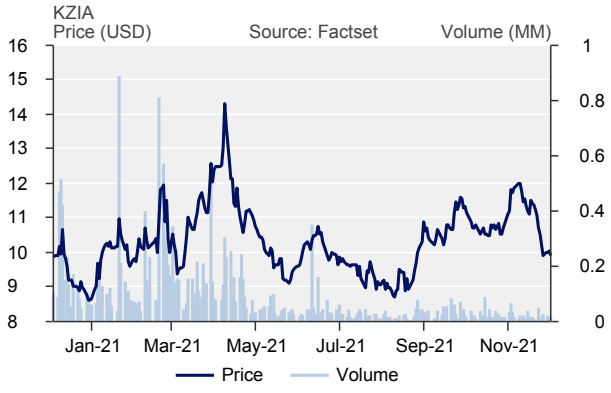
Biotechnology

KZIA - NASDAQ December 3, 2021

Closing Price 12/2/21	**$10.01**
Rating:	Buy
12-Month Target Price:	$18.00
52-Week Range:	$8.48 - $14.89
Market Cap (M):	132.1
Shares O/S (M):	13.2
Float:	NA
Avg. Daily Volume (000):	27.0
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	AUD6,545	AUD11,903	AUD13,688
H2	AUD17,589	AUD12,895	AUD14,829
FY	AUD24,133	AUD24,798	AUD28,517



Kazia Therapeutics is listed on the ASX (ticker: KZA) and with ADR's traded on NASDAQ (ticker: KZIA). 1 ADR = 10 ordinary Kazia shares. Modeling and historical financials are recorded in AUD while the price target, current price, and market data are translated into USD.

Naureen Quibria, Ph.D.
(212) 895-3620
nquibria@maximgrp.com

Kazia Therapeutics Limited

Buy

Final P2 Paxalisib Data Largely Incremental; More Pax Data in 2022 – Reiterate Buy

Summary

- **Yesterday (12/2), after the market close, Kazia reported final results from its Phase 2 study of paxalisib (PI3K/mTOR inhibitor) in newly diagnosed glioblastoma (GBM) patients.**
- **Data highlights. The results support efficacy and safety data previously reported at SNO 2020. On the key metric of progression-free survival (PFS) in the intent-to-treat (ITT) population (n=30), patients on paxalisib reached a mPFS of 8.4 months (identical to the prior reported mPFS of 8.4 mos), which compares favorably to 5.3 mos for temozolomide (historical). Median overall survival (OS) in the ITT was 15.7 mos vs. 12.7 mos for temozolomide historically.**
- **While the mOS is now lower than the prior update at SNO 2020 of 17.5 mos, the drug is clearly active and still suggests a competitive profile, in our view, particularly given the aggressive and intractable nature of the tumor type.**
- **Conclusion. Paxalisib (pax) is presently the subject of eight ongoing investigator-sponsored trials (ISTs), including the pivotal GBM AGILE study. Although data from GBM AGILE is at least another year away, the study continues to accrue with activation of sites into new territories (recently in Canada; Europe and China are expected in CY22). Initial data from several of the ongoing ISTs are expected in 1H22. In our view, positive data should further validate a role for paxalisib in brain cancers and help the stock appreciate. Reiterate Buy.**

Details

The Phase 2 study evaluated paxalisib (PI3K/mTOR inhibitor) in patients with newly diagnosed glioblastoma (GBM) with unmethylated MGMT promoter status. Patients were treated with the drug following surgical resection and chemoradiotherapy.

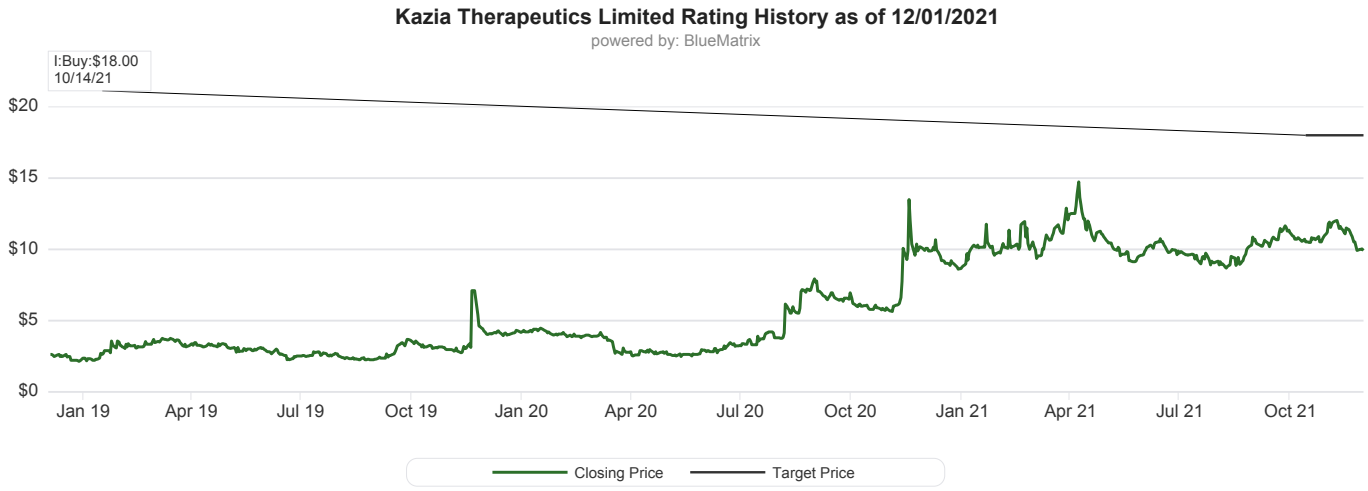
- **Study design.** The open-label, single-arm study was designed in two parts. Step 1 (dose-escalation, n=9) was conducted to determine the maximum tolerated dose (MTD), which came to 60 mg. Step 2 (expansion n=21) was conducted to determine preliminary evidence of clinical activity in newly diagnosed patients.
- **Interim results.** Recruitment was completed in February 2020 and interim results were reported at SNO 2020 (November 2020). For the entire study population (n=29), paxalisib treatment saw a median progression-free survival of 8.4 months which compares favorably to historical 5.3 months for standard of care (soc) therapy temozolomide (TMZ) in a similar patient population. Median overall survival on paxalisib was 17.5 months vs. 12.7 months (historical) with existing therapy.
- **Final results.** Yesterday (12/2), Kazia reported final results from the study. Median PFS in the ITT population (n=30) was 8.4 months (identical to interim data readout). Median OS in the intent-to-treat population was 15.7 months (reduced from 17.5 reported at SNO 2020), which still compares very favorably to 12.7 months reported historically with temozolomide in this patient group. Of note, in the modified ITT (mITT) population (n=27), which includes only those patients evaluable for efficacy, OS increased to 15.9 months. Safety results were consistent with prior studies; hyperglycemia, oral mucositis and skin rash were among the most drug-related toxicities.

GBM AGILE. On the basis of the Phase 2 study, paxalisib (pax) entered the International, physician-led GBM AGILE trial. Established by the collective work of over 130 leading experts in glioblastoma, the GBM AGILE trial is tailored to streamline the discovery of treatments. Importantly for Kazia, the trial is intended

to serve as the pivotal study for paxalisib in multiple markets, including the US, EU, and China. GBM AGILE is led by the nonprofit, international partnership GCAR (Global Coalition for Adaptive Research). GCAR is also supported by the FDA and other regulatory agencies. The trial itself is a two-stage, multi-arm, platform, adaptive Phase 2/3 trial 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 site in Canada was announced on 11/28 (Europe and China are expected in CY22). We expect results from the study for the paxalisib arm around mid-CY23, with potential for regulatory approval in CY24.

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: 12/02/21
		% 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.	**89%**	**55%**
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.	**11%**	**46%**
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 the launch of paxalisib in GBM in the US, EU and China in CY24; and in brain metastases in the US in CY25 and in the EU and China in CY26, with a 70% risk adjustment. A 30% discount is 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 AUD.

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.

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

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.

DISCLAIMERS

Some companies that Maxim Group LLC follows are emerging growth companies whose securities typically involve a higher degree of risk and more volatility than the securities of more established companies. The securities discussed in Maxim Group LLC research reports may not be suitable for some investors. Investors must make their own determination as to the appropriateness of an investment in any securities referred to herein, based on their specific investment objectives, financial status and risk tolerance.

This communication is neither an offer to sell nor a solicitation of an offer to buy any securities mentioned herein. This publication is confidential for the information of the addressee only and may not be reproduced in whole or in part, copies circulated, or disclosed to another party, without the prior written consent of Maxim Group, LLC ("Maxim").

Information and opinions presented in this report have been obtained or derived from sources believed by Maxim to be reliable, but Maxim makes no representation as to their accuracy or completeness. The aforementioned sentence does not apply to the disclosures required by FINRA Rule 2241. Maxim accepts no liability for loss arising from the use of the material presented in this report, except that this exclusion of liability does not apply to the extent that such liability arises under specific statutes or regulations applicable to Maxim. This report is not to be relied upon in substitution for the exercise of independent judgment. Maxim may have issued, and may in the future issue, other reports that are inconsistent with, and reach different conclusions from, the information presented in this report. Those reports reflect the different assumptions, views and analytical methods of the analysts who prepared them and Maxim is under no obligation to ensure that such other reports are brought to the attention of any recipient of this report.

Past performance should not be taken as an indication or guarantee of future performance, and no representation or warranty, express or implied, is made regarding future performance. Information, opinions and estimates contained in this report reflect a judgment at its original date of publication by Maxim and are subject to change without notice. The price, value of and income from any of the securities mentioned in this report can fall as well as rise. The value of securities is subject to exchange rate fluctuation that may have a positive or adverse effect on the price or income of such securities. Investors in securities such as ADRs, the values of which are influenced by currency volatility, effectively assume this risk. Securities recommended, offered or sold by Maxim: (1) are not insured by the Federal Deposit Insurance Company; (2) are not deposits or other obligations of any insured depository institution; and (3) are subject to investment risks, including the possible loss of principal invested. Indeed, in the case of some investments, the potential losses may exceed the amount of initial investment and, in such circumstances, you may be required to pay more money to support these losses.

ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

Corporate Headquarters

New York City
300 Park Ave., 16th Floor
New York, NY 10022
Tel: 212-895-3500

Miami Beach
555 Washington Ave., Suite 320
Miami Beach, FL 33139
Tel: 786-864-0880

Capital Markets/Syndicate: 212-895-3695
Corporate Finance: 212-895-3811
Corporate Services: 212-895-3631
Equity/Options Trading: 212-895-3790
Equity Research: 212-895-3736
Fixed Income Trading: 212-895-3875
Global Equity Trading: 212-895-3623
Institutional Sales: 212-895-3873
Institutional Sales Trading: 212-895-3873
Portfolio/Transition Trading: 212-895-3567
Prime Brokerage: 212-895-3723
Wealth Management: 212-895-3624

Woodbury, Long Island

100 Crossways Park Drive West
Suite 207
Woodbury, NY 11797
Tel: 516-393-8300

Red Bank, New Jersey

246 Maple Avenue
Red Bank, NJ 07701
Tel: 732-784-1900

West Palm Beach, Florida

105 South Narcissus Avenue
Suite 222
West Palm Beach, FL 33401
Tel: 561-465-2605

San Rafael, California

4040 Civic Center Drive
Suite 200
San Rafael, CA 94903
Tel: 212-895-3670

Aventura, Florida

20801 Biscayne Blvd
Suite 432 / 433
Aventura, FL 33180
Tel: 516-396-3120

Stamford, Connecticut

700 Canal Street
Stamford, CT 06902