BELL POTTER

27 August 2020

Speculative

See key risks on Page 3 and Biotechnology Risk Warning on Page 5. Speculative securities may not be suitable for Retail Clients.

Analyst
John Hester 612 8224 2871
Tanushree Jain 612 8224 2849

Authorisation
TS Lim 612 8224 2810

Kazia Therapeutics

Strength To Strength

Recommendation
Buy (unchanged)
Price
$1.03
Valuation
$1.50 (previously $1.00)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**45.6%**
Dividend yield	**0**
Total expected return	**45.6%**

Company Data & Ratios	
Enterprise value	**$89.4m**
Market cap	**$87.4m**
Issued capital	**94.6m**
Free float	**100%**
Avg. daily val. (52wk)	**$162,000**
12 month price range	**$0.34 - $1.24**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.56	0.38	0.37
Absolute (%)	76.00	160.53	167.57
Rel market (%)	75.54	150.29	173.33

Absolute Price

SOURCE: IRESS

FY20 Result Summary

Kazia released its FY20 result and annual report earlier today. The company spent $9.5m in on clinical trials in FY20 for the development of its two drug candidates and reported a net loss for the year of $12.4m. Cash as at 30 June 2020 was $8.7m providing the company with sufficient funding until early 2021.

The pipeline of news flow in relation to the development of paxalisib over the next few months appears full. The key items are 1) final results from the 30 patient phase II trial in glioblastoma 2) interim results from the phase I clinical trial in DIPG at St Jude Children's Research Hospital 3) Interim results from the phase II clinical trial in HER2+ brain metastases at Dana-Farber Cancer, and finally 4) recruitment to the GBM AGILE pivotal study is expected to commence later this calendar year. KZA also expects to report final results from the phase I trial of Cantrixil in ovarian cancer.

The annual report provided updated data in regard to pricing of paxalisib should it reach commercialisation. In the US during 2018, the median cost of a newly approved cancer drug was US$148,000 per year of treatment – nearly double the selling price assumed in our financial model. The ultimate price achieved by the drug is determined by amongst other things its effect size and health economics data. The company estimates global market for Glioblastoma (not including DIPG or other brain metastases) at US$1.5bn. Based on this data we have revised upward our selling price estimate for paxalisib. The model retains a significant discount to reflect the inherent risk in clinical trials. This upgrade to selling price is the key driver of the lift in valuation.

Retain Buy (Speculative), Valuation raised to $1.50

We retain our Buy rating. Valuation is raised to $1.50. The contractual arrangement for GBM AGILE remains under negotiation, including the company's funding requirement. The financial model assumes the company raises further equity to fund its obligation, however, this is likely to be one of several options available should the next set of data from the phase II GBM trial be consistent with the earlier interim data.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	1.0	4.3	7.2	44.0
EBIT $m	-12.7	-19.7	-18.8	16.0
NPAT (underlying) $m	-12.4	-19.8	-18.9	15.9
NPAT (reported) $m	-12.4	-19.8	-18.9	15.9
EPS underlying (cps)	-17.0	-12.5	-11.9	10.0
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	10.3
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	10.00
Franking	0%	0%	0%	100%
Yield %	0%	0%	0%	971%
ROE %	-88%	-75%	-259%	131%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Regulatory Concessions

In recent weeks KZA has made a series of encouraging announcements regarding regulatory concessions with the FDA. These concessions are designed to accelerate the regulatory approval of promising new drugs through the agency.

7 Aug – paxalisib awarded rare pediatric disease designation (RPDD) by the FDA for the treatment of Diffuse Intrinsic Pontine Glioma (DIPG).

DIPG is a rare form of brain cancer in children, of which there are approximately 300 cases per year in the US. The disease is fatal in all cases with median survival less than 1 year.

With RPDD granted, Kazia may now be eligible to receive a 'rare pediatric disease priority review voucher' (PRV) if paxalisib is approved for DIPG.

A PRV grants the holder an expedited six-month review of a new drug application by the FDA. PRVs can be sold to other companies and have historically commanded prices between US$68 million and US$350 million.

We expect interim data from the DIPG study being conducted St Judes Children's Research Hospital (Memphis) in 2H CY2020. St Judes is a leading hospital in the US for the treatment of childhood cancers. Encouraging data is likely to warrant further clinical studies.

20 Aug – paxalisib granted fast track GBM. Key advantages include enhanced access to the FDA throughout the development process, eligibility to apply for accelerated approval and priority review at the time of an NDA submission.

24 Aug – paxalisib granted orphan drug designation (ODD) for the treatment of malignant glioma which includes DIPG. ODD can provide drug developers with up to seven years of Orphan Drug Exclusivity (ODE), extending the effective life of a commercial product. It also provides opportunities for grant funding, protocol assistance, and financial benefits, such as a waiver of New Drug Application fees, and tax credits.

Figure 1 - 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
Cantrixil	Recurrent Ovarian Cancer	Phase 1	28	Completed recruitment	Part A - dose escalation, Part B Expansion Cohort	Kazia Thereapeutics	NCT02903771

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

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 27 August 2020

Recommendation	Buy, Speculative
Price	$1.03
Valuation	$1.50

Table 1 - Financial summary

`	FY19	FY20	FY21e	FY22e	FY23e
Year Ending June					
R&D incentive	1.4	1.0	4.3	7.2	7.2
Total Revenue	**1.5**	**1.0**	**4.3**	**7.2**	**44.0**
COGS	-	-	-	-	-
Gross profit	1.5	1.0	4.3	7.2	44.0
Expenses Net of R&D	-6.5	-9.5	-16.0	-16.0	-16.0
Other expenses	-3.9	-3.2	-8.0	-10.0	-12.0
Total Expenses	-12.2	-13.7	-24.0	-26.0	-28.0
EBIT	-10.7	-12.7	-19.7	-18.8	16.0
Interest income	0.0	0.0	0.2	-0.1	-0.1
Pre tax profit	(10.6)	(12.7)	(19.5)	(18.9)	15.9
Tax expense	0.3	0.3	-	-	-
NPAT- normalised	**(10.3)**	**(12.4)**	**(19.5)**	**(18.9)**	**15.9**
Reported NPAT	(10.3)	(12.4)	(19.5)	(18.9)	15.9

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-6.7	-8.8	-19.6	-18.7	16.1
Net interest	0.0	0.0	0.2	-0.1	-0.1
Operating cash flow	-6.7	-8.8	-19.4	-18.8	16.0
Proceeds from asset sales	2.4	0.0	0.0	0.0	0.0
Free cash flow	-4.3	-8.8	-19.4	-18.8	16.0
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	3.8	12.1	32.0	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	-0.5	3.3	12.6	-18.8	16.0
Cash at beginning of period	6.0	5.4	8.7	21.3	2.5
FX adjustment	-0.1	0.0	0.0	0.0	0.0
Cash at year end	**5.4**	**8.7**	**21.3**	**2.5**	**18.4**

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	5.4	8.7	21.3	2.5	18.4
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	35.5	16.7	32.7
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	26.5	7.6	23.5
Share capital	36.6	48.8	80.8	80.8	80.8
Other equity	2.5	1.5	1.4	1.4	1.4
Retained earnings	(24.9)	(36.2)	(55.7)	(74.6)	(58.7)
Reserves	-	-	-	-	-
Shareholders Equity	14.2	14.1	26.5	7.6	23.5

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-16.6	-17.0	-12.3	-11.9	10.0
Normalised EPS (cps)	-16.6	-17.0	-12.3	-11.9	10.0
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**10.3**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	91.4	57.3	11.6	- 34.0	-
Book Value Per Share (cps)	22.9	14.9	16.7	4.8	14.8
Price/Book (x)	4.5	6.9	6.2	21.5	7.0
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	0.0	0.0
All Other expenses	-2.4	-0.8	-4.0	-4.0
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.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research/Banks	612 8224 2810	tslim
Analysts			
Lafitani Sotiriou	Diversified Financials/Fintech	613 9235 1668	lsotiriou
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare	612 8224 2849	tnjain
Elyse Shapiro	Healthcare	613 9235 1877	eshapiro
Steven Anastasiou	Industrials	613 9235 1952	sanastasiou
James Filius	Industrials	613 9235 1612	jfilius
Sam Haddad	Industrials	612 8224 2819	shaddad
Alex McLean	Industrials	612 8224 2886	amclean
Hamish Murray	Industrials	613 9235 1813	hmurray
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
Damien Williamson	Industrials	613 9235 1958	dwilliamson
Peter Arden	Resources	613 9235 1833	parden
David Coates	Resources	612 8224 2887	dcoates
Stuart Howe	Resources	613 9235 1856	showe
Associate			
Joseph House	Associate Analyst	+61 3 9235 1624	jhouse

Bell Potter Securities Limited
ACN 25 006 390 7721
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
Posperity 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