BELL POTTER

12 October 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

Approval Study Substantially Funded

Recommendation
Buy (unchanged)
Price
$0.79
Valuation (12 months)
$2.00 (previously $1.50)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

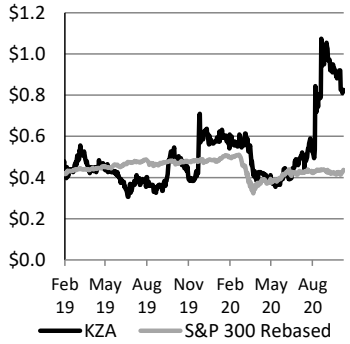
Expected Return	
Capital growth	**153%**
Dividend yield	**0.0%**
Total expected return	**153%**

Company Data & Ratios	
Enterprise value	**$65.1m**
Market cap	**$92.1m**
Issued capital	**115.1**
Free float	**100%**
Avg. daily val. (52wk)	**$176,000**
12 month price range	**$0.35 - $1.18**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.97	0.50	0.48
Absolute (%)	-17.75	59.01	66.96
Rel market (%)	-20.48	57.20	73.73

Absolute Price



SOURCE: IRESS

Commercial Agreement for GBM Agile Imminent

Following the recent capital raise for $25m (fully underwritten) the company is now substantially funded to complete both the current phase II trial in glioblastoma and GBM Agile, being the approval study in the same indication.

The company is yet to disclose the payment schedule for GBM Agile and the other key commercial terms, however, it is reasonable to assume this raising will largely, if not fully fund the program. Following the capital raise we expect the company will have cash reserves of $33m.

The upcoming news flow is expected to include execution of the Agreement for GBM Agile and recruitment of the first patient on the study. Further detail on the trial design including patient numbers and design are likely at that time. Of equal or greater significance for all stakeholders is the next interim update from the phase II program in glioblastoma with this data due before Christmas 2020. The effect size in the first 9 patients on the trial was highly material with a survival benefit over the standard of care of 5 months. While there was no control group in this single arm study, the likelihood of this being due to chance is low, hence the interest from various investigators not only at GBM Agile but from the various investigator led studies as well. We also expect a further series of announcements on the progress of these various investigator led studies in 1Q CY21.

Retain Buy (Speculative), Valuation raised to $2.00

The forecast includes the adjustment to the balance sheet and shares on issue for the underwritten capital raise. Valuation is calculated based on the theoretical shares on issue following the capital raise in line with the company's statement to the market for the issue of new shares. Other earnings adjustments include an update to R&D costs based on new information regarding GBM Agile. The trial will take 2 to 3 years to complete from November 2020. Valuation is amended to $2.00 from $1.50 and we maintain our Buy (speculative) recommendation.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	1.0	4.3	4.5	41.3
EBIT $m	-12.7	-19.7	-10.5	27.3
NPAT (underlying) $m	-12.4	-19.5	-10.6	27.2
NPAT (reported) $m	-12.4	-19.5	-10.6	27.2
EPS underlying (cps)	-17.0	-15.4	-8.4	21.5
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	3.8
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%	74%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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Previous Funding Assumptions Now Updated

We had previously estimated Kazia's share of the phase III trial would be ~$48m over three years. It now appears the cost will be substantially less at ~$25m. We had previously assumed a larger capital raise at a lower price to fund this commitment.

The company will now issue ~31.5m shares representing dilution of 33% to the previous 94m shares on issue. The issue price was $0.80.

The combination of the higher than expected issue price with lower dilution are the key drivers of the increase in valuation. There are no significant changes to our revenue projections.

The implied market capitalisation at $2.00 with 126m shares on issue (following dilution) is $252m. In relative terms this remains well below an indicative valuation for a stage 3 asset in an orphan indication[1].

How do we think about risk in the approval study ?

Oncology is a well funded area of clinical development and this is why at any given oncology conference there are a sea of companies with various assets in clinical development, many of which are hoping to attract the interest of larger development partners. Many seek to combine a new anti-cancer agent with one of the leading immuno oncology drugs in order to generate a synergistic outcome.

In most cases the drug development candidate has little or no efficacy as a monotherapy and in our view this is leading indicator of whether or not the combination is likely to show a survival benefit. Many do not ever run monotherapy trials in humans.

Thinking about Paxalisib and these issue amongst others, and the key points are:

- The drug is not designed to work in combination with any other agent. Patients in the phase II received paxalisib as an adjuvant therapy following surgical resection and initial therapy with temozolomide (TMZ). Due to the genetic profile of the disease (MGMT unmethylated) these patients are known to receive little or no benefit from the TMZ. It is reasonable to conclude that the entire 5 month survival benefit shown in the interim data is attributable to paxalisib;
- The approval study will be a randomized, blinded and controlled study with the control being TMZ. We believe the risk of the control group doing significantly better than the long established pattern of survival from the standard of care is remote. It is only the unmethylated patients who will be included in the control group;
- We assume that the patient population in the approval study will be substantially the same as the patient group in the phase II. i.e. similar age range with no

[1] Viralytics was acquired in 2017 by Merck for ~$460m with a single phase II asset.

significant co-morbidities. The key inclusion criteria for the study are set out in the description of the phase II study at clinicaltrials.gov. Any deviation from these key inclusion criteria may be an additional risk factor. The inclusion criteria are:

- Age ≥ 18 years;
- Life expectancy > 12 weeks;
- Present with histologically confirmed intracranial (supratentorial) unmethylated MGMT promotor status GBM (WHO Grade IV astrocytoma) with a MGMT status that has been confirmed by validated PCR or validated alternate genomic analysis;
- Have undergone maximal surgical resection of their tumor and within 6 weeks of surgery received initial treatment with XRT/TMZ which consisted of XRT by external beam to a partial brain field in daily fractions of 2.0 Gray (Gy), to a planned total dose to the tumor of 60.0 Gy, in conjunction with TMZ oral QD 75 mg/m2 in accordance with the Stupp regimen;

- Paxalisib is not first in class. There are 4 other PI3K inhibitor drugs already approved by the FDA (none of which pass through the blood brain barrier and for this reason have no efficacy in glioblastoma). Any first in class therapy would be expected to receive additional attention from regulators; finally
- Paxalisib is a small molecule drug that is relatively straight forward to manufacture in the hands of an experienced API manufacturer. It is highly stable molecule and the same batch of drug that was used for the phase II trial will be used in the phase III.

While there are numerous other risks in the phase III trial, in our view the major risk factors that have the potential to complicate the result are the key patient inclusion criteria and the potential for an unexpected result in the control group. There is little room for judgement in the inclusion criteria and the likelihood of an unexpected outcome in the control group is remote – particularly because of the bio-marker.

We take additional comfort in the observation that the effect size in the interim read out in the phase II was of such significance, (and assuming this is repeated in the phase III) that any out performance in the control group is unlikely to effect statistical difference in the final outcome of the phase III particularly across a large group.

Finally the bar for approval is low. Any extension in survival benefit (subject to an adequate safety profile) is likely to gain approval. A more significant OS benefit is likely to lead to a higher more attractive pricing.

News Flow

The upcoming news flow is expected to include the following items:

- Execution of the Agreement for GBM Agile and recruitment of the first patient on the study;
- Further detail on the trial design including patient numbers and design are likely at that time;
- The next interim update from the phase II program in glioblastoma with this data due before Christmas 2020. The effect size in the first 9 patients on the trial was highly material with a survival benefit over the standard of care of 5 months. While there was no control group in this single arm study, the likelihood of this being due to chance is low;

- We also expect a further series of announcements on the progress of these various investigator led studies in 1Q CY21.

Retain Buy (Speculative), Valuation raised to $2.00

We have adjusted the balance sheet and shares on issue in the forecast for the underwritten capital raise. Valuation is calculated based on the theoretical shares on issue following the capital raise in line with the company's statement to the market for the issue of new shares (i.e. 31.5m new shares). Other earnings adjustments include an update to R&D costs based on new information regarding GBM Agile. The trial will take 2 to 3 years to complete from November 2020.

The valuation excludes the potential future costs of clinical trials associated with adjacent indications that are the subject of ongoing investigator led studies in the US (refer figure 2). The current phase I studies are mostly funded by the investigators with minimal commitment from Kazia.

The implied market capitalisation at our target price is ~$252m. In our view this is likely to be beneath the floor price the Board would consider in the event of an unsolicited takeover offer for the company. We expect the likelihood of an offer will increase as various regulatory and clinical hurdles are met.

Figure 1 – Changes to earnings

	2021			2022		
	New	Old	% change	New	Old	% change
Revenues	4.3	4.3	0%	4.5	7.2	-38%
EBIT	-19.7	-12.7	-55%	-10.5	-18.8	44%
NPAT	-19.5	-19.8	1%	-10.6	-18.9	44%
EPS	-15.4	-12.5	-23%	-8.4	-11.9	30%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Figure 2 - Summary 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 III	up to 200	Ethics approvals	Randomised Controlled Study	Kazia Therapeutics/GBM Agile	NCT03970447
	Brain metastases - any source	Phase II	150	Recruiting	Three treatment cohorts. Pts receive one of three drugs, one of which is Paxalisib.	Alliance for clinical trials in Oncology and Genentech	NCT03994796
	Brain metastases - breast cancer	Phase II	47	Recruiting	Non randomised, single arm, combination study of Paxalisib with Trastuzumab	Dana Farber Cancer Institute	NCT03765983
	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
	Brain Metastases - any source	Phase 1	36	Recruiting	3+3 dose escalation cohorts on paxalisib and radiation therapy	Memorial Sloan Kettering	NCT04192981
	CNS Lymphoma	Phase II	25	Ethics approvals	Single Arm, open label	Dana Farber Cancer Institute	Not yet registered
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 12 October 2020

Recommendation	Buy, Speculative
Price	$0.79
Valuation (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**	**3.8**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	71.6	44.9	13.3	- 35.3	-
Book Value Per Share (cps)	22.9	14.9	15.9	7.5	29.0
Price/Book (x)	3.5	5.4	5.1	10.8	2.8
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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