EDISON

Kazia Therapeutics

Paxalisib Update

Paxalisib trial still on track for H220 start

Pharma & biotech

In the current viral pandemic, it is worth recalling that brain cancers will arise during and after the epidemic. The core business case for Kazia remains strong as it is developing the only brain penetrating PI3K inhibitor agent in trials to treat glioblastoma. In the current Phase II, the 21-patient expansion cohort was fully recruited in February. No hospitalisation is needed to continue with this study; it is oral dosing. The potentially pivotal Phase III using the AGILE trial network is on track for an H220 start. H120 results showed cash of A$6.4m. Our indicative value remains A$137m.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/18	2.9	(11.0)	(22.2)	0.0	N/A	N/A
06/19	1.5	(7.7)	(12.9)	0.0	N/A	N/A
06/20e	1.5	(8.7)	(12.6)	0.0	N/A	N/A
06/21e	1.5	(11.1)	(15.4)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptionals and share-based payments.

Phase II enrolment completed

In the ongoing paxalisib (GDC-0084) Phase II, the last enrolled patient started dosing on 27 February after surgery, TMZ chemotherapy and radiotherapy (Stupp regimen). This means Kazia is accumulating a further 21 patients' worth of data in this expansion cohort. This formally tests the effects of food on paxalisib (GDC-0084) absorption (1:1 fed: fasted) and provides survival data. Patients continue the study until disease progression or unacceptable toxicity. Note that Kazia has sufficient supplies of paxalisib to continue this trial. It plans a further update in April. Kazia presented a poster on initial Phase IIa (NCT03522298) data in November 2019. If hospital visits for trial monitoring become difficult or impossible due to the COVID-19 virus, online monitoring is possible.

Progression to Phase III on track for H220

In the 20 February H120 results statement, the potentially pivotal study (AGILE) was scheduled for an H220 start. AGILE is a US study so might be restricted by the coronavirus pandemic if viral cases occupy the intensive care unit space and if it proves dangerous to conduct brain surgery. Currently, the AGILE study remains on track for a H220 start. New glioblastoma patients will continue to present and desperately need treatment options. In case the study is affected, given the US virus response is still patchy and limited, we have also modelled a scenario in which the trial effectively starts in H121. This would still make a 2025 launch after accelerated FDA review feasible and a deal in 2023–24 possible.

Valuation: Core value remains A$137m

Kazia is aiming for a 2024 paxalisib US launch and, assuming no trial delay, our valuation remains unchanged. In a possible six-month delay scenario, we assume 2020 cost reductions and estimate a slightly reduced value of A$130m. We note that scientific and clinical paxalisib fundamentals remain strong and Kazia quickly completed the current expansion cohort recruitment. Kazia had A$6.4m cash at 31 December 2019 and may conserve cash in the short term if needed. New Cantrixil data might be released by mid-2020; progression for this programme is assumed to require a partner. If the AGILE study runs as planned, Kazia will need further capital by H121.

31 March 2020

Price	**A$0.39**
Market cap	**A$28m**
	US$0.76/A$
Cash (A$m) at 31 December 2019	6.4
Shares in issue	72.17m
Free float	91%
Code	KZA
Primary exchange	ASX
Secondary exchange	Nasdaq

Share price performance

%	1m	3m	12m
Abs	(34.7)	(35.8)	(16.3)
Rel (local)	(18.2)	(14.5)	0.9
52-week high/low	A$0.74	A$0.32	

Business description

Kazia Therapeutics is an ASX and Nasdaq-listed biotechnology company. It is developing the PI3K/mTOR inhibitor paxalisib for drug-resistant brain cancer and Cantrixil for ovarian cancer.

Next events

Update on paxalisib Phase II	Q220

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Edison profile page

Kazia Therapeutics is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

Year end 30 June (A$000s)	2018	2019	2020e	2021e
PROFIT & LOSS				
Sales, royalties, milestones	693	34	0	0
Other (includes R&D tax rebate)	2,200	1,431	1,500	1,500
Revenue	2,893	1,465	1,500	1,500
R&D expenses	(9,774)	(6,476)	(7,200)	(9,100)
SG&A expenses	(4,051)	(2,594)	(3,000)	(3,500)
Other	0	0	0	0
EBITDA	(10,932)	(7,604)	(8,700)	(11,100)
Operating Profit (before amort. and except.)	(11,142)	(7,711)	(8,700)	(11,100)
Intangible Amortisation	(1,336)	(1,084)	(1,000)	(1,000)
Exceptionals	8,411	0	0	0
Operating Profit	(6,687)	(10,568)	(9,700)	(12,100)
Net Interest	119	0	0	0
Profit Before Tax (norm)	(11,023)	(7,711)	(8,700)	(11,100)
Profit Before Tax (reported)	(6,344)	(10,568)	(9,700)	(12,100)
Tax benefit	305	298	0	0
Profit After Tax (norm)	(10,718)	(7,413)	(8,700)	(11,100)
Profit After Tax (reported)	(6,039)	(10,270)	(9,700)	(12,100)
Average Number of Shares Outstanding (m)	48.4	57.5	68.9	72.20
EPS - normalised (c)	(22.2)	(12.9)	(12.6)	(15.4)
EPS - diluted	(21.1)	(12.4)	(12.2)	(14.9)
EPS - reported	(12.5)	(17.9)	(14.1)	(16.8)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	18,915	13,662	12,662	11,662
Intangible Assets	14,579	13,494	12,494	11,494
Tangible Assets	1	0	0	0
Investments	4,335	168	168	168
Current Assets	9,260	7,514	2,614	2,514
Stocks	0	0	0	0
Debtors	2,535	1,711	1,711	1,711
Cash	5,956	5,433	533	433
Other	768	370	370	370
Current Liabilities	(3,888)	(1,900)	(1,900)	(1,900)
Creditors	(2,067)	(1,764)	(1,764)	(1,764)
Short term borrowings	0	0	0	0
Other	(1,821)	(136)	(136)	(136)
Long Term Liabilities	(5,046)	(5,081)	(5,081)	(16,081)
Long term borrowings	0	0	0	(11,000)
Other long term liabilities	(5,046)	(5,081)	(5,081)	(5,081)
Net Assets	19,242	14,195	8,295	(3,805)
CASH FLOW				
Operating Cash Flow	(8,780)	(6,714)	(8,700)	(11,100)
Net Interest	119	0	0	0
Tax	0	0	0	0
Capex	0	0	0	0
Acquisitions/disposals	150	2,359	0	0
Equity Financing	0	3,816	4,000	0
Dividends	0	0	0	0
Other	0	0	(200)	0
Net Cash Flow	(8,511)	(539)	(4,900)	(11,100)
Opening net debt/(cash)	(14,455)	(5,956)	(5,433)	(533)
HP finance leases initiated	0	0	0	0
Other	13	16	0	0
Closing net debt/(cash)	(5,956)	(5,433)	(533)	10,567

Source: Kazia Therapeutics accounts, Edison Investment Research

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