# Kazia Therapeutics

Business update

## Paxalisib Chinese rights licensed

Pharma & biotech

**Kazia has announced it has signed an agreement for the Greater China rights to paxalisib with Simcere Pharmaceuticals. The deal includes an US$11m upfront (US$7m in cash, and US$4m in an equity investment), up to US$281m in milestone payments and royalties in the mid-teens. This is a key development for Kazia because not only does this payment help alleviate the near-term financing needs of the company, but the deal illustrates the potential value of this asset to partners.**

| Year end | Revenue ($m) | PBT ($m) | EPADR ($) | DPADR ($) | P/E (x) | Gross yield (%) |
|---|---|---|---|---|---|---|
| 06/19 | 1.1 | (5.3) | (0.91) | 0.00 | N/A | N/A |
| 06/20 | 0.8 | (7.7) | (1.01) | 0.00 | N/A | N/A |
| 06/21e | 12.0 | 2.8 | 0.23 | 0.00 | 55.9 | N/A |
| 06/22e | 0.9 | (8.8) | (0.62) | 0.00 | N/A | N/A |

Note: Converted at A$1.40/US$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

## An established partner

Kazia's partner for the transaction is Simcere Pharmaceuticals, a publicly traded company (HKSE: 2096) with a significant presence in the Chinese pharmaceutical market. The company had sales of ¥5.0bn in 2019 and reported earnings of ¥1.0bn in 2019 from its portfolio of over 40 products, primarily branded generics. It also has existing distribution relationships with over 2,000 hospitals in China.

## Simcere is part of a shift in the Chinese market

There has been significant regulatory reform in China to encourage the approval and marketing of proprietary drugs (developed domestically or licensed internationally). However, significant preference is still given to domestic drug developers and manufacturers. Simcere is well positioned to take advantage of these reforms with its existing manufacturing and distribution capacity and has been in licensing a large number of assets from both domestic sources and overseas.

## GBM a major issue in China as in West

Many oncology indications have different incidence rates in China compared to other countries such as those in the West, but glioblastoma multiforme (GBM) is a major unmet medical need globally. The estimated rates in China (1–4 per 100,000 persons) is similar or slightly lower than the US (3.5 per 100,000).

## Valuation: Increased on deal to US$215m or US$16.60

We have increased our valuation US$215m or US$16.60 per basic ADR, from US$190 or US$15.02 per basic ADR. This increase is from the Simcere licensing deal (US$11m from upfront payments and US$14.1m from cash flows). This has reduced our expected future financing requirement to US$7m from US$14m previously.

**30 March 2021**

| | |
|---|---|
| **Price** | **$12.86** |
| **Market cap** | **$162m** |
| ADR/Ord conversion ratio | 1:10 |
| Net cash ($m) at 31 December 2020 | 13.9 |
| ADRs in issue | 12.6m |
| ADR code | KZIA |
| ADR exchange | NASDAQ |
| Underlying exchange | ASX |
| Depository | BNY |

### ADR share price performance


| | | |
|---|---|---|
| 52-week high/low | $13.47 | $2.56 |

### 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

| | |
|---|---|
| Dana-Farber BCBM Phase II | CY21 |
| Sloan-Kettering BM Phase II | CY21 |
| NIH BM Phase II | CY21 |

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***Kazia Therapeutics is a research client of Edison Investment Research Limited***

## Simcere licenses paxalisib rights in Greater China

Kazia announced in March 2021 that it has signed an agreement with Simcere Pharmaceuticals (HKSE: 2096), an established, China-based drug manufacturer, for the rights to paxalisib in Greater China. The deal terms included: a US$11m upfront as US$7m in cash and a US$4m equity investment in Kazia (shares undisclosed, priced at 20% premium "to recent trading"), up to US$281m in milestone payments and royalties in the mid-teens. Simcere will be responsible for developing and marketing paxalisib in Greater China (PRC, Hong Kong, Macau, Taiwan). The above milestones and royalties are for the first indication of GBM and additional undisclosed milestones are available for other indications. Kazia will remain responsible for the global development of the drug and for its role in the pivotal GBM AGILE study, but Simcere will perform any clinical development activities necessary for approval in China. The upfront payment for this deal is a similar size to other recent China regional GBM deals from Novocure (US$15m, with Zai Lab) and Mimivax (US$10m, with Fosun). The milestone payments for the Kazia deal are larger than most comparables (eg US$138m for Mimivax), but it is difficult to make conclusions given their undisclosed nature.

The Chinese pharmaceutical industry has been undergoing rapid change with the advent of new regulatory reforms aimed at both encouraging the approval of innovative, proprietary medications as well as improving access to generic medications. It has reformed its regulatory apparatus to conform with international standards and to allow for the relatively speedy approval of drugs that have been approved in other geographies. At the same time, it has instituted plans to control pricing on generic medications, such as the so-called 4+7 Volume Based Procurement Plan. Under this plan the government negotiates for lots of generic medications at steeply discounted prices. These combined developments have reshaped the landscape of the Chinese drug industry substantially in favour of developing new medicines instead of generics. This being said, the regulatory structure in China still strongly favours domestic companies and products manufactured domestically, so it is commonplace for foreign drug developers to partner their products with Chinese companies for distribution there.

Kazia's partner Simcere reflects the above shift toward proprietary development internally as it transitions from primarily a manufacturer of branded generics to a full-fledged drug developer. It is achieving this through a combination of in licensing and internal development, and it has an extensive pipeline of early stage assets. Paxalisib, by virtue of being in the Phase II/III GBM AGILE study, will be the most advanced development asset the company has in licensed, as its other clinical programs are in Phase I or earlier. Simcere had revenue of ¥5.0bn in 2019 and reported earnings of ¥1.0bn during the period.

The reported rate of GBM in China is approximately similar to the US and Europe, if slightly lower. The yearly incidence in the US is approximately 3.5/100,000,[1] whereas estimates for China are in the range of 1–4/100,000.[2]

## Valuation

We have increased our valuation to US$215m or US$16.60 per basic ADR, from US$190 or US$15.02 per basic ADR. This increase is from the inclusion of the Simcere licensing deal and

[1] Faleh A and Juweid M (2017) Chapter 8: Epidemiology and Outcome of Glioblastoma. In: De Vleeschouwer S, editor. *Glioblastoma* [Internet]. Codon Publications

[2] Chang L, et al. (2014) Treating malignant glioma in Chinese patients: update on temozolomide. *Onco Targets Ther* 7, 235-244.

future cash flows into our model. US$11m is from upfront payments (included in our net cash line), and US$14.1m is from our NPV based model. This is offset slightly by the increase in shares from the equity part of the deal which we estimate at 0.32m ADRs (based on a 20% premium to the 5 day VWAP A$1.4685/share). Our valuation of paxalisib for the Chinese market is based on the following assumptions:

- We assume a 15% royalty payable to Kazia, and that approximately half (US$130m) of the US$281m in milestones (US$30m in clinical regulatory milestones and US$100m in sales-based milestones) will be paid over the lifetime of the drug. Our first upcoming hypothetical milestone in our model is US$5m on completion of the Phase II portion of GBM AGILE in 2023.
- We model approval for the drug slightly later in China (2026) compared to the US and Europe (2025) to allow for the completion of a Chinese bridging study (done at Simcere's cost) to support approval there.
- Our China pricing is lower than the US at US$29,000 at launch in 2026 (compared to US$169,000 at launch in the US). There is significant pricing pressure in China both from regulators and the market as it is still in large part a cash-pay system, or at least a cash up front, reimbursement later system.
- We only consider patients covered under the government's urban health plans (UEBMI and URBMI programs) as a viable market, reflecting approximately 35% of the population. We may change this as access to healthcare among China's rural population improves.

Our peak penetration is 25%, the same as the US and Europe.

We are only modelling the Chinese market for GBM at this time, although we may add other indications like breast cancer brain metastases (BCBMs) in the future. Otherwise our models remain unchanged.

**Exhibit 1: Valuation of Kazia**

| Development Program | Indication | Clinical stage | Prob. of success | Launch year | Patent/Exclusivity Protection | Launch Pricing ($/course) | Peak sales (US$m) | rNPV (US$m) |
|---|---|---|---|---|---|---|---|---|
| Paxalisib | GBM | Phase II | 35% | 2025 | 2037 | 169,000 | 450 | 173.66 |
| | BCBMs | Phase II | 5% | 2029 | 2037 | 183,000 | 249 | 6.15 |
| Cantrixil | OC | Phase I complete | 15% | 2027 | 2040 | 124,000 | 174 | 6.05 |
| Total | | | | | | | | 185.86 |
| Net cash and equivalents (FQ221 + Oasmia and Simcere upfronts) (US$m) | | | | | | | | 28.83 |
| Total firm value (US$m) | | | | | | | | 214.69 |
| Total basic ADRs (m) | | | | | | | | 12.9 |
| Value per basic ADR (US$) | | | | | | | | 16.60 |
| Dilutive options (as ADRs, m) | | | | | | | | 0.45 |
| Total diluted ADRs | | | | | | | | 13.4 |
| Value per diluted ADR | | | | | | | | 16.24 |

Source: Kazia Therapeutics reports, Edison Investment Research

# Financials

The only change to our near-term forecasts has been the inclusion of the cash (US$7m) and stock (US$4m) components of the Simcere upfront payment in our models for the 2021 fiscal year (as revenue and equity offerings respectively). This has reduced our expected financing requirement for the company to US$7m from US$14m (which we include as illustrative debt in 2024, compared to 2023 previously).

## Exhibit 2: Financial summary

| $'k | 2019 | 2020 | 2021e | 2022e |
|---|---|---|---|---|
| 30-June | IFRS | IFRS | IFRS | IFRS |
| INCOME STATEMENT | | | | |
| Revenue | 1,117.9 | 757.8 | 12,003.4 | 865.0 |
| Cost of Sales | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Profit | 1,117.9 | 757.8 | 12,003.4 | 865.0 |
| R&D | 4,625.4 | 6,781.7 | 5,846.4 | 4,746.4 |
| SG&A | 2,704.0 | 2,635.6 | 4,285.6 | 5,871.3 |
| EBITDA | (5,260.9) | (7,697.7) | 2,833.1 | (8,791.0) |
| Normalized operating profit | (5,261.0) | (7,697.7) | 2,833.1 | (8,791.0) |
| Amortization of acquired intangibles | (774.5) | (774.5) | (774.5) | (774.5) |
| Exceptionals | (1,337.4) | (458.8) | 0.0 | 0.0 |
| Share-based payments | (176.0) | (187.2) | (187.2) | (187.2) |
| Reported operating profit | (7,548.9) | (9,118.3) | 1,871.4 | (9,752.7) |
| Net Interest | 0.0 | 0.0 | 0.0 | 0.0 |
| Joint ventures & associates (post tax) | 0.0 | 0.0 | 0.0 | 0.0 |
| Exceptionals | 0.0 | 0.0 | 0.0 | 0.0 |
| Profit Before Tax (norm) | (5,261.0) | (7,697.7) | 2,833.1 | (8,791.0) |
| Profit Before Tax (reported) | (7,548.9) | (9,118.3) | 1,871.4 | (9,752.7) |
| Reported tax | 213.0 | 213.0 | (71.4) | 372.2 |
| Profit After Tax (norm) | (5,261.0) | (7,404.0) | 2,725.0 | (8,455.5) |
| Profit After Tax (reported) | (7,335.9) | (8,905.3) | 1,799.9 | (9,380.5) |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 |
| Discontinued operations | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income (normalized) | (5,261.0) | (7,404.0) | 2,725.0 | (8,455.5) |
| Net income (reported) | (7,335.9) | (8,905.3) | 1,799.9 | (9,380.5) |
| Basic average number of ADRs outstanding (m) | 5.8 | 7.3 | 11.9 | 13.6 |
| EPADR - basic normalized ($) | (0.91) | (1.01) | 0.23 | (0.62) |
| EPADR - diluted normalized ($) | (0.91) | (1.01) | 0.23 | (0.62) |
| EPADR - basic reported ($) | (1.28) | (1.22) | 0.15 | (0.69) |
| Dividend (A$) | 0.00 | 0.00 | 0.00 | 0.00 |
| **BALANCE SHEET** | | | | |
| Fixed Assets | 9,758.8 | 8,864.4 | 12,497.4 | 10,294.3 |
| Intangible Assets | 9,638.9 | 8,864.4 | 8,089.9 | 7,315.3 |
| Tangible Assets | 0.0 | 0.0 | 0.0 | 0.0 |
| Investments & other | 119.9 | 0.0 | 4,407.5 | 2,979.0 |
| Current Assets | 5,367.3 | 7,609.7 | 26,844.3 | 19,601.7 |
| Stocks | 0.0 | 0.0 | 0.0 | 0.0 |
| Debtors | 1,221.9 | 965.9 | 1,093.9 | 568.8 |
| Cash & cash equivalents | 3,881.3 | 6,260.0 | 25,366.6 | 18,649.1 |
| Other | 264.0 | 383.8 | 383.8 | 383.8 |
| Current Liabilities | (1,357.4) | (3,619.6) | (2,495.8) | (2,615.6) |
| Creditors | (1,260.0) | (2,492.1) | (2,261.2) | (2,380.9) |
| Tax and social security | 0.0 | 0.0 | 0.0 | 0.0 |
| Short term borrowings | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | (97.4) | (1,127.5) | (234.7) | (234.7) |
| Long Term Liabilities | (3,629.6) | (2,764.8) | (3,905.2) | (3,533.0) |
| Long term borrowings | 0.0 | 0.0 | 0.0 | 0.0 |
| Other long term liabilities | (3,629.6) | (2,764.8) | (3,905.2) | (3,533.0) |
| Net Assets | 10,139.1 | 10,089.7 | 32,940.7 | 23,747.4 |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 |
| Shareholders' equity | 10,139.1 | 10,089.7 | 32,940.7 | 23,747.4 |
| **CASH FLOW** | | | | |
| Op Cash Flow before WC and tax | (5,260.9) | (7,697.7) | 2,833.1 | (8,791.0) |
| Working capital | 252.1 | 1,192.2 | (4,518.9) | 1,701.2 |
| Exceptional & other | 213.0 | 213.0 | (71.4) | 372.2 |
| Tax | 0.0 | 0.0 | 0.0 | 0.0 |
| Net operating cash flow | (4,795.9) | (6,292.5) | (1,757.2) | (6,717.5) |
| 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 | 2,725.5 | 8,671.2 | 20,863.8 | 0.0 |
| Dividends | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 1,685.1 | 0.0 | 0.0 | 0.0 |
| Net Cash Flow | (385.3) | 2,378.7 | 19,106.6 | (6,717.5) |
| Opening net debt/(cash) | (4,254.4) | (3,881.3) | (6,260.0) | (25,366.6) |
| FX | 12.2 | 0.0 | 0.0 | 0.0 |
| Other non-cash movements | 0.0 | 0.0 | 0.0 | 0.0 |
| Closing net debt/(cash) | (3,881.3) | (6,260.0) | (25,366.6) | (18,649.1) |

Source: Company data, Edison Investment Research

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