BELL POTTER

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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

GBM Agile In More Detail

Recommendation
Buy (unchanged)
Price
$0.79
Valuation
$2.00 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**153%**
Dividend yield	**0%**
Total expected return	**153%**

Company Data & Ratios	
Enterprise value	**$124.5m**
Market cap	**$99.5m**
Issued capital	**126.2m**
Free float	**100%**
Avg. daily val. (52wk)	**$194,000**
12 month price range	**$0.35 - $1.18**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.89	0.57	0.45
Absolute (%)	-11.92	38.84	76.16
Rel market (%)	-11.94	39.65	87.42

Absolute Price

SOURCE: IRESS

Multiple Upcoming Catalysts

Kazia has now released its quarterly activity report and cash flow statement. Following the recent capital raise the company has notional cash reserves of $33m less the US$5m that we understand it has now paid for commencement in the GBM Agile pivotal study. We conclude that effective cash as at 30 September is ~$26m. KZA is yet to disclose the full cost of GBM Agile, however, its quarterly report does state that the recent capital raise (for $25m) leaves the company well funded to execute the GBM Agile pivotal study. Had the company elected to fund a standalone study, we estimate the cost would have been at least double and taken potentially years longer.

Earlier in October the company confirmed its participation in the GBM Agile which is a phase II/III study designed for registration of paxalisib in glioblastoma. The remainder of the report describes the trial design in further detail. The only slightly unexpected aspect of the design is that patients will be initially dosed at 45mg for 28 days before stepping up to the higher dose of 60mg as has been used in stage II of the ongoing phase II study. This design is deliberate to identify and treat patients who have adverse reactions to therapy at the lower dose. We have minimal concern that the short term lower dose may adversely effect the outcome of the study.

Recruitment of up to 200 patients is expected to take 2 years with headline data likely in late 2023 or 2024 depending on patient survival and recruitment rates. There are thirty sites across Canada and US participating in the trial which is an extraordinarily high number relative to KZA's market capitalisation and size, and is well beyond anything the company could have achieved had it pursued a standalone study. Paxalisib is the second drug to enter this platform study.

Maintain Buy (Speculative) Valuation $2.00

Our valuation is unchanged and we retain our Buy (Speculative) recommendation. There are no significant changes to earnings. Next catalyst is further interim data from the phase II study in addition to initial data from the DIPG study both due later this month.

Earnings Forecast

Year end June	FY20	FY21e	FY22e	FY23e
Sales (A$m)	1.0	4.3	4.5	41.3
EBITDA (A$m)	-12.7	-19.7	-10.5	27.3
NPAT (reported) (A$m)	-12.4	-19.5	-10.6	27.2
NPAT (adjusted) (A$m)	-12.4	-19.5	-10.6	27.2
EPS (adjusted) (¢ps)	-17.0	-15.4	-8.4	21.5
EPS growth (%)	nm	nm	nm	nm
PER (x)	nm	nm	nm	3.7
FCF Yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (¢ps)	-	-	-	-
Yield (%)	0%	0%	0%	100%
Franking (%)	0%	0%	0%	0%
ROE (%)	-88%	-97%	-112%	74%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Key elements of the trial design

Set out below are the key features of the upcoming GBM Agile study. The study is essentially a randomised, non blinded, controlled study comparing paxalisib to the standard of care therapy in initially diagnosed patients and patients with recurrent disease.

Figure 1 - GBM Agile Trial Design

Number of subjects	Stage 1 – up to 150 (adaptive randomisation) Stage 2 – 50 patients (fixed randomisation)
Endpoints	Primary endpoint – overall survival benefit Secondary endpoint – progression free survival
Design	Open label randomised controlled trial. Stage 1 will run first and there will be a seamless transition into phase 2. Stage 1 – a phase II 'screening' stage will evaluate paxalisib with newly diagnosed unmethylated and recurrent patients only. Stage 1 will stop recruiting patients if it reaches maximum sample size, drops for futility, or evinces inadequate safety. Stage 2 is a phase II confirmatory stage with fixed randomization.
Dosing	All patients will undergo surgical resection and XBT. Patients in the active arm will receive daily dosing of paxalisib until progression. Patients receiving paxalisib will initially be dosed at 45mg daily, increasing to 60mg daily after 30 days continuing on this dose until progression. Patients in the control arm receive standard of care chemotherapy (temozolomide). For those in the recurrent arm, no further surgery or XRT. These patients will go straight onto paxalisib. The control group in the recurrent section group is best supportive care (palliative care).
Patient Population	GBM Agile is recruiting three patient groups of which paxalisib is participating in two of the three. The groups are : • newly diagnosed unmethylated patient (being the target group for paxalisib); • newly diagnosed methylated (paxalisib will not be used in this group); and • recurrent patients i.e. those that have failed on temozolomide following surgery and have experienced tumour regrowth. Patients in the recurrent group will be either methylated or unmethylated.
Start date	Either later CY2020 or early 2021. The study is expected to take 2 to 3 years to complete enrolment.

SOURCE: COMPANY DATA, (XBY – EXTERNAL BEAM THERAPY AT 60GY)

In relation to the recurrent group, the company sponsored phase II did not treat recurrent patients.

In the phase II/III study the investigators have elected to include a sub population of recurrent patients essentially because there is no downside. These patients will be further stratified between methylated or unmethylated.

Generally once the tumours emerge after the initially surgery and adjuvant therapy there are no further treatment options available. In the event that patients in this group show even a modest improvement in overall survival this would represent an additional market for paxalisib, hence it is worth the investment.

Patients won't be allowed to participate twice i.e. as a newly diagnosed patient and a recurrent patient.

The largest group in the study will be newly diagnosed, unmethylated patients – i.e. the group which has no response to temozolomide.

The trial is limited to adults only. The investigator led studies as outlined on the following pages continue to recruit patients across a variety of indications including in childhood disease.

In GBM AGILE, progression has to be confirmed by two consecutive scans, at least a month apart. This design (a) it is a more robust measure of progression, and (b) patients will generally spend at least a month longer on drug than they would otherwise. This design cuts out false signals from a phenomenon called 'pseudo-progression', in which a patient can look like they have progressed, but it's actually just swelling.

Patients are scanned every eight weeks if they are newly diagnosed, and every six weeks if they are recurrent. The recurrent patients progress sooner, hence the greater frequency of scans.

For the newly diagnosed patients, after surgery they typically have up to two weeks of recovery time, then commence six weeks of radiotherapy, and then have up to another two weeks. The interval from surgery to commencing treatment will typically be around 8-10 weeks.

OUR COMMENTS

The study is officially described as an open label, however, we do not expect interim data readouts. The FDA generally frowns upon interim readouts in pivotal studies. At best we can expect an announcement that the study has progressed from stage I to stage II at some point. There may be some data regarding secondary endpoints.

There will be a select group including the principal investigator and key statisticians that will review data on a monthly basis once recruitment reaches 50 patients. This group will be responsible for the steering the adaptive design of the trial as data accrues.

The ongoing data will be locked to persons outside this group (including Kazia).

We note the study is not blinded, however it is randomised. This (the non blinding) is a consequence of the study being a platform study for at least two drugs. During the course of the study one or more drugs may be added or leave the GBM Agile. In addition paxalisib is known to have distinctive side effects which will become obvious to patients and physicians.

The reading of the scans by radiologists is blinded i.e. the radiologist won't know which patients received paxalisib vs SOC.

The final statistical analysis will be calculated from all trial participants (up to 200) participating in the trial. While the FDA generally wants data from two separate trials for new drug approvals, this is normally waived for cancer trials particularly where there is no alternative therapy. In this case, GBM Agile will effectively provide two sets of data from stage 1 and stage 2 in these sequentially run studies.

Next catalyst is further interim data from the phase II study later this month in addition to initial data from the DIPG childhood brain cancer study being conducted at St Judes in Memphis.

Figure 2 - Overview of clinical trial program

	Indication	Stage	n	Progress	Design	Sponsor	Registration
Paxalisib	Glioblastoma	Phase II	27	Completed recruitment	Single Arm, open label	Kazia Thereapeutics	NCT03522298
	Glioblastoma	Phase II/III	up to 200	Ethics approvals	Three treatment cohorts. Pts receive one of three drugs, one of which is Paxalisib.	Alliance for clinical trials in Oncology and Genentech	NCT03970447
	DIPG (childhood brain cancer)	Phase II	41	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

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 2 November 2020

Recommendation	Buy, Speculative
Price	$0.79
Target (12 months)	$2.00

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**	**41.3**
COGS	-	-	-	-	-
Gross profit	1.5	1.0	4.3	4.5	41.3
Expenses Net of 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	27.3
Interest income	0.0	0.0	0.2	-0.1	-0.1
Pre tax profit	(10.6)	(12.7)	(19.5)	(10.6)	27.2
Tax expense	0.3	0.3	-	-	-
NPAT- normalised	**(10.3)**	**(12.4)**	**(19.5)**	**(10.6)**	**27.2**
Reported NPAT	(10.3)	(12.4)	(19.5)	(10.6)	27.2

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-6.7	-8.8	-19.6	-10.4	27.4
Net interest	0.0	0.0	0.2	-0.1	-0.1
Operating cash flow	-6.7	-8.8	-19.4	-10.5	27.3
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	27.3
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	27.3
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**	**31.6**

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	5.4	8.7	14.9	4.4	31.6
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	45.9
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	36.7
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)	(39.1)
Reserves	-	-	-	-	-
Shareholders Equity	14.2	14.1	20.1	9.5	36.7

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-16.6	-17.0	-15.4	-8.4	21.5
Normalised EPS (cps)	-16.6	-17.0	-15.4	-8.4	21.5
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**3.7**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	70.1	44.0	13.0	- 34.5	-
Book Value Per Share (cps)	22.9	14.9	15.9	7.5	29.0
Price/Book (x)	3.5	5.3	5.0	10.5	2.7
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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