BELL POTTER

18 November 2020

Speculative

See key risks on Page 5 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

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Kazia Therapeutics

Results Unlikely Due To Chance

Recommendation
Buy (unchanged)
Price
$1.565
Valuation (12 months)
$2.76 (previously $2.00)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

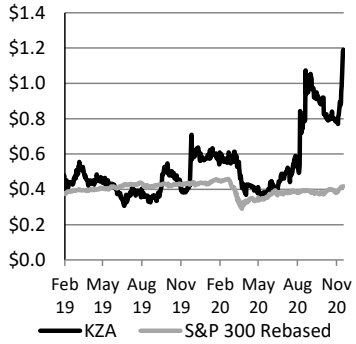
Expected Return	
Capital growth	**76.0%**
Dividend yield	**0.0%**
Total expected return	**76.0%**

Company Data & Ratios	
Enterprise value	**$222.2m**
Market cap	**198.1m**
Issued capital	**126.2m**
Free float	**100%**
Avg. daily val. (52wk)	**$210,000**
12 month price range	**$0.35 - $1.69**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.80	0.78	0.39
Absolute (%)	48.75	52.37	202.87
Rel market (%)	43.71	46.09	205.61

Absolute Price



SOURCE: IRESS

Latest Interim Data Confirms Efficacy in GBM

Kazia has released the latest interim data from its phase II study evaluating the safety and efficacy of its PI3K/mTOR inhibitor paxalisib in newly diagnosed patients with unmethylated glioblastoma (GBM). As the final patient was enrolled in March 2020, the study is near completion and we do not expect any significant change verses current data when finalised in 2021. The data is presented in a poster at the Society for Neuro Oncology (SNO) meeting being conducted in the US this weekend.

Amongst the 29 patients in this single arm study the median overall survival is 17.4 months which is basically unchanged from the 17.7 months reported at the last interim update in June 2020. The data is now more mature and in more patients, hence we conclude there is minimal risk the outcome is due to chance. Enrolment of the first patient in the approval study (GBM Agile) is due within weeks. Subject to confirmation of the survival benefit in this randomised controlled study, we expect that Kazia has an approvable drug, potentially on market in 2024. Generally new cancer therapies are approved on the basis of a single phase III, particularly in disease with Orphan indication.

Also at SNO, St Jude Hospital released early data from its study investigating the use of Paxalisib in the treatment of early childhood brain cancer known as DIPG. The investigator reported a 6 month progression free survival rate of 96% amongst trial participants vs 58% in historical control. The trial is continuing.

Valuation Increased to $2.76, Maintain Buy Rating

Based on the consistency of the data from the phase II trial the risk of failure in a phase III trial is in our view considerably diminished. Accordingly the valuation is raised by 38% to $2.76. The valuation is based on a DCF. EPS for FY21/FY22 is unchanged, FY23 is raised by 18%. While a partnering deal remains a potential outcome, we now believe it is more likely the company will be subject to a takeover offer from a large pharma group.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	1.0	4.3	4.5	46.2
EBIT $m	-12.7	-19.7	-10.5	32.2
NPAT (underlying) $m	-12.4	-19.5	-10.6	32.1
NPAT (reported) $m	-12.4	-19.5	-10.6	32.1
EPS underlying (cps)	-17.0	-15.4	-8.4	25.3
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	6.2
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	100%
Yield %	0%	0%	0%	0%
ROE %	-88%	-97%	-112%	77%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Efficacy Data Now Unlikely Due To Chance

29 patients included in interim data

Kazia has released the latest interim data from its phase II study evaluating the safety and efficacy of its PI3K/mTOR inhibitor paxalisib in newly diagnosed glioblastoma patients with unmethylated glioblastoma. As the final patient was enrolled in March 2020, the study is all but complete and we do not expect any significant change in the efficacy data.

SAFETY:

The key points are:

- The max tolerable dose in the study is 60mg. Most patients received this dose with the exception of 6 patients in the dose escalation cohort who received 75mg. Paxalisib is an oral medication, dosed daily. Patients remain on drug until disease progression;
- Toxicities were highly consistent with other PI3K/mTOR inhibitors and with prior use of this drug; and
- The most common adverse events were rash, stomatitis (inflammation of mouth and lips including mouth ulcers), hyperglycemia (high blood sugar levels), fatigue, nausea and decreased appetite. There was no evidence of pneumonitis (inflammation of lung tissue), cardiac toxicity, GI perforation, infection, CNS toxicity or liver toxicity.

EFFICACY

We summarise the progress of the interim data announcements as follows.

Figure 1 - Efficacy data - phase 2

(all efficacy data in months)	Nov-20	Jun-20	Nov-20	Standard of care
Progression free survival	8.4	8.5	8.4	5.3
95% CI	7.3 - 10.0	8.1 - NR	NR	na
Overall survival	17.4	17.7	na	12.7
95% CI	15.0 - NR	10.5 - NR	NR	na
Patients (n)	29	27	9	na

SOURCE: COMPANY DATA

There are twenty nine patients in the per protocol group with 1 patient being excluded for non-compliance in this latest interim data.

We note the extension in the bottom end of the 95% confidence interval for OS from 10 to 15 months. The statisticians are yet to report the top end of the 95% CI mainly because patient survival data continues to mature. We understand at least two patients remain alive 2 years post diagnosis, with one of these still progression free and remaining on the drug at 27 months.

We note the 95% CI for PFS at 7.3 – 10.0 months which is encouraging and is a fairly tight range. The bottom end of the range remains well above the median 5.3 months on standard of care. This difference may seem a minor point, but has significant implications for pricing and reimbursement.

At the conclusion of this phase II study next year we expect the median overall survival to be in the range of 17 to 18 months relative to the standard of care at 12.7 months. The

survival benefit of almost 5 months should be considered a major step forward in the treatment of the disease.

Provided the safety and efficacy data are sustained in the approval study we are confident not only that the drug will be approved, but that it will enjoy a healthy price point. We estimate at least US$100,000 per year of treatment.

This latest data is highly consistent with the earlier data points, now in more patients and with a substantially longer period under treatment.

DIPG

Diffuse Intrinsic Pontine Glioma (DIPG) is a rare and aggressive form of childhood brain cancer. St Jude Hospital in Memphis Tennessee is running this single arm investigator sponsored study with and intent to treat population of 27 patients, 23 of which actually received drug. The trial is now fully recruited.

Due to the nature and location of these tumours, they are not suitable for surgery, hence the primary therapy is drug and radiotherapy. The disease has a 100% mortality rate, hence significant unmet need.

The investigators have not supplied a formal survival analysis at this time, however, the company has supplied the following statement.

'In terms of PFS, the proportion of patients alive and progression-free at six months (PFS6) was 96%, which compares favourably to an historical control of 58%. However, the authors note that PFS can be a complex endpoint to interpret in DIPG trials due to the confounding effect of incidental radiological changes associated with radiation therapy'

The DIPG study is trialling the combination of Paxalisib with radiotherapy. This is not unlike the treatment protocol for GBM where patients first undergo surgery, followed by adjuvant radiotherapy followed by Paxalisib.

Further in relation to the DIPG study, we note the additional comment by the lead investigator Dr Christopher Tinkle, "*DIPG is an extremely treatment resistant disease, and no drug has ever shown convincing efficacy as a monotherapy".*

The comment is not surprising and neither are we discouraged by the message. Drugs for the treatment of DIPG must also pass through the blood brain barrier (as is the care for GBM). Other than temozolomide (which is not suitable for children) no other drug has ever been effective in the treatment of brain cancers.

The investigators are continuing with the study and clearly do not see it as a futile exercise. We are encouraged by the initial data and look forward to further analysis in 2021.

The trial is continuing and is likely to report final data in mid CY2021.

The FDA has previously granted orphan drug status and rare paediatric disease designation to Paxalisib. These two designations provide a significant set of incentives and IP protection for Paxalisib post approval. The 7 year orphan drug exclusivity and the RPD voucher are two of the most tangible benefits.

Changes to earnings and valuation

The changes to earnings and valuation result from our assessment of now reduced development risk for paxalisib. The data released today goes a substantial way to confirming that the earlier efficacy data was unlikely due to chance. The data from this single arm study (in GBM) is now fairly robust, however, as there is no control group there remains an element of doubt in regards to the effect size.

Nevertheless we now deem it is appropriate to reduce the risk of failure in GBM from 50% to 40%. Accordingly the DCF model increases in value with the value per share now estimated at $2.76.

There remain several levers for further upward revaluation subject to the continuation of meaningful clinical data.

The DCF assumes the company partners the drug for commercialisation with a series of upfront milestone payments and royalties.

The board may also consider a takeover offer for the company as an exit. The implied enterprise value of the company at our $2.76 valuation is a mere US$268m.

It is doubtful the Board would regard an offer at this level as worthy of taking to shareholders. A recent comparable transaction was Merck's acquisition of Viralytics in 2018 for ~US$350m. VLA had not commenced a phase III study with its single asset. With the phase II study in GBM now all but complete, KZA should be considered a late stage drug developer.

Figure 2 - Summary of earnings changes

	2021			2022			2023		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	4.3	4.3	0%	4.5	4.5	0%	46.2	41.3	12%
EBIT	-19.7	-19.7	0%	-10.5	-10.5	0%	32.2	27.3	-18%
NPAT	-19.5	-19.5	0%	-10.6	-10.6	0%	32.1	27.2	-18%
EPS	-15.4	-15.4	0%	-8.4	-8.4	0%	25.3	21.5	-18%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Valuation is amended to $2.76 (from $2.00) and we retain our Buy (Speculative) recommendation.

Figure 3 - Clinical Trial Program Overview

	Indication	Stage	n	Progress	Design	Sponsor	Registration
Paxalisib	Glioblastoma	Phase II	30	Completed recruitment	Single Arm, open label	Kazia Thereapeutics	NCT03522298
	Glioblastoma	Phase II/III	up to 200	Ethics approvals	Three treatment cohorts. Randomised controlled study	Alliance for clinical trials in Oncology and Genentech	NCT03970447
	DIPG (childhood brain cancer)	Phase II	27	Active, Not Recruiting	Various treatment cohorts on paxalisib and radiation therapy	St Jude Children's Research Hospital	NCT03696355
	Primary CNS Lymphoma	Phase II	25	Ethics approvals	Single Arm, open label	Dana Farber Cancer Institute	Not yet registered
	Brain Metastases	Phase II	150	Recruiting	Any brain metastses with clinically validated alternation in PI3K pathway	National Cancer Institute	NCT03994796
	Brain metastases - breast cancer	Phase II	47	Recruiting	Non randomised, single arm, combination study of Paxalisib with Trastuzumab	Dana Farber Cancer Institute	NCT03765983
	Brain Metastases - any source	Phase 1	36	Recruiting	3+3 dose escalation cohorts on paxalisib and radiation therapy	Memorial Sloan Kettering	NCT04192981
Cantrixil	Recurrent Ovarian Cancer	Phase 1	28	Completed recruitment	Part A - dose escalation, Part B Expansion Cohort	Kazia Thereapeutics	NCT02903771

SOURCE: COMPANY DATA

Paxalisib belongs to a drug class (PI3K) where there are already multiple drugs on market (though none indicated for glioblastoma) and where the mechanism of action is well understood. Generally new cancer therapies are approved on the basis of a single phase III, particularly in disease with Orphan indication.

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 and Cantrixil 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.

Kazia Therapeutics
as at 18 November 2020

Recommendation	Buy, Speculative
Valuation	$1.565
Target (12 months)	$2.76

Table 1 - Financial summary

	FY19	FY20	FY21e	FY22e	FY23e
Year Ending June					
R&D incentive	1.4	1.0	4.3	4.5	4.5
Total Revenue	**1.5**	**1.0**	**4.3**	**4.5**	**46.2**
COGS	-	-	-	-	-
Gross profit	1.5	1.0	4.3	4.5	46.2
R&D	-6.5	-9.5	-19.0	-10.0	-8.0
Other expenses	-3.9	-3.2	-5.0	-5.0	-6.0
Total Expenses	-12.2	-13.7	-24.0	-15.0	-14.0
EBIT	-10.7	-12.7	-19.7	-10.5	32.2
Interest income	0.0	0.0	0.2	-0.1	-0.1
Pre tax profit	(10.6)	(12.7)	(19.5)	(10.6)	32.1
Tax expense	0.3	0.3	-	-	-
NPAT- normalised	**(10.3)**	**(12.4)**	**(19.5)**	**(10.6)**	**32.1**
Reported NPAT	(10.3)	(12.4)	(19.5)	(10.6)	32.1

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-6.7	-8.8	-19.6	-10.4	32.3
Net interest	0.0	0.0	0.2	-0.1	-0.1
Operating cash flow	-6.7	-8.8	-19.4	-10.5	32.2
Proceeds from asset sales	2.4	0.0	0.0	0.0	0.0
Free cash flow	-4.3	-8.8	-19.4	-10.5	32.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	3.8	12.1	25.6	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	-0.5	3.3	6.2	-10.5	32.2
Cash at beginning of period	6.0	5.4	8.7	14.9	4.4
FX adjustment	-0.1	0.0	0.0	0.0	0.0
Cash at year end	**5.4**	**8.7**	**14.9**	**4.4**	**36.5**

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	5.4	8.7	14.9	4.4	36.5
Receivables	1.7	1.4	1.4	1.4	1.4
Other current assets	0.4	0.5	0.5	0.5	0.5
Property, Plant and Equipment	-	-	-	-	-
Intangibles	13.5	12.4	12.4	12.4	12.4
Other non current assets	0.2	-	-	-	-
Total assets	21.2	23.0	29.1	18.6	50.8
Trade payables	1.8	3.5	3.5	3.5	3.5
Other liabilities	1.4	1.8	1.9	2.0	2.1
Deferred taxes	3.7	3.4	3.4	3.4	3.4
Provisions	0.1	0.2	0.2	0.2	0.2
Total Liabilities	7.0	8.9	9.0	9.1	9.2
Net Assets	14.2	14.1	20.1	9.5	41.6
Share capital	36.6	48.8	74.4	74.4	74.4
Other equity	2.5	1.5	1.4	1.4	1.4
Retained earnings	(24.9)	(36.2)	(55.7)	(66.3)	(34.2)
Reserves	-	-	-	-	-
Shareholders Equity	14.2	14.1	20.1	9.5	41.6

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-16.6	-17.0	-15.4	-8.4	25.3
Normalised EPS (cps)	-16.6	-17.0	-15.4	-8.4	25.3
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**6.2**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	138.8	87.1	25.7	- 68.3	-
Book Value Per Share (cps)	22.9	14.9	15.9	7.5	32.9
Price/Book (x)	6.8	10.5	9.9	20.9	4.8
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	1H20	2H20	1H21e	2H21e
Revenues	0.6	0.4	0.6	3.7
R&D Expense	-4.2	-5.3	-12.0	-7.0
All Other expenses	-2.4	-0.8	-3.0	-2.0
EBIT	-6.2	-6.5	-7.4	-12.3

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.

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