EDISON

Kazia Therapeutics

Clinical update

Cantrixil final Phase I data reported

Pharma & biotech

Kazia Therapeutics announced the final data from both parts of the Phase I dosing study of cantrixil for the treatment of metastatic ovarian cancer. Of the 16 patients evaluable for efficacy, one had a complete response (CR) and two had a partial response (PR). This response rate data has not changed significantly since the dosing portion of the study was completed in 2018. The company will seek partners for the further development of the product, while it focuses its efforts on paxalisib.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/19	1.6	(7.4)	(0.13)	0.00	N/A	N/A
06/20	1.1	(10.8)	(0.15)	0.00	N/A	N/A
06/21e	1.4	(11.4)	(0.10)	0.00	N/A	N/A
06/22e	1.5	(12.0)	(0.09)	0.00	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Final data a long time coming

The trial was a dose escalation/expansion study with the primary endpoint of determining the maximum tolerated dose (MTD) of cantrixil, which was found to be 5mg/kg in the earlier dose escalation portion of the study (Part A). Patients received two cycles of cantrixil monotherapy followed by up to six cycles in combination with other chemotherapy. The study completed recruitment in August 2019 and the last patient visit was in March 2020.

One CR, two PRs, similar to previous data

The efficacy data from the current release is very similar to previous releases on this study: one CR and two PRs. The company previously reported one CR and two PRs from the Phase I dosing portion of the study (Part A), and we assume that these are the same patients in the current report. Progression free survival (PFS) was not reported for the current data release, but was previously reported at 5.5 months (n=9) for Part A.

Partnering expected for further development

It is encouraging to see cantrixil have activity in this population of heavily pre-treated patients. Kazia did not break down patient prior treatment characteristics for the current data set, but previous reports from Part A had a median of four prior treatments, of which a median of three were platinum therapies. However, we expect the company to focus its resources on the advancement of paxalisib, which recently reported positive data and is moving into pivotal studies.

Valuation: Cantrixil removed until partnership secured

We have lowered our valuation to A$244.1m or A$1.93 per share, from A$257.1m or A$2.04 per share, because we have removed cantrixil from our model until the company secures a partner for its further development. Otherwise our assumptions remain unchanged.

10 December 2020

Price	**A$1.42**
Market cap	**A$179m**
	A$1.40/US$
Net cash (A$m) at 30 September 2020	6.54
Shares in issue	126.2m
Free float	60.1%
Code	KZA
Primary exchange	ASX
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	58.7	54.3	124.5
Rel (local)	48.4	34.3	120.3
52-week high/low	A$1.75		A$0.36

Business description

Kazia Therapeutics is a pharmaceutical company with lead asset paxalisib, a PI3K inhibitor licensed from Genentech that can cross the blood-brain barrier, which is entering a pivotal study for GBM. It is also being investigated for other brain cancers such as breast cancer brain metastases.

Next events

BCBM Phase II results	H220
First patient in GBM AGILE	Early 2021
GBM Phase IIa complete	H121

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Edison profile page

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Cantrixil Phase I done, but partner needed to advance

On 9 December 2020, Kazia reported the top-line final data from the Phase I dose escalation/expansion study of cantrixil for the treatment of recurrent metastatic ovarian cancer. The study began in 2016, when the dose escalation portion of the study (Part A) was initiated. This portion of the study was successful in determining the MTD of 5mg/kg in October 2018, at which time it transitioned to the dose expansion portion of the study (Part B). Part B enrolled 14 patients who were evaluable for efficacy at the MTD, and the company's current update is the first including data on these patients.

However, the efficacy data presented in the current release is very similar to previous reports on Part A: one CR and two PRs (overall response rate (ORR): 19%). We assume that these are the same responders from Part A, and therefore no responses were seen in the expansion cohort. No additional efficacy analysis was presented like PFS, which again makes us assume that the data from the expansion cohort underperformed the previous Part A. This response rate is roughly similar to what is seen with other chemotherapies in this population.[1] It is difficult however to draw any definitive conclusions from response rates alone, and we expect better insight when the full PFS survival analysis is published. The company previously reported a PFS of 5.5 months for Part A. The company stated that it expects to present the complete data from the study (including PFS and other parameters) at a medical conference in the first half of CY21. We will be better able to evaluate if this drug will have a role in the treatment of this disease at that time. Our current assessment, however, is that although cantrixil appears to have some activity in this population of heavily pre-treated patients, further development work will be needed to identify effective treatment strategies such as a more well-defined subgroup of patients.

The company has stated that it intends to seek a partner for the further development of cantrixil, while it focuses its efforts on developing paxalisib, its PI3K inhibitor in development for glioblastoma multiforme. We recently reported on the very encouraging results from the drug in Phase II, which confirmed an attractive safety profile and good efficacy in a very difficult disease. We agree with the decision to focus on this program. The company recently formally started its participation in the pivotal Phase II/III GBM AGILE study, and stated that first patients are expected to be enrolled in early 2021.

Valuation

We have removed cantrixil from our valuation, which has reduced it to A$244.1m or A$1.93 per share from A$257.1m or A$2.04 per share. We intend to add the product back into our valuation in the future if the company secures a partnership for its further development. Otherwise our remaining valuation assumptions remain unchanged.

[1] Pujade-Lauraine E, et al. (2019) Management of Platinum-Resistant, Relapsed Epithelial Ovarian Cancer and New Drug Perspectives. Journal of Clinical Oncology, *J Clin Oncol* 37, 2437-2448.

Exhibit 1: Valuation of Kazia

Development Program	Indication	Clinical stage	Probability. of success	Launch year	Patent/ exclusivity protection	Launch pricing (US$/ course)	Peak sales (US$m)	rNPV (A$m)
Paxalisib	GBM	Phase II	35%	2025	2037	169,000	450	212.52
	BCBMs	Phase II	5%	2029	2037	183,000	249	8.36
Total								220.88
Net cash and equivalents (fiscal Q121 + subsequent transactions) (A$m)								23.23
Total firm value (A$m)								244.11
Total basic shares (m)								126.2
Value per basic share (A$)								1.93
Dilutive options (m)								4.54
Total diluted shares (m)								130.70
Value per diluted share (A$)								1.90

Source: Kazia Therapeutics reports, Edison Investment Research

Financials

Our financial forecasts remain unchanged. We previously did not include costs associated with the cantrixil program in our forecasts because of the company's stated intent to partner the program. The company has a future financing requirement of A$20m, which we include in our forecasts as illustrative debt in FY23.

Exhibit 2: Financial summary

A$'000s	2019	2020	2021e	2022e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	1,565.0	1,060.9	1,404.8	1,521.8
Cost of Sales	0.0	0.0	0.0	0.0
Gross Profit	1,565.0	1,060.9	1,404.8	1,521.8
R&D	6,475.6	9,494.3	10,285.0	10,845.0
SG&A	3,785.6	3,689.9	3,899.9	3,977.9
EBITDA	(7,365.3)	(10,776.8)	(11,433.6)	(11,954.7)
Normalised operating profit	(7,365.4)	(10,776.8)	(11,433.6)	(11,954.7)
Amortization of acquired intangibles	(1,084.3)	(1,084.3)	(1,084.3)	(1,084.3)
Exceptionals	(1,872.3)	(642.4)	0.0	0.0
Share-based payments	(246.4)	(262.1)	(262.1)	(262.1)
Reported operating profit	(10,568.5)	(12,765.7)	(12,780.1)	(13,301.1)
Net Interest	0.0	0.0	0.0	0.0
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(7,365.4)	(10,776.8)	(11,433.6)	(11,954.7)
Profit Before Tax (reported)	(10,568.5)	(12,765.7)	(12,780.1)	(13,301.1)
Reported tax	298.2	298.2	487.7	507.6
Profit After Tax (norm)	(7,365.4)	(10,776.8)	(11,433.6)	(11,954.7)
Profit After Tax (reported)	(10,270.3)	(12,467.5)	(12,292.3)	(12,793.5)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(7,365.4)	(10,776.8)	(11,433.6)	(11,954.7)
Net income (reported)	(10,270.3)	(12,467.5)	(12,292.3)	(12,793.5)
Basic average number of shares outstanding (m)	58	73	118	133
EPS - basic normalised (A$)	(0.13)	(0.15)	(0.10)	(0.09)
EPS - diluted normalised (A$)	(0.13)	(0.15)	(0.10)	(0.09)
EPS - basic reported (A$)	(0.18)	(0.17)	(0.10)	(0.10)
Dividend (A$)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	13,662.3	12,410.1	11,325.8	10,241.5
Intangible Assets	13,494.5	12,410.1	11,325.8	10,241.5
Tangible Assets	0.0	0.0	0.0	0.0
Investments & other	167.8	0.0	0.0	0.0
Current Assets	7,514.2	10,653.6	21,334.7	9,537.3
Stocks	0.0	0.0	0.0	0.0
Debtors	1,710.7	1,352.3	923.7	1,000.6
Cash & cash equivalents	5,433.9	8,764.0	19,873.7	7,999.4
Other	369.6	537.3	537.3	537.3
Current Liabilities	(1,900.3)	(5,067.5)	(3,494.2)	(3,651.5)
Creditors	(1,763.9)	(3,488.9)	(3,165.6)	(3,323.0)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	0.0	0.0	0.0
Other	(136.4)	(1,578.5)	(328.5)	(328.5)
Long Term Liabilities	(5,081.4)	(3,870.7)	(3,382.9)	(2,875.3)
Long term borrowings	0.0	0.0	0.0	0.0
Other long term liabilities	(5,081.4)	(3,870.7)	(3,382.9)	(2,875.3)
Net Assets	14,194.8	14,125.6	25,783.3	13,252.0
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	14,194.8	14,125.6	25,783.3	13,252.0
CASH FLOW				
Op Cash Flow before WC and tax	(7,365.3)	(10,776.8)	(11,433.6)	(11,954.7)
Working capital	352.9	1,669.1	(1,632.5)	(427.2)
Exceptional & other	298.2	298.2	487.7	507.6
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(6,714.2)	(8,809.5)	(12,578.4)	(11,874.3)
Capex	0.0	0.0	0.0	0.0
Acquisitions/disposals	0.0	0.0	0.0	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	3,815.7	12,139.7	23,688.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	2,359.1	0.0	0.0	0.0
Net Cash Flow	(539.4)	3,330.2	11,109.6	(11,874.3)
Opening net debt/(cash)	(5,956.2)	(5,433.9)	(8,764.0)	(19,873.7)
FX	17.1	0.0	0.0	0.0
Other non-cash movements	0.0	0.0	0.0	0.0
Closing net debt/(cash)	(5,433.9)	(8,764.0)	(19,873.7)	(7,999.4)

Source: Kazia Therapeutics reports, Edison Investment Research

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