BELL POTTER

6 December 2021

Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Analyst
John Hester 612 8224 2871

Authorisation
Tanushree Jain 612 8224 2849

Kazia Therapeutics

Headline Data - 3 Month Survival Benefit

Recommendation
Buy (unchanged)
Price
$1.20
Valuation
$2.40 (previously $2.50)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

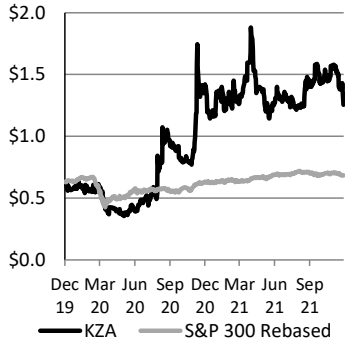
Expected Return	
Capital growth	**100%**
Dividend yield	**0.0%**
Total expected return	**100%**

Company Data & Ratios	
Enterprise value	**$139.5m**
Market cap	**$159.1m**
Issued capital	**132.6m**
Free float	**99%**
Avg. daily val. (52wk)	**$189,000**
12 month price range	**$1.10 - $1.88**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.49	1.38	1.39
Absolute (%)	-19.19	-13.04	-13.67
Rel market (%)	-17.85	-9.10	-23.89

Absolute Price



SOURCE: IRESS

Three month survival benefit in first line therapy

Kazia has reported the headline data from its phase II clinical study of paxalisib in newly diagnosed unmethylated glioblastoma. In this single arm, monotherapy trial which enrolled 30 patients, median progression free survival was extended by 3 months to 8.4 months and median overall survival was extended by 3 months to 15.7 months. Three patients were lost to follow up. Excluding these three patients median overall survival was extended to 15.9 months.

Interim data from November 2020 had reported median overall survival at 17.4 months, hence the last few patients appeared to underperform the earlier patients, nevertheless, the 3 month median overall survival benefit remains clinically significant in this indication where there have been no new therapies for years. As this trial did not have a control arm it is not possible to measure relative performance. If this survival benefit is reproduced in the pivotal study we are confident the drug could be a commercial success.

Safety was consistent with previous studies. The main side effects were hyperglycaemia, mouth ulcers and skin rash all of which are generally manageable. Kazia is now 11 months into enrolment of the pivotal trial involving ~200 patients in a randomised controlled trial. There are at least two dozen sites recruiting patients in the US with more scheduled to join. Headline data should be available in CY2023. There is a clear unmet need in glioblastoma so the question now is whether the FDA may consider an accelerated approval based on the phase II data. The company is yet to conduct a post phase II discussion with the agency where it would be appropriate consider this question.

Investment View: Maintain Buy Speculative, Valuation $2.40

The next catalyst for the stock will be the first readouts from investigator led studies currently underway in the US - due in early CY2022. Cash at 30 September was $19.6m which is expected to provide ~12 months working capital. There are no changes to earnings in the forecast period and we maintain our Buy (Speculative) recommendation. Valuation is reduced to $2.40 reflecting a small decrease in median overall survival in the headline data.

Earnings Forecast

June Year End	FY21	FY22e	FY23e	FY24e
Revenues $m	15.2	0.0	41.7	86.3
EBIT $m	-8.9	-21.5	21.6	77.8
NPAT (underlying) $m	-8.4	-21.5	21.5	77.7
NPAT (reported) $m	-8.4	-21.5	21.5	77.7
EPS underlying (cps)	-6.4	-16.3	16.3	58.9
EPS growth %	nm	nm	nm	262%
PER (x)	nm	nm	7.7	2.1
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	na	na	57%	67%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Survival Benefit Confirmed

Kazia has reported the final data from its single arm, phase II study investigating the use of paxalisib in the treatment of glioblastoma.

The highlights from the data were as follows:

- Median progression free survival (PFS) of 8.4 months; and
- Median overall survival of 15.7 months.

Both endpoints represent a material extension in comparison to the standard of care as highlighted in figure1.

Figure 1 - Data Summary with 95% confidence intervals

(all efficacy data in months)	Dec-21	Nov-20	Jun-20	Standard of care
Progression free survival	8.4	8.4	8.5	5.3
95% CI	6.6 - 10.2	7.3 - 10.0	8.1 - NR	na
Median overall survival	15.7	17.4	17.7	12.7
95% CI	19.1 - 11.1	15.0 - NR	10.5 - NR	na
Patients (n)	30	29	27	na

SOURCE: COMPANY DATA

The phase II trial enrolled 30 patients. Of these data was collected from 27. The remaining 3 patients were lost to follow up or otherwise no data was collected.

KZA also reported on the modified intent to treat group (mITT) which excluded the 3 patients for which there was no follow up data. This group of 27 patients reported median overall survival of 15.9 months (95% CI 12.8 – 19.1) as compared to 15.7 months.

We note that the final few patients in the study appeared to under perform the earlier patients as evidenced by the contraction in median overall survival from 17.4 months to 15.7 months. The reasons for this remain unknown. The company is yet to fully analyse the data, however, some explanation may emerge when the peer reviewed data is published in 2022.

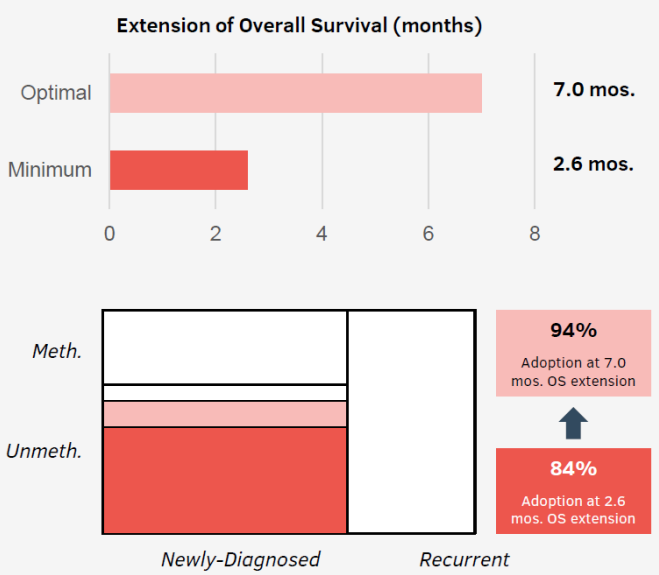
We also note the quite wide 95% confidence intervals in the final data which indicates there was a wide range of patient responses in the treatment group. We speculate that some of the factors which may explain this include patient age and or disease state at diagnosis. This confidence interval data is not particularly meaningful without a properly powered, blinded, randomised controlled study.

Despite the small contraction in median overall survival from the earlier interim data, the 3 month extension in survival remains meaningful. If this extension to median survival is repeated in a phase III study we are confident that the company would have a highly commercial asset.

We note the recent company prepared data presented at the November 2021 AGM. The company had an external provider conduct primary market research in the United States investigating the likely adoption rate for paxalisib.

The data indicates that even with a short extension in overall survival, paxalisib is likely to gain good support from oncologists.

Figure 2 - Adoption rates newly diagnosed unmethylated patients



SOURCE: COMPANY DATA

The responses to the market research indicate that 84% of oncologists would prescribe paxalisib with a median overall survival benefit of 2.6 months.

The phase III program which is currently recruiting patients has several cohorts including newly diagnosed unmethylated, newly diagnosed methylated and patient with recurrent disease. The key group of interest are the newly diagnosed unmethylated patients who are randomised to receive the standard of care (temozolomide) or paxalisib. This patient group are the same group as those treated in the phase II study.

For comparison purposes we highlight the relative performance of Bayer's oral kinase inhibitor drug Stivarga. Stivarga is a second line therapy in the treatment of metastatic colorectal cancer. It is also approved as second line therapy for gastrointestinal stromal tumours. According to the FDA label, the drug produced a median survival benefit of 1.4 months in a randomised controlled trial (i.e. 6.4 months vs 5.0 months) in mCRC. In the GI tumour trial the drug failed to produce a survival benefit but it did produce a 3.9 month extension in progression free survival.

Stivarga has a far worse safety profile compared to paxalisib. In clinical trials, median duration of therapy was 7.3 weeks with 61% of patients requiring a dosing holiday and 38% of patients having their dose reduced. Dermatological toxicity was the most common cause for discontinuation. The drug also produces significant off target side effects in the GI tract and hepatotoxicity amongst others.

Despite its modest extension in median survival, in the most recent quarterly financial statements from Bayer, the 9 month YTD revenues for Stivarga were €357m (US$420m) and on a pro-rata basis FY21 revenues are US$560m.

Colorectal cancer is a ~3x larger indication than Glioblastoma, nevertheless we provide the comparison for the purposes of demonstrating adoption rates for new drugs in the treatment of disease where patients have no other treatment options.

We conclude that a 3 month median overall survival benefit with paxalisib is likely to make a commercially successful drug. Valuation is reduced by 10cps to $2.40 reflecting a modest adjustment to estimated long dated future earnings associated with the 1.4 months decline in overall survival as discussed above.

Risk Areas

The key risk include but are not limited to the follow items:

Kazia's ability to achieve profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise or partner both Paxalisib and Cantrixil. There is no guarantee that the company will achieve these goals.

Kazia does not currently generate revenue from product sales and revenues are not anticipated in the short to medium term. The company is likely to continue to rely on shareholders to fund the business of the foreseeable future.

Clinical trial risk

KZA may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct future clinical trials. There is also no assurance that either of the drugs under development will prove to be safe and efficacious in clinical trials, or that the regulatory approval to manufacture and market its products will be received. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.

Paxalisib must both undergo a comprehensive and highly regulated development and review process before receiving approval for marketing.

The company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales to fund sufficient revenues for continued operations and growth, may not be achieved.

Arrangements with third-party collaborators

Kazia may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of its products (including for the GBM Agile study). These collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. There is no assurance that Kazia will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals. If Kazia is unable to find a partner, it would be required to develop and commercialise its products at its own expense. This may place significant demands on the Company's internal resources and potentially delay the commercialisation.

Requirement to raise additional funds

The company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the company is unsuccessful in obtaining funds when they are required, it may need to delay or scale down its operations.

Intellectual property

The company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the company may incur substantial costs in asserting or defending its intellectual property rights.

Figure 3 - Summary clinical program

	Indication	Stage	n	Progress	Design	Sponsor	Registration
Paxalisib	Glioblastoma	Phase II	30	Completed recruitment	Single Arm, open label	Kazia Thereapeutics	NCT03522298
	Glioblastoma GBM Agile	Phase II/III	up to 200	Ethics approvals	Three treatment cohorts. Randomised controlled study	Alliance for clinical trials in Oncology and Genentech	NCT03970447
	Glioblastoma with kinetic diet	Phase II	33	Ethics approvals	Open label, two arm study investigating paxalisib with ketogenic diet	Weill Cornell Cancer Center, NY	TBA
	Brain Metastases	Phase II	50	Recruiting	Any brain metastses with clinically validated alternation in PI3K pathway	Alliance for clinical trial in Oncology	NCT03994796
	Brain metastases - breast cancer	Phase II	47	Recruiting	Non randomised, single arm, combination study of Paxalisib with Trastuzumab	Dana Farber Cancer Institute	NCT03765983
	Primary CNS Lymphoma	Phase II	25	Ethics approvals	Single Arm, open label	Dana Farber Cancer Institute	NCT04906096
	DIPG & DMG'S	Phase II	TBA	Ethics approvals	Paxalisib to be partnered with ONC022	Pacific Pediatric Neuro-oncology consortiu	TBA
	DIPG (childhood brain cancer)	Phase II	27	Recruiting	Various treatment cohorts on paxalisib and radiation therapy	St Jude Children's Research Hospital	NCT03696355
	Brain Metastases - any source	Phase 1	36	Recruiting	3+3 dose escalation cohorts on paxalisib and radiation therapy	Memorial Sloan Kettering	NCT04192981
EVT801	A range of advanced solid tumours	Phase 1	60	Recruiting	Single arm, dose ascending	Kazia Thereapeutics	NA

SOURCE: ASSEMBLED FROM COMPANY DATA

Kazia Therapeutics
as at 6 December 2021

Recommendation	Buy, Speculative
Price	$1.20
Valuation	$2.40

Table 1 - Financial summary

`	FY20	FY21	FY22e	FY23e	FY24e
Year Ending June					
R&D incentive	1.0	-	-	-	-
License income - paxalisib	-	10.0	-	41.7	-
License income - Cantrixil	-	5.2	-	-	-
Total Revenue	**1.0**	**15.2**	**-**	**41.7**	**86.3**
COGS	-	-	-	-	(1.4)
Gross profit	1.0	15.2	-	41.7	84.9
R&D spend - paxalisib	-9.5	-14.5	-10.0	-8.0	0.0
R&D spend - EVT801	0.0	0.0	-4.0	-5.0	0.0
Amortisation	-1.1	-1.3	-1.5	-1.1	-1.1
Other expenses	-2.1	-5.7	-6.0	-6.0	-6.0
Total Expenses	-13.7	-24.1	-21.5	-20.1	-7.1
EBIT	-12.7	-8.9	-21.5	21.6	77.8
Interest income	0.0	0.0	0.0	-0.1	-0.1
Pre tax profit	(12.7)	(8.9)	(21.5)	21.5	77.7
Tax expense	0.3	0.5	-	-	-
NPAT- normalised	**(12.4)**	**(8.4)**	**(21.5)**	**21.5**	**77.7**
Reported NPAT	(12.4)	(8.4)	(21.5)	21.5	77.7

Cashflow (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Gross cashflow	-8.8	-9.1	-19.4	23.3	79.6
Net interest	0.0	0.0	0.0	-0.1	-0.1
Operating cash flow	-8.8	-9.1	-19.4	23.2	79.5
Clinical trial deposit - GBM Agile	0.0	0.0	0.0	0.0	0.0
Free cash flow	-8.8	-9.1	-19.4	23.2	79.5
Other investments	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	12.1	28.1	0.0	0.0	0.0
Movement in borrowings	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Change in cash held	3.3	19.0	-19.4	23.2	79.5
Cash at beginning of period	5.4	8.7	27.6	8.2	31.4
FX adjustment	0.0	-0.1	0.0	0.0	0.0
Cash at year end	**8.7**	**27.6**	**8.2**	**31.4**	**110.9**

Balance Sheet (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	8.7	27.6	8.2	31.4	110.9
Receivables	1.4	0.1	0.1	0.1	0.1
Other current assets	0.5	1.7	1.7	1.7	1.7
Property, Plant and Equipment	-	-	-	-	-
Intangibles	12.4	22.0	20.5	19.4	18.3
Other non current assets	-	6.7	6.7	6.7	6.7
Total assets	23.0	58.1	37.2	59.3	137.7
Trade payables	3.5	4.9	4.9	4.9	4.9
Other liabilities	1.8	12.0	12.6	13.2	13.9
Deferred taxes	3.4	3.0	3.0	3.0	3.0
Provisions	0.2	0.3	0.3	0.3	0.3
Total Liabilities	8.9	20.2	20.8	21.4	22.1
Net Assets	14.1	37.9	16.4	37.9	115.6
Share capital	48.8	80.3	80.3	80.3	80.3
Other equity	1.5	1.8	1.8	1.8	1.8
Retained earnings	(36.2)	(44.2)	(65.7)	(44.2)	33.5
Reserves	-	-	-	-	-
Shareholders Equity	14.1	37.9	16.4	37.9	115.6

Valuation Ratios (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Reported EPS (cps)	-17.0	-6.4	-16.3	16.3	58.9
Normalised EPS (cps)	-17.0	-6.4	-16.3	16.3	58.9
EPS growth (%)	nm	nm	nm	nm	262%
PE(x)	**nm**	**nm**	**nm**	**7.4**	**2.0**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	66.8	9.9	-38.8	0.0	1.6
Book Value Per Share (cps)	14.9	28.7	12.4	28.7	87.6
Price/Book (x)	8.1	4.2	9.6	4.2	1.4
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	nm
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

Interim Results	1H21	2H21	1H22e	2H22e
Revenues	0.0	15.2	0.0	0.0
R&D Expense	-2.9	-11.6	-5.0	-5.0
Amortisation	-0.5	-0.8	-0.8	-0.7
All Other expenses	-3.0	-3.0	-3.0	-3.0
EBIT	-6.4	-2.5	-9.3	-12.2

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
Chris Savage	Head of Research/Industrials	612 8224 2835	csavage
Analysts			
TS Lim	Banks	612 8224 2810	tslim
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare	612 8224 2849	tnjain
Marcus Barnard	Industrials	618 9326 7673	mbarnard
Sam Brandwood	Industrials	612 8224 2850	sbrandwood
James Filius	Industrials	613 9235 1612	jfilius
Sam Haddad	Industrials	612 8224 2819	shaddad
Hamish Murray	Industrials	613 9235 1813	hmurray
Jonathan Snape	Industrials	613 9235 1601	jsnape
David Coates	Resources	612 8224 2887	dcoates
Stuart Howe	Resources	613 9235 1856	showe
Brad Watson	Resources	618 9326 7672	bwatson
Regan Burrows	Resources	618 9326 7677	rburrows
Joseph House	Resources	613 9235 1624	jhouse
Olivia Hagglund	Industrials	612 8224 2813	ohagglund
Associates			
Michael Ardrey	Associate Analyst	613 9256 8782	mardrey
Daniel Laing	Associate Analyst	612 8224 2886	dlaing

Bell Potter Securities Limited
ABN 25 006 390 772
Level 29, 101 Collins Street
Melbourne, Victoria, 3000
Telephone +61 3 9256 8700
www.bellpotter.com.au

Bell Potter Securities (HK) Limited
Room 1701, 17/F
Prosperity Tower, 39 Queens Road
Central, Hong Kong, 0000
Telephone +852 3750 8400

Bell Potter Securities (US) LLC
Floor 39
444 Madison Avenue, New York
NY 10022, U.S.A
Telephone +1 917 819 1410

Bell Potter Securities (UK) Limited
16 Berkeley Street
London, England
W1J 8DZ, United Kingdom
Telephone +44 7734 2929