Biotechnology

KZIA - NASDAQ January 31, 2022

Closing Price 1/28/22	**$6.26**
Rating:	Buy
12-Month Target Price:	$18.00
52-Week Range:	$6.02 - $14.89
Market Cap (M):	82.7
Shares O/S (M):	13.2
Float:	NA
Avg. Daily Volume (000):	26.7
Debt (M):	$0.0
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)

	2021A	2022E	2023E
H1	A$6,545	A$11,903	A$13,688
H2	A$17,589	A$12,895	A$14,829
FY	A$24,133	A$24,798	A$28,517

Kazia Therapeutics is listed on the Austrialan Stock exchange under the ticker KZA and with ADR's traded on NASDAQ under the ticker KZIA. 1 ADR = 10 ordinary Kazia shares. Modeling and historical financials are recorded in A$ while the price target, current price, and market data are translated into USD.

Kazia Therapeutics Limited

Buy

Studies on Track, Cash through YE22

Summary

- **Last night, Kazia provided an operational update on its ongoing programs.**
- **Studies on track. While the lead candidate, paxalisib (PI3K/mTOR inhibitor), studies are ongoing, the Phase 1 study of follow-on drug candidate, EVT801 (VEGFR3 inhibitor) has also cleared the first cohort.**
- **Upcoming catalysts. Near-term, we expect data readouts from one or more of the investigator-sponsored trials (ISTs), while the pivotal GBM AGILE study continues to enroll (see below, Exhibit 2).**
- **Cash balance. The company has cash runway ($A15.2M or ~$11.M USD) through YE22 and is positioned to reach multiple data readouts. We believe shares may rebound with positive results.**

Details

Potential catalysts in 2022. Although timing is uncertain, initial data may be reported from the following: **(1)** Phase 2 brain metastases study by the Alliance Group; **(2)** Phase 2 brain mets study of paxalisib (pax) in combination with radiation at Memorial Sloan Kettering; **(3)**; Phase 2 breast cancer brain mets (BCBM) study of pax in combination with trastuzumab at the Dana-Farber Cancer Institute (DFCI); **(4)** Phase 2 primary CNS lymphoma study at DFCI; **(5)** Phase 1 dose-escalation portion of EVT801 study.

GBM AGILE. As a reminder, the GBM AGILE trial is tailored to streamline the discovery of treatments in glioblastoma multiforme (GBM, see Exhibit 1). GBM AGILE is led by the nonprofit, international partnership GCAR (Global Coalition for Adaptive Research) and is supported by the FDA and other regulatory agencies. For Kazia, the trial is intended to serve as the pivotal study for paxalisib in multiple markets, including the US, EU and China. The study is designed to investigate the therapies in both newly diagnosed and recurrent GBM patient populations (in biomarker-defined populations) vs. one rolling control group (soc) for those therapies. The primary endpoint is overall survival; secondary endpoints include progression free survival and tumor response. Recent developments in the study include: (1) expansion into the first site in Canada in November 2021 (Europe and China are expected in CY22); (2) Chinese regulatory acceptance of partner, Simcere Pharmaceutical's (2096.HK - NR) IND for paxalisib in China (GBM AGILE is expected to open in China mid-CY22), and; (3) screening of over 1000 patients by GCAR in the GBM AGILE study to date. We expect interim results from the study around mid-CY23, with potential for regulatory approval in CY24.

EVT801 is a selective VEGFR3 inhibitor drug candidate. Few have targeted VEGFR3 specifically to inhibit lymphangiogenesis (formation of lymphatic vessels). While several commercial drugs do inhibit VEGFR3 (such as sorafenib), they are multi-tyrosine kinase inhibitors; and thus, have other targets, which can often lead to significant side effects. In contrast, Kazia's small molecule, EVT801, is a narrow spectrum inhibitor of the VEGFR3 tyrosine kinase with residual activity against VEGFR2 and TAK1. Given that EVT801 has a high degree of specificity for VEGFR3 (versus other signaling proteins in the VEGF pathway), it should exhibit a differential activity profile in the clinic from others in its class, including minimizing toxicity. An improved safety profile would suggest that the drug may allow for longer duration of treatment and enable combinations with other therapeutics such as checkpoints, in our view. Following evaluation of EVT801 as a monotherapy, Kazia expects to assess EVT801 as an adjunct to immunotherapy (see Exhibit 3). EVT801 is currently being evaluated in a Phase 1 dose-escalation study; initial data may be reported in 2H22.

(continued on page 2)

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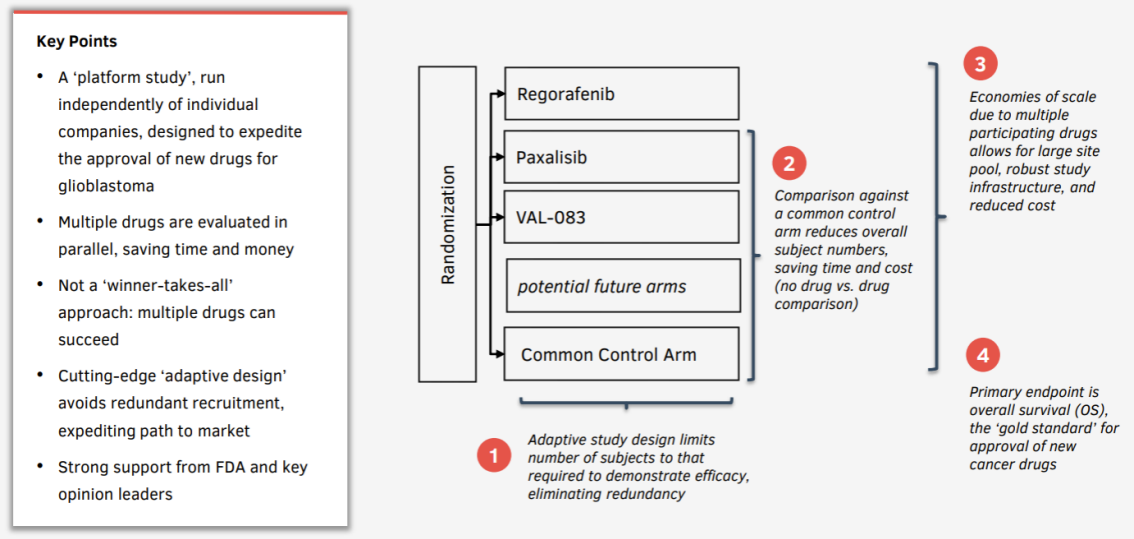
Exhibit 1. GBM AGILE study. The trial is a two-stage, multi-arm, platform, adaptive Phase 2/3 study that is also under one master protocol. It allows for multiple therapies or combinations of therapies from different biotech/pharma partners to be evaluated in concert. The study is designed to investigate the therapies in both newly diagnosed and recurrent GBM patient populations (in biomarker-defined populations) vs. one rolling control group (soc) for those therapies. The primary endpoint is overall survival; secondary endpoints include progression free survival and tumor response. Kazia's paxalisib joined the International GBM AGILE study in October 2020. Bayer's (BAYRY - NR) regorafenib was the first drug to be included into the trial, followed by pax. This was followed by Kintara's (KTRA - Buy) VAL-083. Most importantly for Kazia, GBM AGILE provides pax an expedited path to registration, offering an existing infrastructure that allows for faster recruitment while reducing costs. Expansion into a new clinical site in Canada was announced on 11/28. Europe and China (via partnership with Simcere Pharmaceuticals) are expected to come online in CY22. Note, local data is needed in China for drug approval. We expect interim results from the study around mid-CY23, with potential for regulatory approval in CY24.



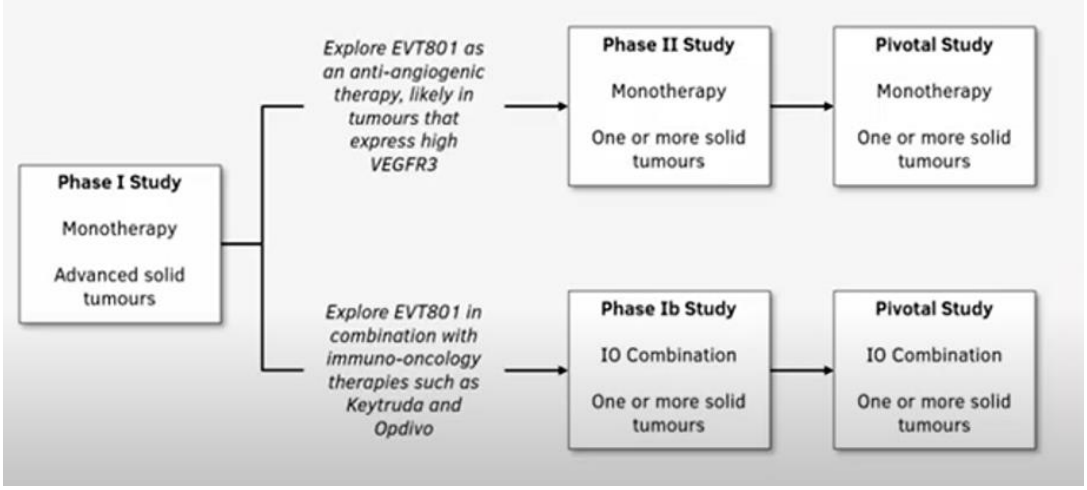
Source: Company Reports.

Exhibit 2. Paxalisib: multiple ongoing clinical programs. Paxalisib is presently being evaluated in eight clinical trials in multiple forms of brain cancer, including the groundbreaking pivotal GBM AGILE trial. Seven of the studies are investigator-sponsored, several of which are expected to yield data in 2022.

Primary Brain Cancer				
Glioblastoma (combination with ketogenic diet)	II	33-60	Start-up	Weill Cornell Medicine
Glioblastoma (GBM AGILE)	II / III	Up to 200 on paxalisib	Recruiting	Global Coalition for Adaptive Research
DIPG and DMGs	I	27	Follow-up	St. Jude Children's Research Hospital
DIPG and DMGs	II	TBD	Start-up	Pacific Pediatric Neuro-Oncology Consortium
Primary CNS Lymphoma	II	25	Recruiting	DANA-FARBER CANCER INSTITUTE
Secondary (Metastatic) Brain Cancer				
Brain Metastases (combination with radiotherapy)	I	Up to 36	Recruiting	Memorial Sloan Kettering Cancer Center
Breast Cancer Brain Metastases (combination with trastuzumab)	II	Up to 47	Recruiting	DANA-FARBER CANCER INSTITUTE
Brain Metastases ('Alliance' multi-drug study)	II	50	Recruiting	NIH NATIONAL CANCER INSTITUTE

Source: Adapted from Company Reports.

Exhibit 3. EVT801 strategy. In November 2021, Kazia enrolled its first patient in the Phase 1 study evaluating the safety/tolerability and preliminary efficacy of EVT801 in advanced/metastatic solid tumors. The trial is enrolling up to 90 patients across two sites in France. Initial indications to be explored include renal cell carcinoma (kidney cancer), hepatocellular carcinoma (liver cancer), and soft tissue sarcoma. The primary objective is to determine the maximum tolerated dose (MTD) and / or a recommended Phase 2 dose (RP2D), in addition to safety outcomes. The study also has a second phase that includes a biomarker expansion cohort to explore pharmacodynamic outcomes. Following this, Kazia also expects to explore combination with immunotherapies such as checkpoints.

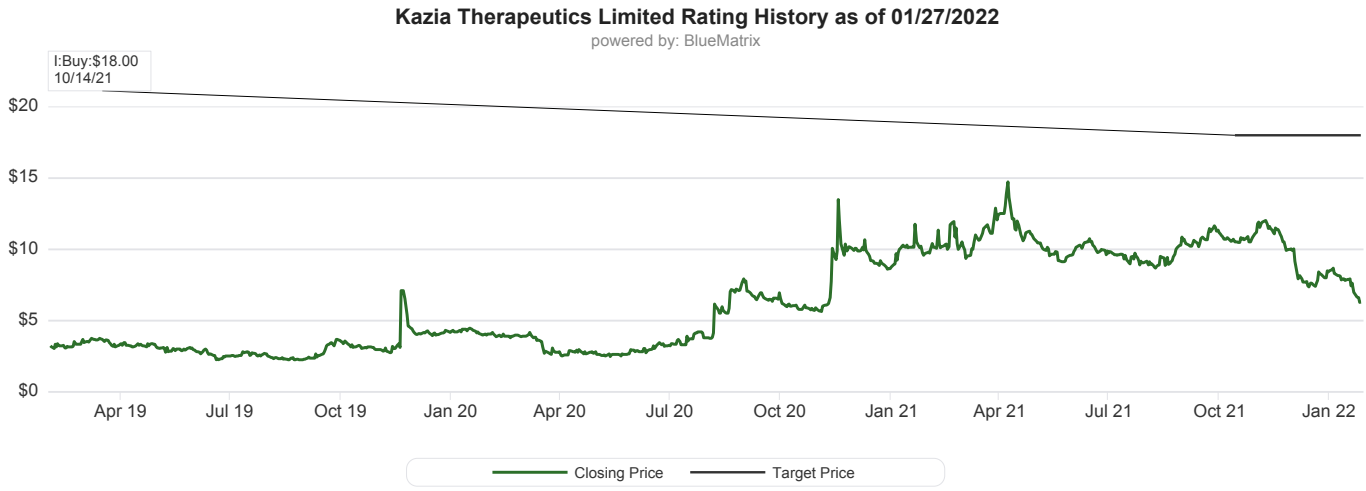


Source: Company Reports.

Maintain Buy, $18 price target. We arrive at our $18 PT by employing a blended methodology that consists of free cash flow, discounted EPS, and sum-of-the-parts (SOTP) models, which assume a 30% discount rate. Our Buy rating and $18 PT is based on our expectation for a positive clinical outcome for paxalisib in the P3 GBM AGILE study and in brain metastases. We assume risk-adjusted revenues for paxalisib in these indications. We do not currently ascribe value to the EVT801 program, which we view as potential upside.

Company overview: *Kazia Therapeutics is an oncology-focused biotechnology company based in Sydney, Australia. The company's pipeline includes two clinical-stage drug assets being developed across a range of oncology indications: paxalisib (PI3K/mTOR inhibitor) for CNS-based cancers and EVT801 (VEGFR3 inhibitor) for solid tumors.*

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 01/30/22
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**90%**	**56%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	**10%**	**39%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**0%**	**0%**
	**See valuation section for company specific relevant indices*		

I, Naureen Quibria, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Kazia Therapeutics Limited

Maxim Group expects to receive or intends to seek compensation for investment banking services from Kazia Therapeutics Limited in the next 3 months.

KZIA: For Kazia Therapeutics Limited, we use the BTK (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

KZIA: We model risk-adjusted revenues for paxalisib in 1L GBM, and in brain metastases. A discount is then applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks

KZIA: Aside from general market and other economic risks, risks particular to our price target and rating for Kazia Therapeutics Limited include: (1) the regulatory and clinical risk associated with product development; (2) the rate and degree of progress of product development; (3) the rate of regulatory approval and timelines to potential commercialization of products; (4) the level of success achieved in clinical trials; (5) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (6) the liquidity and market volatility of

the company's equity securities; (7) regulatory and manufacturing requirements and uncertainties; (8) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (9) inability, of product(s), if approved, to gain adequate market share and maintain adequate revenue growth; (10) impact of comprehensive tax reform in the US and Ex-US tax policy; (11) delays related to COVID-19 could impact the company's ability to operate and conduct clinical trials; (12) failure of third-parties to meet contractual obligations, potentially impacting drug development; (13) the ability to access capital via equity financing or convertible debt securities, which will likely have a dilutive effect on shareholders; (14) foreign exchange fluctuations as the company is domiciled in Australia and reports results in Aussie dollars (A$).

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

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Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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