BELL POTTER

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Speculative

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

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Kazia Therapeutics

China Out License Deal

Recommendation
Buy (unchanged)
Price
$1.595
Target (12 months)
$3.60 (previously $2.76)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

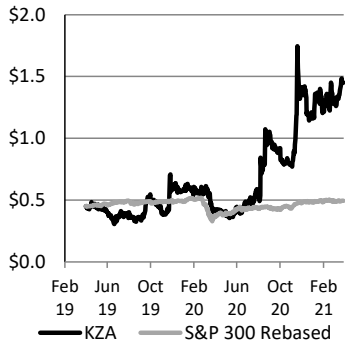
Expected Return	
Capital growth	**125.0%**
Dividend yield	**0.0%**
Total expected return	**125.0%**

Company Data & Ratios	
Enterprise value	**$236.6m**
Market cap	**$206.6m**
Issued capital	**129.5**
Free float	**100%**
Avg. daily val. (52wk)	**$323,000**
12 month price range	**$0.35 - $1.78**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.43	1.15	0.41
Absolute (%)	1.75	26.64	256.02
Rel market (%)	2.41	23.55	211.30

Absolute Price



SOURCE: IRESS

US$291m Headline Deal For China

Kazia has announced an out license deal for Paxalisib with Simcere Pharmaceuticals Group Ltd – a company listed on the HKSE (market cap ~US$3bn). Simcere currently has ~40 products on market in China. KZA remains well funded to complete its current clinical program, therefore, this transaction was driven by a need to secure a high quality partner for the very large and highly complex market in China including the surrounding territories of Taiwan, Hong Kong and Macau.

We expect headline results from the approval study for Paxalisib in mid to late 2022. The data from the same study is also likely to meet regulatory requirements in China meaning that a separate study is unlikely. Even though a launch remains well off, management at Kazia wanted to accelerate a partnering deal in China in order to maximise the available time for the partner to engage with regulators prior to approval. As we understand the Chinese market is notoriously complex and requires expert local knowledge and lot of time in order to bring a new drug to market.

We estimate peak sales for glioblastoma in greater China at US$127m annually. The addressable market is much larger, however, market penetration is significantly lower than Europe, USA and Australia.

Kazia will receive a US$7m upfront cash payment and issue the equivalent of US$4m in new equity to Simcere (representing 2.3% dilution). Milestone payments to Kazia total US$281m subject to normal development and commercial milestones and are in addition to royalties. The IP protection in China runs until at least 2031.

Investment View: Upgrade to Valuation, Retain Buy (Spec)

We estimate the value of the Simcere transaction at approximately $1.00 per share. Our valuation is increased to $3.60 from $2.76 following a re-assessment of the global market opportunity for paxalisib. We have also updated earnings for the recent out license deal for Cantrixil. FY21 NPAT decreases by $12.3m to a loss of $7.2m. FY22 loss is increased by $2.1m to $12.7m. We maintain our Buy (speculative) rating. We estimate KZA has ~$30m in cash reserves following this announcement.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	1.0	18.7	4.5	46.2
EBIT $m	-12.7	-7.4	-12.6	31.1
NPAT (underlying) $m	-12.4	-7.2	-12.7	31.0
NPAT (reported) $m	-12.4	-7.2	-12.7	31.0
EPS underlying (cps)	-17.0	-5.6	-9.8	23.9
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	6.7
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%	-19%	-51%	55%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Greater China Out Licence Deal

Kazia Therapeutics has announced a transaction to out license its lead asset Paxalisib in China, Hong Kong, Macau and Taiwan (collectively greater China). The out license partner is Simcere Pharmaceuticals Group (HKSE:2096). Simcere assumes all responsibility for development and commercialisation in these territories.

The Chinese regulator is likely to recognise data from the ongoing GBM Agile phase III study for the purposes of approval. The trial is currently recruiting patients in the US and shortly in China. We expect approval in late 2023 or early 2024. Accelerated approval based on the results from the phase II study is a possibility.

Key financial terms of the deal are as follows:

- Kazia will receive an upfront of US$11m (A$14.2m) comprising US$7m in cash and issue US$4m in new equity;
- Up to US$281m in development and commercialisation milestones. Details of these milestone points were not discussed, however, they are likely to be in line with normal practice i.e. approval, product launch, cumulative sales; and
- Tiered double digit percentage royalty of net sales.

The headline deal value of US$292m is comparable with recent deals in oncology assets in the region. The new equity will be issued at 20% premium to closing price prior to the stock going into trading halt. We estimate the new stock will be issued at ~$1.74. Following the issue of new shares, Simcere will own ~2.3% of the KZA.

ADDRESSABLE MARKET

Kazia estimates there are approximately 22K to 25K new cases of GBM is these markets annually. Current treatment is surgery, followed by radiotherapy and temozolomide. This is also the standard of care in western markets.

ESTIMATE VALUE PER SHARE

The average price of new cancer therapies in the US is estimated at ~US$148,000 per patient. Assuming this proxy for paxalisib pricing once approved and then allowing for an 80% discount in pricing for China, the annual value of the addressable market in greater China is estimated at ~$423m. Assuming 30% market penetration, we estimate peak sales for greater China at ~US$127m in year five following launch.

We have used an abbreviated discounted cash flow calculation to estimate the potential value of this deal over 10 years. The model assumes no terminal value as we expect the IP protection on paxalisib ends in ~2031. The key assumptions are shown in figure 1 below. Based on these assumptions the estimated value per share is ~$1.00.

IP PROTECTION

Being a new chemical entity paxalisib will enjoy a minimum of 5 years of marketing exclusivity from launch in the US before any generic may appear. Assuming paxalisib is approved in the US in late 2023/early 2024, the five year exclusivity extends to ~2029 which is approximately the same time that the key composition of matter patents expire.

The key patents on paxalisib are granted in China and these expire shortly after the US in 2031. For these reasons there is no terminal value in the DCF model. There is the possibility of an extension to the patents via a patent extension mechanism in these jurisdictions as well as the US. We have not factored this into our valuation estimates.

This deal in no way limits Kazia's ability to pursue other regional deals in markets where specialist local knowledge is required to ensure the drug is able to reach patients. The

company did not specify whether further deals are in the pipeline, however, in our view Japan is the next most obvious territory for a license deal.

Figure 1 - Summary DCF model for Greater China

	Calendar year		2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
US$	Year		1	2	3	4	5	6	7	8	9	10
Revenues $m						31.7	38.1	95.2	101.6	127.0	127.0	127.0
Cumulative $m						31.7	69.8	165.1	266.7	393.7	520.6	647.6
Royalty income $m		13%				4.1	5.0	12.4	13.2	16.5	16.5	16.5
Royalty payable to Genentech		3%				(0.1)	(0.1)	(0.4)	(0.4)	(0.5)	(0.5)	(0.5)
Upfront and milestones $m (BP estimates)			11.0		50.0	55.0		37.0	37.0	37.0	37.0	38.0
Net inflows $m			11.0	0.0	50.0	59.0	4.8	49.0	49.8	53.0	53.0	54.0
Discount for risk			40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Risk adjusted cash flow			6.6	0.0	30.0	35.4	2.9	29.4	29.9	31.8	31.8	32.4
Discount rate in NPV calc %		15%	0.87	0.76	0.66	0.57	0.50	0.43	0.38	0.33	0.28	0.25
Discounted cash flows			5.7	0.0	19.7	20.2	1.4	12.7	11.2	10.4	9.0	8.0
Net Present value $m			98.5									
Shares on issue (m) including new share to Simcere			129.6									
Value per share US$			0.76									
Value per share A$			1.00									

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our previous valuation estimate of $2.76 included a component for rest of the world inclusive of China. Based on our estimates in Figure 1 we previously undervalued the opportunity in China.

We now exclude China from our ROW estimate. Our revised valuation of $3.60 is based on a revised DCF valuation which now has cohorts for the US, China (including Hong Kong, Taiwan and Macau) and ROW.

Figure 2 - Summary of earnings changes

	2021			2022			2023		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	18.7	4.3	337%	4.5	4.5	0%	46.2	46.2	0%
EBIT	-7.4	-19.7	62%	-12.6	-10.5	-20%	31.1	32.2	-4%
NPAT	-7.2	-19.5	63%	-12.7	-10.6	-20%	31.0	32.1	-4%
EPS	-5.6	-15.4	64%	-9.8	-8.4	-17%	23.9	25.3	-6%

SOURCE: BELL POTTER SECURITIES

The key changes to earnings in FY21 include the US$7m cash upfront from Simcere plus the US$4.0m cash upfront for the recent out licence deal for Cantrxil. The vast majority of the milestones from the Simcere deal are assumed to fall outside of the forecast period. EPS each year is diluted by virtue of the new shares issued to Simcere. FY22 also includes an increase in the cost base which is based on the run rate from the recent half year financial statements.

Kazia Therapeutics

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.

Figure 3 - Clinical Trial Overview

	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
	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
	DIPG	Phase 1	TBA	Ethics approvals	Paxalisib to be partnered with ONC022	PNOC	TBA

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Kazia Therapeutics
as at 30 March 2021

Recommendation	Buy, Speculative
Price	$1.595
Target (12 months)	$3.60

Table 1 - Financial summary

	FY19	FY20	FY21e	FY22e	FY23e
Year Ending June					
R&D incentive	1.5	1.0	4.3	4.5	4.5
License income - paxalisib	-	-	9.2	-	41.7
License income - Cantrixil	-	-	5.2	-	-
Total Revenue	**1.5**	**1.0**	**18.7**	**4.5**	**46.2**
COGS	-	-	-	-	-
Gross profit	1.5	1.0	18.7	4.5	46.2
Clinical trials and development	-6.5	-9.5	-19.0	-10.0	-8.0
Amortisation	-1.1	-1.1	-1.1	-1.1	-1.1
Other expenses	-2.8	-2.1	-6.0	-6.0	-6.0
Total Expenses	-12.2	-13.7	-26.1	-17.1	-15.1
EBIT	-10.7	-12.7	-7.4	-12.6	31.1
Interest income	0.0	0.0	0.2	-0.1	-0.1
Pre tax profit	(10.6)	(12.7)	(7.2)	(12.7)	31.0
Tax expense	0.3	0.3	-	-	-
NPAT- normalised	**(10.3)**	**(12.4)**	**(7.2)**	**(12.7)**	**31.0**
Reported NPAT	(10.3)	(12.4)	(7.2)	(12.7)	31.0

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-6.7	-8.8	-6.7	-11.4	32.3
Net interest	0.0	0.0	0.2	-0.1	-0.1
Operating cash flow	-6.7	-8.8	-6.5	-11.5	32.2
Clinical trial deposit - GBM Agile	0.0	0.0	-7.0	0.0	0.0
Free cash flow	-6.7	-8.8	-13.5	-11.5	32.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	3.8	12.1	30.8	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	-2.9	3.3	17.3	-11.5	32.2
Cash at beginning of period	6.0	5.4	8.7	26.0	14.5
FX adjustment	-0.1	0.0	0.0	0.0	0.0
Cash at year end	**5.4**	**8.7**	**26.0**	**14.5**	**46.6**

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	5.4	8.7	26.0	14.5	46.6
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	11.3	10.2	9.1
Other non current assets	0.2	-	7.0	7.0	7.0
Total assets	21.2	23.0	46.1	33.5	64.6
Trade payables	1.8	3.5	3.0	3.0	3.0
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	8.5	8.6	8.7
Net Assets	14.2	14.1	37.6	24.9	55.9
Share capital	36.6	48.8	79.6	79.6	79.6
Other equity	2.5	1.5	1.4	1.4	1.4
Retained earnings	(24.9)	(36.2)	(43.4)	(56.1)	(25.1)
Reserves	-	-	-	-	-
Shareholders Equity	14.2	14.1	37.6	24.9	55.9

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-16.6	-17.0	-5.6	-9.8	23.9
Normalised EPS (cps)	-16.6	-17.0	-5.6	-9.8	23.9
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**6.7**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	141.5	88.8	7.9	14.0	-
Book Value Per Share (cps)	22.9	14.9	29.0	19.2	43.1
Price/Book (x)	7.0	10.7	5.5	8.3	3.7
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	1H21	2H21e
Revenues	0.6	0.4	0.0	18.7
R&D Expense	-4.2	-5.3	-2.9	-16.1
Amortisation	-0.5	-0.6	-0.5	-0.6
All Other expenses	-1.9	-0.2	-3.0	-3.0
EBIT	-6.2	-6.5	-6.4	-1.0

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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