

Kazia Therapeutics

GDC-0084 Phase II/III

An agile pivot

Kazia Therapeutics has [announced](#) that GDC-0084, its promising glioblastoma drug, will join (subject to definitive agreement) the pivotal GBM AGILE trial. AGILE is a clinician-led trial that currently enables fast access to 11 US glioblastoma centers. GDC-0084 could be dosed from Q2/Q3 CY20. Data from the 20-patient stage of the GDC-0084 Phase II should be available during 2020. Our indicative value remains at \$93m.

Year end	Revenue (\$m)	PTP* (\$m)	EPADR (c)	DPADR (\$)	P/E (x)	Gross yield (%)
06/18	2.2	(8.4)	(16.84)	0.0	N/A	N/A
06/19	1.1	(5.9)	(9.80)	0.0	N/A	N/A
06/20e	1.1	(6.6)	(9.60)	0.0	N/A	N/A
06/21e	1.1	(8.4)	(13.60)	0.0	N/A	N/A

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

AGILE: A new approach to a potentially pivotal study

The Glioblastoma (GBM) Adaptive Global Innovative Learning Environment (GBM AGILE, [NCT03970447](#)) trial is an adaptive Phase II/III platform designed to evaluate multiple therapies against one rolling control group; it currently has 11 US centers and plans to add leading international centers to its network. It is a clinician-led trial with an FDA-agreed single Master Clinical Trial Application. On entering the study, the newly diagnosed GBM AGILE patients undergo surgery to remove the tumor followed by radiation therapy combined with temozolomide (TMZ) (Stupp regimen). The difference tested is overall survival in the randomized maintenance phase using either TMZ or GDC-0084.

AGILE uses a stage 1, which recruits up to 150 patients to assess efficacy compared against patients with a similar profile in the control arm. If this stage appears positive, up to 50 patients might be recruited to a stage 2 expansion cohort for confirmatory data. Currently, the kinase inhibitor regorafenib ([Stivarga](#), Bayer), approved for advanced gastrointestinal cancers but not GBM, is being tested. AGILE has several advantages: a faster start, an existing design and an expanding infrastructure plus involvement of key opinion leaders, a big benefit in the event of positive data, regulatory review and launch. However, Kazia will not have direct control over the study, so any problems or delays might take longer to resolve.

Kazia presented a [poster](#) in 2019 on the Phase IIa ([NCT03522298](#)) GDC-0084 dose-ranging results showing median progression-free survival (PFS) of 8.4 months in TMZ-resistant patients. Published studies indicate comparison PFS values of 5.9 months. Kazia is recruiting a 20-patient expansion cohort and further data should be available during 2020; this will help to inform AGILE expectations.

Cantrixil efficacy indications expected in 2020

Cantrixil is in a small Phase I study, with results expected by management in H120. Cantrixil could become a standard treatment for third-line ovarian cancer patients who now have few therapy alternatives. Interim data were presented in [September](#).

Valuation: Indicative value of \$93m

Kazia is aiming for a 2024 GDC-0084 US launch. It had \$3.7m cash at 30 June 2019, boosted in H120 by a \$2.6m net placing and the expected cash \$1.0m tax credit in December. We maintain our indicative value of \$93m (\$12.9/share). We have assumed that Cantrixil will be partnered if the current trial data is strong.

Pharma & biotech

13 January 2020

Price **\$4.56**
Market cap **\$33m**

ADR/Ord conversion ratio 10/1

Cash (\$m) at 30 June 2019 3.7

ADRs in issue 7.2m

ADR code KZIA

ADR exchange NASDAQ

Underlying exchange ASX

Depository BNY

ADR share price performance



52-week high/low \$7.40 \$2.28

Business description

Kazia Therapeutics is an ASX- and Nasdaq-listed biotechnology company. It is developing the PI3K/mTOR inhibitor GDC-0084 for drug-resistant brain cancer and Cantrixil for ovarian cancer.

Next events

Cantrixil Phase I preliminary efficacy data H120

Interim FY20 results Q120

AGILE recruitment Q2/Q320

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Kazia Therapeutics is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

	US\$000s	2018	2019	2020e	2021e
Year end 30 June		AASB	AASB	AASB	AASB
PROFIT & LOSS					
Sales, royalties, milestones		527	26	0	0
Other (includes R&D tax rebate)		1,672	1,088	1,140	1,140
Revenue		2,199	1,114	1,140	1,140
R&D expenses		(7,428)	(4,921)	(5,472)	(6,916)
SG&A expenses		(3,079)	(1,972)	(2,280)	(2,660)
Other		0	0	0	0
EBITDA		(8,308)	(5,779)	(6,612)	(8,436)
Operating Profit (before GW and except.)		(8,468)	(5,861)	(6,612)	(8,436)
Intangible Amortization		(1,016)	(824)	(760)	(760)
Exceptionals		6,392	0	0	0
Operating Profit		(5,082)	(8,032)	(7,372)	(9,196)
Net Interest		91	0	0	0
Profit Before Tax (norm)		(8,378)	(5,861)	(6,612)	(8,436)
Profit Before Tax (reported)		(4,822)	(8,032)	(7,372)	(9,196)
Tax benefit		232	227	0	0
Profit After Tax (norm)		(8,146)	(5,634)	(6,612)	(8,436)
Profit After Tax (reported)		(4,590)	(7,805)	(7,372)	(9,196)
Average Number of Shares Outstanding (m)		48.4	57.5	68.9	72.2
Average Number of ADRs Outstanding (m)		4.84	5.75	6.89	7.22
EPS - normalized (c)		(16.84)	(9.80)	(9.60)	(13.60)
EPS - diluted		(16.04)	(9.39)	(9.26)	(11.29)
Dividend per share (c)		0.0	0.0	0.0	0.0
Earnings per ADR - normalized (c)		(168.4)	(98.0)	(96.0)	(136.0)
Earnings per ADR - diluted (c)		(160.4)	(93.9)	(92.6)	(112.9)
Dividend per ADR (c)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		14,376	10,383	9,623	8,863
Intangible Assets		11,080	10,255	9,495	8,735
Tangible Assets		1	0	0	0
Investments		3,295	128	128	128
Current Assets		7,037	5,711	1,987	1,911
Stocks		0	0	0	0
Debtors		1,927	1,300	1,300	1,300
Cash		4,527	4,129	405	329
Other		584	281	281	281
Current Liabilities		(2,955)	(1,444)	(1,444)	(1,444)
Creditors		(1,571)	(1,341)	(1,341)	(1,341)
Short term borrowings		0	0	0	0
Other		(1,384)	(103)	(103)	(103)
Long Term Liabilities		(3,835)	(3,862)	(3,862)	(12,222)
Long term borrowings		0	0	0	(8,360)
Other long term liabilities		(3,835)	(3,862)	(3,862)	(3,862)
Net Assets		14,624	10,788	6,304	(2,892)
CASH FLOW					
Operating Cash Flow		(6,673)	(5,103)	(6,612)	(8,436)
Net Interest		91	0	0	0
Tax		0	0	0	0
Capex		0	0	0	0
Acquisitions/disposals		114	1,793	3,040	0
Equity Financing		0	2,900	0	0
Dividends		0	0	0	0
Other		0	0	(152)	8,360
Net Cash Flow		(6,469)	(410)	(3,724)	(76)
Opening net debt/(cash)		(10,986)	(4,527)	(4,129)	(405)
HP finance leases initiated		0	0	0	0
Other		10	12	0	(8,360)
Closing net debt/(cash)		(4,527)	(4,129)	(405)	8,031

Source: Kazia Therapeutics accounts, Edison Investment Research

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