Wednesday, 18 November 2020

FLASH NOTE

CORPORATE CONNECT

Kazia Therapeutics

SNO Presentations: Late-Interim Results from Phase II GBM & Phase I DIPG Studies Released

Share Price & Estimated Future Price

Price in 12-months*	$2.05
Current Price	$1.61
Implied Increase/Dec	+27%

* Price at end FY21/beginning FY22

Paxalisib's phase II trial in unmethylated MGMT promoter proven glioblastoma multiforme (uGBM) is as **positive as a single arm trial can be**, while the **phase I trial in diffuse intrinsic pontine glioma (DIPG) enables paxalisib combination studies in the indication.**

The Event & Interpretation: Updated paxalisib data will be presented at the 2020 Society for Neuro-Oncology Annual Meeting for the GBM and DIPG trials. The final data from these trials is unlikely to change much and, as such investors should treat this data as final. **The data from both trials meets our expectations**.

Progression free survival (PFS) of 8.4-months (m) and overall survival (OS) of 17.5m will be disclosed for the GBM study. This is an expected result since cohort 2 results should tend to cohort 1. Still, the similarity is surprising. Relative to Hegi et al [NEJM] 2005, the data from this trial show a solid improvement of +3.1m for PFS and +4.8m for OS. A recent systematic review of GBM trials (Marenco-Hillembrand et al [2020] J Neurooncol) found that GBM OS had not improved much since 2005, if at all. Paxalisib will begin the pivotal GBM AGILE trial in early CY21 and it can uncover a paxalisib OS benefit of under a month, according to Kazia. **Thus, we think today's results are as 'positive' for efficacy as possible, given the trial's single arm nature.**

DIPG researchers use PFS at 6m and OS at 12m to assess new interventions because of DIPG's extraordinary aggressiveness. The St Jude Children's Research Hospital DIPG study will report PFS(6) and OS(12) of 96.2% (±3.8%) and 48.6% (±10.5%), respectively. These values are solid compared to the literature; however, we believe they did not differ from St Jude's experience with DIPG. Our view is that **paxalisib on its own is unlikely to benefit DIPG patients**, as foreshadowed by the 12% probability of success we gave this particular DIPG approval pathway.

Overall, paxalisib's safety remained best of the PI3K inhibitors, food/drug intake had no effect and an appropriate dose of paxalisib for children was identified.

Going Forward: With positive phase II results in hand, paxalisib's development for GBM will not skip a beat as it commences GBM AGILE. DIPG is a bit more complicated, but, as indicated by Kazia, a clear way forward exists.

Paxalisib's mechanism of action is well defined, making it perfect for combination therapy studies. Multiple altered biochemical pathways are believed to drive and explain DIPG's extreme nature. When one pathway is blocked, another simply compensates. As per expert advice, Kazia is already close to agreeing to a new DIPG study, where paxalisib will be the therapy core, with another drug(s) used to block a further pathway(s). we expect the company will make paxalisib's future in DIPG clear once a trial has been formally agreed to with researchers.

We see things coming together very well for paxalisib. With known dose and good safety profile in children, DIPG becomes a rapid way of trialling drug combinations. Any signal in that cancer, will likely show benefit in some others. Since the trials are open label, further studies of a combination therapy can commence when a signal is seen. This strategy could have benefits for a variety brain tumours, including uGBM. In fact, if approved, paxalisib-based combination therapies could be used in practice for GBM based on studies run before GBM AGILE completes. Combination therapy use could quickly and permanently embed paxalisib as the first-line treatment for uGBM almost on single agent approval. DIPG and uGBM are close to, if not the, hardest cancers to treat. A paxalisib-based combination therapy only needs to provide a small uptick in efficacy to be virtually impossible to beat head-to-head in uGBM and, likely, other brain tumours.

Conclusion: We retain our 12m target with results as expected. The way we see the paxalisib story is playing out makes us very comfortable. We will see the first interim analysis from the breast cancer brain metastases study before CY end. A hint of signal and Kazia will look appealing to deep pocked investors, with the larger drug companies close behind, given paxalisib's owner could dictate the brain cancer space for years.

Company Information

ASX Ticker	KZA
NASDAQ Ticker	KZIA
NASDAQ Price (10 Shares per ADR)	USD12.19 (a/h)[1]
Shares on Issue	126.2 million
Fully Diluted Shares on Issue	134.7 million
Market Capitalisation	$203.1 million
ASX Vol. (Shares/Day)[2]	306,084

1 After Hours Market
2 Shares per Day for the Last 20 Trading Days.

Cash Sufficiency

	$ Million
A) Last Appendix 4C	End September, 2020
B) Cash & Equivalents at 4C	6.5
C) Burn[1]	-2.2
E) Estimated Current Q Burn[2]	-1.2
F) Estimated Cash Raised Post 4C[3]	23.7
D) Quarters (Q) Cash Remaining[4]	13.2Q
G) Estimated Current Cash[5]	**29**
H) Significant Estimated New Commitment(s)[6]	Nil

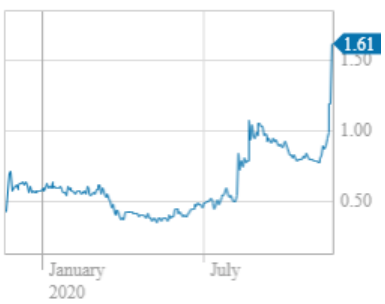
Description of Commitment(s): Not Applicable

1 Burn = Net Cash from/used In Operating Activities;
2 Equals C *(# Days Since previous Q end Q4 / # Days in Current Q);
3 Equals Capital Raising(s) – Estimated Costs; **4** Quarters Cash Remaining = (B + E + F) / C ;
5 Equals B + E + F
6 Equals estimated maximum new significant commitments that the company has or is likely to become contractually or ethically committed to.

Key Personnel

Mr. Iain Ross	Chairman
Dr. James Garner	MD & CEO
Mr. Bryce Carmine	NED
Mr. Steven Coffey	NED

Chart



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Kazia Therapeutics (ASX: KZA)
Market Capitalisation: $203.1

Valuation Data (AUD Million)

Year Ending Jun	FY20A	FY21E	FY22E	FY23E	FY24E
Profit	**(12.5)**	**(12.2)**	**(16.6)**	**(16.2)**	**(8.4)**
EPS (¢)	(11.0)	(13.2)	(12.9)	(17.6)	(17.1)

Balance Sheet (AUD Million)

Year Ending Jun	FY20A	FY21E	FY22E	FY23E	FY24E
Cash & Equivalents	7.6	21.2	7.5	22.4	15.5
R&D Tax Rebate	1.4	1.5	2.1	2.1	0.9
Current Assets	**9.0**	**22.7**	**9.6**	**24.5**	**16.4**
Intangibles	12.4	11.3	10.2	9.2	8.1
Non-Current Assets	**12.4**	**11.3**	**10.2**	**9.2**	**8.1**
Total Assets	**21.4**	**34.0**	**19.9**	**33.6**	**24.5**
Trade & Other Payables	3.5	3.1	4.0	4.1	2.4
Provisions	0.2	0.2	0.2	0.2	0.2
Contingent Consider.	1.4	1.4	1.4	1.4	1.4
Current Liabilities	**5.1**	**4.7**	**5.6**	**5.7**	**4.0**
Deferred Tax	3.4	3.1	2.8	2.6	2.3
Contingent Consider.	0.5	0.6	0.8	1.1	1.5
Non-Current Liabilities	**3.9**	**3.7**	**3.7**	**3.7**	**3.8**
Total Liabilities	**8.9**	**8.4**	**9.3**	**9.4**	**7.8**
Net Assets	**12.5**	**25.6**	**10.6**	**24.3**	**16.7**
Contributed Equity	48.8	72.6	72.6	100.8	100.8
Reserves/Other	2.5	1.5	1.5	1.5	1.5
Accumulated Losses	(36.2)	(48.4)	(65.0)	(81.2)	(89.6)
Total Equity	**14**	**26**	**9**	**21**	**13**

Profit and Loss (AUD Million)

Year Ending Jun	FY20A	FY21E	FY22E	FY23E	FY24E
Total Revenue	**1.0**	**1.6**	**1.6**	**2.3**	**2.3**
R&D Tax Rebate	*1.0*	*1.4*	*1.5*	*2.1*	*2.1*
Expenses	**(13.8)**	**(14.1)**	**(18.5)**	**(18.8)**	**(10.9)**
EBITDA	(11.8)	(11.6)	(15.9)	(15.6)	(7.7)
D&A	(1.1)	(1.1)	(1.1)	(1.1)	(1.1)
EBIT	**(12.9)**	**(12.7)**	**(17.0)**	**(16.7)**	**(8.8)**
Net Interest	0.1	0.2	0.1	0.2	0.2
Profit - Pre-Tax	**(12.8)**	**(12.5)**	**(16.9)**	**(16.5)**	**(8.6)**
Tax	0.3	0.3	0.3	0.3	0.3
Profit - After-Tax	**(12.5)**	**(12.2)**	**(16.6)**	**(16.2)**	**(8.4)**
Comprehensive Profit	**(12.5)**	**(12.2)**	**(16.6)**	**(16.2)**	**(8.4)**

Cashflow (AUD Million)

Year Ending Jun	FY20A	FY21E	FY22E	FY23E	FY24E
Operating Cashflow	**(9.2)**	**(10.2)**	**(13.7)**	**(13.3)**	**(6.8)**
Investing Cashflows	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Financing cashflows	**12.1**	**23.8**	**0.0**	**28.2**	**0.0**
Net Equity Raised	12.1	23.8	0.0	28.2	0.0
ΔCash	2.9	13.6	(13.7)	14.9	(6.8)
Cash	**7.6**	**21.2**	**7.5**	**22.4**	**15.5**

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