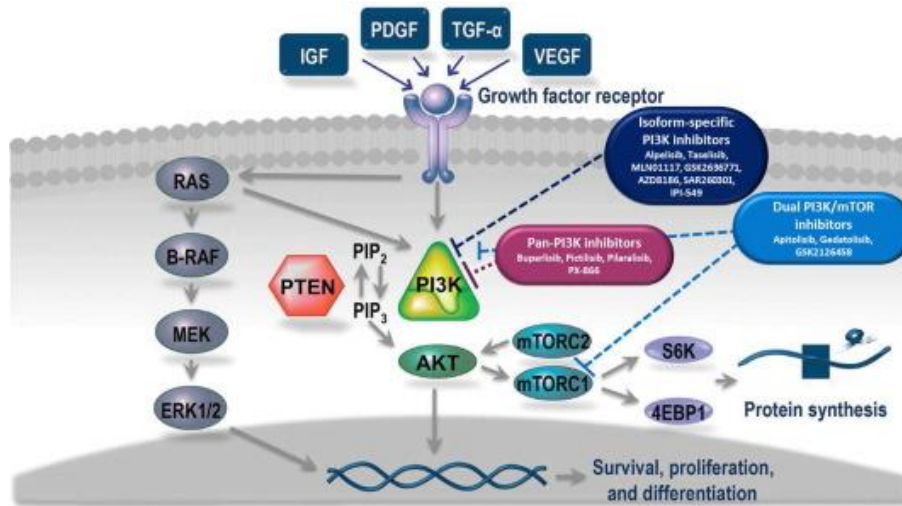
Source: Hegi et al, NEJM, 2005.

2. PI3K-inhibitors are proven cancer therapies and paxalisib is unique among them. Kazia in-licensed the global rights to paxalisib, the company's lead development product, from Genentech in 2016 and has achieved successful results a Phase 2 clinical study for the treatment of newly-diagnosed GBM. Paxalisib is a small molecule that belongs to a class of therapeutics called PI3K-inhibitors (Exhibit 5). PI3K-inhibitors act by inhibiting the Phosphatidylinositol-3-kinase (PI3K)/AKT/mammalian target of rapamycin (mTOR) signaling, which is one of the most important intracellular signaling pathways and is considered a master regulator for cancer. By blocking PI3K/AKT/mTOR signaling, PI3K inhibitors can affect numerous downstream receptor tyrosine kinases, which in turn inhibits cancer cell survival, proliferation, and differentiation (Exhibit 6). Several PI3K-inhibitors have demonstrated strong clinical efficacies and over the last six years have been approved in both the U.S. and the EU for numerous cancer indications. Notably among these are Zydelig (idelalisib) by Gilead (GILD; not rated) for the treatment of chronic lymphocytic leukemia and indolent non-Hodgkin's lymphoma, Aliqopa (copanlisib) by Bayer (BAYRY; not rated) for the treatment of follicular lymphoma, Piqray (alpelisib) by Novartis (NVS; not rated) for the treatment of breast cancer, and Copiktra (duvelisib) by Secura Bio (private) for the treatment of chronic lymphocytic leukemia, small lymphocytic leukemia, and follicular lymphoma. In our view, the clinical benefit demonstrated by these PI3K-inhibitors in both clinical studies and real-world practice suggest that PI3K is highly specific therapeutic target against cancer, which reduces the development risk for paxalisib. Furthermore, we note that many of these PI3K-inhibitors have similar adverse event profiles and are now widely used in clinical practice, which suggests that physicians may be well-practiced in managing paxalisib's potential side effects, further reducing the drug's development risk.

Exhibit 5: Chemical Structure of Paxalisib (GDC-0084)

Source: Heffron et al, ACS Medicinal Chemistry Letters, 2016.






Exhibit 6: Paxalisib Mechanism of Action



Source: Janku, *Cancer Treatment Reviews*, 2017.

While paxalisib is similar to other PI3K-inhibitors in its mechanism of action, it has several unique features that make it particularly well-suited for the treatment of GBM and other tumors of the central nervous system. Most importantly, it is the only PI3K-inhibitor used in the clinic that has been shown to be able to pass through the blood-brain barrier (BBB), a highly selective semipermeable border of endothelial cells that prevents solutes in the circulating blood from crossing into the brain (Exhibit 7). In preclinical studies, paxalisib was found to be able to penetrate both the mouse and the rat BBB, with a measured brain-to-plasma concentration ratio of between 1.4-3.3 one hour after injection. Furthermore, the drug was found to have excellent metabolic stability in blood, in the liver, and in the brain. Finally, we note that unlike the already-approved PI3K-inhibitors on the market, which typically only target 1-2 specific isoforms of PI3K, paxalisib is a pan-PI3K inhibitor that can inhibit all four common forms of PI3K at K_i of between 2-46 nM, and inhibit mTOR at 70 nM, which can help block potential compensating feedback loops. Taken together, we believe that these unique properties make paxalisib uniquely suited among PI3K-inhibitors for targeting GBM and other brain tumors.

Exhibit 7: Comparison of Paxalisib (GDC-0084) to Other Marketed PI3K-Inhibitors

Zydelig (idelalisib)	Aliqopa (copanlisib)	Copiktra (duvelisib)	Piqray (alpelisib)	GDC-0084
				
FDA Approved July 2014 (blood cancers) [accelerated approval] ✓	FDA Approved September 2017 (blood cancers) [accelerated approval] ✓	FDA Approved October 2018 (blood cancers) [accelerated approval] ✓	FDA Approved May 2019 (breast cancer) [accelerated approval] ✓	In phase II human trials under US FDA oversight (brain cancer)
Does <u>not</u> cross blood-brain barrier ✗	Does <u>not</u> cross blood-brain barrier ✗	Does <u>not</u> cross blood-brain barrier ✗	Does <u>not</u> cross blood-brain barrier ✗	<u>Does</u> cross blood-brain barrier ✓
Potentially fatal liver toxicity and diarrhoea ✗	Potentially fatal infections ✗	Potentially fatal infections & diarrhoea ✗	Limited toxicities to date ✓	Appears generally safe and well-tolerated thus far ✓

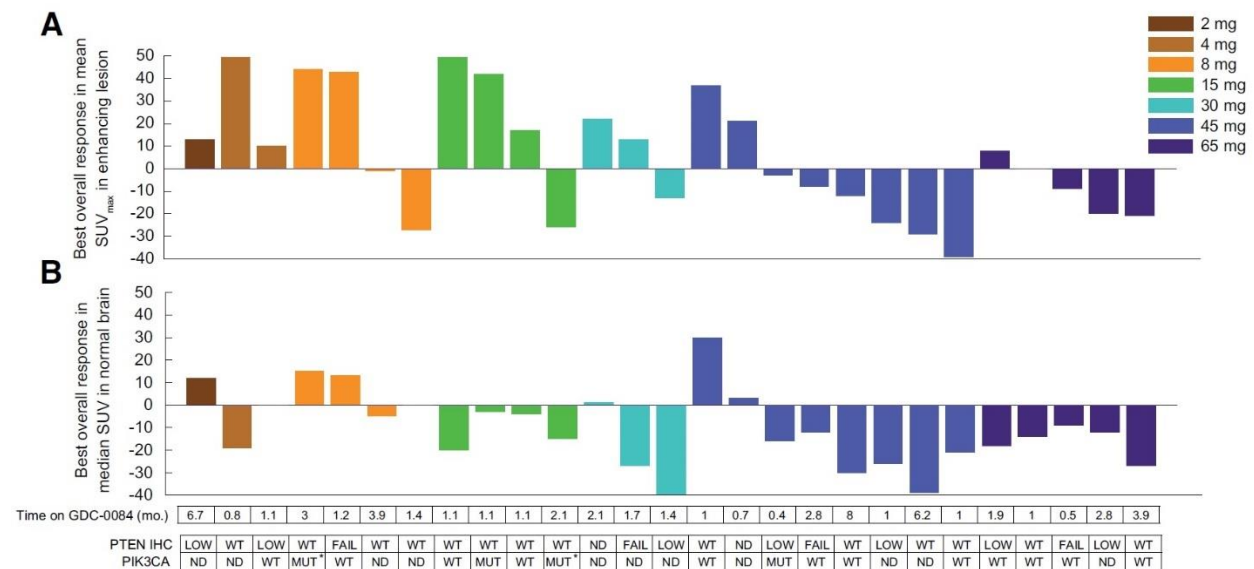
Source: *Kazia presentation*, 2019.

The PI3K/Akt/mTOR signaling network has been found to be highly activated in almost 90% of all glioblastoma. Notably, previous preclinical research suggested that while the PI3K signaling cascade

appears to play only a minor role in GBM cell survival, it appears to be critical in regulating the motility of differentiated glioblastoma cells. In our view, this may be of particular interest as one of the foremost aspects that make glioblastoma highly lethal and difficult to treat is the tumor’s ability to diffuse and invade the surrounding brain tissue. Therefore, if paxalisib treatment is able to shut down the tumor cells’ ability to migrate, it could lead to improved outcomes from traditional localized treatment such as surgery, radiation and chemotherapy, and lead to prolonged survival.

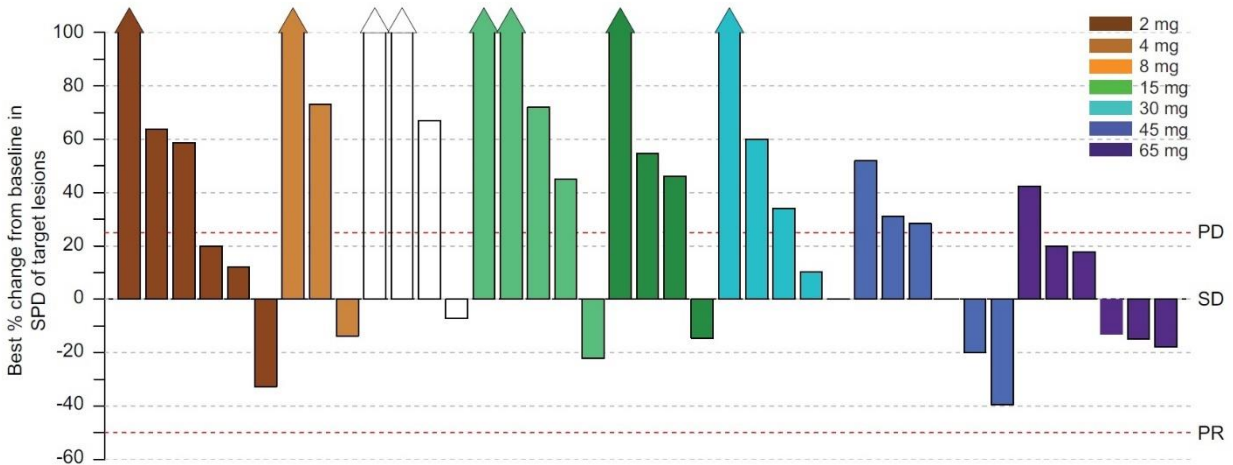
3. Paxalisib has demonstrated clinical benefit and a quick route to market. Since 2012, paxalisib has been investigated in seven clinical studies across a variety of CNS malignancies. Genentech, who originally discovered the drug candidate, completed a Phase 1 study in patients with progressive or recurrent high-grade gliomas in 2015. The primary objectives of this first-in-man study were to assess the safety, tolerability, and pharmacokinetics of paxalisib using a standard 3x3 design. A total of 47 heavily pretreated patients were enrolled into eight cohorts who received drug doses ranging from 2-65 mg per day. In terms of safety, paxalisib was found to be generally well-tolerated. The reported dose-limiting toxicities were bradycardia and myocardial ischemia, stomatitis, and mucosal inflammation. A total of seven patients (15%) experienced serious adverse events (SAEs) including dry skin, fatigue, hyperglycemia, myocardial ischemia, pneumonia, pruritus, and stomatitis, but we note that there were no SAEs higher than grade 3. Six patients (13%) experienced SAEs that resulted in dose reduction or discontinuation. We note that these safety results from the Phase 1 study suggest that paxalisib may be a safer drug compared to other approved PI3K inhibitors. For example, in the Phase 2 study of Aliqopa for the treatment of relapsed or refractory lymphomas, SAEs were reported in 50% of patients, dose reductions or interruptions occurred in over 70% of patients, and 4 out of 84 patients (5%) died due to drug-related side effects. Notably, unlike buparlisib, another PI3K inhibitor that has been tested in GBM, paxalisib treatment did not lead to any neuropsychiatric complications. In terms of efficacy, while no objective responses were assessed using RANO criteria, 7 out of 27 patients (26%) with FDG-PET data showed a metabolic partial response (Exhibit 8). A distinct trend toward lower SUV is seen in patients who received the 45 mg or 65 mg doses, which suggest a dose responsiveness to the drug. Nineteen patients (40%) on the study experienced stable disease as their best response (Exhibit 9). In our view, while the drug only achieved limited clinical benefits in the heavily pretreated patients (mean number of prior therapies = 3) in this Phase 1 study, it nonetheless showed promising signs of efficacy that warrant additional investigation.

Exhibit 8: Partial Metabolic Responses Observed in Phase 1 Study of Paxalisib



Source: Wen et al, Clin Can Res, 2020.

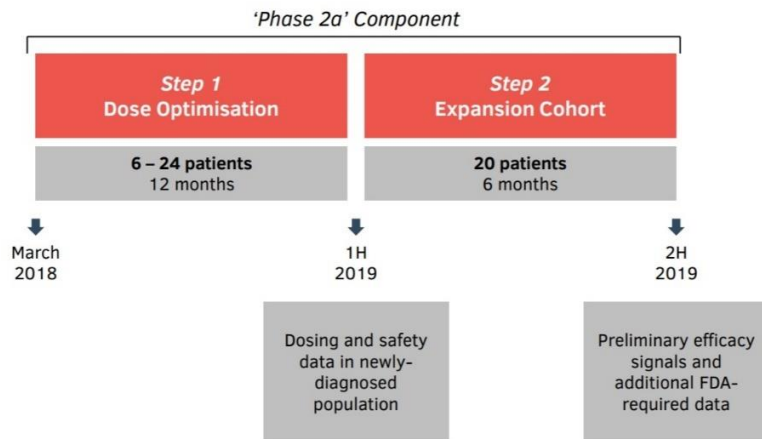
Exhibit 9: Patient Response Shows a Trend Towards Stable Disease at Higher Doses



Source: Wen et al, Clin Can Res, 2020.

Following the acquisition of global rights to paxalisib from Genentech in 2016, Kazia initiated a company sponsored Phase 2 study in newly-diagnosed GBM that has presented the most compelling results of clinical efficacy to date. The study is conducted in the US and is expected to enroll a total of 32 patients, divided into a dose-escalation cohort followed by a dose expansion cohort (Exhibit 10). Patients enrolled in this study must have newly-diagnosed GBM with unmethylated MGMT promotor status, which means that they are unlikely to benefit from TMZ treatment, and must have undergone maximal surgical resection and external beam radiation therapy in accordance with the Stupp regimen. According to the study protocol, patients will receive 60 mg or 75 mg of paxalisib per day together with standard of care TMZ until disease progression. The primary outcome measure of the study is safety and tolerability, while the secondary outcome measures include overall survival (OS), progression-free survival (PFS), disease control rate (DCR), metabolic response, and pharmacokinetics.

Exhibit 10: Design of the Paxalisib Phase 2 Study



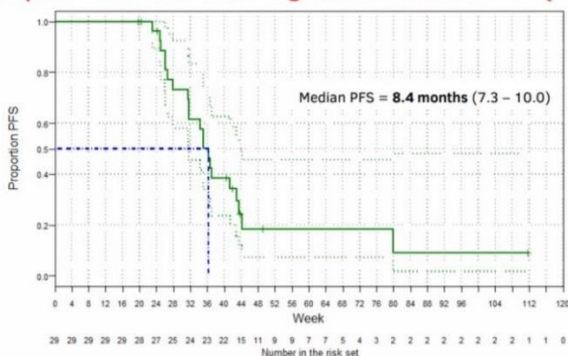
Source: Kazia presentation, 2019.

Kazia presented the latest interim results from the Phase IIa study at the 2020 Society of Neuro-Oncology annual meeting held in December. A total of 29 patients have so far received paxalisib and are evaluable for response as of August 31, 2020, with 24 patients having received the 60 mg dose and 5 patients the 75 mg dose. Overall, they achieved a median PFS of 8.4 months (CI: 7.3-10.0) and a median OS of 17.5 months (CI: 15.0-NR, Exhibit 11). We note that these results compare favorably to historical outcomes in similar patients treated using the standard of care, which on average resulted in median PFS of 5.4 months and median OS of 14.4 months (Exhibit 12). Furthermore, the latest update remains consistent with the

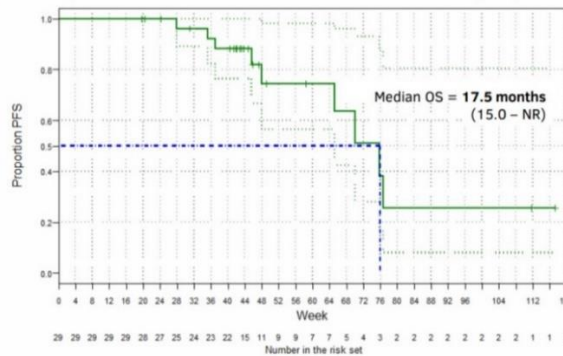
previous results from this study, which provides us with additional confidence in the fidelity of the results. Based on these results, we believe paxalisib has the potential to become the new standard of care for the treatment of unmethylated MGMT GBM and generate risk-adjusted revenue of A\$395M by 2030.

Exhibit 11: Patients Achieve Strong PFS and OS in Phase 2 Study

Kaplan-Meier Curve of Progression-Free Survival (PFS)



Kaplan-Meier Curve of Overall Survival (OS)



Source: Wen et al, SNO poster, 2020.

Exhibit 12: Historical PFS and OS Results of Radiation Plus TMZ in Patients With Unmethylated MGMT GBM

Study Publication	Number of patients	Median PFS (months)	Median OS (months)
Hegi et al, 2005.	60	5.3	12.7
Gilbert et al, 2013.	254	5.7	14.0
Chinot et al, 2014.	225	5.8	14.6
Nabors et al, 2015.	89	4.1	13.4
Herrlinger et al, 2016.	61	5.99	17.5
Average		5.4	14.4

Sources: H.C. Wainwright Research and Hegi et al, *NEJM*, 2005, Gilbert et al, *J Clin Oncol*, 2013, Chinot et al, *NEJM*, 2014, Nabors et al, *Neuro-Oncol*, 2015, Herrlinger et al, *J Clin Oncol*, 2016.

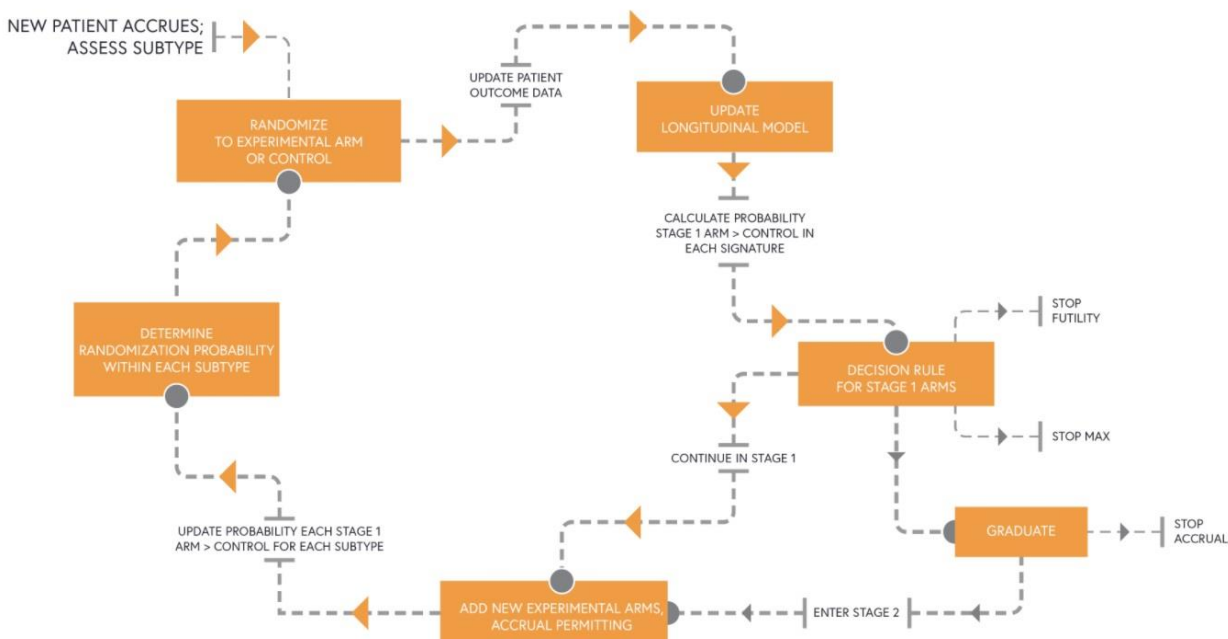
In addition to demonstrating clinically meaningful survival benefits in this difficult-to-treat patient population, paxalisib's encouraging safety profile has provided us with additional confidence in the drug's ability to achieve regulatory and commercial success. We note that while PI3K inhibitors have well-documented anti-tumor properties, many physicians remain wary of using them in the clinic due to their equally well-documented severe side effects; three of the four approved drugs in this class, Zydelig, Aliqopa, and Copiktra, all have recorded cases of patient fatalities due to adverse events during their clinical studies. Among these drugs, the most dangerous side effects are elevated liver enzymes and opportunistic infections of the lungs and the GI tract. In comparison, paxalisib has not shown either of these effects and its adverse events profile appears to be more similar to that of Piqray with hyperglycemia and rash being the most common serious side effects (Exhibit 13). According to management, while the side effects seen in the Phase 2 study did occasionally lead to treatment discontinuations and dosing holidays, they are also ones that physicians are generally familiar with and have been well-managed. Therefore, while paxalisib is by no means a completely safe drug, we believe it is likely to be one of the safest PI3K inhibitors to reach the market and is unlikely to be met with same physician pushback as seen with the earlier PI3K drugs.

Exhibit 13: Drug-Related Side Effects in Patients Receiving 60 mg Paxalisib (n=24)

Term	Gr 1	Gr 2	Gr 3	Gr 4	Total (%)
Rash	4	6	7		17 (71%)
Fatigue	2	10	2		14 (58%)
Stomatitis	4	6	1		11 (46%)
Decr. appetite	5	5	1		11 (46%)
Nausea	3	5	1		9 (38%)
Hyperglycemia	1	2	5		8 (33%)
Diarrhea	5	1			6 (25%)
Decr. neutrophils	2	3		1	6 (25%)
Vomiting	3	2	1		6 (25%)
Decr. weight	3	2			5 (21%)
Decr. platelets	4	1			5 (21%)
Dehydration		4	1		5 (21%)
Dysgeusia		4			4 (17%)
Decr. lymphocytes	1	2			3 (13%)
Drug reaction			3		3 (13%)
Malaise	2	1			3 (18%)
Incr. cholesterol	2				2 (8%)
Pruritis	1		1		2 (8%)

Source: Wen et al, SNO poster, 2020.

4. GBM AGILE provides paxalisib with an accelerated path to market. In October 2020, Kazia entered into a definitive agreement with the Global Coalition for Adaptive Research (GCAR), a non-profit international partnership of leading clinical research investigators, to participate in the GCAR's GBM AGILE pivotal study for the treatment of GBM. GBM AGILE was conceived in 2015 as a new type of randomized, adaptive clinical trial to improve and accelerate the development of novel therapies against GBM. It has worked with over 130 oncologists and researchers and has the support of organizations including the Cure Brain Cancer Foundation, the National Foundation for Cancer Research, and National Brain Tumor Society. The GCAR has obtained regulatory buy-in for the study from the FDA, Health Canada, the NMPA (China FDA) and is in discussions with the EMA to expand into Europe as well. GBM AGILE uses a streamlined, fully adaptive design that allows patient randomization, cohort expansion, and the addition of new treatments and combinations based on updated patient outcomes (Exhibit 14). Bayer's Stivarga (regorafenib) was the first drug to be included in GBM AGILE in 2018. Since then, the study has enrolled over 150 patients and is expected to include both Kazia's paxalisib and Kintara Therapeutics' (KTRA; not rated) VAL-083 starting in 2021. According to management, while the study participants will share a common control group, each drug will be tested in its own individual arm. The initial agreement with GCAR will cover an initial cohort of 50 patients, after which there will be monthly reviews for safety, efficacy, and futility. If investigators see a positive signal in these early results, up to 150 additional patients can be enrolled into the paxalisib arm. If paxalisib can demonstrate clinical benefit, the study design calls for another 50 patients to be enrolled into a confirmatory cohort, and final study analysis is expected to include the results from the initial, expansion, and confirmatory cohorts. In our view, GBM AGILE allows Kazia to quickly generate clinically meaningful results and bring paxalisib to the market. We believe that topline results from the GBM AGILE study can be expected as early as CY2H23, with potential U.S. and EU approvals for paxalisib by CY1H25. Furthermore, we note that participation in the GBM AGILE study is likely to require far less financial investment than a traditional, Phase 3, randomized study. As part of the agreement, Kazia is expected to supply the drug and pay an initial fee of \$5M, with further fees based on number of patients enrolled. Overall, we expect the cost to Kazia for GBM AGILE to be 50-66% cheaper than a comparably sized traditional Phase 3 pivotal study.

Exhibit 14: GBM AGILE Has a Non-Traditional, Highly Adaptive Study Design

Source: GCAR publication, 2020.

5. Additional indications beyond GBM provide significant upside. In addition to GBM, Kazia is collaborating with clinicians to investigate the use of paxalisib against a variety of other cancers. In our view, the most promising of these programs are the company's collaborations with St. Jude Children's Hospital for the treatment of diffuse intrinsic pontine glioma (DIPG) and with the Dana-Farber Cancer Institute for the treatment of brain metastases caused by breast cancer. DIPG is a rare and aggressive type of brain tumor that primarily affects children between five and seven years old. Approximately 200-300 new patients are diagnosed with DIPG each year in the U.S. Standard of care therapy for DIPG primarily consists of external beam radiation therapy. Surgery is rare due to it occurring in a region of the brain that is difficult to operate on and no chemotherapy drug has so far demonstrated any survival benefit. The company is currently collaborating with St. Jude on a Phase 1 dose-escalation study in pediatric patients with DIPG. The partners presented the initial results from this study at the 2020 SNO annual meeting in December and showed that: (1) the maximum tolerated dose in children is 27 mg/m²; (2) similar to adults, the main side effects of note in children included hyperglycemia, oral mucositis, and rash; and (3) while paxalisib treatment has so far not demonstrated an overall survival benefit compared to historical controls, the proportion of patients alive and progression-free at 6 months (PFS6) was 96%, compared 58% in historical controls. Overall, we believe these results suggest that paxalisib can be safely used to treat pediatric patients and has shown encouraging signs of efficacy against a disease for which there is no good treatment. Building upon these efforts, the company entered into a development collaboration with the Pacific Pediatric Neuro-Oncology Consortium (PNOC), an international non-profit consortium of clinical sites, in December 2020 to investigate paxalisib against DIPG in the upcoming PNOC022 study. PNOC022 aims to bring together several of the most promising candidates in the global pipeline for DIPG and test them in different combinations, and we believe initial results from this study could be available by YE2021. Finally, we note that while we only expect DIPG to generate modest additional sales for the company due to the limited number of patients, in August 2020 the U.S. FDA has granted paxalisib the Rare Pediatric Disease Designation (RPDD) for the treatment of DIPG. Therefore, if paxalisib is eventually approved for this indication, the company may be eligible to receive a "rare pediatric disease priority review voucher" (PRV), which in recent years has commanded prices of between \$68-350M when sold to other companies.

We believe the treatment of brain cancer metastases is another major opportunity for the company for the following reasons: (1) approximately 10-15% of women with advanced breast cancer, including up to 50% of patients with metastatic HER2+ and triple-negative breast cancer, develop brain metastases; (2) brain

metastases are particularly difficult to treat and require medication that can pass through the BBB, while the majority of breast cancer drugs do not pass the BBB; and (3) PI3K inhibitors have proven efficacy in treating breast cancer, with Piqray receiving accelerated approval for the treatment of PIK3CA mutation in HR+/HER2- advanced breast cancer in May 2019. To explore the potential of the drug in this indication, the company has partnered with the Dana-Farber Cancer Institute, who is currently running a Phase 2 study of paxalisib plus Roche's Herceptin (trastuzumab) for the treatment of brain metastases in patients with HER2+ breast cancer. The study design calls for a total of 47 patients who will receive 45 mg of paxalisib in combination with the standard 8 mg/kg dose of Herceptin. The primary outcome measure of the study is overall response rate in CNS as measured by the RANO-BM criteria and secondary objectives include duration of response, OS and PFS. Currently, we expect the initial results from this study to be available in early-2021 and final results in early-2022. While we have not yet included the treatment of brain metastases in our revenue paxalisib projections due to a lack of clinical results, we note that it is a very large indication with over 200,000 patients per year in the U.S. alone, and therefore, any positive results from this study could lead to significant upside to our estimates.

Financials

Revenues. Kazia reported FY2020 financial results on August 27 for the year ended June 30, 2020. The company reported financial and other incomes of A\$1.1M in the year. For FY2021, we expect the company to report financial and other incomes of A\$1.4M. We expect Kazia's first product, paxalisib, to reach the market in FY2025, and we project the company's risk-adjusted revenues to grow from A\$39M in FY2025 to A\$408M in FY2030, for a 5-year CAGR of 60%.

Net income and EPS. Kazia reported a net loss of A\$12.5M or A\$0.17 per diluted common share in FY2020. For FY2021, we expect the company to report a net loss of A\$15.8M, or A\$0.13 per diluted common share. We expect FY2026 to be the company's first profitable year with a net income of A\$72.7M. Please refer to the detailed income statement for our estimates of net income and earnings or loss per diluted share for the forecast period, FY2021E-2030E.

Cash. Kazia reported cash and cash equivalents of A\$8.8M and no debt at the end of FY2020. In October 2020 (FY1H21), the company completed a follow-on equity offering for gross proceeds of A\$25M and announced a *pro forma* cash position of A\$31M post-transaction. According to our projections, Kazia has sufficient capital to maintain operations and fund the development of new pipeline products into FY2023. In our current projections, we assume that the company will raise an additional A\$33.4M from equity at the end of FY2022. Please refer to the risks section for our detailed projections of Kazia's cash runway.

Valuation

We value the ADS of Kazia using a risk-adjusted net present value (rNPV) analysis. In order to account for uncertainties in operations and to remain conservative in our estimates, we use a discount rate of 14.0%, found by adding a 5.0% premium on top of the calculated weighted average cost of capital (WACC) of 9.0%, to discount all future revenues. Furthermore, while we believe the company R&D pipeline could lead to potential upsides and future product launches, in order to remain conservative, we are assuming a 0% terminal growth rate in our rNPV analysis.

Key Model Assumptions

In our financial model, we assume that all future Kazia products would be commercialized independently in the U.S., and the company would receive royalty payments in return from commercial partners for sales in the EU plus U.K. We assume that paxalisib will initially be priced at A\$163,800 per patient (US\$126,000) in the U.S. and at A\$131,040 (US\$100,800) per patient in the EU plus U.K. at launch, and that we would see average price increases of 3% per year. We note that according to the license agreement with Genentech, Kazia is expected to pay Genentech a low single-digit percentage royalty based on net sales, which we have assumed to be 3% and have included in the COGS. We expect the company to receive a 25% royalty on net sales of paxalisib in the EU from commercial partners. We have adjusted the projected revenues for each indication based on their corresponding phase of development (Exhibit 18). Currently,

we expect paxalisib to launch in FY2025 for the treatment of newly diagnosed GBM and pediatric DIPG and contribute risk-adjusted revenues of A\$401M by FY2030. Potential upside to our estimates includes: (1) faster-than-expected market uptake; (2) commercialization in additional indications; (3) market approvals in ex-U.S. and ex-EU territories; (4) higher-than-expected prices; (5) revenue from additional partnerships; and (6) future products which we have not yet included in our projections.

Exhibit 18: Probability of Market Launch Used in Our Risk-Adjusted Projections

Current Phase	Probability
Phase I	20.1%
Phase I/II	20.1%
Phase II	26.1%
Phase II/III	26.1%
Phase IIa	26.1%
Phase IIb	26.1%
Phase III	48.5%
Filed	90.0%
Marketed	100.0%

Source: Wong and Siah. Biostatistics, 2018.

Exhibit 19: Projected Kazia Product Revenues, FY2024E – 2030E

A\$ ('000)	Risk Adjustment	FY2024E	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E
Paxalisib								
Newly Diagnosed GBM US	48.5%		28,391	112,929	174,987	230,214	280,582	295,594
Newly Diagnosed GBM EU+U	48.5%		9,700	38,431	59,313	77,723	94,352	99,005
Pediatric DIPG US	20.1%		441	1,755	2,720	3,578	4,361	4,594
Pediatric DIPG EU+UK	20.1%		147	583	899	1,178	1,430	1,501
Total Product Revenues		-	38,680	153,698	237,919	312,694	380,725	400,694

Source: H.C. Wainwright estimates.

In our rNPV model, we use the calculated WACC of 9.0% and add a 5.0% risk premium to arrive at a 14% discount rate. Using a 0% terminal growth rate, we arrive at an rNPV of A\$374M for the expected future revenues from paxalisib. To this we add *pro forma* net cash of A\$31M held by Kazia following the October 2020 equity offering to arrive at a 12-month price target of A\$2.21 per diluted share. Using the December 31, 2020 exchange rate of US\$1.00 = A\$1.30 and the conversion rate of 1 ADS = 10 common shares, we arrive at a 12-month price target of US\$17.01 per ADS, which we round to \$17.00 (Exhibit 20).

Exhibit 20: rNPV Analysis

rNPV Analysis										
(A\$ in '000)	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total Revenue	1,404	1,495	1,730	1,610	40,485	155,783	241,019	317,100	386,671	408,458
COGS	-	-	-	-	(8,896)	(30,740)	(42,825)	(56,285)	(68,530)	(72,125)
General Expenses	(17,498)	(19,227)	(20,002)	(23,762)	(34,122)	(52,299)	(69,089)	(82,879)	(91,540)	(48,683)
Operating Income	(16,094)	(17,732)	(18,272)	(22,152)	(2,534)	72,745	129,105	177,936	226,600	287,651
Tax	298	298	298	298	149	-	(15,850)	(48,932)	(62,315)	(32,880)
Net Income	(15,796)	(17,434)	(17,974)	(21,854)	(2,385)	72,745	113,255	129,004	164,285	254,771
Periods	0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5	9.5
Discount Rate	14.0%	0.94	0.82	0.72	0.63	0.55	0.49	0.43	0.37	0.33
Discounted Income	(14,794)	(14,323)	(12,953)	(13,815)	(1,322)	35,386	48,325	48,285	53,939	73,376
								Terminal Growth		0.0%
								Terminal Value		524,114
								Discounted TV		172,082
Total NPV	374,185									
Net Cash	31,084									
# of Shares ('000)	183,230									
Price per share (A\$)	2.21									
Price per share (US\$)	17.01									
Exchange rate USD/AUD	1.30									

Source: H.C. Wainwright estimates.

Risk Analysis

In addition to the typical risks associated with biotechnology companies, risks specific to Kazia to be considered are as follows:

Clinical and regulatory risk. We believe clinical and regulatory risk to be the primary risks facing the company. Kazia is required to successfully complete clinical studies in order to secure marketing approvals, improve physician adoption, and secure reimbursement approvals for its products in the U.S., the EU, and the U.K. Clinical studies are inherently risky due to variability in patients' and disease conditions and may be subject to numerous uncertainties. The FDA and the EMA regulates all human regenerative medicine products in the U.S. and the EU, respectively, and all future Kazia products must first be approved by these agencies before they can be marketed.

Commercial and partnership risk. We believe commercial and partnership risk to be another key risk factor facing the company. All of Kazia's future revenues are expected to come from direct sales in the U.S. and royalties and milestone payments derived from the sales of its products by commercial partners in the EU plus U.K. If the company is unable to successfully market its products, unable to secure partners for its products or if the partners are unable to commercialize the products, or if product uptake and market penetration are lower than expected, it may negatively impact our revenue projections.

Pipeline risk. We note that our valuation of KZIA shares is entirely based on the potential future revenues generated by a single clinical asset, paxalisib. Should paxalisib fail to achieve positive results in clinical studies, it may substantially impact the company's share price. While Kazia has additional products in its product pipeline beyond paxalisib, such as Cantrixil, currently we do not expect these products to generate material revenue for the company.

Reimbursement risk. We believe that for Kazia products to achieve the projected sales in our model, they would require broad reimbursement support from public and private payers in the U.S. as well as from public payers in the EU plus U.K. We note that in recent years, reimbursement agencies have grown warier of systematically reimbursing high priced drug that provide marginal benefit. Furthermore, if U.S. Medicare spending growth continues to outpace GDP growth, and the government's ability to fund healthcare becomes impaired, changes could be made to policy that would negatively affect the company's business.

Pandemic risk. The ongoing COVID-19 pandemic has caused industry-wide disruptions to clinical studies, regulatory review, and supply chains, and we expect it to continue be a risk through at least FY2022. To date, Kazia's operations has not been significantly impacted by COVID-19. While the company and the FDA now have plans in place to alleviate the impact of the pandemic, we believe it nonetheless remains a risk to our timeline and financial estimates.

Financial risk. Kazia held cash and cash equivalents of A\$8.8M at the end of FY2020 and completed a A\$25M equity offering in October 2020. While we believe the company has sufficient capital to fund operations into FY2023, any potential capital raises may result in diluted ownership interest.

Exhibit 21: Projected Cash Needs For Kazia, FY2021-2023

AUD ('000) Except Per Share Data	FY 2020A	1H21E	2H21E	FY 2021E	1H22E	2H22E	FY 2022E	1H23E	2H23E	FY 2023E
Cash burn	(8,810)	(6,328)	(8,206)	(14,534)	(6,388)	(9,622)	(16,011)	(6,587)	(10,197)	(16,783)
Cash and cash equivalents	8,764	24,756	16,550	16,550	10,162	34,020	34,020	27,433	17,236	17,236
Capital raise	12,139	22,320	-	22,320	-	33,480	33,480	-	-	-
Assumed (*actual) price per common share	0.40*	0.80*	-	0.80*	-	1.20	1.20	-	-	-
Periods of cash remaining		3.9	2.0		1.6	3.5		4.2	1.7	

Source: H.C. Wainwright estimates.

Legal and intellectual property risk. Kazia licensed its lead product candidate, paxalisib (GDC-0084) from Genentech in October 2016. Since then, Kazia has continued to pursue robust protection for the intellectual property associated with the drug. Paxalisib is currently protected by a suite of patents covering composition of matter, method of manufacture, formulation, and methods of use in the U.S., the EU and China as well as other jurisdictions, which is expected to last until at least 2031. However, management

could potentially fail to protect the company's intellectual property or may infringe the proprietary rights of third parties. If future IP challenges are judged against Kazia, it could negatively affect the company's financial position.

Industry risk. Emerging biotechnology and pharmaceuticals stocks are inheritably volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and its stock price. We do not expect this volatility to subside in the near term.

For additional risk considerations, please refer to the company's public filings.

Income Statement

FY Jun 30

AUD ('000) Except Per Share Data	1H19A	2H19A	FY 2019A	1H20A	2H20A	FY 2020A	1H21E	2H21E	FY 2021E	FY 2022E
Total Revenue	1,198	367	1,565	658	403	1,061	618	787	1,404	1,495
Cost of goods sold	-	-	-	-	-	-	-	-	-	-
Gross Income	1,198	367	1,565	658	403	1,061	618	787	1,404	1,495
Research and development expenses	3,708	2,768	6,476	4,195	5,299	9,494	6,358	7,312	13,670	15,066
Selling, general, and administrative expenses	2,086	1,700	3,786	2,325	1,365	3,690	2,252	1,576	3,828	4,161
Operating Income (Loss)	(4,596)	(4,101)	(8,697)	(5,862)	(6,261)	(12,123)	(7,992)	(8,102)	(16,094)	(17,732)
Income tax benefit (expense)	149	149	298	149	149	298	149	149	298	298
Net Income (Loss)	(6,028)	(4,242)	(10,270)	(5,881)	(6,586)	(12,467)	(7,843)	(7,953)	(15,796)	(17,434)
Basic EPS	(0.11)	(0.07)	(0.18)	(0.09)	(0.08)	(0.17)	(0.06)	(0.06)	(0.13)	(0.11)
Diluted EPS	(0.11)	(0.07)	(0.18)	(0.09)	(0.08)	(0.17)	(0.06)	(0.06)	(0.13)	(0.11)
Basic Shares Outstanding ('000)	52,916	62,091	57,504	65,482	80,625	73,054	124,598	124,598	124,598	154,598

Source: Company reports and H.C. Wainwright estimates.

Income Statement

FY Jun 30

AUD ('000) Except Per Share Data	FY 2018A	FY 2019A	FY 2020A	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E
Total Revenue	13,108	1,565	1,061	1,404	1,495	1,730	1,610	40,485	155,783	241,019	317,100	386,671	408,458
Cost of goods sold	-	-	-	-	-	-	-	8,896	30,740	42,825	56,285	68,530	72,125
Gross Income	13,108	1,565	1,061	1,404	1,495	1,730	1,610	31,589	125,044	198,194	260,815	318,141	336,334
Research and development expenses	9,774	6,476	9,494	13,670	15,066	15,674	16,308	16,717	17,053	17,396	17,745	18,102	18,466
Selling, general, and administrative expenses	5,598	3,786	3,690	3,828	4,161	4,328	7,454	17,405	35,246	51,693	65,134	73,438	80,966
Operating Income (Loss)	(2,264)	(8,697)	(12,123)	(16,094)	(17,732)	(18,272)	(22,152)	(2,534)	72,745	129,105	177,936	226,600	236,902
Income tax benefit (expense)	305	298	298	298	298	298	298	149	-	(15,850)	(48,932)	(62,315)	(65,148)
Net Income (Loss)	(6,039)	(10,270)	(12,467)	(15,796)	(17,434)	(17,974)	(21,854)	(2,385)	72,745	113,255	129,004	164,285	171,754
Basic EPS	(0.12)	(0.18)	(0.17)	(0.13)	(0.11)	(0.12)	(0.13)	(0.01)	0.42	0.65	0.74	0.94	0.98
Diluted EPS	(0.12)	(0.18)	(0.17)	(0.13)	(0.11)	(0.12)	(0.13)	(0.01)	0.40	0.62	0.71	0.90	0.94
Basic Shares Outstanding ('000)	48,377	57,504	73,054	124,598	154,598	154,598	174,598	174,598	174,598	174,598	174,598	174,598	174,598

Source: Company reports and H.C. Wainwright estimates.

Balance Sheet

AUD ('000) Except Per Share Data	FY 2018A	FY 2019A	FY 2020A
Assets			
Cash and cash equivalents	5,434	8,764	16,550
Trade and other receivables	1,711	1,352	2,095
Inventory	-	-	-
Other current assets	370	537	537
Total Current Assets	9,260	7,515	10,653
Financial assets	168	-	-
PPE	-	-	-
Intangible assets	13,494	12,410	11,326
Total Assets	21,177	23,063	30,508
Liabilities & Shareholders' Equity			
Trade and other payables	1,764	3,489	4,410
Provisions	136	191	191
Deferred income	-	-	-
Contingent considerations	-	1,387	1,387
Total Current Liabilities	1,900	5,067	5,988
Deferred tax	3,711	3,413	3,413
Contingent considerations	1,371	458	458
Total Liabilities	6,982	8,938	9,859
Contributed equity	36,642	48,781	71,101
Other contributed equity	464	464	464
Reserves	2,037	1,066	1,066
Accumulated losses	(24,948)	(36,186)	(51,982)
Total Shareholders' Equity	14,195	14,125	20,649
Total Liabilities and Stockholders' Equity	21,177	23,063	30,508

Source: Company reports.

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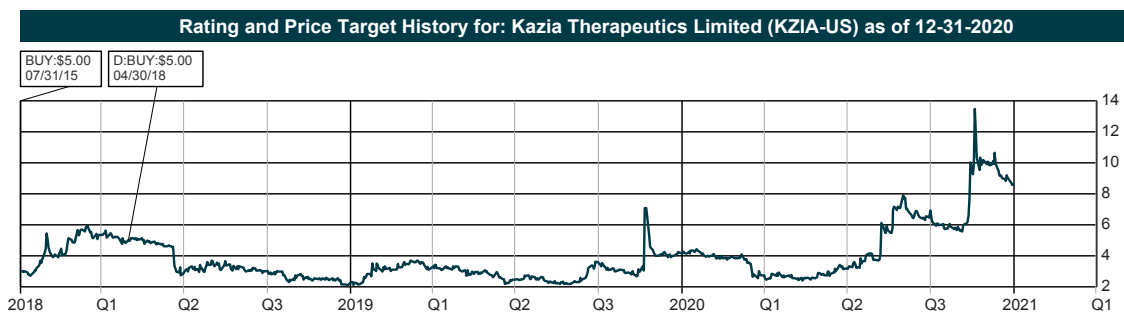
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			Count	Percent
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